OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

Board Meeting, Thursday, September 26, 2013
10:00 a.m.

Department of Consumer Affairs
1625 North Market Blvd.
Suite N220
El Dorado Conference Room
Sacramento, CA 95834

OMBC Phone (916) 928-8390

TABLE OF CONTENTS

TAB 1

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.
OSTEOPATHIC MEDICAL BOARD OF CALIFONIA
1300 National Drive, Suite 150, Sacramento, CA 95834-1991
P (916) 928-8390 F (916) 928-8392 | www.ombc.ca.gov

OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

BOARD MEETING

Notice of Public Meeting: Notice is hereby given that pursuant to the call of the President, David Connett, D.O., a public meeting of the Osteopathic Medical Board of California shall be held as follows:

Date:	Thursday, September 26, 2013
Time:	10:00 a.m. – 5:00 p.m. (or until the end of business)
Location:	Department of Consumer Affairs Headquarters Building (HQ) 1625 North Market Blvd., Suite N220 El Dorado Conference Room Sacramento CA 95834 (916) 928-8390

AGENDA

(Action may be taken on any items listed on the agenda and may be taken out of order)

Open Session

1. Roll Call / Establish Quorum
   Call to Order

2. Approval of Minutes – May 2, 2013 Board Meeting
   June 12, 2013 Teleconference

3 President's Report – David Connett, D.O.

   - Introductory Statement

4. Administrative Hearing

   - 10:30 a.m. Michael Duffy, D.O. - Petition for Early Termination or Probation

5. Closed Session

   - Deliberations on petition(s) for early termination of probation (Government Code Section 11126(c)(3).)
   - Deliberations on disciplinary or enforcement actions (Government Code Section 11126(c)(3).)

Return to Open Session

6. Executive Director's Report – Angie Burton

- Staffing
- Diversion Program
- Budget
- BreEZe
- Enforcement Report / Discipline (Corey Sparks)

7. Sunset Review Follow-up

- Code of Ethics – Dr. Connett & Dr. Krpan
- Internet Prescribing – Dr. Zammuto, Ms. Mercado, & Dr. Krpan

8. Guest Speaker – Richard Riemer, D.O.

- Chronic pain guidelines for the "Chronic Noncancer Pain"
- Discussion – Dr. Connett

9. Legislation

- AB 154 – Abortion (Enrolled)
- AB 186 – Professions and Vocations: Military Spouses: Temporary License
- AB 213 – Healing Arts: Licensure and Certification Requirements: Military Experience
- AB 635 – Drug Overdose Treatment: Liability
- AB 809 – Healing Arts: Telehealth
- AB 1003 – Professional Corporations: Healing Arts Practitioners
- AB 1057 – Professions and Vocations: Licenses: Military Service (Enrolled)
- AB 1288 – Medical Board of California and Osteopathic Medical Board of California: Licensing: Application Process (Chapter 307)
- SB 304 – Healing Arts: Boards
- SB 305 – Healing Arts: Boards
- SB 809 – Controlled Substances: Reporting (CURES)

10. Regulations

- Consumer Protection Enforcement Initiative (CPEI)
- Disciplinary Guidelines Revisions

11. Agenda Items for Next Meeting

12. Future Meeting Dates

13. Public Comment

13. Adjournment

For further information about this meeting, please contact Machiko Chong at 916-928-7636 or in writing 1300 National Drive, Suite 150 Sacramento CA 95834. This notice can be accessed at www.ombc.ca.gov

The meeting facilities are accessible to the physically disabled. A person, who needs a disability-related accommodation or modification in order to participate in the meeting, may make a request by contacting Machiko Chong, ADA Liaison, at (916) 928-7636 or e-mail at Machiko.Chong@dca.ca.gov or send a written request to the Board's office at 1300 National Drive, Suite 150, Sacramento, CA 95834-1991. Providing your request at least five (5) business days before the meeting will help to ensure availability of the requested accommodation.

TAB 2

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY · GOVERNOR EDMUND G. BROWN JR.
OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
1300 National Drive, Suite 150, Sacramento, CA 95834-1991
P (916) 928-8390 F (916) 928-8392 | www.ombc.ca.gov

DRAFT
BOARD MEETING MINUTES

Thursday, May 2, 2013

BOARD MEMBERS PRESENT:
Joseph Provenzano, D.O., President
Keith Higginbotham, Esq., Vice President
Alan Howard, Board Member
Jane Xenos, D.O., Board Member
Scott Harris, Esq., Board Member
David Connett, D.O., Board Member
Claudia Mercado, Board Member
Joseph Zammuto, D.O., Board Member

STAFF PRESENT:
Angelina Burton, Executive Director
Laura Freedman, Esq., Legal Counsel, DCA
Machiko Chong, Executive Analyst
Donald Krpan, D.O., Medical Consultant
Corey Sparks, Lead Enforcement Analyst

The Board meeting of the Osteopathic Medical Board of California (OMBC) was called to order by President, Joseph Provenzano, D.O. at 10:08 a.m. at the Western University of Health Sciences, 701 E Second Street – Health Education Center (HEC) Classroom A (1st Floor), Pomona, CA 91766.

1. Roll Call:

Dr. Provenzano called roll and determined that a quorum was present.

2. Approval of Minutes – January 31, 2013 Board Meeting:

Dr. Provenzano called for approval of the Board Meeting minutes of January 31, 2013. M – Connett, S – Higginbotham to approve the minutes with no additions or corrections. Motion passed unanimously.

3. Presidents Report:

Dr. Provenzano wanted to thank all of those that attended the Sunset Hearing and felt that the entire experience was very noteworthy. He also made note that he was able to attend a meeting held by the National Board of Osteopathic Medical Examiners (NBOME) where he was able to contribute feedback to the board for reconstruction of the Comprehensive Licensing Examination (COMLEX). He stated that the NBOME is

interested in establishing a pilot program with the OMBC that would be 3 tiered encompassing Continuing Medical Education (CME) in terms of competency and a COMVEX examination of some sort. He stated that it would be in conjunction with The Osteopathic Physicians and Surgeons of California (OPSC) in terms of CME.

Dr. Provenzano notified the board that the American Association of Osteopathic Examiners (AAOE) elected Geraldine O'Shea, D.O. as its new president.

The Federation of State Medical Boards (FSMB) held their annual conference in Boston, MA on the 3rd week of April which Dr. Provenzano attended. During the conference news broke of the Boston Marathon bombing, Dr. Provenzano filled the board in on what the atmosphere was like during the conference and its surrounding areas before he asked for a moment of silence for those lives that were lost during the bombing. At the meeting in Boston there were talks of implementing Interstate Compacts which would resolve boundary disputes, institutionalize and manage interstate issues pertaining to allocation of natural resources, and create administrative agencies which have jurisdiction over a wide variety of state concerns (e.g. State Transportation, Taxation, Education, etc.). Dr. Provenzano provided the board with slides to review that were provided by FSMB regarding what the implementation would involve.

4. Executive Director's Report:

Angie Burton reported the following:

- Staffing –The Board is still operating with the same number of staff and has recently shifted the Licensing Unit Staff Services Analyst (SSA) into a position vacant within the Enforcement Unit, which is now adequately staffed with the new addition. Due to the new vacancy that has opened within the Licensing Unit, the board has initiated the documents needed to fill the Staff Services Analyst (SSA) vacancy and are hoping to advertise and fill the position before the end of July 2013. The request that was submitted to advertise and hire a Staff Services Manager to oversee office productivity has been approved by DCA, however it is still pending approval by California Department of Human Resources (CalHR) at the State Personnel Board (SPB) and an answer should be received in the near future. Additionally, the board will be hiring two Permanent Intermittent (PI) employees to assist with clerical support and complete other tasks in office as needed such as No Longer Interested (NIL) notifications, answer phones, filing, etc.
- Budget – Mrs. Burton stated that the board recently completed and submitted the FY 2014/2015 Budget Change Proposals (BCPs) and requested the implementation of three (3) full time positions within the board which she is hoping to have approved. The board still has 39.55% of the budget remaining from the FY 2012/2013 allocation and with 3 months remaining until the conclusion of the Fiscal Year the board is in good shape. A small amount of money was spent within Enforcement, however for the months of April, May, and June there should be a notable increase in the funds used as the board has worked on quite a few cases.

- Diversion – Currently there are eleven participants enrolled in the OMBC Diversion Program. 7 of the 11 participants are on board stipulated probations, and the remaining are self-referrals. None of the participants have been terminated for non-compliance and are in good standing. The Board is extremely happy with the current diversion program through Maximus.
- DCA with the help an outside vendor (Accenture) is implementing a new board/bureau wide system named BreEZe which is supposed to streamline the initial application and renewal process decreasing the amount of phone calls received by each board and allowing applicants to complete tasks through an online database, however the system testing has fallen behind schedule. The Go-Live date was scheduled for May, however that date has since been postponed and they have yet to determine a future date.
- Enforcement/ Discipline - The boards Lead Enforcement Analyst Corey Sparks compiled a report and created a separate colored graph. During the report the board discussed action that may cause a case to be opened by the board against a physician, and what possible outcomes may occur depending on the scenario. The students in attendance were also able to ask questions so that they could gain a better understanding of what processes and procedures are involved when the board takes action.

5. Legislation

AB 410:
Provided for informational purpose, bill has not been moved to hearing due to cancellation of scheduled date.

AB 1278:
This bill would prohibit an osteopathic physician and surgeon from recommending, prescribing, or providing integrative cancer treatment to cancer patients unless certain requirements are met. The bill would specify that a failure of a physician and surgeon to comply with these requirements constitutes unprofessional conduct and cause for discipline by the individual's licensing entity. The bill would require the State Department of Public Health to investigate violations of these provisions and to hold hearings with respect to compliance with these provisions. Dr. Xenos asked about the background of the bill and how it would affect osteopathic physicians. Mrs. Burton stated that because there is a large amount of osteopathic physicians licensed that practice alternative medicine; many of them may opt to provide alternative care for cancer. Because of alternative treatment used the physicians have to ensure that they are notifying their patients that there is conventional treatment available for cancer that can be provided. Dr. Xenos made note that the bill also referenced treatment for Lyme disease and found it interesting that it had too been incorporated into the bill, adding that she was also concerned about the tonality and what may be constituted as disciplinary action. Dr. Connett addressed the Lyme disease issue and informed the board that there were many practitioners that are not only surreptitiously diagnosing patients with Lyme disease but are also using labs that are providing less than accurate data to determine the actual existence of the disease. The labs that have been used to complete the tests

have since been sanctioned; however they continue to administer the Lyme disease test. Unfortunately, some of the practitioners that are using the resources provided by the sanctioned labs are also administering "other than" standard care to patients as opposed to those practitioners that are following the proper guidelines. Laura Freedman noted that this bill was just an amendment to an existing law and that the disciplinary action regarding the use of the alternative treatment discussed has already been addressed and written. Per Kathleen Creason, Executive Director, Osteopathic Physicians and Surgeons of California (OPSC), the organization opposes the bill citing that it limits the physician's ability to practice and would restrict the board's decision making capabilities when it comes to individual cases or accusations.

SB 701:
Provided for informational purpose, bill has not been moved to hearing due to cancellation of scheduled date.

SB 305:
This bill pertains to the Sunset Bill, which coincides with the Sunset hearing that was completed in March 2013

SB 809:
Documents provided for informational purposes.

6. Closed Session

- The Board moved into closed session to deliberate on disciplinary or enforcement actions pursuant to Government Code Section 11126(c)(3).

Return to Open Session

7. Sunset Review:

Dr. Provenzano discussed creating a subcommittee to refine the Code of Ethics as discussed at the Sunset Hearing, for presentation at the next session as an agenda item. His hopes are for board approval to be given so that it may then begin the regulation process to be completed by December of 2014.

A subcommittee was created to track Internet prescribing and create a definite policy for the board to follow for procedural reference. Dr. Krpan provided the board with a policy model that was created by the American Osteopathic Association, which he will make available to the subcommittee for creation of the boards policy. Dr. Zammuto volunteered to be chair of the committee and Ms. Mercado volunteered to participate on the committee. Dr. Krpan offered to assist Dr. Zammuto and Ms. Mercado with the compilation of the Internet Prescribing policy.

A subcommittee was created to work on the Code of Ethics comprised of Dr. Connett sitting as the Chair of the committee. Dr. Krpan offered to assist Dr. Connett with his subcommittee duties.

Mr. Harris posed a question regarding the board keeping its continued existence in light of SB 305, and wanted to know if motions needed to be made with regards to that for record keeping purposes. Motion to support SB 305, M – Higginbotham, S - Harris of SB 305. There were no comments made by the board with all being in favor of the motion. Per Ms. Creason (OPSC) the organization continues to support autonomy of OMBC from the Medical Board of California. After clarification by Ms. Freedman, Dr. Provenzano elected to use the Code of Ethics and Internet Prescribing as follow up items that were raised during the Sunset Review for the next board meeting; M – Higginbotham S – Dr. Connett.

8. Regulations:

Ms. Freedman explained that previously there had been a concern about delays in length of time enforcement matters were taken. Because of the concerns the department took a pro-active approach for all boards and created some suggested language that would help shorten the time period that it took for investigations to begin the review process and complete. The target timeframe for is 18 months.

Ms. Freedman explained the proposed regulations, and motion was made to accept the CPEI, M – Dr. Zammuto, S – K. Higginbotham.

Mr. Harris suggested that Sect 1631, Subsection (c) (1) be modified to report any arrest or conviction.

M – Mr. Harris, S - Dr. Zammuto to adopt regulation of CPEI with an amendment to modify Sub (c) to reflect that any arrest or any conviction regardless of felony be adopted. Both maker and the second of the original motion agreed to the adoption with the requested amendments.

Ms. Freedman recommended that the other regulations be reviewed so that they match what we ask physicians at the time of renewal so that the wording is consistent. The board was in favor of passing the motion.

9. Uniform Standards Related to Substance Abuse and Disciplinary Guidelines:

The board reviewed the timeline of the board actions taken to decide on and modify the Uniform Standards Related to Substance Abuse and Disciplinary Guidelines, and determined that at this point in time additional help from the board would be of benefit. Ms. Freedman made note that the board wants to ensure that they Disciplinary Order has clear instructions on what the expectations are of the physician, so that in the future if they fail to comply with the expectations they would be subject to revocation. She recommended that the language of proposed regulation Sect. 1663 be reviewed and any questions or concerns be directed to either her or Mrs. Burton. Dr. Provenzano volunteered to help Mr. Harris on the subcommittee to work on the verbiage for the medical aspect of the Uniformed Standards.

10. Agenda Items for Next Board Meeting:

- Maintenance of Licensure (MOL) & Competency
- Development of Statewide Guideline for prescription opioid and substance abuse
- AB 831 Drug overdoses
- Code of Ethics and Telemedicine
- Uniform Standards and Disciplinary Guideline revisions (for a later date and time)

11. Future Meeting Dates:

- Thursday, September 26, 2013 @ 10:00 am
- Thursday, January 23, 2014 @ 10:00am – Sacramento

12. Public Comments

There were no public comments.

13. Adjournment

There being no further business, the Meeting was adjourned at 2:07 p.m.

STATE OF CALIFORNIA
DCA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.
OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
1300 National Drive, Suite 150, Sacramento, CA 95834-1991
P (916) 928-8390 F (916) 928-8392 / www.ombc.ca.gov

DRAFT
BOARD MEETING MINUTES

Wednesday, June12, 2013

BOARD MEMBERS PRESENT:
Keith Higginbotham, Esq., Vice President
Alan Howard, Board Member
Scott Harris, Esq., Board Member
Jane Xenos, D.O., Board Member
David Connett, D.O., Board Member
Claudia Mercado, Board Member
Joseph Zammuto, D.O., Board Member
James Lally, D.O., Board Member

STAFF PRESENT:
Angelina Burton, Executive Director
Laura Freedman, Esq., Legal Counsel, DCA
Machiko Chong, Executive Analyst

The Board meeting of the Osteopathic Medical Board of California (OMBC) was called to order by Interim Board President/ Vice President, Keith Higginbotham, Esq. at 4:08 p.m. The meeting was held by teleconference.

1. Roll Call:

Mr. Higginbotham called roll and determined that a quorum was present.

Dr. Lally was welcomed to the board.

2. Election of Officers

Mr. Higginbotham called for election of Officers of the Osteopathic Medical Board

Election of Officers is as follows:

- BOARD PRESIDENT:

Joseph Zammuto, D.O. was nominated by James Lally, D.O. for Board President.

David Connett, D.O., was nominated by Mr. Harris.

Mr. Higginbotham called for vote on nomination of Dr. Connett. Vote was taken by roll call. Ayes – 5, Nays – 3

3. Public Comments

There were no public comments.

4. Adjournment

There being no further business, the Meeting was adjourned at 4:17 p.m.

TAB 3

This page has intentionally been left blank

TAB 4

This page has intentionally been left blank

TAB 5

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR

OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
1300 National Drive, Suite 150, Sacramento, CA 95834
P (916) 928-8390 F (916) 928-8392 | www.ombc.ca.gov

Executive Director's Report
Board Meeting – September 26, 2013
El Dorado Conference Room
1625 North Market Blvd.
Sacramento, CA 95834

STAFFING

- Current number of fulltime staff is seven.
  - Enforcement – 3
  - Licensing – 2 (includes one vacant position)
  - Administrative – 2
    - One Medical Consultant .5 position
- Received approval from CalHR to create a Staff Services Manager position. Recruitment process started in June – interviews conducted and selection was made. Ms. Francine Davies joined the OMBC staff on July 31, 2013.
- Created two Permanent Intermittent (PI) positions. PI's may work up to 1500 hours per year. Interviews were conducted in June. Positions were filled in July. One PI staff is handling all new license applications. The other PI staff is our new receptionist and support staff for enforcement, licensing and administrative units.
- One of our enforcement staff is currently covering the vacant position in licensing. We are currently working on recruiting for this position and hope to have the vacancy filled by end of October.

Statistics:

Currently, there are 6820 osteopathic physicians and surgeons holding California license. Of the 6820 licensees, 1539 reside out-of-state. 627 licensees hold inactive status licenses

Since the last Board Meeting of the OMBC, there have been:

261 Applications filed for licensure
230 Initial licenses Issued
41 Applications filed for fictitious name permits
34 Fictitious name permits issued

DIVERSION PROGRAM

There are currently 12 participants in the OMBC diversion program. Of the 12 participants, 8 are board-referrals, 4 are self-referrals. The current contract with Maximus, Inc. was extended through December 2014. The Diversion Program Managers (DPM) of the seven Boards currently under contract with Maximus, Inc. are meeting regularly and working on a new Request for Proposal (RFP).

The OMBC Diversion Evaluation Committee (DEC) meets quarterly. We currently have three DEC members and OMBC staff is represented by Dr. Donald Krpan at each of these DEC meetings. The last DEC meeting was held in Los Angeles on September 16, 2013.

BUDGET

The Osteopathic Medical Board Fund Condition is provided for information.

- Reserve Fund - Current year – $2,450,000 – 16 months in reserve
- $1,500,000 General Fund loan is still outstanding

Budget Bill language that requires the Boards and Committees within DCA, that utilize CURES, to pay for the upgrade of the CURES database. In FY 2015-16 and ongoing the SB 809 CURES fee of $6.00 annually will be used to pay for the operation of the CURES database

OMBC updated all PCs in preparation for implementation of the new database BreEze. The pc's were purchased with funds from last year's budget. Additionally, this year, OMBC will be purchasing a new photocopier to replace our current, nine-year old copier, and replacing the postage meter, which is old and no longer under a maintenance contract.

BREEZE

Update on the BreEze project will be presented by Mr. Awet Kidane, Chief Deputy Director, DCA.

ENFORCEMENT

The enforcement statistics report is included in the Board packet. The report will be presented by Mr. Corey Sparks, Lead Enforcement Analyst

0264 Osteopathic Medical Board
Analysis of Fund Condition

Prepared 8/8/2013

(Dollars in Thousands)

13-14 Governor's Budget w/ CURES Funding $1.5 Million GF Loan Outstanding	ACTUAL 2011-12	CY 2012-13	Governor's Budget BY 2013-14	BY+1 2014-15	BY+2 2015-16
BEGINNING BALANCE	$ 4,416	$ 2,893	$ 2,676	$ 2,450	$ 2,242
Prior Year Adjustment	$ 37	$ -	$ -	$ -	$ -
Adjusted Beginning Balance	$ 4,453	$ 2,893	$ 2,676	$ 2,450	$ 2,242
REVENUES AND TRANSFERS					
Revenues:					
125600 Other regulatory fees	$ 29	$ 37	$ 40	$ 40	$ 40
125700 Other regulatory licenses and permits	$ 244	$ 249	$ 279	$ 279	$ 279
125800 Renewal fees	$ 1,176	$ 1,245	$ 1,286	$ 1,286	$ 1,286
125900 Delinquent fees	$ 6	$ 10	$ 8	$ 8	$ 8
141200 Sales of documents	$ -	$ -	$ -	$ -	$ -
142500 Miscellaneous services to the public	$ -	$ -	$ -	$ -	$ -
150300 Income from surplus money investments	$ 13	$ 5	$ 9	$ 15	$ 14
150500 Interest Income From Interfund Loans	$ -	$ -	$ -	$ 1	$ 2
160400 Sale of fixed assets	$ -	$ -	$ -	$ -	$ -
161000 Escheat of unclaimed checks and warrants	$ -	$ -	$ -	$ -	$ -
161400 Miscellaneous revenues	$ -	$ -	$ -	$ -	$ -
Totals, Revenues	$ 1,468	$ 1,546	$ 1,622	$ 1,629	$ 1,629
Transfers from Other Funds GF Loan Repayment					
Transfers to Other Funds GF Loan	$ -1,500				
Totals, Revenues and Transfers	$ -32	$ 1,546	$ 1,622	$ 1,629	$ 1,629
Totals, Resources	$ 4,421	$ 4,439	$ 4,298	$ 4,079	$ 3,871
EXPENDITURES					
Disbursements:					
0840 SCO (State Operations)	$ 2	$ 2	$ -	$ -	$ -
8880 Financial Information System of CA (State Operations)	$ 5	$ 9	$ 8	$ -	$ -
8860 FSCU Assessment	$ 2	$ -	$ -	$ -	$ -
1110 Program Expenditures (State Operations)	$ 1,519	$ 1,752	$ 1,798	$ 1,797	$ 1,833
CURES	$ -	$ -	$ 42	$ 40	$ -
Total Disbursements	$ 1,528	$ 1,763	$ 1,848	$ 1,837	$ 1,833
FUND BALANCE					
Reserve for economic uncertainties	$ 2,893	$ 2,676	$ 2,450	$ 2,242	$ 2,038
Months in Reserve	19.7	17.4	16.0	14.7	13.1

NOTES:

A. ASSUMES WORKLOAD AND REVENUE PROJECTIONS ARE REALIZED IN BY+1 AND ON-GOING.

B. ASSUMES INTEREST RATE AT .30%.

C. ASSUMES APPROPRIATION GROWTH OF 2% PER YEAR BEGINNING IN BY+1

OMBC Enforcement Report – 2Q 2013

Enforcement/Discipline – Between April 1, 2013 and June 30, 2013 (2Q), the OMBC received a total of 108 complaints and 402 complaints for the last 12 months (YTD 07/01/2012 – 06/30/2013). The breakdown of the complaints is as follows:

Type of Complaints

Type of Complaints	2Q 2013	2Q %	2Q Inv.	YTD	% YTD	YTD Inv.
Substance Abuse	1	1%	2	3	1%	3
Drug Violation	2	2%	1	4	1%	2
Unsafe/Unsanitary	1	1%	0	2	0%	0
Fraud	1	1%	1	3	1%	1
Non-Jurisdiction	0	0%	0	3	1%	0
Negligence/incompetence	66	61%	1	263	65%	4
Other	1	1%	0	6	1%	4
Unprofessional Conduct	24	22%	1	80	20%	4
Sexual Misconduct	2	2%	2	6	1%	5
Out of State Discipline	2	2%	4	9	2%	4
Unlicensed/Aiding & Abetting	3	3%	0	4	1%	2
Criminal Conviction	5	5%	2	19	5%	3
Total	108	100.00%	14	402	100.00%	32

Table 1

Of the 108 complaints OMBC received, 66 were negligence/incompetence and 24 unprofessional conduct. The pie chart below (Figure 1) displays the breakdown. Obviously, the majority are negligence/incompetence which account for 61% of the total. 14 complaints were sent out for formal investigations for 2Q 2013 whereas 32 were sent during the last 12 months.

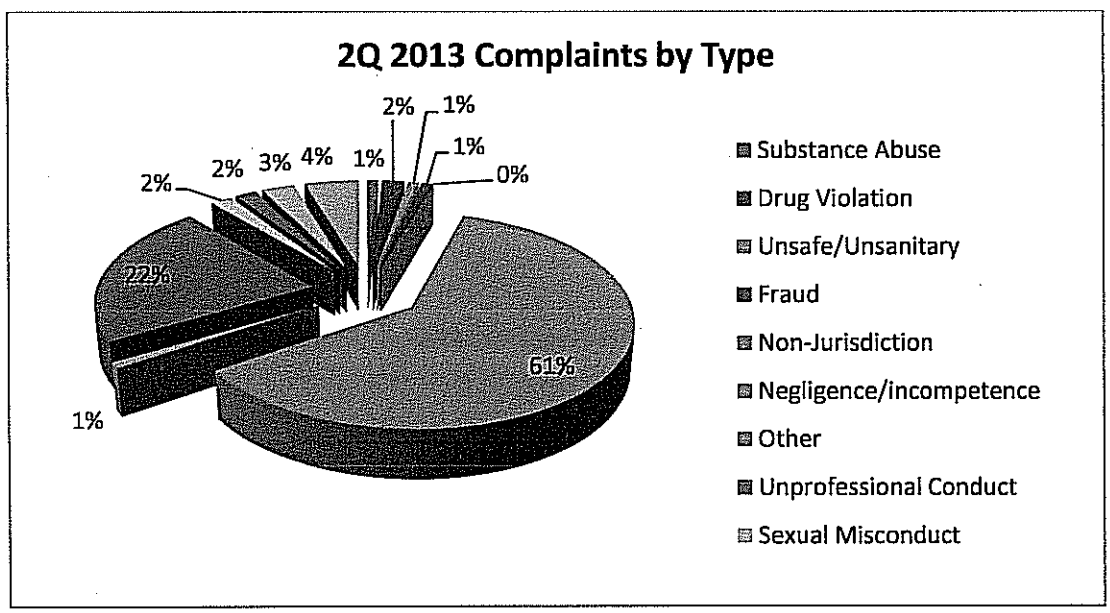


Figure 1: 2Q 2013 Complaint types

Source of Complaints

Source of Complaint	2Q 2013	%	2Q Inv.	YTD	%	YTD Inv.
Public	75	69%	1	313	78%	9
Licensees	3	3%	0	7	2%	0
Internal	6	6%	2	14	3%	6
Other DCA Board	0	0%	0	1	0%	1
Trade	0	0%	0	1	0%	0
Law Enforcement	5	5%	3	16	4%	5
Other CA agency	0	0%	0	2	0%	0
Other State agency	2	2%	6	8	2%	6
Section 800	12	11%	2	28	7%	2
Fed Gov	0	0%	0	0	0%	0
Anonymous	2	2%	0	7	2%	2
Other Gov Agy	2	2%	0	4	1%	0
Industry	1	1%	0	1	0%	1
Total	108	100.00%	14	402	100.00%	32

Table 2

Of the 108 complaints received in 2Q 2013, OMBC received 75 from the public (consumers, patients, families, etc.); 12 from Section 800's, 6 from internal, and 5 from law enforcement. The Public complaints account for 69% of the total. The distribution of the source of complaints for 2Q 2013 is similar to the year-to-date distribution.

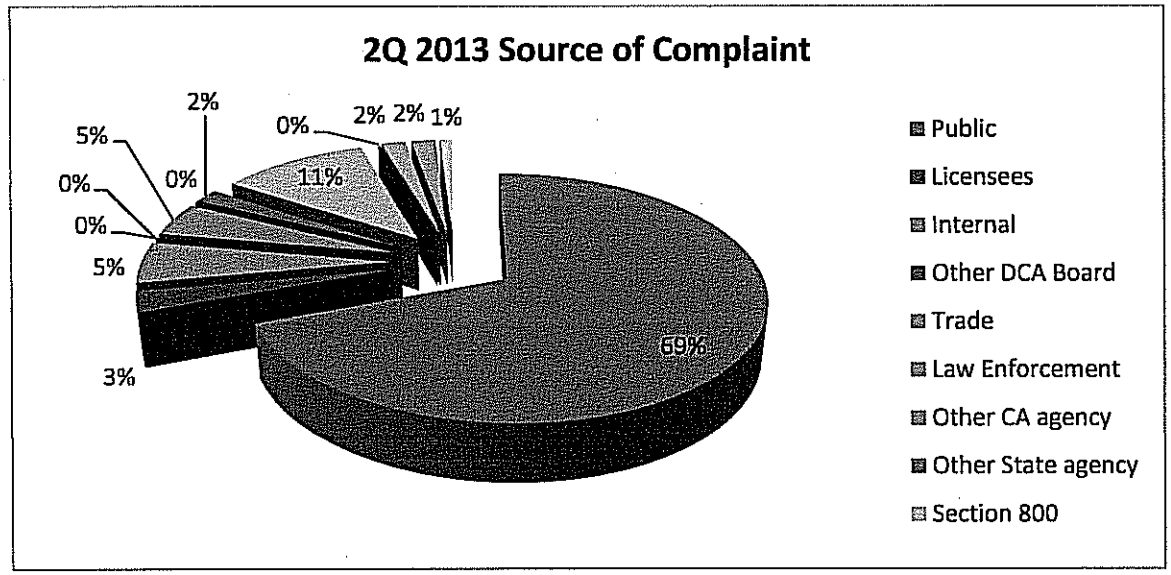


Figure 2: 1Q 2013 Source of Complaints

Closures

	COMPLAINT CLOSURE STATS FOR 2Q 2013*						
	No Merit	Citation	With Merit	Inv.	Disciplined	Others	Totals
Sub Abuse				1			1
Drug Related Offense							
Unsafe/Unsanitary Conditions							
Fraud							
Non-Jurisdiction	2						2
Negligence/incompetence	44		3	4		1	52
Other Category							
Unprofessional Conduct	9		2				11
Sexual Misconduct				2			2
Disciplined by Other State			1	4		2	7
Unlicensed/Unregistered	1			1			2
Criminal Charges			2			2	4
Totals	56		8	12		5	81

Table 3: Complaint Closure for 2Q 2013

A total of 81 complaints were closed during 2Q 2013, of which 52 were complaints of negligence/incompetence. 296 complaints were closed during the last year and 226 of these were negligence/incompetence. 56 complaints (69%) were closed with no merit; 8 complaints (10%) closed with merit; 12 complaints (15%) closed by formal investigation and 5 closed for other reasons.

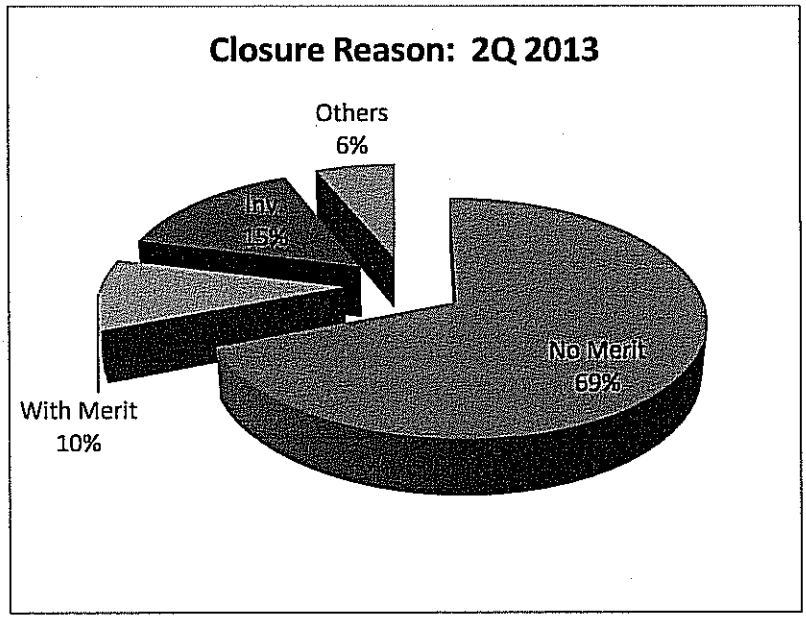


Figure 3: 1Q 2013 Closures

Cases to Formal Investigation

Of the 402 complaints received during the last year, 32 complaints (8%) were sent to formal investigations, including 14 during the second quarter of 2013. In figure 4, we see that there were 5 Sexual Misconduct cases in the last year including 2 during 2Q 2013. In the 2Q there was also an increase in Out of State Disciplined cases.

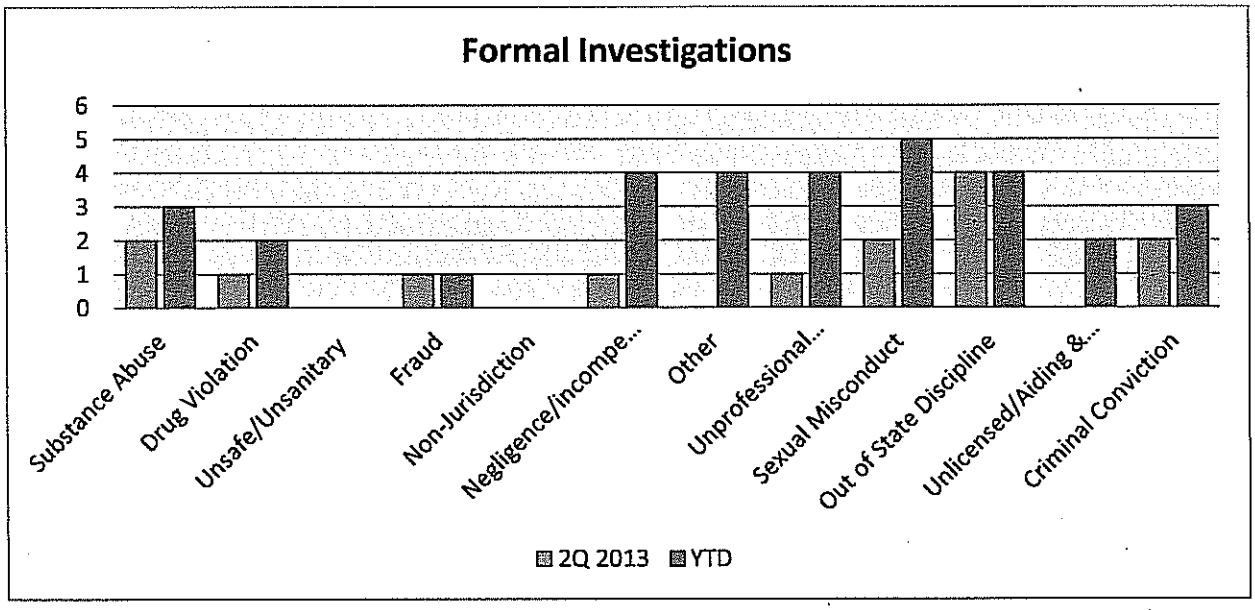


Figure 4: 2Q & YTD formal investigations

Desk and Formal Investigations

	3Q/ 2012			4Q/2012			1Q/2013			2Q/2013			Totals
Desk Inv.	7/12	8/12	9/12	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	YTD
Assigned	26	29	28	40	30	27	20	30	39	49	12	48	378
Closed	28	28	15	19	17	30	1	13	22	21	31	16	241
Pending	223	221	232	249	260	254	272	288	304	329	302	331	331
	3Q/ 2012			4Q/2012			1Q/2013			2Q/2013			Totals
Field Inv.	7/12	8/12	9/12	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	YTD
Assigned	1	3	2	4	2	3	1	1	1	3	8	3	32
Closed	3	6	5	1	0	3	1	4	1	3	7	2	36
Pending	28	25	22	25	27	27	27	24	24	24	25	26	26
	3Q/ 2012			4Q/2012			1Q/2013			2Q/2013			Totals
All Inv.	7/12	8/12	9/12	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	YTD
Assigned	26	29	28	40	30	27	20	30	39	49	12	48	378
Closed	31	34	20	20	17	33	2	17	23	24	38	18	277
Pending	251	246	254	274	287	281	299	312	328	353	327	357	357

Table 4: Desk, Field, and All Investigations

For desk investigations, we see a consistent pattern until January 2013 where there is a substantial decrease in case closures and assigned. This was due in part to staff transitions and the enforcement staff helping the licensing staff with renewals. Notably, in May 2013, we see only 12 cases assigned for desk investigations but 8 were assigned to formal and 7 were closed, which is a deviation (see Figure 5 on the following page). For year to date investigation totals, there were 378 assigned cases, 277 closed, and 357 pending (Figure 6).

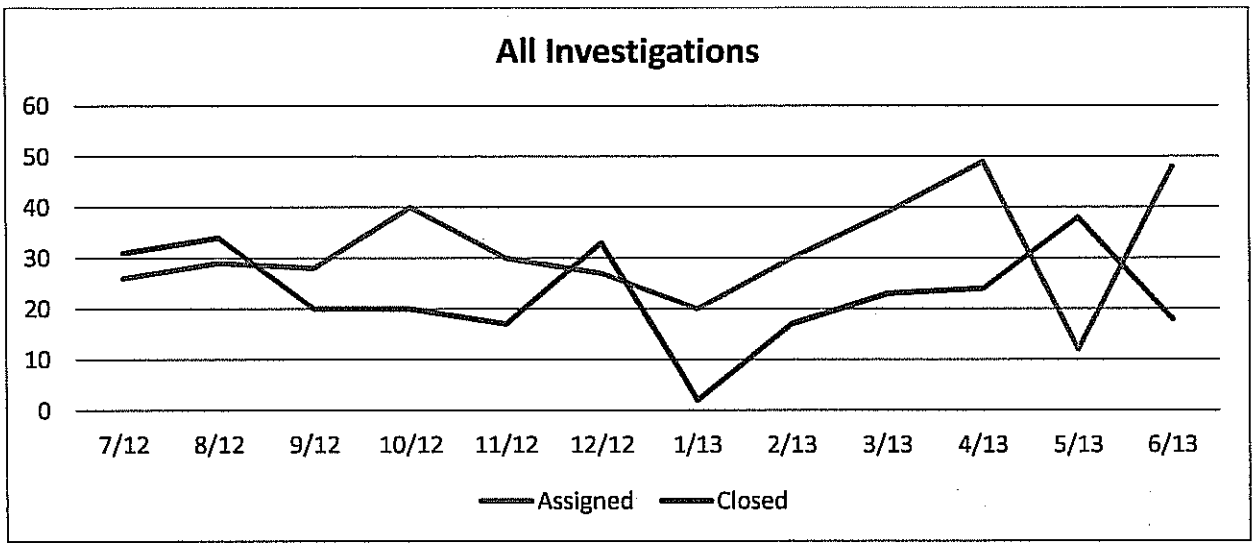


Figure 5: Desk and Field Investigations

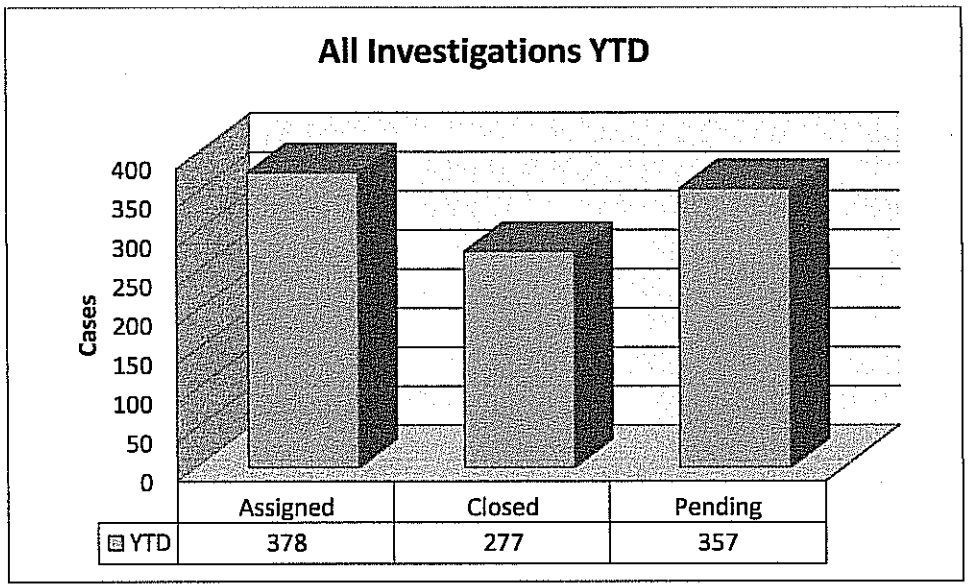


Figure 6: All Investigations YTD

Average Days to Close Investigation

	3Q/ 2012			4Q/2012			1Q/2013			2Q/2013			
Ave Days Closed	7/12	8/12	9/12	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	YTD
Desk Inv	199	264	276	325	124	503	1023	132	327	145	305	115	269
Field Inv	303	320	312	354	0	588	1	499	681	1292	326	401	449
All Inv.	209	274	285	326	124	510	512	218	342	288	309	147	292

Table 5: Average Days to Close Investigation

The average day-to- close desk investigations was fairly consistent for the last year until December 2012 when the staff transition took place and the licensing renewals required additional staff. In Figure 7 on the following page, there is a substantial increase in the time for OMBC enforcement staff to close investigation complaints during the end of 2012 and beginning of 2013. Field investigations saw a substantial increase in the average days to close for the month of April.

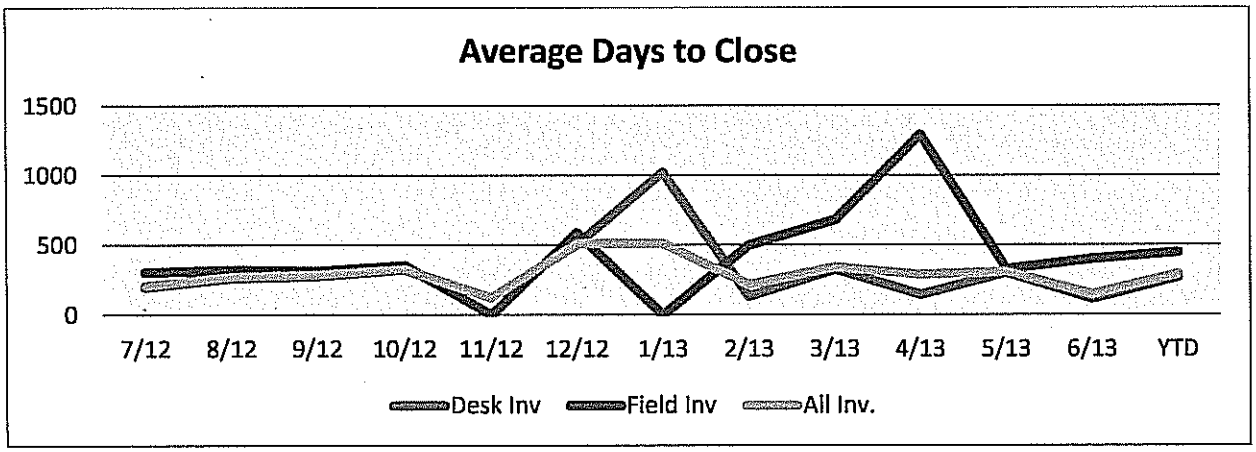


Figure 7: Average Days to Close Investigation

Enforcement Actions

	3Q/ 2012			4Q/2012			1Q/2013			2Q/2013			
	7/12	8/12	9/12	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	YTD
AG Cases Initiated	1	4	4	0	0	1	1	2	0	1	6	0	20
SOI Filed	0	0	0	0	0	0	0	0	0	0	0	1	1
Acc Filed	2	0	1	0	1	1	1	1	1	4	0	5	17
SOI Decision/Stips	0	0	0	1	0	1	0	0	0	0	0	0	2
ACC Decision/Stips	2	0	1	0	0	1	0	1	0	0	1	0	6
SOI Final Order (Dec/Stip)	0	0	0	1	0	1	0	0	0	0	0	0	2
ACC Final Order (Dec/Stip)	2	0	1	0	0	1	0	1	0	0	1	0	6
Closed w/out Disc Action	0	0	1	1	1	0	0	0	0	0	0	0	3
Citations	0	0	0	0	0	0	0	0	0	0	0	0	0
Interim Sus Orders Issued	0	0	0	2	0	0	0	0	0	0	0	0	2
PC 23 Orders Issued	0	0	1	0	0	1	0	0	0	0	0	0	2
AG Cases Pending	21	25	27	25	24	23	24	25	25	26	30	30	30

Table 6: Enforcement Actions YTD

During the 2Q 2013, 7 cases were initiated to the Attorney General; 9 Accusations were filed; 1 Stipulation and 1 Disciplinary Order. There are currently 30 AG cases pending. Figure 8 breaks down the Enforcement actions for 2Q 2013.

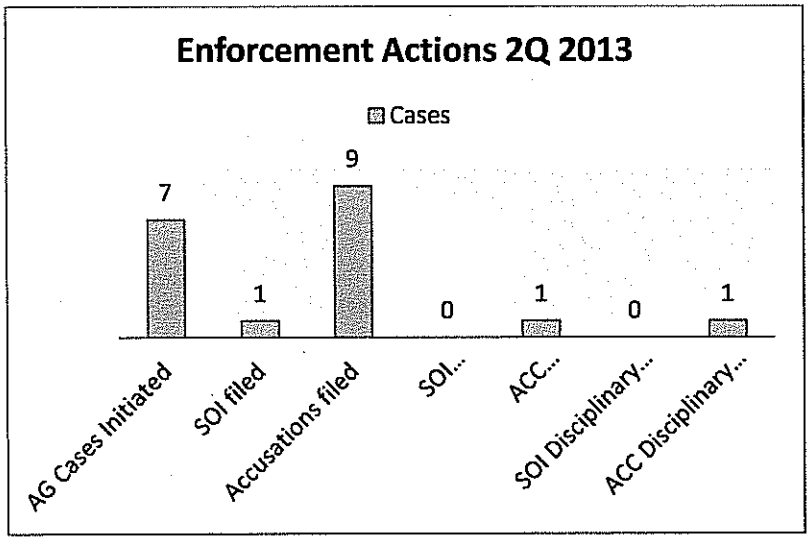


Figure 8: 2Q 2013 Enforcement Actions

Performance Measures

		3Q/ 2012			4Q/2012			1Q/2013			2Q/2013			
		7/12	8/12	9/12	10/12	11/12	12/12	1/13	2/13	3/13	4/13	5/13	6/13	YTD
PM1	Complaints Vol	33	31	35	38	27	38	19	34	25	33	40	30	383
PM1	Conv/Arrest Rpt Vol	1	0	2	1	3	1	1	2	3	2	1	2	19
PM2	Cycle Time-Intake/OMBC	7	14	11	14	20	27	35	30	29	18	44	33	23
PM3	Cycle Time-No Disc/OMBC	196	264	276	326	124	494	1023	154	342	281	305	147	282
PM4	Cycle Time- Discipline/AG	460	0	1004	80	491	1249	0	516	0	0	1836	0	766

Table 3: Performance Measures

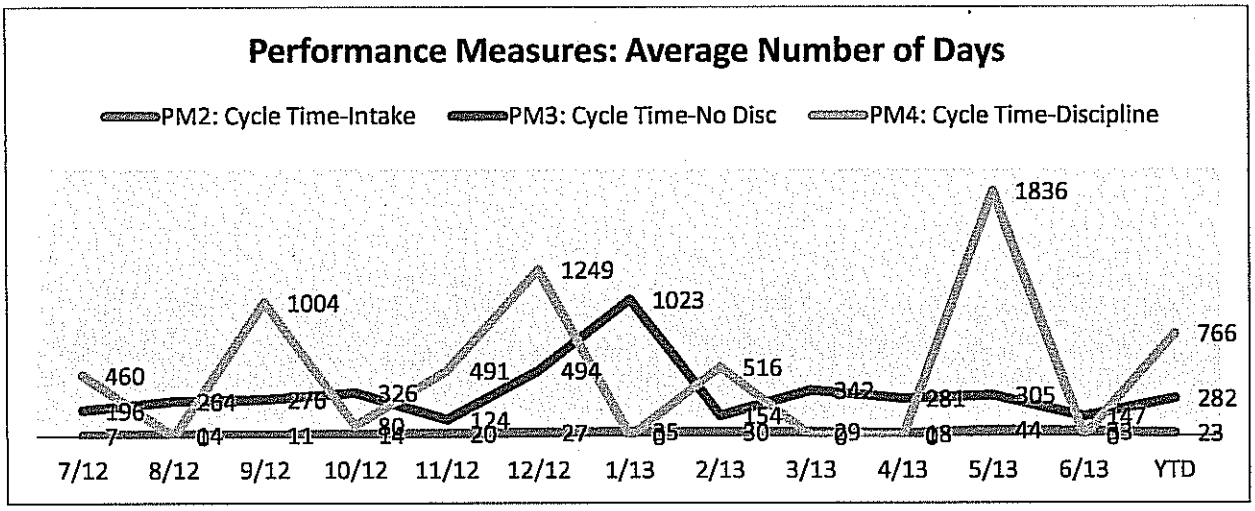


Figure 9: Performance Measures YTD

PM1: COMPLAINTS VOLUME and CONV/ARREST REPORTS VOLUME: Number of complaints and convictions/arrest orders received within the specified time period.

PM2: CYCLE TIME-INTAKE: Average number of days to complete Complaint Intake during the specified time period.

PM3: CYCLE TIME – NO DISCIPLINE: Average number of days to complete Complaint Intake and Investigation steps of the Enforcement process for Closed Complaints not resulting in Formal Discipline during the specified time period.

PM4: CYCLE TIME – DISCIPLNE: Average number of days to complete Enforcement process (Complaint Intake, Investigation, and Formal Discipline steps) for Cases Closed which had gone to the Formal Discipline step during the specified time frame.

Probation

Currently there are 32 open probation cases. The total amount due for cost recovery is $423,003.53 and to date the Board has recovered $116,015.00.

TAB 6

Osteopathic Medical Board of California-Code of Ethics - DRAFT

The Osteopathic Medical Board of California Code of Ethics is adapted from the American Osteopathic Association Code of Ethics annotated with corresponding section numbers from this document with enclosed crosswalks from the Business and Professions Standards in the laws relating to the practice of Osteopathic Medicine Edition 2005 or the California Code of Regulations specific to healthcare regulation. The code of ethics of the American Osteopathic Association was not adopted in its entirety due to conflicts with current state law or inability to enforce such a provision under California state law.

1. Section 1-The physician shall keep in confidence whatever he/she may learn about a patient in the discharge of professional duties. Information shall be divulged by the physician when required by law or when authorized by the patient. (Business and Professional Code 2263, Violation of Professional Confidence-the willful, unauthorized violation of professional confidence constitutes unprofessional conduct.)

2. Section 2-The physician shall give a candid account of the patient's condition to the patient or to those responsible for the patient's care. (Business and Professional codes 2220.08 (B) A division of Medical Quality: Authority; 2225.5 Records Requests Compliance; 2261 Making False Statements; 2262.

3. Section 3-A physician-patient relationship must be founded on mutual trust, cooperation, and respect. The patient, therefore, must have complete freedom to choose his/her physician. The physician must have complete freedom to choose patients whom he/she will serve. However, the physician should not refuse to accept patients for reasons of discrimination, including, but not limited to, the patient's race, creed, color, sex, national origin, sexual orientation, gender identity or handicap. In emergencies, a physician should make his/her services available. (Business and Professional Code 125.6 Unprofessional Conduct-discrimination; 2395 – 98 Emergency Care- Scene of an Emergency, Emergency Care-Obstetrical Services, Emergency Care-Medical Complications, Emergency Care-Informed Consent, and Emergency Care-Athletic Events.

4. Section 4- A physician is never justified in abandoning a patient. The physician shall give a written one month's notice to patient or to those responsible for the

patient's care when he/she withdraws from the case so that in other physician may be engaged.

5. Section 5-A physician shall practice in accordance with the body of systemized and scientific knowledge related to the healing arts. A physician shall maintain competence in such systemized and scientific knowledge through study and clinical applications. California Code of Regulations-CCRS Division 16, Article 9, Sections 1635-1641, Business and professions Code 2454.5 Adoption and Administration of Continuing Education Standards, 2190.5 Continuing Medical Education-Pain Management.

6. Section 6-Under the law a physician may advertise, but no physician shall advertise or solicit patients directly or indirectly through the use of matters or activities which are false or misleading. Business and Professional Codes 651 Advertising, Fraudulent, Misleading or, Deceptive, 2271 – 73 False or Misleading Advertising, Advertising Without Use of Name, Employment of Cappers and Steerers.

7. Section 7-A physician shall not hold forth or indicate possession of any degree recognized as the basis for licensure to practice the healing arts unless he is actually licensed on the basis of that degree. A physician shall designate his/her osteopathic school of practice and all professional uses of his/her name. Indications of specialty practice, membership in professional societies, and related matters shall be governed by the rules promulgated by the American Osteopathic Association. Business and Professional Codes §2235 Procuring License by Fraud, §2274 – 76 Misuse of Titles, Election of M. D., §2288 – 89 Impersonation-Examination, Impersonation-Practice of Medicine, §2453.5 Board Certification.

8. Section 8-A physician should not hesitate to seek consultation whenever he/she believes it is advisable for the care of the patient.

9. Section 9-In any dispute between or among physicians regarding the diagnosis and treatment of a patient, the attending physician has the responsibility for the final decisions, consistent with any applicable hospital rules or regulations.

10. Section 10-Any fee charged by a physician shall compensate the physician for services actually rendered there shall be no division of professional fees for referrals of patients. Business and Professional Code §650 Consideration for Referrals Prohibited, §2284 Fee Sharing Prohibited-Employment of Acupuncturists.

11. Section 11-A physician shall respect the law. When necessary a physician shall attempt to help to formulate the law by all proper means in order to improve patient care and public health.

12. Section 12-It is considered sexual misconduct for a physician to have sexual contact with any current patient whom the patient has interviewed and/or upon whom a medical or surgical procedure has been performed. Business and professional codes §726 – 29 Sexual Relations with Patients, Evidentiary Rule, Psychotherapists-Knowledge of Sexual Conduct with Previous Psychotherapist, Psychotherapist Sexual Exploitation, §2246 Sexual Exploitation.

13. Section 13-Sexual-harassment by physician is considered unethical. Sexual harassment is defined as physical or verbal intimidation of a sexual nature involving a colleague or subordinate in the workplace or academic setting, when such conduct creates an unreasonable, intimidating, hostile or offensive workplace or academic setting. Business and professional codes §729 Psychotherapist Sexual Exploitation, §2246 Sexual Exploitation.

OMBC Committee on Internet Prescribing and Prescriptions - DRAFT

Members: Board member Joseph A. Zammuto; Board member Claudia Mercado; Consultant Donald Krpan, D.O.

Conference call June 13, 2013 at 8:00 AM

E-mail Correspondence: 6/16/13; 6/22/13; 7/1/13; 7/10/13

Purpose: To develop official statement for the OMBC as it relates to the Business and Professional Code 2242.

In preparation for this meeting the committee reviewed documents from: The Federation of State Medical Boards. A composite review of all 50 states positions on internet prescribing and prescriptions

OMBC STATEMENT:

It is unprofessional conduct for a physician to initially prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the physician make an informed medical judgment based on the circumstances of the situation and on his/her training and experience. . This will require that the physician:

- Personally perform an appropriate history and physical examination,
- make a diagnosis,
- and formulate a therapeutic plan.

This process must be documented appropriately, and include a discussion of the diagnosis with the patient and the evidence for it, and the risk and benefits of various treatment option and insure the availability of the physician or coverage for the patient for appropriate follow up care.

Prescribing for a patient whom the physician has not personally examined may be suitable under certain circumstances. These may include, but not limited to: Admission orders for a newly hospitalized patient; Prescribing for a patient of another physician for whom the prescriber is taking call; Prescribing for a patient examined by a licensed nurse practioner or licensed physician assistant; or Continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

Prescribing drugs to individuals the physician has never met based solely on answers to a set of questions, as is common in internet or toll-free telephone prescribing is inappropriate and unprofessional.

Highlights:

1) There must exist a doctor-patient relationship.
2) There must be Face to Face, Hands on, In-Person Examination.
3) There must be a valid diagnosis.
4) The prescribed medication must be appropriate and necessary for the treatment of an acute, chronic, or recurrent condition that has been validly diagnosed.
5) There must be retrievable medical records of the encounter.
6) There must be documentation of the prescriptions
7) There must be a follow up exam and monitoring of the medication.
8) Online questionnaires are not a valid encounter for prescriptions.
9) The only exception to the rules is on-call physicians prescribing for a limited time of 72 hours worth of medication.

DRAFT #2

BACKGROUND PAPER FOR THE OSTEOPATHIC MEDICAL BOARD

Joint Oversight Hearing, March 11, 2013

Senate Committee on Business, Professions and Economic Development and Assembly Committee on Business, Professions and Consumer Protection

IDENTIFIED ISSUES, BACKGROUND AND RECOMMENDATIONS FOR THE OSTEOPATHIC MEDICAL BOARD

BRIEF OVERVIEW OF THE OSTEOPATHIC MEDICAL BOARD

Function of the Osteopathic Medical Board

The Osteopathic Medical Board of California (Board) was established in 1922 when the Osteopathic Initiative Act was passed by electorate. In 1962, another initiative was passed providing the Legislature the authority to amend the Osteopathic Initiative Act. To date, the only restriction on the Legislature's power is that it may not fully repeal the Osteopathic Initiative Act unless the number of licensed osteopathic physicians (DOs) falls below 40.

In 2002, the Board volunteered to be included under the umbrella of the California Department of Consumer Affairs (DCA). As one of the regulatory entities within the DCA, the Board is charged with the licensing and regulation of DOs. The Board's statutes and regulations set forth the requirements for licensure and provide the Board the authority to discipline a licensee.

The current Board mission statement, as stated in its 2010-2015 Strategic Plan, is as follows:

The Osteopathic Medical Board leads by promoting excellence in medical practice, licensure and regulation, as the voice and resource towards protection of the public.

The current Board vision statement, as stated in its 2010-2015 Strategic Plan, is as follows:

The Osteopathic Medical Board is the leader in medical regulation for osteopathic physicians in the state of California; serving as an innovative catalyst for effective policy and standards.

Osteopathic medicine was developed more than 130 years ago by Andrew Taylor Stills, MD, DO. Osteopathic medicine brings a unique philosophy to traditional medicine. Osteopathic physicians are fully licensed to prescribe medication and practice in all medical specialty areas including surgery. They are trained to consider the health of the whole person and use their hands to help diagnose and treat their patient.
Osteopathic physicians are one of the fastest growing segments of health care professionals in the United States with the 4th largest osteopathic population being employed in California. There are 4,986 DOs in California

with active licenses and an additional 941 ~~of these~~ DOs with California licenses ~~reside~~ residing in other states. There are 645 DOs who maintain inactive licenses.

Osteopathic physicians are similar to doctors of medicine (MDs) in that both are considered to be "complete physicians." Complete physicians have taken the prescribed amount of pre-medical training, graduated from an undergraduate institution with an emphasis on science courses, and received four years of training in medical school. The same laws govern the required training for DOs and MDs who are licensed in California. In fact, BPC § 2453 states: "...it is the policy of this State that holders of MD degrees and DO degrees shall be accorded equal professional status and privileges as licensed physicians and surgeons." Licensing examinations are also comparable in rigor and comprehensiveness to those given to MDs.

Osteopathic physicians are required to complete a year of post-graduate training, e.g. residency or rotating internship, in a hospital with an approved post-graduate training program. Osteopathic physicians utilize all scientifically accepted methods of diagnosis and treatment, including the use of drugs and surgery and are licensed in all fifty states to perform surgery and prescribe medication in accredited and licensed hospitals and medical centers.

Osteopathic physicians may refer to himself/herself as a "Doctor" or "Dr." but in doing so, must clearly state that he/she is a DO or osteopathic physician and surgeon. He or she may not state or imply that he or she is a MD while being licensed in California as a DO.

A key difference between the two professions is that DOs have additional dimension in their training and practice, one not taught in medical schools which grant MD degrees. Osteopathic medicine gives particular recognition to the musculoskeletal system which comprises over 60% of body mass. A DO is trained to recognize that all body systems, including the musculoskeletal system, are interdependent, and a disturbance in one can cause altered functions in other systems of the body. The osteopathic physician is also trained in how this interrelationship of body systems is facilitated by the nervous and circulatory systems. The emphasis on the relationship between body structure and organic functioning is intended to provide a broader base for the treatment of the patient as a unit. These concepts require a thorough understanding of anatomy and the development of special skills in diagnosing and treating structural problems through manipulative therapy. Osteopathic physicians use structural diagnosis and manipulative therapy along with all of the other traditional forms of diagnosis and treatment to care effectively for patients in order to relieve their distress.

To meet its responsibilities for regulation of the DO profession, the Board is authorized by law to:

- Monitor licensees for continued competency by requiring approved continuing education.
- Take appropriate disciplinary action whenever licensees fail to meet the standard of practice, or otherwise commit unprofessional conduct.
- Determine that osteopathic medical schools and hospitals are in compliance with medical education curriculum and post-graduate training requirements.
- Provide rehabilitation opportunities for licensees whose competency may be impaired due to abuse of alcohol or other drugs.

Initially, the Board was comprised of five Osteopathic Physicians appointed by the Governor to staggered three year terms. In 1991 two Public members, ~~one appointed by the Speaker of the Assembly and one by the Senate Rules Committee~~, appointed by the Governor, were added to the Board. In 2010, two additional ~~Governor~~ Speaker of the Assembly and by the Senate Rules Committee appointed public members were added. All Board meetings are subject to the Bagley-Keene Open Meetings Act.

The following table lists all members of the Board including background on each member, appointment date, term expiration date and appointing authority.

Board Members	Appointment Date	Term Expiration Date	Appointing Authority
David Connett, DO (professional member) served as Associate Dean of Clinical Services at Western University of Health Sciences, Pomona, CA since 2007 and Vice Chairman at the Healthcare Facilities Accreditation Program since 2000. From 2003-2007, he was Vice President and Chief Medical Officer at Garden City Hospital and Medical Director at Exempla Healthcare. Dr. Connett served as Family Medicine Program Director and Medical Director at HealthONE from 1992-2003 and was Chief of Aerospace Medicine for the US Air Force from 1985 to 1991. He earned a Doctor of Osteopathic Medicine degree from the College of Osteopathic Medicine of the Pacific at the Western University of Health Sciences.	06/09/12	6/1/15	Governor
Joseph Zammuto, DO (professional member) has been a partner and physician at Center Medical Group Inc, since 1997 and a physician at Medpartners-Mullikin Medical Group from 1995 to 1997. He was a partner and physician at Zammuto and Zinni Medical Inc. from 1991 to 1995, owner of Joseph Zammuto D.O., from 1984 to 1991. Dr. Zammuto earned his Doctor of Osteopathic Medicine degree from the Chicago College of Osteopathic Medicine.	06/07/12	6/1/15	Governor
Michael Feinstein, DO (professional member) has served as a physician at Encompass Medical Group since 2000 and was a physician at Sharp Reese Stealy Medical Group from 1998 to 2000. He was a physician at Family Practice Associates of San Diego from 1978 to 1998. He earned his Doctor of Osteopathic Medicine degree from the Philadelphia College of Osteopathic Medicine.	06/07/12	6/1/15	Governor
Jane Xenos, DO (professional member) has operated her own practice since 1991. She earned her Doctor of Osteopathic Medicine degree from the College of Osteopathic Medicine of the Pacific at the Western University of Health Sciences. Dr. Xenos is Board Certified in neuromuscular medicine/osteopathic manual medicine and family practice.	06/07/12	6/1/15	Governor
Joseph Provenzano, DO (professional member) has served as a family medicine doctor at Sutter-Gould Medical Group since 1990. Previously, Dr. Provenzano served as an emergency room physician at Fisher-Mangold Emergency Physicians from 1988- 1990. Dr. Provenzano served on the Board of Directors of the Gould Medical Group, Inc from 2000 to 2006 and Board of Directors of the Sutter Gould Medical Group from 2007 to 2010. He has also served as the Director of Graduate Medical Education OPTI Program for Orthopedics at the Midwestern Osteopathic Medical School since 2011. Dr. Provenzano earned his Doctor of Osteopathic Medicine degree from University of North Texas Health Center at Fort Worth Texas College of Osteopathic Medicine.	4/19/10	6/1/12	Governor

Scott Harris, Esq., (public member) is a former Deputy Attorney General with the California Department of Justice, and in 2010 formed S J Harris Law. He is also an Adjunct Professor of Law at Loyola Law School, Los Angeles.	12/2/10	1/01/13	Governor
Allen Howard, (public member) has served as a project manager for American President Lines, a global leader in container shipping, logistics and technology management since 2004. Mr. Howard previously held several positions including director for the TNT Post Group, where he worked from 1994-2002.	12/2/10	1/01/13	Governor
Claudia Mercado, MBA (public member) blends her entrepreneurship spirit and passion for the development of the Hispanic community with her expertise in business management and cross-cultural relations in her work at Rocket Lawyer Incorporated. As a Business Specialist, she leads the initiative to implement a marketing strategy to bring accessible and affordable legal services to every Hispanic household and small business owner in the United States. Ms. Mercado is a strong supporter of Non-Profit Hispanic Professional Organizations and a strong advocate for increased access to higher education and political equality. She currently serves as a San Jose Chapter board member for the National Society of Hispanics MBA's and is an alumna of the Hope Leadership Institute Class of 2012. Mercado holds a bachelor's degree in Political Legal Economic Analysis and a Masters degree in Business Administration from the Lorry I. Lokey Graduate School of Business.	8/18/2012	6/1/2013	Senate Rules Committee
Keith Higginbotham, Esq., (public member) is the owner and sole proprietor of The Law Office of Keith Alan Higginbotham in Los Angeles. Mr. Higginbotham serves as Chairman of the Los Angeles County Bar Association Commercial Law and Bankruptcy Section, DAP/Pro bono Subcommittee since 2008. He is also on the Board of Directors, LA County Association Bankruptcy Section as the Consumer Liaison since 2005. He served as President of the Central District Consumer Bankruptcy Attorney Association in 2011-2012. Mr. Higginbotham served as an Administrative Assistant to then Legislative Director to Senator Art Torres, State Capital, Sacramento from 1985 to 1991. He was a Committee Consultant to the Senate Judiciary Committee, the Senate Appropriations Committee and the Senate Budget Committee. Mr. Higginbotham received his JD degree from McGeorge School of Law at the University of the Pacific.	07/01/12	6/1/15	Speaker of the Assembly

The Board has organized two committees which serve as an essential component to help the Board deal with specific policy and/or administrative issues. The committees research policy issues and concerns, referred by the Board staff, the public, or licensees.

The following is a description of committees that have been established by the Board:

Diversion Evaluation Committee (DEC)

The DEC is established in statute (BPC § 2360). The purpose of the DEC is to manage a treatment program for DOs whose competency may be threatened or diminished due to substance abuse.

The DEC is comprised of three licensed DOs who are appointed by the Board and who serve at the pleasure of the Board. The appointees must have experience in the diagnosis and treatment of substance abuse.

The DEC not only has the responsibility to accept, deny or terminate a participant, they also prescribe in writing for each participant a treatment and rehabilitation plan including requirements for supervision and surveillance.

Consultants Committee (CC)

The members of the CC represent a range of osteopathic medical disciplines and are responsible for reviewing complaints against licensed DOs and the associated medical records. The members receive training and case-by-case guidance as to the interpretation and application of relevant law.

The process for referring a case entails the Board staff sending the complaint file to members of the CC to review along with any relevant medical records. The consultants then prepare a written report explaining their conclusions and recommendations. All quality of care complaint cases are retained for ten years from date the Board receives the complaint (BPC § 2029).

Based on the information in the file, a consultant may conclude:

- The complaint is without merit and should be closed without further action.
- The complaint may have merit but there is clearly insufficient evidence to take further action.
- The complaint appears to have merit and should be made the subject of a more detailed investigation leading to possible disciplinary action or even referral to criminal prosecution.

The Board is a dues paying member of the Federation of State Medical Boards (FSMB). The FSMB is comprised of representatives of all medical boards in the U.S. States and Territories. During the FSMB's annual meeting, salient topics including licensure, enforcement, credentialing, working with underserved populations, and telemedicine are discussed and resolutions offered.

The annual FSMB dues are $2,000.00. As a benefit to the members, the FSMB gives each participating board a $3,600.00 scholarship to cover the costs of travel to the annual meeting. However, the Board has not been active or participated in FSMB activities for the past six years due to DCA's mandated state limitation on out of state travel for Board members and staff.

(For more detailed information regarding the responsibilities, operation, and functions of the Board please refer to the Board's *2012 Oversight Report*)

PRIOR SUNSET REVIEW: CHANGES AND IMPROVEMENTS

The Board was last reviewed in 2005 by the Joint Commission on Boards, Commission, and Consumer Protection (JCBCCP). During the previous sunset review, the JCBCCP raised 6 issues and included a set of recommendations to address those issues. Below, are actions which the Board and Legislature addressed over the past 8 years. Those which were not addressed and which may still be of concern to this Committee are addressed more fully under the "Current Sunset Review Issues" section.

In November, 2012, the Board submitted its required sunset report to this Committee. In the report, the Board described actions it has taken since its prior review to address the recommendations of the JCBCCP. According to the Board, the following are some of the more important programmatic and operational changes, enhancements, and other important policy decisions or regulatory changes made:

Addition of the Naturopathic Medicine Committee

The Board had a major change in 2009 when the Legislature placed the Naturopathic Medicine Committee within the Board. The Board was increased at that time from seven, five professional and two public, to nine members. The two added members were Naturopathic Doctors and were considered public members. These appointments were in violation of BPC § 3600 1.5 which states, "public members shall not be a licensee of any board...nor of any initiative act." In response, the Osteopathic Physicians and Surgeons of California (OPSC) sponsored SB 1050, supported by the Board and the Naturopathic Medicine Committee. Passage of SB 1050 made the Naturopathic Medicine Committee independent and resulted in the removal of the two naturopathic doctors from the Board. These two vacancies were replaced by two public members, one appointed by the Speaker of the Assembly and one by the Senate Pro Tempore.

Strategic Plan

The Board reported that in 2010 it completed its Strategic Plan. In April of 2012, the Board updated the plan. The Board reported that it is beginning a study for implementation of the Strategic Plan.

Code of Ethics

During the 2005 Sunset Review hearing, the JCBCCP inquired why the Board had not adopted a Code of Ethics. The opinion of the JCBCCP was that nearly all other licensed professions abide by a Code of Ethics enforceable by their respective licensing board.

In both its 2005 and 2012 report, the Board noted that its licensees are "expected" to abide by the American Osteopathic Association's (AOA) voluntary Code of Ethics. The Board indicated:

> *After a diligent study requested by the Sunset Review Committee, determined a Code of Ethics is not necessary and will not be included in the regulation as all ethical violations are currently in statute and duplication is unnecessary.*

This was presented in the form of a motion and was passed unanimously by the Board.

Board Merger

During the 2005 Sunset Review hearing, the JCBCCP raised the issue of the OMB merging with the MBC. The JCBCCP inquired:

> *In light of the fundamental and statutorily required equality between DOs and MDs, is there a continuing need for two separate Boards to regulate those who hold unrestricted licenses as physicians and surgeons?*

In its recent report, the Board responded:

> *The history of the interactions between the Board and the MBC has been rather stormy. The Board was created in 1922 by initiative in response to the refusal of the MBC to continue to license DOs....It is perceived that any attempt to eliminate the Board and place DOs under the MBC would be met with fierce opposition and the legality of altering the 1922 ~~initative~~ initiative which would also be challenged.*

Repayment of General Fund Loan

During the 2005 Sunset Review hearing, the JCBCCP inquired about the status of the loan the Board made to ıe General fund in 2002-2003. The Board indicated in its recent report that the $2,700,000.00 sum that was borrowed from the Board was subsequently repaid in full with interest in 2006-2007. In fiscal year 2010-2011,

the General Fund borrowed $1,500,00.00 with ~~on~~ no established schedule for repayment. On the basis of the prior repayment, the Board stated that they have confidence that the current loan will also be repaid.

Legislation Sponsored by or Affecting the Board

The Board reported, with the exception of SB 1050, there has been no sponsored legislation or major studies since the last sunset review.

Pending Regulations

Since the Board's last sunset review in 2005, the Board reports that there have been no regulatory changes. Currently, the Board is working to develop regulations in the following four areas:

- The Board has maintained the licensure fees at $200 for initial licensure and $400 for renewals. The Board has maintained the renewal fees at $400 whereas the Medical Board of California (MBC) has increased this fee to $800. In applying for the increase for renewals to $800 the MBC agreed to relinquish the option to obtain cost recovery from physicians who have violated the code of practice. The Board opines that the individuals who violate the code should be responsible for expenses associated with investigation and prosecution and on this basis has not requested an increase in renewal fees which would place the burden for costs on physicians who are practicing within the accepted standards. In 2005, the Board applied for and was granted an increase from $200 to $400 for initial licensure. The process has begun to generate the regulation to achieve the requested and approved increase.

- The Board is structuring a regulation to comply with 16 CA ADC §1355.4, which requires that a physician prominently display the name and contact information for the agency by which he/she is licensed.

- The Board is structuring a regulation for implementation of SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008).

- The Board is in the process of amending its Disciplinary Guidelines, to assist in better uniformity and applicably for enforcement actions.

- The Board is drafting a regulation to increase the maximum citation and fine amount to $5,000.00.

CURRENT SUNSET REVIEW ISSUES

The following are areas of concern for the Board to consider along with background information regarding the particular issue. There are also recommendations the Committee staff have made regarding particular issues or problem areas which need to be addressed. The Board and other interested parties, including the professions, have been provided with this Background Paper and are asked to respond to both the issues identified and the recommendations of the Committee staff.

CODE OF ETHICS

ISSUE #1: Should DOs have to abide by a Code of Ethics enforceable by the Board?

Background: The Board does not currently have in place an enforceable Code of Ethics for its licensees. This is highly unusual among consumer protection boards and was highlighted during the 2005 sunset review process.

In both its 2005 and 2012 report, the Board notes that its licensees are "expected" to abide by the American Osteopathic Association's (AOA) voluntary Code of Ethics. However, this expectation is not enforceable by the Board. The Board responded: "Nothing in the law or regulations requires osteopathic physicians and surgeons to adhere to the AOA standards." Nor, as the board pointed out in 2005, does the AOA have any jurisdiction to enforce its voluntary Code if one of the Board's licensees does not abide by that Code. By not itself adopting the AOA Code, or something like it the Board appears to have abdicated its responsibility to adopt regulations in this exceptionally important area.

In 2005, the Board told Committee staff that the Attorney General had advised them there was no need for them to adopt a Code of Ethics (Conversation with Linda Bergmann, Executive Director, Board on Dec. 2, 2004). This advice was apparently oral since the Board had no documentary evidence for it. To date, Committee staff has not been able to confirm with the Attorney General's staff what specifically might underlie this advice, nor provide a reason that it might be sound.

The Board continues to suggest to the Committee that the Board lacks the ability to promulgate such regulations:

> *Regulations would be impossible to obtain as there is no statute defining ethics. Ethics means conforming to a set of standards of conduct of a given profession or group, and is not defined in law. (2005 Board Response to Committee's Sunset Review Follow-up Questions*, page 2).
>
> *Our interpretation of the law is that only the law defines the professional practices that are within the Board's regulatory authority. Therefore, we would not have the authority to enforce a set of standards that embellish what is found in the law. (2012 Board Oversight Report, page 13).*

However, the Board, like all regulatory entities with a mandate to protect the public interest, has full authority to promulgate regulations concerning the ethics and professional responsibility of its licensees. The fact that "ethics" is not, itself, defined in law, does not prevent the Board from promulgating regulations that will fulfill its ability to achieve its paramount duty to protect the public in carrying out its "licensing, regulatory and disciplinary functions." (BPC § 2450.1) That authority supports the ability of the Board to define what ethics are appropriate for DOs as a matter of protection of the public.

It appears there may be continued misunderstanding. In 2005, a Deputy Attorney General familiar with boards and commissions suggested to Committee staff that an Attorney General might have advised the Board that they should not adopt, *in its entirety*, the AOA Code of Ethics, since such national standards are frequently updated, and it would be incumbent on the Board to keep up with changes made at the national level as they are adopted. This is certainly an issue, but it is equally true of any set of standards. Even if the Board established its own Code of Conduct entirely independent of the AOA Code of Ethics, it would have to revisit it periodically to make certain it is up-to-date and appropriate in a changing environment.

The Board can easily address even the more obvious issue with the AOA Code. The Board could adopt the AOA Code in regulation by reference, in a manner that would incorporate any changes as they are adopted nationally. Or, the Board could adopt the AOA Code as it now stands, follow any national changes as they evelop, and adopt the changes. Or, it could adopt parts of the AOA Code the Board agreed with, and modify or adapt others.

The Committee continues to reserve concern about the Board's lack of action in regards to this issue. This is especially since this kind of administrative decision making is not only commonplace among boards, it is an essential characteristic of an administrative agency of any kind. Moreover, any staff time that would have to be involved in tracking changes by the national organization is more than outweighed by the current problem of having no enforceable standards in place whatsoever.

Staff Recommendation: *In line with its recommendation made during the 2005 Sunset Review Hearing, the Committee maintains that the Board utilizes either the existing AOA code of ethics or create its own set of ethical standards which will give licensees more guidance on ethical conduct, and which the Board will then have the ability to enforce with specificity by December 1, 2014.*

The Osteopathic Medical Board staff will prepare and present in draft, a Code of Ethics for the Board to review at its next Board Meeting on May 2, 2013 and will have an approved Code of Ethics in place with ability to enforce prior to December 1, 2014.

BOARD MERGER

ISSUE #2: Should the Board be merged with the MBC?

Background: Since the initiative establishing the Board in 1922, California's public policy has been clear that DOs are to be treated equally with MDs. For example, BPC § 2453(a) states: "It is the policy of this state that holders of MD. degrees and DO degrees shall be accorded equal professional status and privileges as licensed physicians and surgeons."

Moreover, this equality is so firmly established that it extends to a statutorily mandated rule of non-discrimination. BPC § 2453(b) states:

> *Notwithstanding any other provision of law, no health facility subject to licensure under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, no health care service plan, nonprofit hospital service plan, policy of disability insurance, self-insured employer welfare benefit plan, and no agency of the state or of any city, county, city and county, district, or other political subdivision of the state shall discriminate with respect to employment, staff privileges, or the provision of, or contracts for, professional services against a licensed physician and surgeon on the basis of whether the physician and surgeon holds an MD or DO degree.*

This equality, as well as the vastly coextensive education and training of MDs and DOs, and the exact parity of their unrestricted licenses and scopes of practice, raise a perennial question: Is there a continual need to have two separate regulatory bodies for these virtually identical professions? The question is particularly timely in light of the Governor's well-publicized desire to eliminate redundancies and inefficiencies in state government, and particularly in the structure of the state's boards and commissions.

The primary difference between DOs and MDs appears to be essentially one of emphasis. According to the Board, DOs have a different philosophy of medicine, focused on the interrelationship of the body's systems, a focus MDs do not share. Aside from that, both professions apparently have identical licenses, identical scopes of practice, and must be treated by insurers, hospitals, and government entities identically. They are held to apparently virtually identical standards of practice by hospital Peer Review Organizations and liability insurers, and, both the Board and the MBC use the same prosecutors when their licensees are subject to formal accusations.

As was highlighted in the 2005 Sunset Review report, the Committee reiterates the question: In light of the fundamental and statutorily required equality between DOs and MDs, is there a continuing need for two separate boards to regulate those who hold unrestricted licenses as physicians and surgeons?

Staff Recommendation: *Consistent with the question raised during the 2005 Sunset Review hearing, the Committee encourages the Board to consider the feasibility of merging with the MBC.*

The Osteopathic Medical Board (OMBC) remains opposed to any suggestion for a merger with the Medical Board of California (MBC). The MBC on two occasions during the 20th century had the prerogative to license and monitor osteopathic physicians, and in both instances refused to accept the responsibility. From 1907 until 1919 the MBC licensed DO's who were considered drugless practitioners. During that time some of the DO's challenged and passed the examination which expanded their scope of practice and allowed them to write prescriptions. In 1919, the MBC arbitrarily decided to discontinue licensing DO's. The DO's became active and sponsored the 1922 Initiative Measure (The Osteopathic Act) which resulted in the establishment of the Board of Osteopathic Examiners (BOE) ensuring the viability of the profession in the State of California. DO's were licensed and monitored under the Osteopathic Act by the BOE from 1922 until 1962, when a merger was enacted by referendum (Chapter 48, 1962 First Extraordinary Session). The purpose of the referendum measure was to facilitate an agreement in principle to effectively merge the D.O. and M.D. professions. The key provisions of this measure were:

a. Osteopathic physicians and surgeons could choose to be licensed as M.D.'s, and if so would be under the jurisdiction of the Board of Medical Examiners instead of the BOE.
b. The Osteopathic Act was modified to rescind the authority of the BOE to issue new licenses to osteopathic physicians and surgeons, but the BOE would continue to have authority over D.O.'s who chose not to become M.D.'s.

The net result was that of the 2400 D.O.'s licensed in California in 1962, 2000 chose to accept the M.D. degree for a nominal fee of $65. The 400 D.O.'s who did not accept the M.D. degree continued to be licensed and governed by the BOE. The BOE was scheduled to become extinct when the number of D.O.'s dwindled to less than 40 licensees. THE MERGER OF 1962 WAS AN OVERT ATTEMPT TO ELIMINATE THE OSTEOPATHIC PROFESSION IN THE STAT OF CALIFORNIA, THE OPPORTUNITY TO OBTAIN THE M.D. DEGREE WAS A ONE-TIME OFFER AND THE MBC REFUSED TO LICENSE ANY ADDITIONAL D.O.'s ON THE BASIS THAT THEY WERE NOT GRADUATES OF ACCREDITED MEDICAL SCHOOLS. However, the provisions that rescinded the licensing authority of the BOE were successfully challenged by out-of-state osteopathic physicians, many of whom were returning from tours of duty in Southeast Asia, who were effectively barred by these provisions from being licensed to practice in California, unless they had been so licensed before 1962. In 1974 the California Supreme Court reinstated the BOE's licensing authority (see D'Amico v. Board of Medical Examiners 11 C.3d 1,24), and the BOE immediately resumed its function as the sole agency with authority to license D.O.'s in California. As late as 1982-84 D.O.'s were not credentialed by Kaiser on the basis of their training but on the basis of their degree; this issue was challenged and for the past 30 years, D.O.'s have been appropriately credentialed and professionally respected and treated by Kaiser. Overall, D.O.'s do not feel that they have been treated fairly by the MBC when licensure is discussed. Currently, if a D.O. and an M.D. incorporate and apply for a fictitious name permit, (Corporation Code states physicians and surgeons must own at least 51% of shares), the MBC will require the M.D. to own a minimum of 51% of the shares and the D.O. can only hold 49%. The OMBC feels that because D.O.'s are also physicians and surgeons and that a corporation owned by a D.O. and an M.D. can have a 50/50 split in shares.

The MBC will not grant a fictitious name to a corporation unless the M.D. is at least 51% shareholder. The OMBC will issue a fictitious name permit to a corporation with a D.O. and an M.D. being 50/50 shareholders.

The OMBC continues to participate in a well organized and legislatively required diversion program. The OMBC has not raised fees for license renewals to cover the costs of investigation and prosecution. It is the belief of the OMBC that physicians who are practicing within the accepted standards should be held harmless and that physicians who violate the standards should be held responsible and bear the burden of cost recovery.

This matter will be placed on the agenda at our next board meeting for further discussion.

USE OF TECHNOLOGY

ISSUE #3: Webcasting meetings.

Background: The Board reported that it has only webcast one meeting since joining DCA. The Board reported that it webcast a meeting in 2010 "...when the Governor added the Naturopathic Medicine Committee under its purview. Due to the amount of resistance the Board received from its licensee population, and after receiving a legal opinion from DCA, the Board decided to webcast the proceedings of that meeting."

The Committee is concerned about the Board's lack of use of technology in order to make the content of the Board meetings more available to the public. Webcasting is an important tool that can allow for remote members of the public to stay apprised of the activities of the Board as well as well as trends in the profession.

Staff Recommendation: *The Board should inform the Committee of the reason that they have been unsuccessful in webcasting meetings. The Committee recommends that the Board utilize webcasting at future meetings in order to allow the public the best access to meeting content, activities of the Board and trends in the profession.*

The availability of a webcasting staff was not made known to the Osteopathic Medical Board until recently, when Department of Consumer Affairs reached out to the Boards that their technical staff was available and would encourage the use of webcasting for all Board Meetings. Upon receiving this information, OMBC staff immediately contacted DCA and asked them to reserve staff for our next Board meeting to be held in Pomona on May 2, 2013. We were recently informed that DCA has lost their webcasting technical staff, however, they will be purchasing additional webcasting equipment to loan to Boards so they can webcast the meetings themselves. OMBC has no technical staff, however, will make every effort to webcast all future Board Meetings with equipment made available by DCA until they hire webcasting technical team.

ISSUE #4: Posting meeting materials to the website.

Background: The Board reported that it does not have an IT staff. Thus, the Board utilizes DCA's IT department to post "...only the mandated and very basic information" to their website. The Board explained that they do not post meeting materials or minutes to the website. However, the Board reported a desire to use the website as "...a tool to reach consumers and DOs. The Board wishes to educate consumers and recruit more DOs to California to meet the State's ever changing health care needs."

The Committee is concerned about the Board's lack of use of the website in order to make meeting content available to the public. The Committee has reviewed the process for posting information online and does not feel that an additional staff person is needed in order to complete this task.

Staff Recommendation: *The Committee requests that the Board begin posting meeting materials to their website as well as sending links to the meeting materials via their listserve immediately.*

The Osteopathic Medical Board staff is currently working on posting board meeting materials on our website and will create an "E-mail list" of interested parties to notify them when materials are available on our website.

LICENSE PORTABILITY

ISSUE #5: License portability for military personnel and their spouses.

First Lady Michelle Obama and Dr. Jill Biden launched the Joining Forces campaign in order to assist military veterans and their spouses in accessing the workforce. In response to this campaign, Governors in over 20 states signed pro-military spouse license portability laws. Additionally, on January 24, 2011, U.S. President Barack Obama presented "Strengthening Our Military Families: Meeting America's Commitment," a document urging agencies to support and improve the lives of military families.

As a result of the Joining Forces campaign and the President's directive, the Department of Transportation and the Department of Defense issued a joint report to highlight the impact of state occupational licensing requirements on the careers of military spouses, who frequently move across state lines. Released in February 2012, the report, "Supporting our Military Families: Best Practices for Streamlining Occupational Licensing Across State Lines" revealed that approximately 35% of military spouses work in professions that require state licenses or certification and that military spouses are ten times more likely to have moved to another state in the last year compared to their civilian counterparts. In a 2008 Defense Manpower Data Center survey of active duty military spouses, participants were asked what would have helped them with their employment search after their last military move. Nearly 40% of those respondents who have moved indicated that 'easier state-to-state transfer of certification' would have helped them."

As a result of the survey, the Department of Transportation and the Department of Defense issued several recommendations, including the authorization of temporary licenses for military spouses if the applicant met state requirements. The report's recommendation specified:

> *Temporary licenses allow applicants to be employed while they fulfill all of the requirements for a permanent license, including examinations or endorsement, applications and additional fees. In developing expedited approaches that save military spouses time and money, DOD does not want to make licensure easier for military spouses to achieve at the expense of degrading their perceived value in their profession.*

everal bills have been presented to the Legislature across the past few years that deal with providing expedited licenses to military veterans and spouses, exempting active duty military personnel from continuing education requirements and licensing fees. In 2012, AB 1904 (Block, Chapter 399, Statues of 2012) was signed and

requires a Board under the DCA to expedite the licensure process for military spouses and domestic partners of a military member who is on active duty in California.

As part of the 2012-2013 Budget Package, the California Legislature directed the DCA to prepare a report on the implementation of BPC § 35 relating to military experience and licensure. The law indicates:

> *It is the policy of this state that, consistent with the provision of high-quality services, persons with skills, knowledge, and experience obtained in the armed services of the United States should be permitted to apply this learning and contribute to the employment needs of the state at the maximum level of responsibility and skill for which they are qualified. To this end, rules and regulations of boards provided for in their code shall provide for methods of evaluation education, training and experience obtained in the armed services, if applicable to the requirements of the business, occupation or profession regulated... Each board shall consult with the Department of Veterans Affairs and the Military Department before adopting these rules and regulations. (BPC §35)*

The DCA provided a list of boards that accept military experience and those who do not. The Osteopathic Medicine Board was included in the list of boards that do not have specific statutes or regulations authorizing the acceptance of military experience towards licensure.

The Committee is supportive of the Federal and State efforts to assist licensed military personnel and their family members enjoy better license portability. The Committee encourages licensing boards to examine their ability to exempt licensees from CE and licensing fee requirements during duty as well as waiving any licensing fees that have accrued upon the end of their duty term. The Committee is also supportive of standards for granting temporary licenses or expediting the licensing process for military spouses.

Staff Recommendation: *The Board should make every attempt to comply with BPC § 115.5 in order to expedite licensure for military spouses. The Board should also consider waiving the fees for reinstating the license of an active duty military licensee.*

The Board discussed this issue at their January 31, 2013 Board meeting. The Board is also supportive of the efforts to assist licensed military personnel and their family members and is willing to work to provide assistance in expediting the license At the January 31, 2013 meeting, the Board agreed that we will add a question box to our license application asking "Are you an Active Military Personnel or a spouse of an Active Military personnel"

Applications with "Yes" marked for this question will be escalated and priority will be given to these applications. This question will also be added to our On-Line application form once the BreEze On-Line license application is up and running.

As far as the issue of military experience being applied toward licensure requirements, military does not offer Osteopathic Medical School, or other training in the field of Osteopathic Medicine ; however, an individual completing his/her postgraduate training in an approved military hospital will be considered equivalent to those completing their training in any other approved residency program.

Additionally, Osteopathic Medical Board has created a link on our website to the DCA website posting this information for our osteopathic physician applicants and licensees.

BUDGET

ISSUE #6: **Why are the operating expenses & equipment (OE&E) expenditures so high?**

Background: In its recent report to the Committee, the Board detailed its expenditures by program component. The Board noted that over the past four years, 62% of its expenditures have been dedicated to OE&E. Specifically, the OE&E for the Board's enforcement activity has almost doubled in the past fiscal year. Additionally, the OE&E has decreased significantly for the licensing and diversion components.

Expenditures by Program Component

	~~FY 2008/09~~		~~FY 2009/10~~		~~FY 2010/11~~		~~FY 2011/12~~	
	~~Personnel Services~~	~~OE&E~~	~~Personnel Services~~	~~OE&E~~	~~Personnel Services~~	~~OE&E~~	~~Personnel Services~~	~~OE&E~~
~~Enforcement~~	~~128,736~~	~~232,096~~	~~127,764~~	~~216,202~~	~~143,842~~	~~185,289~~	~~144,956~~	~~335,359~~
~~Examination~~	-	-	-	-	-	-	-	-
~~Licensing~~	~~193,104~~	~~348,144~~	~~191,646~~	~~324,304~~	~~215,763~~	~~277,934~~	~~217,934~~	~~86,447~~
~~Administration *~~	~~64,368~~	~~116,048~~	~~63,882~~	~~108,102~~	~~71,921~~	~~92,645~~	~~153,151~~	~~28,816~~
~~DCA Pro Rata~~	-	~~99,700~~	-	~~105,766~~	-	~~161,665~~	-	~~195,372~~
~~Diversion (if applicable)~~	~~64,368~~	~~116,048~~	~~63,882~~	~~108,102~~	~~71,921~~	~~92,645~~	~~72,478~~	~~28,816~~
~~TOTALS~~	~~$450,576~~	~~$912,036~~	~~$447,174~~	~~$862,476~~	~~$503,447~~	~~$810,178~~	~~$588,019~~	~~$674,810~~

~~*Administration includes costs for executive staff, board, administrative support, and fiscal services.~~

The Committee is aware of the Board's reported budgetary constraints. As such, the Committee is curious about why there is such high OE&E for 2011-2012. The Committee is also interested in the low expenditures for licensing and diversion.

Staff Recommendation: *The Board should advise the Committee of the significant inconsistencies in its OE&E, licensing, and diversion program components.*

After careful review of the table above, we noticed that the numbers are incorrect. We had our DCA budget analyst review and amend our figures. Listed below are the accurate numbers:

Table 3. Expenditures by Program Component - Modified to show additional data

	FY 2008/09			FY 2009/10			FY 2010/11			FY 2011/12		
	Per Services	OE&E	%	Per Services	OE&E	%	Per Services	OE&E	%	Per Services	OE&E	%
Enforcement	128,736	$ 603,066	54%	127,764	$ 577,745	54%	143,842	$ 452,541	45%	144,956	$ 633,591	48%
Examination	-	-	-	-	-	-	-	-	-	-	-	-
Licensing	193,104	$ 87,129	21%	191,646	$ 74,292	20%	215,763	$ 75,663	22%	217,434	$ 85,603	19%
Admin	64,368	$ 28,368	7%	63,882	$ 24,188	7%	71,920	$ 24,635	7%	153,151	$ 27,871	11%
Pro Rata*	-	$ 165,107	12%	-	$ 162,063	12%	-	$ 232,705	18%	-	$ 248,434	15%
Diversion	64,369	$ 28,368	7%	63,883	$ 24,188	7%	71,920	$ 24,635	7%	72,478	$ 27,871	6%
TOTALS	$ 450,577	$ 912,037	100%	$ 447,175	$ 862,475	100%	$ 503,445	$ 810,178	100%	$ 588,019	$ 1,023,369	100%

* Enforcement includes personnel OE&E, AG, OAH, and investigative service costs.
* Pro Rata includes DCA distributed costs and Statewide Pro Rata.

Over the last four fiscal years, approximately 50% of the Boards expenditures have been spent on Enforcement, 21% on Licensing, 8% on Administration, 14% on Pro Rata, and 7% on Diversion. During the same time period, Personnel Services represented 36% of the Boards expenditures, while OE&E was 64%.

ENFORCEMENT

ISSUE #7: How does the Board plan to regulate Internet prescribing?

Background: The Board indicated that it regulates Internet prescribing in accordance with BPC § 2242.1. According to the law, no licensee shall prescribe, dispense, or furnish on the Internet any "dangerous drug or device" defined as any drug or device bearing the legend: "caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import without prior examination of the patient. Violation of this law constitutes unprofessional conduct. In its recent report to the Committee, the Board reported that it "... investigates instances where osteopathic physicians are involved in this type of practice and prosecutes physicians found guilty of substandard care." They reported that "much of this activity goes without notice to the licensing agency...and internet prescribing is an ongoing problem for the Board."

The Committee is concerned with the Board's ability to effectively regulate DOs who may be engaged in the practice of Internet prescribing. The Committee notes that the Board indicated that there should be a national effort to monitor Internet prescribing.

Staff Recommendation: *In light of the Board's concerns about regulating the practice of Internet prescribing and the board's recommendation about national regulation of this practice, the Committee recommends that the Board create a subcommittee to research the issue of Internet prescribing and create policy recommendations for regulating this practice.*

The Board will add as an agenda item "Internet Prescribing" and the creation of a subcommittee to research the issue and create policy to regulate the practice.

The Committee should be familiar that is considered unprofessional conduct for a licensee to prescribe medication without a prior good faith history and physical examination and the Board will take disciplinary action in cases where physicians are proven to violate these principles. Internet prescribing is on the Board's radar and the Board is vigilant in this respect. Identification of offenders is the current major impediment.

ISSUE #8: What has led to the time lag in cases referred to the Attorney General?

Background: According to the Board's recent report to the Committee, enforcement cases which were referred to the Attorney General for formal discipline extended considerably beyond the target time frame of 540 days. For fiscal year 2010-2012, the average time required to complete the entire enforcement process for cases resulting in formal discipline was 1152 days. The Board's enforcement staff recognized the significant lag time and "became more interactive with the Office of the Attorney General" resulting in a decrease from 1152 to 949 for completion of cases referred to the Attorney General for formal discipline. The Committee is encouraged by the recent decrease to the processing time, but remains concerned that the Board's 540 day target time frame is still being exceeded by a significant quantity. The Committee is also concerned with the potential harm to the public that may be incurred if an unscrupulous licensee continues to practice during a lengthy disciplinary case review by the Attorney General.

Staff Recommendation: *The Committee recommends that the Board specify how they "became more interactive" with the Attorney General's office and indicate what additional measures can be taken to expedite processing of enforcement cases.*

The Osteopathic Medical Board staff has made a dedicated effort to work with the Sworn Investigators of the Medical Board and the offices of the Attorney General in a collegial manner for public protection. The Osteopathic Medical Board has opted to not participate in vertical prosecution as the Medical Board investigators and the Deputy Attorney General on a give case take command and exclude consideration by the Osteopathic Medical Board staff and create a more expensive and delayed resolution to any specific case. It is felt that elimination of vertical prosecution has been a major factor in the decrease in time from 1152 to 949 days and it is believed that the number will further decrease in the absence of vertical prosecution. The Osteopathic Medical Board staff has begun a campaign of regular contact with the office of the Attorney General to hasten the process at that level. There have been instances in the past five years when there has been no liaison with the Attorney General's office apparently as a result of lack of shortage of staff at that level. It is the belief of the Osteopathic Medical Board staff that frequent calls and encouragement has expedited the time required to complete cases referred for prosecution. The Osteopathic Medical Board staff will continue to make the necessary contacts to expedite processing. It is hoped that the Attorney General's office will be able to attract and hire the necessary staff to help the Osteopathic Medical Board to meet the target time frame of 540 days.

ISSUE #9: What has contributed to increased complaints?

Background: In its recent report to the Committee, the Board indicated that case loads for complaints "...are steadily increasing each year. Cases are becoming increasingly complex." The Board attributes this increase to the increase in the licensing population. The Board has the option of utilizing the Sworn Investigators from the MBC. However, the Board indicated that they only utilize the MBC's officers Sworn Investigators on less than 1/3 of the enforcement cases (Conversation with Angie Burton, Executive Director, Board on February 14, 2013).

Considering the Board's noted difficulty monitoring enforcement cases, the Committee is concerned about the Board's ability to continue monitoring enforcement cases.

Staff Recommendation: *The Committee recommends that the Board indicate how they plan to address the increasing number of enforcement cases. The Committee recommends that the Board consider getting additional assistance with enforcement from the MBC?*

The Osteopathic Medical Board has more than doubled of the number of licensees in the past ten years and it is anticipated that there will be another doubling in the next ten years. The number of consumer complaints has increased proportionately with the additional number of osteopathic physician providers. It should be noted that the case loads are not increasingly more complex; the complexity has remained unchanged. There are, however, more of all types of cases including those of greater magnitude and legal difficulty. The Osteopathic Medical Board utilizes the Medical Board's sworn investigators in less than one-third of enforcement cases as the balance of cases do not require the enhanced degree of investigation and are handled in-house by the Osteopathic Medical Board's medical consultants. The Medical Board's sworn investigators are always called upon when their services are deemed needed and appropriate. The Osteopathic Medical Board's difficulty in

monitoring cases can and will be overcome and appropriate oversight will be achieved when the needed and requested staff are brought on board. With the recent addition of an enforcement analyst and in-house medical consultant, this is a start in achieving our goals. With an in-house medical consultant added to the Osteopathic Medical Board staff, the there .s no longer a need to forward complaints out of office to outside medical consultants, which cuts weeks, even months in completing complaint reviews. The Osteopathic Medical Board has the budget and has requested approval for a supervisory staff to assist in the timely assignment of complaint cases to further reduce the time from intake to completion of cases. The Osteopathic Medical Board plans to submit another BCP in 2013 for additional staffing to keep up with the increasing number of osteopathic practitioners licensed in California, which undoubtedly will increase the number of complaints.

ISSUE #10: Should the OMB utilize the Franchise Tax Board's Interagency Intercept Collections program (IIC)?

Background: The Franchise Tax Board is responsible for administering the IIC program. The IIC intercepts (offsets) refunds when individuals have delinquent debts owed to government agencies and California colleges. The types of intercepted payments include personal income tax refunds, lottery winnings, and unclaimed property disbursements.

In its recent report to the Committee, the Board indicated that it does not utilize the Franchise Tax Board's program to collect outstanding fines.

The Committee is concerned that the Board is not using the Franchise Tax Board's intercepts to collect outstanding fines.

;taff Recommendation: *The Board should provide an explanation detailing why it is not using the Franchise Tax Board's intercepts.*

The Osteopathic Medical Board allows cost recovery payment ordered as a probationary term to be paid over the period of their probation, i.e. three-year probation, five-year probation, etc. and has success in collecting these costs. If respondent does not pay these costs, it would constitute a violation of their probation; therefore, respondents are willing to pay these costs without the need for FTB's interception. Osteopathic Medical Board is not against the use of FPT and will utilize them should the need arise.

STAFFING

ISSUE #11: Why was the Board's budget change proposal (BCP) denied?

Background: The Osteopathic Medicine Act provides authority for the Board to regulate the profession of osteopathic medicine. The Board is charged with protecting its licensees and the consumers of osteopathic medicine. Included in the Board's basic authority is the ability for the Board to approve or deny licenses, take enforcement actions, pursue legislation, and conduct administrative duties.

In its recent report to the Committee, the Board indicated that there have been various constraints that have affected its ability to carry out its mandates. Specifically, the following deficiencies were noted:

1. No major studies have been conducted.
2. No consumer outreach efforts have been initiated

3. No participation in national organizations such as the FSMB
4. Inability to process licenses in a timely manner
5. No NLI notifications are sent to DOJ
6. Inefficiency processing and renewing applications
7. Minimal cite and fine is utilized
8. Limited use of the Board's website to post information for the public
9. No meetings are webcast

The Board reported that these deficiencies are directly related to a lack of staff that would be responsible for completing these salient tasks. Currently, the Board has an Executive Officer and five additional support staff. Additionally, the Board reported that their 2013-2014 BCP for additional staff was denied by DCA.

The Committee is extremely concerned about the Board's ability to regulate the profession as they have limited staff which prevents them from performing essential tasks that will help ensure consumer protection.

Staff Recommendation: *The Board should inform the Committee of its plan to continue carrying out its various duties if no additional staff is allocated for the Board. The Board may want to explore the possibility of hiring temporary or part-time staff to assist with completing critical tasks. Additionally, the Committee encourages the Board to seriously consider the benefits of merging with the MBC in order to ensure that the essential duties of the Board are carried out in the spirit of consumer protection.*

The Board received information that the 2013/2014 BCP was approved by DCA, but rejected by the Agency as not meeting the Department of Finance requirements. We received no other information as to which requirements our BCP did not meet, although this information was requested. We asked for a meeting with Agency, however, this did not take place. The BCP submitted by DCA for staffing under the CPEI (Consumer Protection Enforcement Initiative), provided the Osteopathic Medical Board with one additional analyst in enforcement, along with a half-time medical consultant. With the addition of these two new positions, which were filled in December 2012 and January 2013, respectively, it is anticipated that the time it is taking for intakes and investigative processes of complaints will be reduced; additionally, with the added enforcement staff, we will be able to better utilize our Cite and Fine program.

With the growing number of licensees, the workload for processing new license applications and renewals of licenses increases. The implementation of the BreEze database, when the system becomes fully functioning, promises streamlining the license application process and license renewal process and decrease the time to process applications and renewals. The Board, however, does not have enough staff to perform other licensing related duties, such as sending out the "No Longer Interested" notifications to DOJ; and other "housekeeping duties" such as filing, and purging of old files. The Board also lacks staff for administrative duties, such as contracts and purchasing requests, web site maintenance, and oversight of personnel issues. The Board has submitted a request for a staff services manager to assist with these issues and are awaiting approval from HR. If the Board receives authorization to hire a staff services manager, we can request assistance from DCA in possibly bringing in temporary help for these "housekeeping" duties. Recently, due to the BreEze data base implementation, DCA has recommended that Boards look into hiring of Permanent Intermittent positions to help with the transition into this new system and assist with clerical

support needs. The Osteopathic Medical Board will be able to better determine in which units the critical needs for staffing exist, once the BreEze is up and running and staff can assess their needs.

The Osteopathic Medical Board contracts with the Medical Board of California to utilize their formal investigators. Most complaints received in this office are reviewed and enforcement analysts complete "desk investigations". Certified copies of medical records and other pertinent documents are requested from appropriate parties with the proper authorization from patient/complainant. These certified documents are reviewed by our medical consultant. The medical consultant can determine whether the complaint case has merit or no merit. Cases deemed without merit are closed in this office without further action and the complainant and respondent are both notified of the closure. For cases deemed "with merit," depending on the nature of the complaint, are closed with an "educational letter" sent to the respondent and letting the patient/complainant know that the case will be kept in the office for seven years and if complaints of a similar nature is received, the case could be re-opened. If the medical consultant feels the case needs additional review, the case file is sent to a specialist in the field of the respondent, i.e., cardiology, psychiatry, plastic surgery, etc. for their expert opinion. If the case warrants a formal investigation, it is forwarded to the Medical Board with a request to investigate. Less than one –third of complaints are sent to the Medical Board for formal investigation.

One case, which is mentioned in the Medical Board Background paper, the investigation of Lisa Tseng, D.O., was used as an example why the Osteopathic Medical Board enforcement should be handled by the Medical Board. This case was one that the Osteopathic Medical Board submitted to the Medical Board of California to investigate on behalf of the Osteopathic Medical Board. Placing the Osteopathic Medical Board under the Medical Board would not have made any difference in the outcome of this case, nor would it have sped up the investigation. When the Drug Enforcement Administration and or the District Attorney's office becomes involved with a case, especially cases involving overprescribing of narcotics, the MBC investigators have to work alongside their investigators. This sometimes takes longer than we would like, however, the Osteopathic Medical Board relies on the expertise of the Medical Board Investigators to work these cases to obtain the optimal results. The cases which are taking the longest to complete are the cases which are referred to the Medical Board for formal investigation and/or cases submitted to the Attorney General's Office for discipline.

With the increasing number of licensees, the Board will submit another BCP for additional staffing in 2014.

Continued Regulation of the Profession by the Current Members of the Board

ISSUE #11: Should the current Board continue to license and regulate DOs?

Background: The health and safety of consumers is protected by well-regulated professions. The Board is charged with protecting the consumer from unprofessional and unsafe licensees.

Staff Recommendation: *The Committee recommends that DOs continue to be regulated by the current Board and be renewed again in four years. The Committee maintains its position, and will raise the issue again, that during their four year extension, the Board should seriously consider merging with the MBC.*

This should be ISSUE #12.

Please see response to ISSUE #2.

TAB 7

White Paper:
Osteopathic Medical Board
Clinical Practice Guidelines for the Prescription of Opioids for Chronic NonCancer Pain

Richard B. Riemer, D.O.
Sutter Medical Group-Neuroscience Division
Medical Director, Schools Insurance Authority
Professor of Neurology, Department of Neurology, UC Davis Medical School/Center, Sacramento, CA
Adjunct Professor of Neurology, Touro University-College of Osteopathic Medicine, Vallejo, CA.

Introduction:
Protagonists in the battle against pain, physicians are challenged to strike a balance between benefit and harm, minimizing abuse of prescription drugs, iatrogenic addiction, drug diversion and aberrant-drug behaviors. [1] The April 2011 White House comprehensive action plan on Prescription Drug Abuse notes that ". . . any policy in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use" (The White House, 2011, pp. 1-2).

The escalation in the prescription of opioid analgesics was promoted by physicians good faith efforts to provide compassionate care, and supported, in hindsight, by false claims of low risk for de novo addiction, absent ceiling doses, and rare drug tolerance. [2] Physicians not embracing the paradigm shift, that pain is a disease that can be combated with narcotic analgesics, were labeled "opiophobic" and derelict in their duty and sworn commitment to attenuate what was now labeled the "fifth vital sign". [3] In reality, the long-term effects and effectiveness of this class of medications has been poorly demonstrated, with only weak evidence of clinically significant pain relief in those patients treated for chronic noncancer pain (CNCP). [4] Controlled trials lasting 1-6 months suggest only modest relief compared to placebo and no long-term study has determined whether analgesic effect is maintained. [5-7] The IOM report, *Relieving Pain in America*, comments that "the effectiveness of opioids as pain relievers, especially over the long term, is somewhat unclear".[8] The biologic effects of this class of drugs may result in paradoxical increase in chronic pain, a hypersensitivity syndrome that is thought to occur by central pronociceptive sensitization. [9] Neurobiologic effects measured by structural and functional changes of the human brain are emerging, potentially confirming deleterious effects from brief exposure to this class of drugs and that such neurologic changes that may be immutable. [10, 11] Potential medical risks to the patient are numerous including serious fractures, breathing problems during sleep, immunosuppression, chronic constipations, bowel obstruction, myocardial infarction and tooth decay from xerostomia. Neuroendocrine dysfunction in both sexes potentially causes hypogonadism, erectile dysfunction, infertility, osteoporosis, and depression. [12] The diversion of prescription drugs amongst adolescents is now the most common form of drug abuse. [13] Admission rates to State sponsored substance abuse clinics has soared over a ten year period through 2009. [14]

The societal impact is sobering. In 2010, about 12 million Americans ages 12 or older reported nonmedical use of prescription painkillers in the past year. Nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers. Non medical use of prescription painkillers cost health insurers up to $72.5 billion annually in direct health care costs.

The increased use of prescription painkillers for nonmedical reasons along with growing sales has contributed to a large number of prescription drug overdoses. [15] Defined as a public health epidemic by the CDC, prescription drug overdose now kills more Americans then heroin and cocaine combined, reflecting a five-fold increase since 1990. [16] In 2010, $8.5 billion dollars was spent on narcotic analgesics in the U.S., hydrocodone/APAP was the most dispensed medication, enough to supply every US Adult one 5 mg tablet every four hours for six weeks. (IMS Data). Pertinent to the Osteopathic Medical Board, the physicians that account for nearly 28% of all prescriptions for immediate and long-acting opioids were general practitioners, family practice physicians, and Doctors of Osteopathic Medicine and Internal Medicine physicians. [17]

The challenge

A myriad of Clinical Practice Guidelines and Systematic Reviews that inform best practices for prescribing and monitoring patients taking opioids for CNCP are available. [18-34] A recent critical appraisal of the quality of these guidelines showed overlap in many recommendations for mitigating risk associated with opioid pain medications. [35] Given these gaps in scientific knowledge, experts in this field find themselves in the unenviable position to draft best practice recommendations to curb the deleterious effects of opioids on the individual and assuage the collateral damage to society.

Clinical studies confirm that early prescription of opioids for acute pain, the number of prescriptions, and a escalating daily dose (morphine equivalent dose) correlate with long-term complications, including increased incidence of surgeries, increased duration of disability, greater cost of medical care and increased risk of long-term opioid use. It reasons that a physician's propensity for early prescribing and failure to adhere to best practice guidelines may impact patient outcome and little doubt that the excessive availability of prescription opioids are a fundamental ingredient to the current public health crisis. [36-38] Alternatively, the science of addiction suggests that regardless of predisposition, it is merely the use of the opioid that contribute to misuse, abuse, addiction and a downward spiral toward chronic noncancer pain.

The breadth and seriousness of the prescription drug abuse epidemic has prompted action on Federal Level. [39] For instance, in September of 2013, the FDA has announced updated labeling on all ER/LA opioids. Recognizing the need for more scientific data about benefits and risks of this class of drugs, the FDA will require drug manufacturers to conduct longer term studies and trials of ER/LA opioid pain relievers on the market. There are now States adopting policies in response to the opioid epidemic, including Washington, Colorado, Texas, Minnesota, New York and Massachusetts. In California, no medical regulatory authority (MRA) under the auspices of the Department of Consumer Affairs, has overseen the development and implementation of a guideline for safe and effective opioid use for CNCP. This is the OMB Challenge.

OMB Project

The Osteopathic perspective, education, and skill set are uniquely suited to address the opioid epidemic. Consider the public health and medical challenges posed by the epidemic of opioid prescription drug abuse juxtaposed to the burden of chronic pain that afflicts approximately 100 million Americans, of

which musculoskeletal pain is the primary cause of disability in the aging population. The development of the Osteopathic Medical Board Clinical Practice Guidelines for Prescription of Opioids for Chronic NonCancer Pain (OMB-OpCNCP) would provide a best practice standard of care to ensure safe and responsible opioid prescribing. This living document would be updated as new scientific research and literature continues to unravel the neurobiology of addiction and as scientific inquiry, technological advances and discovery advance our understanding and improve our practice of pain medicine. The OMB would serve as a depository of useful, patient and physician information with instruments that can be easily accessed at point-of-contact, to assist with responsible prescribing, such as downloadable Treatment Agreements, Risk Stratification Tools for Abuse Potential, Psychosocial scales for function, Pain scales, medical guidelines for trials, maintenance, tapering of opioids, helpful information to deal with the "problem patient", opioid conversion tables.

Research Objective

Considering the overlap in clinical practice guideline recommendations intended to assist the clinician in safe initiation and monitoring of opioid prescribing, a preliminary study was designed to review Clinical Practice Guidelines that can be used to inform the safe and effective prescribing of Opioid Analgesics for Chronic NonCancer Pain. This preliminary study serves as a starting point for further development of the OMB-CPG for Prescription of Opioids for CNCP.

Methods

Inclusion and Exclusion Criteria:

Recreating the search methods conducted by Nuchols, et al., Guidelines and systematic reviews addressing chronic pain, acute/subacute pain and neuropathic pain was conducted with emphasis on chronic pain [40]. Documents that focused on opioid prescription for pain were emphasized. Excluded were documents addressing chronic pain associated with cancer pain, pain at the end of life, post-operative pain, pain associated with labor and delivery, pain related to specific diseases. For systematic reviews, exclusions included animal studies, children only.

Search Guidelines

To search, the following sources were explored:

PubMed Search was conducted for Opioids, Guidelines, Publish dates after 200y7, English language.

National Guidelines Clearinghouse

Websites of specialty societies including:

- American Academy of Family Physicians
- American Academy of Pain Medicine
- American Academy of Physical Medicine and Rehabilitation
- American College of Occupational and Environmental Medicine
- American College of Physicians
- American Geriatrics Society
- American Society of Addiction Medicine
- American Society of Anesthesiologists
- American Society of Interventional Pain Physicians
- Association of Military Surgeons of the U.S.
- National Medical Association

- Society of Medical Consultants to the Armed Forces
- International Association of Industrial Accident Boards and Commissions

State Guidelines reviewed:

- California
- Washington State
- Utah
- Colorado

Systematic Reviews were searched using the following data sources:

- AHRQ website
- Health Systems Evidence, McMaster University
- Cochrane Reviews
- PubMed Search

Guideline Evaluation

Both the AMSTAR instrument and the AGREE II were instruments consulted to rate quality of the literature.

A partial listing of the Guidelines reviewed:

1. *VA/DoD Evidence Based Practice: Management of Opioid Therapy for Chronic Pain*. 2010.
2. *Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine*. Anesthesiology, 2010. **112**(4): p. 810-33.
3. Chou R, F.G., Fine PG, Adler JA, Ballanthyne JC, Davies P, et al., *2009 Clinical Guidelines from the American Pain Society and the American Academy of Pain Medicine on the use of chronic opioid therapy in chronic noncancer pain: what are the key messages for clinical practice?* 2009. **119**(7-8): p. 469-77.
4. (2009) *Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review*.
5. *State of Colorado Chronic Pain Disorder Medical Treatment Guidelines*, D.o.L.a. Employment, Editor. 2007.
6. *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*, N.O.U.G.G. (NOUGG), Editor. 2010.
7. *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*, in *Washington State Agency Medical Directors*. 2010, Washington State
8. Kahan, M., A. Mailis-Gagnon, and E. Tunks, *Canadian guideline for safe and effective use of opioids for chronic non-cancer pain: implications for pain physicians.* Pain Res Manag, 2011. **16**(3): p. 157-8.
9. Trescot, A.M., et al., *Opioids in the management of chronic non-cancer pain: an update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines.* Pain Physician, 2008. **11**(2 Suppl): p. S5-S62.
10. Kahan, M., et al., *Canadian guideline for safe and effective use of opioids for chronic noncancer pain: clinical summary for family physicians. Part 2: special populations.* Can Fam Physician, 2011. **57**(11): p. 1269-76, e419-28.

11. Furlan, A.D., R. Reardon, and C. Weppler, *Opioids for chronic noncancer pain: a new Canadian practice guideline.* CMAJ, 2010. **182**(9): p. 923-30.
12. Rolfs RT, J.E., Williams NJ, Sundwall DN, *Utah Clinical Guidelines on Prescribing Opioids for Pain.* 2009, Utah Department of Health: Salt Lake City.
13. Rolfs, R.T., et al., *Utah clinical guidelines on prescribing opioids for treatment of pain.* J Pain Palliat Care Pharmacother, 2010. **24**(3): p. 219-35.
14. Hooten WM, e.a., *Assessment and Management of Chronic Pain, 5th Edition.* 2011, Institute for Clinical Systems Improvement.
15. *California Medical Treatment Utilization Schedule (MTUS): Chronic Pain Medical Treatment Guidelines*, DIR, Editor. 2009.
16. Fishman SM, *Responsible Opioid Prescribing, a Clinicians Guide.* 2nd ed, ed. FSMB. 2012, Washington D.C. : Waterford Life Sciences. 147.

Findings:

The two Clinical Practice Guidelines that scored highest on the AMSTAR and AGREE II were the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain (24) and APS-AAPM Clinical Practice Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain (20). Examples of themes in various Guidelines reviewed include:

- Baseline assessment: Complete history and physical that assesses for the type of pain, prior treatments, review off diagnostic studies, emphasis on biopsychosocial model of disease assessment and treatment, and risk stratification for addiction, misuse, abuse, diversion; psychiatric status, substance use history.
- Determination of a "trial" of opioid analgesics is reasonable
- Assessment of response to opioid analgesic
- Dose Adjustment instructions
- Monitoring compliance
- Treatment of the high dose patient
- Treatment Agreements
- Monitoring for side-effects
- Measuring treatment success with emphasis on improved function versus pain reduction
- Drug selection
- Morphine equivalent dose recommendations
- Referral for specialty consultation
- Special considerations for the use of opioids and treatment of pain in the elderly
- Managing opioid misuse and addiction

No Guideline addressed complementary alternative medical approaches specifically the role of Osteopathic Medicine-diagnosis and manual therapy either in lieu of or adjunctive to pharmacotherapy for chronic pain.

Summary:

There is no single solution to the epidemic of prescription drug abuse in the United States, rather a cooperative effort between numerous stakeholders are necessary, including Public health officials, law

enforcement, government, community based resources and activism, educational institutions (from grammar school to medical schools) and medical regulatory associations. While the personal and societal toll of the epidemic is now measurable in terms of cost, both financial and human, the pendulum is now swinging back to sound medical policies that appreciate the continued access of opioid analgesics for conditions such as pain due to cancer, end-of-life pain, post-surgical pain, while acknowledging the limited evidence for the use of opioids for the treatment of far more common conditions collectively referred to as the chronic noncancer pain. The trial of such drugs for CNCP should be protected as well, since a small percentage may benefit by improving function and reducing pain; but, responsible prescribing practices are required to prevent the untoward and unintentional consequences of the inappropriate use of these agents.

The Osteopathic profession has an advantage in the scripting of responsible guidelines, and the development of resources for physicians and the public, based on the strength and bias of the education which has always emphasized the interconnection between structure and function, and our unique vantage, peering through a window that exposes some of the biologic underpinnings of pain afforded by knowledge in the musculoskeletal system and neurosciences. The public health awareness of the epidemic of prescription drug abuse and the escalating prevalence of chronic pain in the US population demands attention and redress from the professionals that were complicit in this crisis. The generation of OMB Clinical Practice Guidelines for the Prescription of Opioid Analgesics for Chronic Noncancer pain combined with OMB resources for both physicians and patients will be the first coordinated effort by a medical regulatory authority to proactively acknowledge and tangibly address this personal and public health issue.

Moving forward will require careful analysis of Clinical Practice Guidelines and policies that already exist, and modifying these based on a unique Osteopathic perspective and a skill set that is exceptional to our profession.

References:

1. Sullivan, M.D., et al., *Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain.* Pain, 2010. **149**(2): p. 345-53.
2. *The use of opioids for the treatment of chronic pain. A consensus statement from the American Academy of Pain Medicine and the American Pain Society.* Clin J Pain, 1997. **13**(1): p. 6-8.
3. Morgan, J.P., *American opiophobia: customary underutilization of opioid analgesics.* Adv Alcohol Subst Abuse, 1985. **5**(1-2): p. 163-73.
4. Noble, M., et al., *Long-term opioid management for chronic noncancer pain.* Cochrane Database Syst Rev, 2010(1): p. CD006605.
5. Chou, R., et al., *Research gaps on use of opioids for chronic noncancer pain: findings from a review of the evidence for an American Pain Society and American Academy of Pain Medicine clinical practice guideline.* J Pain, 2009. **10**(2): p. 147-59.
6. Martell, B.A., et al., *Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction.* Ann Intern Med, 2007. **146**(2): p. 116-27.
7. Papaleontiou, M., et al., *Outcomes associated with opioid use in the treatment of chronic noncancer pain in older adults: a systematic review and meta-analysis.* J Am Geriatr Soc, 2010. **58**(7): p. 1353-69.

8. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. 2011, Washington D. C. : Institute of Medicine.
9. Chu, L.F., M.S. Angst, and D. Clark, *Opioid-induced hyperalgesia in humans: molecular mechanisms and clinical considerations.* Clin J Pain, 2008. **24**(6): p. 479-96.
10. Upadhyay, J., et al., *Alterations in brain structure and functional connectivity in prescription opioid-dependent patients.* Brain, 2010. **133**(Pt 7): p. 2098-114.
11. Younger, J.W., et al., *Prescription opioid analgesics rapidly change the human brain.* Pain, 2011. **152**(8): p. 1803-10.
12. Vuong, C., et al., *The effects of opioids and opioid analogs on animal and human endocrine systems.* Endocr Rev, 2010. **31**(1): p. 98-132.
13. Sung, H.E., et al., *Nonmedical use of prescription opioids among teenagers in the United States: trends and correlates.* J Adolesc Health, 2005. **37**(1): p. 44-51.
14. *Treatment Episode Data*. 2010, Center for Behavioral Health and Quality, Substance Abuse and Mental Health Services Administration.
15. Paulozzi LJ, J.C., Mack KA, Rudd RA, *Overdoses of Prescription Opioid Pain Relievers---United States, 1999-2008.* CDC Vital Signs, 2011. **60**(43): p. 1478-1492.
16. CDC (2010b) *Unintentional drug poisoning in the United States.* http://www.cdc.gov/HomeandRecreationgalSafety/Poisoning/brief.htm.
17. *Presentation: OutpatientPrescription Opioid, Utilization in the U.S., Years 2000-2009*, U.S.F.D.A., Editor. 2010.
18. *VA/DoD Evidence Based Practice: Management of Opioid Therapy for Chronic Pain*. 2010.
19. *Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine.* Anesthesiology, 2010. **112**(4): p. 810-33.
20. Chou R, F.G., Fine PG, Adler JA, Ballanthyne JC, Davies P, et al., *2009 Clinical Guidelines from the American Pain Society and the American Academy of Pain Medicine on the use of chronic opioid therapy in chronic noncancer pain: what are the key messages for clinical practice?* 2009. **119**(7-8): p. 469-77.
21. Chou R, F.G., Fine PG, Adler JA, Ballanthyne JC, Davies P, et al., *Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain.* J Pain, 2009. **10**(2): p. 113-30.
22. (2009) *Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review.*
23. *State of Colorado Chronic Pain Disorder Medical Treatment Guidelines*, D.o.L.a. Employment, Editor. 2007.
24. *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*, N.O.U.G.G. (NOUGG), Editor. 2010.
25. *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*, in *Washington State Agency Medical Directors*. 2010, Washington State
26. Kahan, M., A. Mailis-Gagnon, and E. Tunks, *Canadian guideline for safe and effective use of opioids for chronic non-cancer pain: implications for pain physicians.* Pain Res Manag, 2011. **16**(3): p. 157-8.
27. Trescot, A.M., et al., *Opioids in the management of chronic non-cancer pain: an update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines.* Pain Physician, 2008. **11**(2 Suppl): p. S5-S62.
28. Kahan, M., et al., *Canadian guideline for safe and effective use of opioids for chronic noncancer pain: clinical summary for family physicians. Part 2: special populations.* Can Fam Physician, 2011. **57**(11): p. 1269-76, e419-28.

29. Furlan, A.D., R. Reardon, and C. Weppler, *Opioids for chronic noncancer pain: a new Canadian practice guideline.* CMAJ, 2010. **182**(9): p. 923-30.

30. Rolfs RT, J.E., Williams NJ, Sundwall DN, *Utah Clinical Guidelines on Prescribing Opioids for Pain.* 2009, Utah Department of Health: Salt Lake City.
31. Rolfs, R.T., et al., *Utah clinical guidelines on prescribing opioids for treatment of pain.* J Pain Palliat Care Pharmacother, 2010. **24**(3): p. 219-35.
32. Hooten WM, e.a., *Assessment and Management of Chronic Pain, 5th Edition.* 2011, Institute for Clinical Systems Improvement.
33. *California Medical Treatment Utilization Schedule (MTUS): Chronic Pain Medical Treatment Guidelines*, DIR, Editor. 2009.
34. Fishman SM, *Responsible Opioid Prescribing, a Clinicians Guide.* 2nd ed, ed. FSMB. 2012, Washington D.C. : Waterford Life Sciences. 147.
35. Nuckols T, e.a., *Identifying Risky Opioid Prescribing Practices.* 2012, UCLA: Los Angeles.
36. Webster, B.S., S.K. Verma, and R.J. Gatchel, *Relationship between early opioid prescribing for acute occupational low back pain and disability duration, medical costs, subsequent surgery and late opioid use.* Spine (Phila Pa 1976), 2007. **32**(19): p. 2127-32.
37. Mahmud, M.A., et al., *Clinical management and the duration of disability for work-related low back pain.* J Occup Environ Med, 2000. **42**(12): p. 1178-87.
38. Franklin, G.M., et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort.* Spine (Phila Pa 1976), 2008. **33**(2): p. 199-204.
39. *Epidemic: Responding to America's Prescription Drug Abuse Crisis.* 2011, Executive Office of the President of the United States.
40. Nuchols, T., et al., *A report to California DIR and CCHSWC: Identifying Risky Opioid Prescribing Practices.* 2012, UCLA and Oregon Health Sciences University

TAB 8

LEGISLATION:

The attached copies of legislative bills are provided for information only. Those bills which were not Chaptered or Enrolled, will have no further action by legislature until January 2014.

Chaptered

AB1288 was approved by the Governor and filed with Secretary of State on September 9, 2013. This bill adds section 2092 to the Business and Professions Code. It requires both the Osteopathic Medical Board and Medical Board to develop a process to give priority review status to applications filed by applicants who can demonstrate, as specified, that he or she intends to practice in a medically underserved area or serve a medically underserved population.

Underserved area or underserved population as defined in Section 128565 of the Health and Safety Code:

d) "Medically underserved area" means an area defined as a health professional shortage area in Part 5 (commencing with Sec. 5.1) of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations or an area of the state where unmet priority needs for physicians exist as determined by the California Healthcare Workforce Policy Commission pursuant to Section 128225.
(e) "Medically underserved population" means the persons served by the Medi-Cal program, the Healthy Families Program, and uninsured populations.

AB 154

California LEGISLATIVE INFORMATION

AB-154 Abortion. (2013-2014)

ENROLLED SEPTEMBER 05, 2013

PASSED IN SENATE AUGUST 26, 2013

PASSED IN ASSEMBLY AUGUST 30, 2013

AMENDED IN SENATE JUNE 24, 2013

AMENDED IN ASSEMBLY APRIL 30, 2013

AMENDED IN ASSEMBLY MARCH 19, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL No. 154

Introduced by Assembly Member Atkins
(Principal coauthor: Senator Jackson)
(Coauthors: Assembly Members Mitchell and Skinner)

January 22, 2013

An act to amend Section 2253 of, and to add Sections 2725.4 and 3502.4 to, the Business and Professions Code, and to amend Section 123468 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 154, Atkins. Abortion.

Existing law makes it a public offense, punishable by a fine not exceeding $10,000 or imprisonment, or both, for a person to perform or assist in performing a surgical abortion if the person does not have a valid license to practice as a physician and surgeon, or to assist in performing a surgical abortion without a valid license or certificate obtained in accordance with some other law that authorizes him or her to perform the functions necessary to assist in performing a surgical abortion. Existing law also makes it a public offense, punishable by a fine not exceeding $10,000 or imprisonment, or both, for a person to perform or assist in performing a nonsurgical abortion if the person does not have a valid license to practice as a physician and surgeon or does not have a valid license or certificate obtained in accordance with some other law authorizing him or her to perform or assist in performing the functions necessary for a nonsurgical abortion. Under existing law, nonsurgical abortion includes termination of pregnancy through the use of pharmacological agents.

Existing law, the Nursing Practice Act, provides for the licensure and regulation of registered nurses, including nurse practitioners and certified nurse-midwives, by the Board of Registered Nursing. Existing law, the Physician Assistant Practice Act, provides for the licensure and regulation of physician assistants by the Physician

Assistant Board within the jurisdiction of the Medical Board of California.

This bill would instead make it a public offense, punishable by a fine not exceeding $10,000 or imprisonment, or both, for a person to perform an abortion if the person does not have a valid license to practice as a physician and surgeon, except that it would not be a public offense for a person to perform an abortion by medication or aspiration techniques in the first trimester of pregnancy if he or she holds a license or certificate authorizing him or her to perform the functions necessary for an abortion by medication or aspiration techniques. The bill would also require a nurse practitioner, certified nurse-midwife, or physician assistant to complete training, as specified, and to comply with standardized procedures or protocols, as specified, in order to perform an abortion by aspiration techniques, and would indefinitely authorize a nurse practitioner, certified nurse-midwife, or physician assistant who completed a specified training program and achieved clinical competency to continue to perform abortions by aspiration techniques. The bill would delete the references to a nonsurgical abortion and would delete the restrictions on assisting with abortion procedures. The bill would also make technical, nonsubstantive changes.

Because the bill would change the definition of crimes, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2253 of the Business and Professions Code is amended to read:

2253. (a) Failure to comply with the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code) constitutes unprofessional conduct.

(b) (1) Except as provided in paragraph (2), a person is subject to Section 2052 if he or she performs an abortion, and at the time of so doing, does not have a valid, unrevoked, and unsuspended license to practice as a physician and surgeon.

(2) A person shall not be subject to Section 2052 if he or she performs an abortion by medication or aspiration techniques in the first trimester of pregnancy, and at the time of so doing, has a valid, unrevoked, and unsuspended license or certificate obtained in accordance with the Nursing Practice Act (Chapter 6 (commencing with Section 2700)) or the Physician Assistant Practice Act (Chapter 7.7 (commencing with Section 3500)), that authorizes him or her to perform the functions necessary for an abortion by medication or aspiration techniques.

(c) In order to perform an abortion by aspiration techniques pursuant to paragraph (2) of subdivision (b), a person shall comply with Section 2725.4 or 3502.4.

SEC. 2. Section 2725.4 is added to the Business and Professions Code, to read:

2725.4. Notwithstanding any other provision of this chapter, the following shall apply:

(a) In order to perform an abortion by aspiration techniques pursuant to Section 2253, a person with a license or certificate to practice as a nurse practitioner or a certified nurse-midwife shall complete training recognized by the Board of Registered Nursing. Beginning January 1, 2014, and until January 1, 2016, the competency-based training protocols established by Health Workforce Pilot Project (HWPP) No. 171 through the Office of Statewide Health Planning and Development shall be used.

(b) In order to perform an abortion by aspiration techniques pursuant to Section 2253, a person with a license or certificate to practice as a nurse practitioner or a certified nurse-midwife shall adhere to standardized procedures developed in compliance with subdivision (c) of Section 2725 that specify all of the following:

(1) The extent of supervision by a physician and surgeon with relevant training and expertise.

(2) Procedures for transferring patients to the care of the physician and surgeon or a hospital.

(3) Procedures for obtaining assistance and consultation from a physician and surgeon.

(4) Procedures for providing emergency care until physician assistance and consultation are available.

(5) The method of periodic review of the provisions of the standardized procedures.

(c) A nurse practitioner or certified nurse-midwife who has completed training and achieved clinical competency through HWPP No. 171 shall be authorized to perform abortions by aspiration techniques pursuant to Section 2253, in adherence to standardized procedures described in subdivision (b).

(d) It is unprofessional conduct for any nurse practitioner or certified nurse-midwife to perform an abortion by aspiration techniques pursuant to Section 2253 without prior completion of training and validation of clinical competency.

SEC. 3. Section 3502.4 is added to the Business and Professions Code, to read:

3502.4. (a) In order to receive authority from his or her supervising physician and surgeon to perform an abortion by aspiration techniques pursuant to Section 2253, a physician assistant shall complete training either through training programs approved by the board pursuant to Section 3513 or by training to perform medical services which augment his or her current areas of competency pursuant to Section 1399.543 of Title 16 of the California Code of Regulations. Beginning January 1, 2014, and until January 1, 2016, the training and clinical competency protocols established by Health Workforce Pilot Project (HWPP) No. 171 through the Office of Statewide Health Planning and Development shall be used as training and clinical competency guidelines to meet this requirement.

(b) In order to receive authority from his or her supervising physician and surgeon to perform an abortion by aspiration techniques pursuant to Section 2253, a physician assistant shall comply with protocols developed in compliance with Section 3502 that specify:

(1) The extent of supervision by a physician and surgeon with relevant training and expertise.

(2) Procedures for transferring patients to the care of the physician and surgeon or a hospital.

(3) Procedures for obtaining assistance and consultation from a physician and surgeon.

(4) Procedures for providing emergency care until physician assistance and consultation are available.

(5) The method of periodic review of the provisions of the protocols.

(c) The training protocols established by HWPP No. 171 shall be deemed to meet the standards of the board. A physician assistant who has completed training and achieved clinical competency through HWPP No. 171 shall be authorized to perform abortions by aspiration techniques pursuant to Section 2253, in adherence to protocols described in subdivision (b).

(d) It is unprofessional conduct for any physician assistant to perform an abortion by aspiration techniques pursuant to Section 2253 without prior completion of training and validation of clinical competency.

SEC. 4. Section 123468 of the Health and Safety Code is amended to read:

123468. The performance of an abortion is unauthorized if either of the following is true:

(a) The person performing the abortion is not a health care provider authorized to perform an abortion pursuant to Section 2253 of the Business and Professions Code.

(b) The abortion is performed on a viable fetus, and both of the following are established:

(1) In the good faith medical judgment of the physician, the fetus was viable.

(2) In the good faith medical judgment of the physician, continuation of the pregnancy posed no risk to life or health of the pregnant woman.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a

crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

AB 186

California LEGISLATIVE INFORMATION

AB-186 Professions and vocations: military spouses: temporary licenses. (2013-2014)

AMENDED IN SENATE JUNE 24, 2013

AMENDED IN ASSEMBLY MAY 24, 2013

AMENDED IN ASSEMBLY APRIL 22, 2013

AMENDED IN ASSEMBLY APRIL 01, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL **No. 186**

Introduced by Assembly Member Maienschein
(Principal coauthor: Assembly Member Hagman)
(Coauthors: Assembly Members Chávez, Dahle, Donnelly, Beth Gaines, *Garcia,* Grove, Harkey, Olsen, ~~and~~ Patterson, *and V. Manuel Pérez*)
(Coauthors: Senators Fuller and Huff)

January 28, 2013

An act to ~~amend~~ *add* Section ~~115.5 of~~ *115.6 to* the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 186, as amended, Maienschein. Professions and vocations: military spouses: temporary licenses.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. Existing law requires that the licensing fees imposed by certain boards within the department be deposited in funds that are continuously appropriated. Existing law requires a board within the department to expedite the licensure process for an applicant who holds a current license in another jurisdiction in the same profession or vocation and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders.

This bill would, in addition to the expedited licensure provisions described above, establish a temporary licensure process for an applicant who holds a current license in another jurisdiction, as specified, and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. The bill would require the temporary license to expire 12 months after issuance, upon issuance of the expedited license, or upon denial of the application for expedited licensure

by the board, whichever occurs first.

~~This bill would require a board within the department to issue a temporary license to an applicant who qualifies for, and requests, expedited licensure pursuant to the above-described provision if he or she meets specified requirements, except as provided. The bill would require the temporary license to expire 12 months after issuance, upon issuance of the expedited license, or upon denial of the application for expedited licensure by the board, whichever occurs first. The bill would authorize a board to conduct an investigation of an applicant for purposes of denying or revoking a temporary license, and would authorize a criminal background check as part of that investigation. The~~

This bill would require an applicant seeking a temporary license to submit an application to the board that includes a signed affidavit attesting to the fact that he or she meets all of the requirements for the temporary license and that the information submitted in the application is accurate, as specified. The bill would also require the application to include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing. *The bill would authorize a board to conduct an investigation of an applicant for purposes of denying or revoking a temporary license and would authorize a criminal background check as part of that investigation. The bill would require an applicant, upon request by a board, to furnish a full set of fingerprints for purposes of conducting the criminal background check.*

This bill would prohibit a temporary license from being provided to any applicant who has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license at the time the act was committed. The bill would provide that a violation of the above-described provision may be grounds for the denial or revocation of a temporary license. The bill would further prohibit a temporary license from being provided to any applicant who has been disciplined by a licensing entity in another jurisdiction, or is the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction. ~~The bill would require an applicant, upon request by a board, to furnish a full set of fingerprints for purposes of conducting a criminal background check.~~

This bill would authorize the immediate termination of any temporary license to practice medicine upon a finding that the temporary licenseholder failed to meet any of the requirements described above or provided substantively inaccurate information that would affect his or her eligibility for temporary licensure. The bill would, upon termination of the license, require the board to issue a notice of termination requiring the temporary licenseholder to immediately cease the practice of medicine upon receipt.

This bill would exclude from these provisions a board that has established a temporary licensing process before January 1, 2014.

Because the bill would authorize the expenditure of continuously appropriated funds for a new purpose, the bill would make an appropriation.

Vote: majority Appropriation: yes Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. *Section 115.6 is added to the Business and Professions Code, to read:*

115.6. (a) A board within the department shall, after appropriate investigation, issue a temporary license to an applicant if he or she meets the requirements set forth in subdivision (c). The temporary license shall expire 12 months after issuance, upon issuance of an expedited license pursuant to Section 115.5, or upon denial of the application for expedited licensure by the board, whichever occurs first.

(b) The board may conduct an investigation of an applicant for purposes of denying or revoking a temporary license issued pursuant to this section. This investigation may include a criminal background check.

(c) An applicant seeking a temporary license pursuant to this section shall meet the following requirements:

(1) The applicant shall supply evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) The applicant shall hold a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a temporary license from the board.

(3) The applicant shall submit an application to the board that shall include a signed affidavit attesting to the fact that he or she meets all of the requirements for the temporary license and that the information submitted in the application is accurate, to the best of his or her knowledge. The application shall also include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing in that jurisdiction.

(4) The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed. A violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the board.

(5) The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(6) The applicant shall, upon request by a board, furnish a full set of fingerprints for purposes of conducting a criminal background check.

(d) A board may adopt regulations necessary to administer this section.

(e) A temporary license issued pursuant to this section for the practice of medicine may be immediately terminated upon a finding that the temporary licenseholder failed to meet any of the requirements described in subdivision (c) or provided substantively inaccurate information that would affect his or her eligibility for temporary licensure. Upon termination of the temporary license, the board shall issue a notice of termination that shall require the temporary licenseholder to immediately cease the practice of medicine upon receipt.

(f) This section shall not apply to a board that has established a temporary licensing process before January 1, 2014.

~~SECTION 1.Section 115.5 of the Business and Professions Code is amended to read:~~

~~115.5.(a)Except as provided in subdivision (d), a board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:~~

~~(1)Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.~~

~~(2)Holds a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a license from the board.~~

~~(b)(1)A board shall, after appropriate investigation, issue a temporary license to an applicant who is eligible for, and requests, expedited licensure pursuant to subdivision (a) if the applicant meets the requirements described in paragraph (3). The temporary license shall expire 12 months after issuance, upon issuance of the expedited license, or upon denial of the application for expedited licensure by the board, whichever occurs first.~~

~~(2)The board may conduct an investigation of an applicant for purposes of denying or revoking a temporary license issued pursuant to this subdivision. This investigation may include a criminal background check.~~

~~(3)(A)An applicant seeking a temporary license issued pursuant to this subdivision shall submit an application to the board which shall include a signed affidavit attesting to the fact that he or she meets all of the requirements for the temporary license and that the information submitted in the application is accurate, to the best of his or her knowledge. The application shall also include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing in that jurisdiction.~~

~~(B)The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed. A violation of this subparagraph may be grounds for the denial or revocation of a temporary license issued by the board.~~

~~(C)The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.~~

~~(D)The applicant shall, upon request by a board, furnish a full set of fingerprints for purposes of conducting a criminal background check.~~

~~(c)~~

~~A board may adopt regulations necessary to administer this section.~~

~~(d)This section shall not apply to a board that has established a temporary licensing process before January 1, 2014.~~

AB 213

California LEGISLATIVE INFORMATION

AB-213 Healing arts: licensure and certification requirements: military experience. (2013-2014)

AMENDED IN ASSEMBLY APRIL 18, 2013

AMENDED IN ASSEMBLY APRIL 15, 2013

AMENDED IN ASSEMBLY APRIL 01, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL No. 213

Introduced by Assembly Member Logue
(Principal coauthor: Assembly Member Pan)
(Coauthors: Assembly Members Conway, Beth Gaines, Harkey, Jones, Morrell, Nestande, and Wilk)

January 31, 2013

An act to add Section 712 to the Business and Professions Code, and to add Section 131136 to the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 213, as amended, Logue. Healing arts: licensure and certification requirements: military experience.

Existing law provides for the licensure and regulation of various healing arts professions and vocations by boards within the Department of Consumer Affairs. Existing law requires the rules and regulations of these healing arts boards to provide for methods of evaluating education, training, and experience obtained in military service if such training is applicable to the requirements of the particular profession or vocation regulated by the board. Under existing law, specified other healing arts professions and vocations are licensed or certified and regulated by the State Department of Public Health. In some instances, a board with the Department of Consumer Affairs or the State Department of Public Health approves schools offering educational course credit for meeting licensing or certification qualifications and requirements.

This bill would require the State Department of Public Health, upon the presentation of evidence by an applicant for licensure or certification, to accept education, training, and practical experience completed by an applicant in military service toward the qualifications and requirements to receive a license or certificate for specified professions and vocations if that education, training, or experience is equivalent to the standards of the department. If a board within the Department of Consumer Affairs or the State Department of Public Health accredits or otherwise approves schools offering educational course credit for meeting licensing and certification qualifications and requirements, the bill would, not later than January 1, 2015, require those schools seeking accreditation or approval to have procedures in place to evaluate an applicant's military education, training, and practical experience toward the completion of an educational program that would

qualify a person to apply for licensure or certification, as specified.

Under existing law, the Department of Veterans Affairs has specified powers and duties relating to various programs serving veterans. Under existing law, the Chancellor of the California State University and the Chancellor of the California Community Colleges have specified powers and duties relating to statewide health education programs.

With respect to complying with the bill's requirements and obtaining specified funds to support compliance with these provisions, this bill would require the Department of Veterans Affairs, the Chancellor of the California State University, and the Chancellor of the California Community Colleges to provide technical assistance to the healing arts boards within the Department of Consumer Affairs, the State Department of Public Health, and to the schools offering, or seeking to offer, educational course credit for meeting licensing qualifications and requirements.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. This act shall be known, and may be cited, as the Veterans Health Care Workforce Act of 2013.

SEC. 2. (a) The Legislature finds and declares all of the following:

(1) Lack of health care providers continues to be a significant barrier to access to health care services in medically underserved urban and rural areas of California.

(2) Veterans of the United States Armed Forces and the California National Guard gain invaluable education, training, and practical experience through their military service.

(3) According to the federal Department of Defense, as of June 2011, one million veterans were unemployed nationally and the jobless rate for post-9/11 veterans was 13.3 percent, with young male veterans 18 to 24 years of age experiencing an unemployment rate of 21.9 percent.

(4) According to the federal Department of Defense, during the 2011 federal fiscal year, 8,854 enlisted service members with medical classifications separated from active duty.

(5) According to the federal Department of Defense, during the 2011 federal fiscal year, 16,777 service members who separated from active duty listed California as their state of residence.

(6) It is critical, both to veterans seeking to transition to civilian health care professions and to patients living in underserved urban and rural areas of California, that the Legislature ensures that veteran applicants for licensure by healing arts boards within the Department of Consumer Affairs or the State Department of Public Health are expedited through the qualifications and requirements process.

(b) It is the intent of the Legislature to ensure that boards within the Department of Consumer Affairs and the State Department of Public Health and schools offering educational course credit for meeting licensing qualifications and requirements fully and expeditiously recognize and provide credit for an applicant's military education, training, and practical experience.

SEC. 3. Section 712 is added to the Business and Professions Code, to read:

712. (a) Not later than January 1, 2015, if a board under this division accredits or otherwise approves schools offering educational course credit for meeting licensing qualifications and requirements, the board shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to evaluate, upon presentation of satisfactory evidence by the applicant, the applicant's military education, training, and practical experience toward the completion of an educational program that would qualify a person to apply for licensure if the school determines that the education, training, or practical experience is equivalent to the standards of the board. A board that requires a school to be accredited by a national organization shall not impose requirements on the school that conflict with the standards of the national organization.

(b) With respect to ~~complying~~ *compliance* with the requirements of this section, including the determination of equivalency between the education, training, or practical experience of an applicant and the board's standards, and obtaining state, federal, or private funds to support compliance with this section, the Department of Veterans Affairs, the Chancellor of the California State University, and the Chancellor of the California

Community Colleges shall provide technical assistance to the boards under this division and to the schools under this section.

(c) Nothing in this section shall interfere with an educational, certification, or licensing requirement or standard set by a licensing entity or certification board or other appropriate healing arts regulatory agency or entity, to practice health care in the state.

SEC. 4. Section 131136 is added to the Health and Safety Code, to read:

131136. (a) Notwithstanding any other provision of law, the department shall, upon the presentation of satisfactory evidence by an applicant for licensure or certification in one of the professions described in subdivision (b), accept the education, training, and practical experience completed by the applicant as a member of the United States Armed Forces or Military Reserves of the United States, the national guard of any state, the military reserves of any state, or the naval militia of any state, toward the qualifications and requirements for licensure or certification by the department if the department determines that the education, training, or practical experience is equivalent to the standards of the department.

(b) The following professions are subject to this section:

(1) Medical laboratory technician as described in Section 1260.3 of the Business and Professions Code.

(2) Clinical laboratory scientist as described in Section 1261 of the Business and Professions Code.

(3) Radiologic technologist as described in Chapter 6 (commencing with Section 114840) of Part 9 of Division 104.

(4) Nuclear medicine technologist as described in Chapter 4 (commencing with Section 107150) of Part 1 of Division 104.

(5) Certified nurse assistant as described in Article 9 (commencing with Section 1337) of Chapter 2 of Division 2.

(6) Certified home health aide as described in Section 1736.1.

(7) Certified hemodialysis technician as described in Section 1247.61 of the Business and Professions Code.

(8) Nursing home administrator as described in Section 1416.2.

(c) Not later than January 1, 2015, if the department accredits or otherwise approves schools offering educational course credit for meeting licensing and certification qualifications and requirements, the department shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to fully accept an applicant's military education, training, and practical experience toward the completion of an educational program that would qualify a person to apply for licensure or certification if the school determines that the education, training, or practical experience is equivalent to the standards of the department. If the department requires a school to be accredited by a national organization, the requirement of the department shall not, in any way, conflict with standards set by the national organization.

(d) With respect to complying with the requirements of this section including the determination of equivalency between the education, training, or practical experience of an applicant and the department's standards, and obtaining state, federal, or private funds to support compliance with this section, the Department of Veterans Affairs, the Chancellor of the California State University, and the Chancellor of the California Community Colleges shall provide technical assistance to the department, to the State Public Health Officer, and to the schools described in this section.

(e) Nothing in this section shall interfere with an educational, certification, or licensing requirement or standard set by a licensing entity or certification board or other appropriate healing arts regulatory agency or entity, to practice health care in California.

AB 635

California LEGISLATIVE INFORMATION

AB-635 Drug overdose treatment: liability. (2013-2014)

ENROLLED SEPTEMBER 12, 2013
PASSED IN SENATE SEPTEMBER 06, 2013
PASSED IN ASSEMBLY SEPTEMBER 09, 2013
AMENDED IN SENATE AUGUST 22, 2013
AMENDED IN SENATE JUNE 24, 2013
AMENDED IN ASSEMBLY APRIL 11, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL No. 635

Introduced by Assembly Member Ammiano
(Principal coauthor: Senator DeSaulnier)

February 20, 2013

An act to amend Section 1714.22 of the Civil Code, relating to drug overdose treatment.

LEGISLATIVE COUNSEL'S DIGEST

AB 635, Ammiano. Drug overdose treatment: liability.

Existing law authorizes a physician and surgeon to prescribe, dispense, or administer prescription drugs, including prescription-controlled substances, to an addict under his or her treatment, as specified. Existing law prohibits, except in the regular practice of his or her profession, any person from knowingly prescribing, administering, dispensing, or furnishing a controlled substance to or for any person who is not under his or her treatment for a pathology or condition other than an addiction to a controlled substance, except as specified.

Existing law authorizes, until January 1, 2016, and only in specified counties, a licensed health care provider, who is already permitted pursuant to existing law to prescribe an opioid antagonist, as defined, and who is acting with reasonable care, to prescribe and subsequently dispense or distribute an opioid antagonist in conjunction with an opioid overdose prevention and treatment training program, as defined, without being subject to civil liability or criminal prosecution. Existing law requires a local health jurisdiction that operates or registers an opioid overdose prevention and treatment training program to collect prescribed data and report it to the Senate and Assembly Committees on Judiciary by January 1, 2015.

Existing law authorizes, until January 1, 2016, and only in specified counties, a person who is not licensed to administer an opioid antagonist to do so in an emergency without fee if the person has received specified training information and believes in good faith that the other person is experiencing a drug overdose. Existing law prohibits that person, as a result of his or her acts or omissions, from being liable for any violation of any

professional licensing statute, or subject to any criminal prosecution arising from or related to the unauthorized practice of medicine or the possession of an opioid antagonist.

This bill would revise and recast these provisions to instead authorize a licensed health care provider who is permitted by law to prescribe an opioid antagonist and is acting with reasonable care to prescribe and subsequently dispense or distribute an opioid antagonist for the treatment of an opioid overdose to a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. The bill would authorize these licensed health care providers to issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist the person at risk. The bill would authorize these licensed health care providers to issue standing orders for the administration of an opioid antagonist by a family member, friend, or other person in a position to assist a person experiencing or suspected of experiencing an opioid overdose.

The bill would provide that a licensed health care provider who acts with reasonable care and issues a prescription for, or an order for the administration of, an opioid antagonist to a person experiencing or suspected of experiencing an opioid overdose is not subject to professional review, liable in a civil action, or subject to criminal prosecution for issuing the prescription or order. The bill would provide that a person who is not otherwise licensed to administer an opioid antagonist, but who meets other specified conditions, is not subject to professional review, liable in a civil action, or subject to criminal prosecution for administering an opioid antagonist.

The bill would also delete the repeal date and reporting requirements and expand the applicability of these provisions statewide.

Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1714.22 of the Civil Code is amended to read:

1714.22. (a) For purposes of this section, the following definitions shall apply:

(1) "Opioid antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of an opioid overdose.

(2) "Opioid overdose prevention and treatment training program" means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:

(A) The causes of an opiate overdose.

(B) Mouth to mouth resuscitation.

(C) How to contact appropriate emergency medical services.

(D) How to administer an opioid antagonist.

(b) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.

(c) (1) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.

(2) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the administration of an opioid antagonist to a person at risk of an opioid-related overdose by a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose.

(d) (1) A person who is prescribed or possesses an opioid antagonist pursuant to a standing order shall receive the training provided by an opioid overdose prevention and treatment training program.

(2) A person who is prescribed an opioid antagonist directly from a licensed prescriber shall not be required to receive training from an opioid prevention and treatment training program.

(e) A licensed health care provider who acts with reasonable care shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for issuing a prescription or order pursuant to subdivision (b) or (c).

(f) Notwithstanding any other law, a person who possesses or distributes an opioid antagonist pursuant to a prescription or standing order shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for this possession or distribution. Notwithstanding any other law, a person not otherwise licensed to administer an opioid antagonist, but trained as required under paragraph (1) of subdivision (d), who acts with reasonable care in administering an opioid antagonist, in good faith and not for compensation, to a person who is experiencing or is suspected of experiencing an overdose shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for this administration.

AB 809

California LEGISLATIVE INFORMATION

AB-809 Healing arts: telehealth. (2013-2014)

AMENDED IN SENATE JUNE 25, 2013

AMENDED IN ASSEMBLY APRIL 29, 2013

AMENDED IN ASSEMBLY APRIL 03, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL No. 809

Introduced by Assembly Member Logue
(Coauthor: Senator Galgiani)

February 21, 2013

An act to amend Section 2290.5 of the Business and Professions Code, relating to telehealth, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 809, as amended, Logue. Healing arts: telehealth.

Existing law requires a health care provider, as defined, prior to the delivery of health care services via telehealth, as defined, to verbally inform the patient that telehealth may be used and obtain verbal consent from the patient for this use. Existing law also provides that failure to comply with this requirement constitutes unprofessional conduct.

This bill would ~~allow the verbal consent for the use of telehealth to apply in the present instance and for any subsequent use of telehealth.~~ *require the health care provider initiating the use of telehealth at the originating site to obtain verbal or written consent from the patient for the use of telehealth, as specified. The bill would require that health care provider to document the consent in the patient's medical record and to transmit that documentation with the initiation of any telehealth to any distant-site health care provider from whom telehealth is requested or obtained. The bill would require a distant-site health care provider to either obtain confirmation of the patient's consent from the originating site provider or separately obtain and document consent from the patient about the use of telehealth, as specified.*

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3 Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2290.5 of the Business and Professions Code is amended to read:

2290.5. (a) For purposes of this division, the following definitions shall apply:

(1) "Asynchronous store and forward" means the transmission of a patient's medical information from an originating site to the health care provider at a distant site without the presence of the patient.

(2) "Distant site" means a site where a health care provider who provides health care services is located while providing these services via a telecommunications system.

(3) "Health care provider" means a person who is licensed under this division.

(4) "Originating site" means a site where a patient is located at the time health care services are provided via a telecommunications system or where the asynchronous store and forward service originates.

(5) "Synchronous interaction" means a real-time interaction between a patient and a health care provider located at a distant site.

(6) "Telehealth" means the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealth facilitates patient self-management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers.

(b) Prior to the delivery of health care via telehealth, the health care provider initiating the use of telehealth at the originating site shall ~~verbally~~ inform the patient about the use of telehealth and ~~request the patient's~~ *obtain* verbal *or written* consent~~, which may apply in the present instance and for any subsequent use of telehealth.~~ *from the patient for the use of telehealth as an acceptable mode of delivering health care services and public health during a specified course of health care and treatment.* The ~~verbal~~ consent shall be documented in the patient's medical ~~record.~~ *record, and the documentation shall be transmitted with the initiation of any telehealth for that specified course of health care and treatment to any distant-site health care provider from whom telehealth is requested or obtained. A distant-site health care provider shall either obtain confirmation of the patient's consent from the originating site provider or separately obtain and document consent from the patient about the use of telehealth as an acceptable mode of delivering health care services and public health during a specified course of health care and treatment.*

(c) Nothing in this section shall preclude a patient from receiving in-person health care delivery services during a *specified* course of *health care and* treatment after agreeing to receive services via telehealth.

(d) The failure of a health care provider to comply with this section shall constitute unprofessional conduct. Section 2314 shall not apply to this section.

(e) This section shall not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law.

(f) All laws regarding the confidentiality of health care information and a patient's rights to his or her medical information shall apply to telehealth interactions.

(g) This section shall not apply to a patient under the jurisdiction of the Department of Corrections and Rehabilitation or any other correctional facility.

(h) (1) Notwithstanding any other provision of law and for purposes of this section, the governing body of the hospital whose patients are receiving the telehealth services may grant privileges to, and verify and approve credentials for, providers of telehealth services based on its medical staff recommendations that rely on information provided by the distant-site hospital or telehealth entity, as described in Sections 482.12, 482.22, and 485.616 of Title 42 of the Code of Federal Regulations.

(2) By enacting this subdivision, it is the intent of the Legislature to authorize a hospital to grant privileges to, and verify and approve credentials for, providers of telehealth services as described in paragraph (1).

(3) For the purposes of this subdivision, "telehealth" shall include "telemedicine" as the term is referenced in Sections 482.12, 482.22, and 485.616 of Title 42 of the Code of Federal Regulations.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts

constituting the necessity are:

In order to protect the health and safety of the public due to a lack of access to health care providers in rural and urban medically underserved areas of California, the increasing strain on existing providers expected to occur with the implementation of the federal Patient Protection and Affordable Care Act, and the assistance that further implementation of telehealth can provide to help relieve these burdens, it is necessary for this act to take effect immediately.

AB 1003

California LEGISLATIVE INFORMATION

AB-1003 Professional corporations: healing arts practitioners. (2013-2014)

AMENDED IN ASSEMBLY APRIL 01, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL **No. 1003**

Introduced by Assembly Member Maienschein

February 22, 2013

An act to amend 13401.5 of the Corporations Code, relating to professional corporations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1003, as amended, Maienschein. Professional corporations: healing arts practitioners.

The Moscone-Knox Professional Corporation Act provides for the organization of a corporation under certain existing law for the purposes of qualifying as a professional corporation under that act and rendering professional services. The act defines a professional corporation as a corporation organized under the General Corporation Law or pursuant to specified law that is engaged in rendering professional services in a single profession, except as otherwise authorized in the act, pursuant to a certificate of registration issued by the governmental agency regulating the profession and that in its practice or business designates itself as a professional or other corporation as may be required by statute. The act authorizes specified listed types of healing arts practitioners to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

This bill would ~~delete professional employees from that authorization, and, instead, would provide that those provisions do not limit the employment of persons duly licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to render professional services, by a designated professional corporation, to the listed licensed professionals specified in the provisions~~ *specify that those provisions do not limit the employment by a professional corporation to only those specified licensed professionals. The bill would authorize any person duly licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to be employed to render professional services by a professional corporation.*

Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. *Section 13401.5 of the Corporations Code is amended to read:*

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed

persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation÷. *This section does not limit the employment by a professional corporation designated in this section to only those licensed professionals listed under each subdivision. Any person duly licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act may be employed to render professional services by a professional corporation designated in this section.*

(a) Medical corporation.

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(b) Podiatric medical corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed chiropractors.

(6) Licensed acupuncturists.

(7) Naturopathic doctors.

(c) Psychological corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed chiropractors.

(8) Licensed acupuncturists.

(9) Naturopathic doctors.

(10) Licensed professional clinical counselors.

(d) Speech-language pathology corporation.

(1) Licensed audiologists.

(e) Audiology corporation.

(1) Licensed speech-language pathologists.

(f) Nursing corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Licensed psychologists.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(g) Marriage and family therapist corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Licensed clinical social workers.

(4) Registered nurses.

(5) Licensed chiropractors.

(6) Licensed acupuncturists.

(7) Naturopathic doctors.

(8) Licensed professional clinical counselors.

(h) Licensed clinical social worker corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Licensed marriage and family therapists.

(4) Registered nurses.

(5) Licensed chiropractors.

(6) Licensed acupuncturists.

(7) Naturopathic doctors.

(8) Licensed professional clinical counselors.

(i) Physician assistants corporation.

(1) Licensed physicians and surgeons.

(2) Registered nurses.

(3) Licensed acupuncturists.

(4) Naturopathic doctors.

(j) Optometric corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Licensed psychologists.

(4) Registered nurses.

(5) Licensed chiropractors.

(6) Licensed acupuncturists.

(7) Naturopathic doctors.

(k) Chiropractic corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Licensed psychologists.

(4) Registered nurses.

(5) Licensed optometrists.

(6) Licensed marriage and family therapists.

(7) Licensed clinical social workers.

(8) Licensed acupuncturists.

(9) Naturopathic doctors.

(10) Licensed professional clinical counselors.

(l) Acupuncture corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Licensed psychologists.

(4) Registered nurses.

(5) Licensed optometrists.

(6) Licensed marriage and family therapists.

(7) Licensed clinical social workers.

(8) Licensed physician assistants.

(9) Licensed chiropractors.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(m) Naturopathic doctor corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed physician assistants.

(5) Licensed chiropractors.

(6) Licensed acupuncturists.

(7) Licensed physical therapists.

(8) Licensed doctors of podiatric medicine.

(9) Licensed marriage and family therapists.

(10) Licensed clinical social workers.

(11) Licensed optometrists.

(12) Licensed professional clinical counselors.

(n) Dental corporation.

(1) Licensed physicians and surgeons.

(2) Dental assistants.

(3) Registered dental assistants.

(4) Registered dental assistants in extended functions.

(5) Registered dental hygienists.

(6) Registered dental hygienists in extended functions.

(7) Registered dental hygienists in alternative practice.

(o) Professional clinical counselor corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Licensed clinical social workers.

(4) Licensed marriage and family therapists.

(5) Registered nurses.

(6) Licensed chiropractors.

(7) Licensed acupuncturists.

(8) Naturopathic doctors.

~~SECTION 1.Section 13401.5 of the Corporations Code is amended to read:~~

~~13401.5.(a)Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, or directors of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the~~

~~total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation.~~

~~(1)Medical corporation.~~

~~(A)Licensed doctors of podiatric medicine.~~

~~(B)Licensed psychologists.~~

~~(C)Registered nurses.~~

~~(D)Licensed optometrists.~~

~~(E)Licensed marriage and family therapists.~~

~~(F)Licensed clinical social workers.~~

~~(G)Licensed physician assistants.~~

~~(H)Licensed chiropractors.~~

~~(I)Licensed acupuncturists.~~

~~(J)Naturopathic doctors.~~

~~(K)Licensed professional clinical counselors.~~

~~(2)Podiatric medical corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed psychologists.~~

~~(C)Registered nurses.~~

~~(D)Licensed optometrists.~~

~~(E)Licensed chiropractors.~~

~~(F)Licensed acupuncturists.~~

~~(G)Naturopathic doctors.~~

~~(3)Psychological corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed doctors of podiatric medicine.~~

~~(C)Registered nurses.~~

~~(D)Licensed optometrists.~~

~~(E)Licensed marriage and family therapists.~~

~~(F)Licensed clinical social workers.~~

~~(G)Licensed chiropractors.~~

~~(H)Licensed acupuncturists.~~

~~(I)Naturopathic doctors.~~

~~(J)Licensed professional clinical counselors.~~

~~(4)Speech language pathology corporation.~~

~~(A)Licensed audiologists.~~

~~(5)Audiology corporation.~~

~~(A)Licensed speech-language pathologists.~~

~~(6)Nursing corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed doctors of podiatric medicine.~~

~~(C)Licensed psychologists.~~

~~(D)Licensed optometrists.~~

~~(E)Licensed marriage and family therapists.~~

~~(F)Licensed clinical social workers.~~

~~(G)Licensed physician assistants.~~

~~(H)Licensed chiropractors.~~

~~(I)Licensed acupuncturists.~~

~~(J)Naturopathic doctors.~~

~~(K)Licensed professional clinical counselors.~~

~~(7)Marriage and family therapist corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed psychologists.~~

~~(C)Licensed clinical social workers.~~

~~(D)Registered nurses.~~

~~(E)Licensed chiropractors.~~

~~(F)Licensed acupuncturists.~~

~~(G)Naturopathic doctors.~~

~~(H)Licensed professional clinical counselors.~~

~~(8)Licensed clinical social worker corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed psychologists.~~

~~(C)Licensed marriage and family therapists.~~

~~(D)Registered nurses.~~

~~(E)Licensed chiropractors.~~

~~(F)Licensed acupuncturists.~~

~~(G)Naturopathic doctors.~~

~~(H)Licensed professional clinical counselors.~~

~~(9)Physician assistants corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Registered nurses.~~

~~(C)Licensed acupuncturists.~~

~~(D)Naturopathic doctors.~~

~~(10)Optometric corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed doctors of podiatric medicine.~~

~~(C)Licensed psychologists.~~

~~(D)Registered nurses.~~

~~(E)Licensed chiropractors.~~

~~(F)Licensed acupuncturists.~~

~~(G)Naturopathic doctors.~~

~~(11)Chiropractic corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed doctors of podiatric medicine.~~

~~(C)Licensed psychologists.~~

~~(D)Registered nurses.~~

~~(E)Licensed optometrists.~~

~~(F)Licensed marriage and family therapists.~~

~~(G)Licensed clinical social workers.~~

~~(H)Licensed acupuncturists.~~

~~(I)Naturopathic doctors.~~

~~(J)Licensed professional clinical counselors.~~

~~(12)Acupuncture corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed doctors of podiatric medicine.~~

~~(C)Licensed psychologists.~~

~~(D)Registered nurses.~~

~~(E)Licensed optometrists.~~

~~(F)Licensed marriage and family therapists.~~

~~(G)Licensed clinical social workers.~~

~~(H)Licensed physician assistants.~~

~~(I)Licensed chiropractors.~~

~~(J)Naturopathic doctors.~~

~~(K)Licensed professional clinical counselors.~~

~~(13)Naturopathic doctor corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed psychologists.~~

~~(C)Registered nurses.~~

~~(D)Licensed physician assistants.~~

~~(E)Licensed chiropractors.~~

~~(F)Licensed acupuncturists.~~

~~(G)Licensed physical therapists.~~

~~(H)Licensed doctors of podiatric medicine.~~

~~(I)Licensed marriage and family therapists.~~

~~(J)Licensed clinical social workers.~~

~~(K)Licensed optometrists.~~

~~(L)Licensed professional clinical counselors.~~

~~(14)Dental corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Dental assistants.~~

~~(C)Registered dental assistants.~~

~~(D)Registered dental assistants in extended functions.~~

~~(E)Registered dental hygienists.~~

~~(F)Registered dental hygienists in extended functions.~~

~~(G)Registered dental hygienists in alternative practice.~~

~~(15)Professional clinical counselor corporation.~~

~~(A)Licensed physicians and surgeons.~~

~~(B)Licensed psychologists.~~

~~(C)Licensed clinical social workers.~~

~~(D)Licensed marriage and family therapists.~~

~~(E)Registered nurses.~~

~~(F)Licensed chiropractors.~~

~~(G)Licensed acupuncturists.~~

~~(H)Naturopathic doctors.~~

~~(b)This section does not limit the employment of persons duly licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to render professional services, by a professional corporation designated in the section, to the licensed professionals listed under each paragraph of subdivision (a).~~

AB 1057

California LEGISLATIVE INFORMATION

AB-1057 Professions and vocations: licenses: military service. (2013-2014)

ENROLLED SEPTEMBER 05, 2013
PASSED IN SENATE AUGUST 26, 2013
PASSED IN ASSEMBLY AUGUST 30, 2013
AMENDED IN SENATE JUNE 03, 2013
AMENDED IN ASSEMBLY APRIL 09, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL No. 1057

Introduced by Assembly Member Medina

February 22, 2013

An act to add Section 114.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1057, Medina. Professions and vocations: licenses: military service.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a licensee or registrant whose license expired while the licensee or registrant was on active duty as a member of the California National Guard or the United States Armed Forces to, upon application, reinstate his or her license without penalty and without examination, if certain requirements are satisfied, unless the licensing agency determines that the applicant has not actively engaged in the practice of his or her profession while on active duty, as specified.

This bill would require each board, commencing January 1, 2015, to inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 114.5 is added to the Business and Professions Code, to read:

114.5. Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

AB 1288

California LEGISLATIVE INFORMATION

AB-1288 Medical Board of California and Osteopathic Medical Board of California: licensing: application processing.
(2013-2014)

Assembly Bill No. 1288

CHAPTER 307

An act to add Sections 2092 and 2099.6 to the Business and Professions Code, relating to healing arts.

[Approved by Governor September 09, 2013. Filed with Secretary of State September 09, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1288, V. Manuel Pérez. Medical Board of California and Osteopathic Medical Board of California: licensing: application processing.

Existing law, the Medical Practice Act, provides for licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law establishes the Osteopathic Medical Board of California and authorizes the board to issue an originating or reciprocal osteopathic physician and surgeon's certificate to an applicant who satisfies specified criteria. Existing law establishes the California Healthcare Workforce Policy Commission and requires the commission to, among other things, identify specific areas of the state where unmet priority needs for primary care exist.

This bill would require the Medical Board of California and the Osteopathic Medical Board of California to develop a process to give priority review status to the application of an applicant who can demonstrate, as specified, that he or she intends to practice in a medically underserved area or serve a medically underserved population.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2092 is added to the Business and Professions Code, to read:

2092. (a) The board shall develop a process to give priority review status to the application of an applicant for a physician and surgeon's certificate who can demonstrate that he or she intends to practice in a medically underserved area or serve a medically underserved population as defined in Section 128565 of the Health and Safety Code.

(b) An applicant may demonstrate his or her intent to practice in a medically underserved area or serve a medically underserved population by providing proper documentation, including, but not limited to, a letter from the employer indicating that the applicant has accepted employment and stating the start date.

SEC. 2. Section 2099.6 is added to the Business and Professions Code, to read:

2099.6. (a) The Osteopathic Medical Board of California shall develop a process to give priority review status to the application of an applicant for an osteopathic physician and surgeon's certificate who can demonstrate that he or she intends to practice in a medically underserved area or serve a medically underserved population as

defined in Section 128565 of the Health and Safety Code.

(b) An applicant may demonstrate his or her intent to practice in a medically underserved area or serve a medically underserved population by providing proper documentation, including, but not limited to, a letter from the employer indicating that the applicant has accepted employment and stating the start date.

SB 304

California LEGISLATIVE INFORMATION

SB-304 Healing arts: boards. (2013-2014)

ENROLLED SEPTEMBER 17, 2013

PASSED IN SENATE SEPTEMBER 11, 2013

PASSED IN ASSEMBLY SEPTEMBER 11, 2013

AMENDED IN ASSEMBLY SEPTEMBER 06, 2013

AMENDED IN ASSEMBLY SEPTEMBER 03, 2013

AMENDED IN ASSEMBLY AUGUST 12, 2013

AMENDED IN SENATE APRIL 24, 2013

AMENDED IN SENATE APRIL 16, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

SENATE BILL No. 304

Introduced by Senator Lieu
(Principal coauthors: Assembly Members Bonilla and Gordon)

February 15, 2013

An act to amend Sections 159.5, 160.5, 2001, 2020, 2021, 2135.7, 2177, 2220.08, 2225.5, 2514, 2569, 4800, 4804.5, 4809.5, 4809.7, and 4809.8 of, to amend, repeal, and add Sections 160 and 4836.1 of, to amend and add Section 2006 of, and to add Sections 2216.3, 2216.4, 2403, 4836.2, 4836.3, and 4836.4 to, the Business and Professions Code, to amend Sections 11529, 12529.6, and 12529.7 of, and to amend and repeal Sections 12529 and 12529.5 of, the Government Code, to amend Section 1248.15 of the Health and Safety Code, and to amend, repeal, and add Section 830.3 of the Penal Code, relating to healing arts, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 304, Lieu. Healing arts: boards.

(1) Existing law provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law authorizes the board to employ an executive director. Existing law provides that those provisions will be repealed on January 1, 2014, and, upon repeal, the board is subject to review by the Joint Sunset Review Committee.

This bill would instead repeal those provisions on January 1, 2018, and subject the board to review by the appropriate policy committees of the Legislature. The bill would authorize the board to employ an executive director by, and with the approval of, the Director of Consumer Affairs.

Existing law authorizes the board to issue a physician and surgeon's license to an applicant who acquired all or part of his or her medical education at a foreign medical school that is not recognized by the board if, among other requirements, the applicant has held an unlimited and unrestricted license as a physician and surgeon in another state or federal territory and has continuously practiced for a minimum of 10 years prior to the date of application or to an applicant who acquired any part of his or her professional instruction at a foreign medical school that has previously been disapproved by the board if, among other requirements, the applicant has held an unlimited and unrestricted license as a physician and surgeon in another state or federal territory and has continuously practiced for a minimum of 20 years prior to the date of application. For the purposes of these provisions, the board may combine the period of time that the applicant has held an unlimited and unrestricted license, but requires each applicant to have a minimum of 5 years continuous licensure and practice in a single state or federal territory.

This bill would instead authorize the board to issue a physician and surgeon's license to an applicant who acquired any part of his or her medical education from an unrecognized medical school if, among other requirements, the applicant has held an unlimited and unrestricted license as a physician and surgeon in another state, a federal territory, or a Canadian province and has continuously practiced for a minimum of 10 years prior to the date of application, or from a disapproved medical school if, among other requirements, the applicant has held an unlimited and unrestricted license as a physician and surgeon in another state, a federal territory, or a Canadian province and has continuously practiced for a minimum of 12 years prior to the date of application. The bill would reduce the minimum number of years that each applicant must have continuous licensure and practice in a single state or federal territory to 2 years and permit the period of continuous licensure and practice to occur in a Canadian province.

Existing law authorizes the Medical Board of California, if it publishes a directory of its licensees, as specified, to require persons licensed, as specified, to furnish specified information to the board for purposes of compiling the directory.

This bill would require that an applicant and licensee who has an electronic mail address report to the board that electronic mail address no later than July 1, 2014. The bill would provide that the electronic mail address is to be considered confidential, as specified.

Existing law requires an applicant for a physician and surgeon's certificate to obtain a passing score on Step 3 of the United States Medical Licensing Examination with not more than 4 attempts, subject to an exception.

This bill would require an applicant to have obtained a passing score on all parts of that examination with not more than 4 attempts, subject to the exception.

Existing law requires that a complaint, with exceptions, received by the board determined to involve quality of care, before referral to a field office for further investigation, meet certain criteria.

This bill would expand the types of reports that are exempted from that requirement.

Existing law provides for a civil penalty of up to $1,000 per day, as specified, to be imposed on a health care facility that fails to comply with a patient's medical record request, as specified, within 30 days.

This bill would shorten the time limit for compliance to 15 days for those health care facilities that have electronic health records.

Existing law establishes that corporations and other artificial legal entities have no professional rights, privileges, or powers.

This bill would provide that those provisions do not apply to physicians and surgeons or doctors of podiatric medicine enrolled in approved residency postgraduate training programs or fellowship programs.

(2) Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensure and regulation of licensed midwives by the Medical Board of California. Existing law specifies that a midwife student meeting certain conditions is not precluded from engaging in the practice of midwifery as part of his or her course of study, if certain conditions are met, including, that the student is under the supervision of a licensed midwife.

This bill would require that to engage in those practices, the student is to be enrolled and participating in a midwifery education program or enrolled in a program of supervised clinical training, as provided. The bill would add that the student is permitted to engage in those practices if he or she is under the supervision of a licensed nurse-midwife.

(3) Existing law provides for the regulation of registered dispensing opticians by the Medical Board of California and requires that the powers and duties of the board in that regard be subject to review by the Joint Sunset Review Committee as if those provisions were scheduled to be repealed on January 1, 2014.

This bill would instead make the powers and duties of the board subject to review by the appropriate policy committees of the Legislature as if those provisions were scheduled to be repealed on January 1, 2018.

(4) Existing law provides for the accreditation of outpatient settings, as defined, by the Medical Board of California, and requires outpatient settings to report adverse events, as defined, to the State Department of Public Health within specified time limits. Existing law provides for the imposition of a civil penalty in the event that an adverse event is not reported within the applicable time limit.

This bill would instead require those outpatient settings to report adverse events to the Medical Board of California within specified time limits and authorize the board to impose a civil penalty if an outpatient setting fails to timely report an adverse event.

(5) Existing law establishes the Medical Quality Hearing Panel, consisting of no fewer than 5 administrative law judges with certain medical training, within the Office of Administrative Hearings. Existing law authorizes those administrative law judges to issue interim orders suspending a license, or imposing drug testing, continuing education, supervision of procedures, or other license restrictions. Existing law requires that in all of those cases in which an interim order is issued, and an accusation is not filed and served within 15 days of the date in which the parties to the hearing have submitted the matter, the order be dissolved.

Under existing law, if a healing arts practitioner is unable to practice his or her profession safely due to mental or physical illness, his or her licensing agency may order the practitioner to be examined by specified professionals.

This bill would extend the time in which the accusation must be filed and served to 30 days from the date on which the parties to the hearing submitted the matter. The bill would also provide that a physician and surgeon's failure to comply with an order to be examined may constitute grounds for an administrative law judge of the Medical Quality Hearing Panel to issue an interim suspension order.

Existing law establishes the Health Quality Enforcement Section within the Department of Justice to investigate and prosecute proceedings against licensees and applicants within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, or any committee under the jurisdiction of the Medical Board of California. Existing law provides for the funding for the section, and for the appointment of a Senior Assistant Attorney General to the section to carry out specified duties. Existing law requires that all complaints or relevant information concerning licensees that are within the jurisdiction of the boards served by the Health Quality Enforcement Section be made available to the Health Quality Enforcement Section. Existing law establishes the procedures for processing the complaints, assisting the boards or committees in establishing training programs for their staff, and for determining whether to bring a disciplinary proceeding against a licensee of the boards. Existing law provides for the repeal of those provisions, as provided, on January 1, 2014.

This bill would extend the operation of those provisions indefinitely and make those provisions applicable to the Physical Therapy Board of California and licensees within its jurisdiction.

Existing law establishes, until January 1, 2014, a vertical enforcement and prosecution model for cases before the Medical Board of California and requires the board to report to the Governor and Legislature on that model by March 1, 2012.

This bill would extend the date that report is due to March 1, 2015.

Existing law creates the Division of Investigation within the Department of Consumer Affairs and requires investigators who have the authority of peace officers to be in the division, except that investigators of the Medical Board of California and the Dental Board of California who have that authority are not required to be in the division.

This bill would require, effective July 1, 2014, that investigators of the Medical Board of California who have the authority of a peace officer be in the division and would protect the positions, status, and rights of those employees who are subsequently transferred as a result of these provisions. The bill would also, effective July 1, 2014, create within the Division of Investigation the Health Quality Investigation Unit.

(6) Existing law, the Veterinary Medicine Practice Act, provides for the licensure and registration of veterinarians and registered veterinary technicians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board. Existing law repeals the provisions establishing the board, and authorizing the board to appoint an executive officer, as of January 1, 2014. Under existing law, the board is subject to evaluation by the Joint Sunset Review Committee prior to its repeal.

This bill would provide that those provisions are instead repealed as of January 1, 2016. The bill, upon repeal of the board, would require that the board be subject to a specifically limited review by the appropriate policy committees of the Legislature.

Existing law authorizes the board, at any time, to inspect the premises in which veterinary medicine, veterinary dentistry, or veterinary surgery is being practiced and requires that those premises be registered with the board. Existing law requires the board to establish a regular inspection program that will provide for random, unannounced inspections.

This bill would require the board to make every effort to inspect at least 20% of veterinary premises on an annual basis and would exclude from inspection those premises that are not registered with the board.

Existing law requires the board to establish an advisory committee, the Veterinary Medicine Multidisciplinary Advisory Committee, to assist, advise, and make recommendations for the implementation of rules and regulations necessary to ensure proper administration and enforcement of specified provisions and to assist the board in its examination, licensure, and registration programs. Existing law requires the committee to consist of 7 members, with 4 licensed veterinarians, 2 registered veterinary technicians, and one public member.

This bill would expand the number of members on the committee to 9 by including one veterinarian member of the board, to be appointed by the board president, and the registered veterinary technician of the board, both of whom would serve concurrently with their terms of office on the board. The bill would additionally require that the committee serve only in an advisory capacity to the board, as specified. The bill would make other technical and conforming changes.

Existing law authorizes a registered veterinary technician or a veterinary assistant to administer a drug under the direct or indirect supervision of a licensed veterinarian when administered pursuant to the order, control, and full professional responsibility of a licensed veterinarian. Existing law limits access to controlled substances by veterinary assistants to persons who have undergone a background check and who, to the best of the licensee manager's knowledge, do not have any drug- or alcohol-related felony convictions. A violation of these provisions is a crime. Existing law repeals these provisions on January 1, 2015.

This bill would instead require, until the later of January 1, 2015, or the effective date of a specified legislative determination, a licensee manager to conduct a background check on a veterinary assistant prior to authorizing him or her to obtain or administer a controlled substance by the order of a supervising veterinarian and to prohibit the veterinary assistant from obtaining or administering controlled substances if the veterinary assistant has a drug- or alcohol-related felony conviction. Because a violation of these provisions would be a crime, this bill imposes a state-mandated local program.

This bill would require that, upon the later of January 1, 2015, or the effective date of a specified legislative determination, a veterinary assistant be designated by a licensed veterinarian and hold a valid veterinary assistant controlled substances permit from the board in order to obtain or administer controlled substances. The bill would, as part of the application for a permit, require an applicant to furnish a set of fingerprints to the Department of Justice for the purposes of conducting both a state and federal criminal history record check. The bill would require an applicant for a veterinary assistant controlled substances permit to apply for a renewal of his or her permit on or before the last day of the applicant's birthday month and to update his or her mailing or employer address with the board. The bill would authorize the board to collect a filing fee, not to exceed $100, from applicants for a veterinary assistant controlled substances permit. Because that fee would be deposited in the Veterinary Medical Board Contingent Fund, which is a continuously appropriated fund, the bill would make an appropriation.

(7) This bill would incorporate additional changes to Section 11529 of the Government Code proposed by SB 670 that would become operative if this bill and SB 670 are enacted and this bill is chaptered last.

(8) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: yes Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 159.5 of the Business and Professions Code is amended to read:

159.5. (a) (1) There is in the department the Division of Investigation. The division is in the charge of a person with the title of chief of the division.

(2) Except as provided in Section 160, investigators who have the authority of peace officers, as specified in subdivision (a) of Section 160 and in subdivision (a) of Section 830.3 of the Penal Code, shall be in the division and shall be appointed by the director.

(b) (1) There is in the Division of Investigation the Health Quality Investigation Unit. The primary responsibility of the unit is to investigate violations of law or regulation within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, the Osteopathic Medical Board of California, the Physician Assistant Board, or any entities under the jurisdiction of the Medical Board of California.

(2) The Medical Board of California shall not be charged an hourly rate for the performance of investigations by the unit.

(3) This subdivision shall become operative on July 1, 2014.

SEC. 2. Section 160 of the Business and Professions Code is amended to read:

160. (a) The chief and all investigators of the Division of Investigation of the department and all investigators of the Medical Board of California and the Dental Board of California have the authority of peace officers while engaged in exercising the powers granted or performing the duties imposed upon them or the division in investigating the laws administered by the various boards comprising the department or commencing directly or indirectly any criminal prosecution arising from any investigation conducted under these laws. All persons herein referred to shall be deemed to be acting within the scope of employment with respect to all acts and matters set forth in this section.

(b) The Division of Investigation of the department, the Medical Board of California, and the Dental Board of California may employ individuals, who are not peace officers, to provide investigative services.

(c) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 3. Section 160 is added to the Business and Professions Code, to read:

160. (a) The chief and all investigators of the Division of Investigation of the department and all investigators of the Dental Board of California have the authority of peace officers while engaged in exercising the powers granted or performing the duties imposed upon them or the division in investigating the laws administered by the various boards comprising the department or commencing directly or indirectly any criminal prosecution arising from any investigation conducted under these laws. All persons herein referred to shall be deemed to be acting within the scope of employment with respect to all acts and matters set forth in this section.

(b) The Division of Investigation of the department and the Dental Board of California may employ individuals, who are not peace officers, to provide investigative services.

(c) This section shall become operative on July 1, 2014.

SEC. 4. Section 160.5 of the Business and Professions Code is amended to read:

160.5. (a) All civil service employees currently employed by the Board of Dental Examiners of the Department of Consumer Affairs, whose functions are transferred as a result of the act adding this section shall retain their positions, status, and rights pursuant to Section 19050.9 of the Government Code and the State Civil Service

Act (Part 2 (commencing with Section 18500) of Division 5 of Title 2 of the Government Code). The transfer of employees as a result of the act adding this section shall occur no later than July 1, 1999.

(b) (1) All civil service employees currently employed by the Medical Board of California of the Department of Consumer Affairs, whose functions are transferred as a result of the act adding this subdivision shall retain their positions, status, and rights pursuant to Section 19050.9 of the Government Code and the State Civil Service Act (Part 2 (commencing with Section 18500) of Division 5 of Title 2 of the Government Code). The transfer of employees as a result of the act adding this subdivision shall occur no later than July 1, 2014.

(2) The transfer of employees pursuant to this subdivision shall include all peace officer and medical consultant positions and all staff support positions for those peace officer and medical consultant positions.

SEC. 5. Section 2001 of the Business and Professions Code is amended to read:

2001. (a) There is in the Department of Consumer Affairs a Medical Board of California that consists of 15 members, 7 of whom shall be public members.

(b) The Governor shall appoint 13 members to the board, subject to confirmation by the Senate, 5 of whom shall be public members. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(c) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 6. Section 2006 of the Business and Professions Code is amended to read:

2006. (a) Any reference in this chapter to an investigation by the board shall be deemed to refer to a joint investigation conducted by employees of the Department of Justice and the board under the vertical enforcement and prosecution model, as specified in Section 12529.6 of the Government Code.

(b) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 7. Section 2006 is added to the Business and Professions Code, to read:

2006. (a) Any reference in this chapter to an investigation by the board shall be deemed to refer to a joint investigation conducted by employees of the Department of Justice and the Health Quality Investigation Unit under the vertical enforcement and prosecution model, as specified in Section 12529.6 of the Government Code.

(b) This section shall become operative on July 1, 2014.

SEC. 8. Section 2020 of the Business and Professions Code is amended to read:

2020. (a) The board, by and with the approval of the director, may employ an executive director exempt from the provisions of the Civil Service Act and may also employ investigators, legal counsel, medical consultants, and other assistance as it may deem necessary to carry this chapter into effect. The board may fix the compensation to be paid for services subject to the provisions of applicable state laws and regulations and may incur other expenses as it may deem necessary. Investigators employed by the board shall be provided special training in investigating medical practice activities.

(b) The Attorney General shall act as legal counsel for the board for any judicial and administrative proceedings and his or her services shall be a charge against it.

(c) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 9. Section 2021 of the Business and Professions Code is amended to read:

2021. (a) If the board publishes a directory pursuant to Section 112, it may require persons licensed pursuant to this chapter to furnish any information as it may deem necessary to enable it to compile the directory.

(b) Each licensee shall report to the board each and every change of address within 30 days after each change, giving both the old and new address. If an address reported to the board at the time of application for licensure or subsequently is a post office box, the applicant shall also provide the board with a street address. If another address is the licensee's address of record, he or she may request that the second address not be disclosed to the public.

(c) Each licensee shall report to the board each and every change of name within 30 days after each change, giving both the old and new names.

(d) Each applicant and licensee who has an electronic mail address shall report to the board that electronic mail address no later than July 1, 2014. The electronic mail address shall be considered confidential and not subject to public disclosure.

(e) The board shall annually send an electronic notice to each applicant and licensee that requests confirmation from the applicant or licensee that his or her electronic mail address is current.

SEC. 10. Section 2135.7 of the Business and Professions Code is amended to read:

2135.7. (a) Upon review and recommendation, the board may determine that an applicant for a physician and surgeon's certificate who acquired his or her medical education or a portion thereof at a foreign medical school that is not recognized or has been previously disapproved by the board is eligible for a physician and surgeon's certificate if the applicant meets all of the following criteria:

(1) Has successfully completed a resident course of medical education leading to a degree of medical doctor equivalent to that specified in Sections 2089 to 2091.2, inclusive.

(2) (A) (i) For an applicant who acquired any part of his or her medical education from an unrecognized foreign medical school, he or she holds an unlimited and unrestricted license as a physician and surgeon in another state, a federal territory, or a Canadian province and has held that license and continuously practiced for a minimum of 10 years prior to the date of application.

(ii) For an applicant who acquired any part of his or her professional instruction from a foreign medical school that was disapproved by the board at the time he or she attended the school, he or she holds an unlimited and unrestricted license as a physician and surgeon in another state, a federal territory, or a Canadian province and has held that license and continuously practiced for a minimum of 12 years prior to the date of application.

(B) For the purposes of clauses (i) and (ii) of subparagraph (A), the board may combine the period of time that the applicant has held an unlimited and unrestricted license in other states, federal territories, or Canadian provinces and continuously practiced therein, but each applicant under this section shall have a minimum of two years continuous licensure and practice in a single state, federal territory, or Canadian province. For purposes of this paragraph, continuous licensure and practice includes any postgraduate training after 24 months in a postgraduate training program that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or postgraduate training completed in Canada that is accredited by the Royal College of Physicians and Surgeons of Canada (RCPSC).

(3) Is certified by a specialty board that is a member board of the American Board of Medical Specialties.

(4) Has successfully taken and passed the examinations described in Article 9 (commencing with Section 2170).

(5) Has not been the subject of a disciplinary action by a medical licensing authority or of adverse judgments or settlements resulting from the practice of medicine that the board determines constitutes a pattern of negligence or incompetence.

(6) Has successfully completed three years of approved postgraduate training. The postgraduate training required by this paragraph shall have been obtained in a postgraduate training program accredited by the ACGME or postgraduate training completed in Canada that is accredited by the RCPSC.

(7) Is not subject to denial of licensure under Division 1.5 (commencing with Section 475) or Article 12 (commencing with Section 2220).

(8) Has not held a healing arts license and been the subject of disciplinary action by a healing arts board of this state or by another state, federal territory, or Canadian province.

(b) The board may adopt regulations to establish procedures for accepting transcripts, diplomas, and other supporting information and records when the originals are not available due to circumstances outside the applicant's control. The board may also adopt regulations authorizing the substitution of additional specialty board certifications for years of practice or licensure when considering the certification for a physician and surgeon pursuant to this section.

(c) This section shall not apply to a person seeking to participate in a program described in Sections 2072, 2073, 2111, 2112, 2113, 2115, or 2168, or seeking to engage in postgraduate training in this state.

SEC. 11. Section 2177 of the Business and Professions Code is amended to read:

2177. (a) A passing score is required for an entire examination or for each part of an examination, as established by resolution of the board.

(b) Applicants may elect to take the written examinations conducted or accepted by the board in separate parts.

(c) (1) An applicant shall have obtained a passing score on all parts of Step 3 of the United States Medical Licensing Examination within not more than four attempts in order to be eligible for a physician's and surgeon's certificate.

(2) Notwithstanding paragraph (1), an applicant who obtains a passing score on all parts of Step 3 of the United States Medical Licensing Examination in more than four attempts and who meets the requirements of Section 2135.5 shall be eligible to be considered for issuance of a physician's and surgeon's certificate.

SEC. 12. Section 2216.3 is added to the Business and Professions Code, to read:

2216.3. (a) An outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code shall report an adverse event to the board no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

(b) For the purposes of this section, "adverse event" has the same meaning as in subdivision (b) of Section 1279.1 of the Health and Safety Code.

SEC. 13. Section 2216.4 is added to the Business and Professions Code, to read:

2216.4. If an accredited outpatient setting fails to report an adverse event pursuant to Section 2216.3, the board may assess the accredited outpatient setting a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable. If the accredited outpatient setting disputes a determination by the board regarding an alleged failure to report an adverse event, the accredited outpatient setting may, within 10 days of notification of the board's determination, request a hearing, which shall be conducted pursuant to the administrative adjudication provisions of Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

SEC. 14. Section 2220.08 of the Business and Professions Code is amended to read:

2220.08. (a) Except for reports received by the board pursuant to Section 801.01 or 805 that may be treated as complaints by the board and new complaints relating to a physician and surgeon who is the subject of a pending accusation or investigation or who is on probation, any complaint determined to involve quality of care, before referral to a field office for further investigation, shall meet the following criteria:

(1) It shall be reviewed by one or more medical experts with the pertinent education, training, and expertise to evaluate the specific standard of care issues raised by the complaint to determine if further field investigation is required.

(2) It shall include the review of the following, which shall be requested by the board:

(A) Relevant patient records.

(B) The statement or explanation of the care and treatment provided by the physician and surgeon.

(C) Any additional expert testimony or literature provided by the physician and surgeon.

(D) Any additional facts or information requested by the medical expert reviewers that may assist them in determining whether the care rendered constitutes a departure from the standard of care.

(b) If the board does not receive the information requested pursuant to paragraph (2) of subdivision (a) within 10 working days of requesting that information, the complaint may be reviewed by the medical experts and referred to a field office for investigation without the information.

(c) Nothing in this section shall impede the board's ability to seek and obtain an interim suspension order or other emergency relief.

SEC. 15. Section 2225.5 of the Business and Professions Code is amended to read:

2225.5. (a) (1) A licensee who fails or refuses to comply with a request for the certified medical records of a patient, that is accompanied by that patient's written authorization for release of records to the board, within 15 days of receiving the request and authorization, shall pay to the board a civil penalty of one thousand dollars ($1,000) per day for each day that the documents have not been produced after the 15th day, up to ten thousand dollars ($10,000), unless the licensee is unable to provide the documents within this time period for good cause.

(2) A health care facility shall comply with a request for the certified medical records of a patient that is accompanied by that patient's written authorization for release of records to the board together with a notice citing this section and describing the penalties for failure to comply with this section. Failure to provide the authorizing patient's certified medical records to the board within 30 days of receiving the request, authorization, and notice shall subject the health care facility to a civil penalty, payable to the board, of up to one thousand dollars ($1,000) per day for each day that the documents have not been produced after the 30th day, up to ten thousand dollars ($10,000), unless the health care facility is unable to provide the documents within this time period for good cause. For health care facilities that have electronic health records, failure to provide the authorizing patient's certified medical records to the board within 15 days of receiving the request, authorization, and notice shall subject the health care facility to a civil penalty, payable to the board, of up to one thousand dollars ($1,000) per day for each day that the documents have not been produced after the 15th day, up to ten thousand dollars ($10,000), unless the health care facility is unable to provide the documents within this time period for good cause. This paragraph shall not require health care facilities to assist the board in obtaining the patient's authorization. The board shall pay the reasonable costs of copying the certified medical records.

(b) (1) A licensee who fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board shall pay to the board a civil penalty of one thousand dollars ($1,000) per day for each day that the documents have not been produced after the date by which the court order requires the documents to be produced, up to ten thousand dollars ($10,000), unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the board shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.

(2) Any licensee who fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board is guilty of a misdemeanor punishable by a fine payable to the board not to exceed five thousand dollars ($5,000). The fine shall be added to the licensee's renewal fee if it is not paid by the next succeeding renewal date. Any statute of limitations applicable to the filing of an accusation by the board shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.

(3) A health care facility that fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of patient records to the board, that is accompanied by a notice citing this section and describing the penalties for failure to comply with this section, shall pay to the board a civil penalty of up to one thousand dollars ($1,000) per day for each day that the documents have not been produced, up

to ten thousand dollars ($10,000), after the date by which the court order requires the documents to be produced, unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the board against a licensee shall be tolled during the period the health care facility is out of compliance with the court order and during any related appeals.

(4) Any health care facility that fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board is guilty of a misdemeanor punishable by a fine payable to the board not to exceed five thousand dollars ($5,000). Any statute of limitations applicable to the filing of an accusation by the board against a licensee shall be tolled during the period the health care facility is out of compliance with the court order and during any related appeals.

(c) Multiple acts by a licensee in violation of subdivision (b) shall be punishable by a fine not to exceed five thousand dollars ($5,000) or by imprisonment in a county jail not exceeding six months, or by both that fine and imprisonment. Multiple acts by a health care facility in violation of subdivision (b) shall be punishable by a fine not to exceed five thousand dollars ($5,000) and shall be reported to the State Department of Public Health and shall be considered as grounds for disciplinary action with respect to licensure, including suspension or revocation of the license or certificate.

(d) A failure or refusal of a licensee to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board constitutes unprofessional conduct and is grounds for suspension or revocation of his or her license.

(e) Imposition of the civil penalties authorized by this section shall be in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Division 3 of Title 2 of the Government Code).

(f) For purposes of this section, "certified medical records" means a copy of the patient's medical records authenticated by the licensee or health care facility, as appropriate, on a form prescribed by the board.

(g) For purposes of this section, a "health care facility" means a clinic or health facility licensed or exempt from licensure pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code.

SEC. 16. Section 2403 is added to the Business and Professions Code, to read:

2403. The provisions of Section 2400 do not apply to physicians and surgeons or doctors of podiatric medicine enrolled in approved residency postgraduate training programs or fellowship programs.

SEC. 17. Section 2514 of the Business and Professions Code is amended to read:

2514. (a) Nothing in this chapter shall be construed to prevent a bona fide student from engaging in the practice of midwifery in this state, as part of his or her course of study, if both of the following conditions are met:

(1) The student is under the supervision of a licensed midwife or certified nurse-midwife, who holds a clear and unrestricted license in this state, who is present on the premises at all times client services are provided, and who is practicing pursuant to Section 2507 or 2746.5, or a physician and surgeon.

(2) The client is informed of the student's status.

(b) For the purposes of this section, a "bona fide student" means an individual who is enrolled and participating in a midwifery education program or who is enrolled in a program of supervised clinical training as part of the instruction of a three year postsecondary midwifery education program approved by the board.

SEC. 18. Section 2569 of the Business and Professions Code is amended to read:

2569. Notwithstanding any other law, the powers and duties of the board, as set forth in this chapter, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 19. Section 4800 of the Business and Professions Code is amended to read:

4800. (a) There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of the following members:

(1) Four licensed veterinarians.

(2) One registered veterinary technician.

(3) Three public members.

(b) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to those issues identified by the appropriate policy committees of the Legislature and shall not involve the preparation or submission of a sunset review document or evaluative questionnaire.

SEC. 20. Section 4804.5 of the Business and Professions Code is amended to read:

4804.5. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 21. Section 4809.5 of the Business and Professions Code is amended to read:

4809.5. The board may at any time inspect the premises in which veterinary medicine, veterinary dentistry, or veterinary surgery is being practiced. The board's inspection authority does not extend to premises that are not registered with the board. Nothing in this section shall be construed to affect the board's ability to investigate alleged unlicensed activity or to inspect a premises for which registration has lapsed or is delinquent.

SEC. 22. Section 4809.7 of the Business and Professions Code is amended to read:

4809.7. The board shall establish a regular inspection program that will provide for random, unannounced inspections. The board shall make every effort to inspect at least 20 percent of veterinary premises on an annual basis.

SEC. 23. Section 4809.8 of the Business and Professions Code is amended to read:

4809.8. (a) The board shall establish an advisory committee to assist, advise, and make recommendations for the implementation of rules and regulations necessary to ensure proper administration and enforcement of this chapter and to assist the board in its examination, licensure, and registration programs. The committee shall serve only in an advisory capacity to the board and the objectives, duties, and actions of the committee shall not be a substitute for or conflict with any of the powers, duties, and responsibilities of the board. The committee shall be known as the Veterinary Medicine Multidisciplinary Advisory Committee. The multidisciplinary committee shall consist of nine members. The following members of the multidisciplinary committee shall be appointed by the board from lists of nominees solicited by the board: four licensed veterinarians, two registered veterinary technicians, and one public member. The committee shall also include one veterinarian member of the board, to be appointed by the board president, and the registered veterinary technician member of the board. Members of the multidisciplinary committee shall represent a sufficient cross section of the interests in veterinary medicine in order to address the issues before it, as determined by the board, including veterinarians, registered veterinary technicians, and members of the public.

(b) Multidisciplinary committee members appointed by the board shall serve for a term of three years and appointments shall be staggered accordingly. A member may be reappointed, but no person shall serve as a member of the committee for more than two consecutive terms. Vacancies occurring shall be filled by appointment for the unexpired term, within 90 days after they occur. Board members of the multidisciplinary committee shall serve concurrently with their terms of office on the board.

(c) The multidisciplinary committee shall be subject to the requirements of Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

(d) Multidisciplinary committee members shall receive a per diem as provided in Section 103 and shall be compensated for their actual travel expenses in accordance with the rules and regulations adopted by the Department of Human Resources.

(e) The board may remove a member of the multidisciplinary committee appointed by the board for continued neglect of a duty required by this chapter, for incompetency, or for unprofessional conduct.

(f) It is the intent of the Legislature that the multidisciplinary committee, in implementing this section, give appropriate consideration to issues pertaining to the practice of registered veterinarian technicians.

SEC. 24. Section 4836.1 of the Business and Professions Code is amended to read:

4836.1. (a) Notwithstanding any other provision of law, a registered veterinary technician or a veterinary assistant may administer a drug, including, but not limited to, a drug that is a controlled substance, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian. However, no person, other than a licensed veterinarian, may induce anesthesia unless authorized by regulation of the board.

(b) Prior to authorizing a veterinary assistant to obtain or administer a controlled substance by the order of a supervising veterinarian, the licensee manager in a veterinary practice shall conduct a background check on that veterinary assistant. A veterinary assistant who has a drug- or alcohol-related felony conviction, as indicated in the background check, shall be prohibited from obtaining or administering controlled substances.

(c) Notwithstanding subdivision (b), if the Veterinary Medical Board, in consultation with the Board of Pharmacy, identifies a dangerous drug, as defined in Section 4022, as a drug that has an established pattern of being diverted, the Veterinary Medical Board may restrict access to that drug by veterinary assistants.

(d) For purposes of this section, the following definitions apply:

(1) "Controlled substance" has the same meaning as that term is defined in Section 11007 of the Health and Safety Code.

(2) "Direct supervision" has the same meaning as that term is defined in subdivision (e) of Section 2034 of Title 16 of the California Code of Regulations.

(3) "Drug" has the same meaning as that term is defined in Section 11014 of the Health and Safety Code.

(4) "Indirect supervision" has the same meaning as that term is defined in subdivision (f) of Section 2034 of Title 16 of the California Code of Regulations.

(e) This section shall become inoperative on the later of January 1, 2015, or the date Section 4836.2 becomes operative, and, as of January 1 next following that date, is repealed, unless a later enacted statute, that becomes operative on or before that date, deletes or extends the dates on which it becomes inoperative is repealed.

SEC. 25. Section 4836.1 is added to the Business and Professions Code, to read:

4836.1. (a) Notwithstanding any other law, a registered veterinary technician or a veterinary assistant may administer a drug, including, but not limited to, a drug that is a controlled substance, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian. However, no person, other than a licensed veterinarian, may induce anesthesia unless authorized by regulation of the board.

(b) A veterinary assistant may obtain or administer a controlled substance pursuant to the order, control, and full professional responsibility of a licensed veterinarian, only if he or she meets both of the following conditions:

(1) Is designated by a licensed veterinarian to obtain or administer controlled substances.

(2) Holds a valid veterinary assistant controlled substance permit issued pursuant to Section 4836.2.

(c) Notwithstanding subdivision (b), if the Veterinary Medical Board, in consultation with the Board of Pharmacy, identifies a dangerous drug, as defined in Section 4022, as a drug that has an established pattern of

being diverted, the Veterinary Medical Board may restrict access to that drug by veterinary assistants.

(d) For purposes of this section, the following definitions apply:

(1) "Controlled substance" has the same meaning as that term is defined in Section 11007 of the Health and Safety Code.

(2) "Direct supervision" has the same meaning as that term is defined in subdivision (e) of Section 2034 of Title 16 of the California Code of Regulations.

(3) "Drug" has the same meaning as that term is defined in Section 11014 of the Health and Safety Code.

(4) "Indirect supervision" has the same meaning as that term is defined in subdivision (f) of Section 2034 of Title 16 of the California Code of Regulations.

(e) This section shall become operative on the date Section 4836.2 becomes operative.

SEC. 26. Section 4836.2 is added to the Business and Professions Code, to read:

4836.2. (a) Applications for a veterinary assistant controlled substance permit shall be upon a form furnished by the board.

(b) The fee for filing an application for a veterinary assistant controlled substance permit shall be set by the board in an amount the board determines is reasonably necessary to provide sufficient funds to carry out the purposes of this section, not to exceed one hundred dollars ($100).

(c) The board may deny, suspend, or revoke the controlled substance permit of a veterinary assistant after notice and hearing for any cause provided in this subdivision. The proceedings under this section shall be conducted in accordance with the provisions for administrative adjudication in Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein. The board may revoke or suspend a veterinary assistant controlled substance permit for any of the following reasons:

(1) The employment of fraud, misrepresentation, or deception in obtaining a veterinary assistant controlled substance permit.

(2) Chronic inebriety or habitual use of controlled substances.

(3) Violating or attempts to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, or of the regulations adopted under this chapter.

(d) The board shall not issue a veterinary assistant controlled substance permit to any applicant with a state or federal felony controlled substance conviction.

(e) The board shall revoke a veterinary assistant controlled substance permit upon notification that the veterinary assistant to whom the license is issued has been convicted of a state or federal felony controlled substance violation.

(f) (1) As part of the application for a veterinary assistant controlled substance permit, the applicant shall submit to the Department of Justice fingerprint images and related information, as required by the Department of Justice for all veterinary assistant applicants, for the purposes of obtaining information as to the existence and content of a record of state or federal convictions and state or federal arrests and information as to the existence and content of a record of state or federal arrests for which the Department of Justice establishes that the person is free on bail or on his or her own recognizance pending trial or appeal.

(2) When received, the Department of Justice shall forward to the Federal Bureau of Investigation requests for federal summary criminal history information that it receives pursuant to this section. The Department of Justice shall review any information returned to it from the Federal Bureau of Investigation and compile and disseminate a response to the board summarizing that information.

(3) The Department of Justice shall provide a state or federal level response to the board pursuant to paragraph (1) of subdivision (p) of Section 11105 of the Penal Code.

(4) The Department of Justice shall charge a reasonable fee sufficient to cover the cost of processing the

request described in this subdivision.

(g) The board shall request from the Department of Justice subsequent notification service, as provided pursuant to Section 11105.2 of the Penal Code, for persons described in paragraph (1) of subdivision (f).

(h) This section shall become operative upon the later of January 1, 2015, or the effective date of the statute in which the Legislature makes a determination that the board has sufficient staffing to implement this section.

SEC. 27. Section 4836.3 is added to the Business and Professions Code, to read:

4836.3. (a) Each person who has been issued a veterinary assistant controlled substance permit by the board pursuant to Section 4836.2 shall biennially apply for renewal of his or her permit on or before the last day of the applicant's birthday month. The application shall be made on a form provided by the board.

(b) The application shall contain a statement to the effect that the applicant has not been convicted of a felony, has not been the subject of professional disciplinary action taken by any public agency in California or any other state or territory, and has not violated any of the provisions of this chapter. If the applicant is unable to make that statement, the application shall contain a statement of the conviction, professional discipline, or violation.

(c) The board may, as part of the renewal process, make necessary inquiries of the applicant and conduct an investigation in order to determine if cause for disciplinary action exists.

(d) The fee for filing an application for a renewal of a veterinary assistant controlled substance permit shall be set by the board in an amount the board determines is reasonably necessary to provide sufficient funds to carry out the purposes of this section, not to exceed fifty dollars ($50).

(e) This section shall become operative on the date Section 4836.2 becomes operative.

SEC. 28. Section 4836.4 is added to the Business and Professions Code, to read:

4836.4. (a) Every person who has been issued a veterinary assistant controlled substance permit by the board pursuant to Section 4836.2 who changes his or her mailing or employer address shall notify the board of his or her new mailing or employer address within 30 days of the change. The board shall not renew the permit of any person who fails to comply with this section unless the person pays the penalty fee prescribed in Section 4842.5. An applicant for the renewal of a permit shall specify in his or her application whether he or she has changed his or her mailing or employer address and the board may accept that statement as evidence of the fact.

(b) This section shall become operative on the date Section 4836.2 becomes operative.

SEC. 29. Section 11529 of the Government Code is amended to read:

11529. (a) The administrative law judge of the Medical Quality Hearing Panel established pursuant to Section 11371 may issue an interim order suspending a license, or imposing drug testing, continuing education, supervision of procedures, or other license restrictions. Interim orders may be issued only if the affidavits in support of the petition show that the licensee has engaged in, or is about to engage in, acts or omissions constituting a violation of the Medical Practice Act or the appropriate practice act governing each allied health profession, or is unable to practice safely due to a mental or physical condition, and that permitting the licensee to continue to engage in the profession for which the license was issued will endanger the public health, safety, or welfare. The failure to comply with an order issued pursuant to Section 820 of the Business and Professions Code may constitute grounds to issue an interim suspension order under this section.

(b) All orders authorized by this section shall be issued only after a hearing conducted pursuant to subdivision (d), unless it appears from the facts shown by affidavit that serious injury would result to the public before the matter can be heard on notice. Except as provided in subdivision (c), the licensee shall receive at least 15 days' prior notice of the hearing, which notice shall include affidavits and all other information in support of the order.

(c) If an interim order is issued without notice, the administrative law judge who issued the order without notice shall cause the licensee to be notified of the order, including affidavits and all other information in support of the order by a 24-hour delivery service. That notice shall also include the date of the hearing on the order, which shall be conducted in accordance with the requirement of subdivision (d), not later than 20 days from

the date of issuance. The order shall be dissolved unless the requirements of subdivision (a) are satisfied.

(d) For the purposes of the hearing conducted pursuant to this section, the licentiate shall, at a minimum, have the following rights:

(1) To be represented by counsel.

(2) To have a record made of the proceedings, copies of which may be obtained by the licentiate upon payment of any reasonable charges associated with the record.

(3) To present written evidence in the form of relevant declarations, affidavits, and documents.

The discretion of the administrative law judge to permit testimony at the hearing conducted pursuant to this section shall be identical to the discretion of a superior court judge to permit testimony at a hearing conducted pursuant to Section 527 of the Code of Civil Procedure.

(4) To present oral argument.

(e) Consistent with the burden and standards of proof applicable to a preliminary injunction entered under Section 527 of the Code of Civil Procedure, the administrative law judge shall grant the interim order where, in the exercise of discretion, the administrative law judge concludes that:

(1) There is a reasonable probability that the petitioner will prevail in the underlying action.

(2) The likelihood of injury to the public in not issuing the order outweighs the likelihood of injury to the licensee in issuing the order.

(f) In all cases in which an interim order is issued, and an accusation is not filed and served pursuant to Sections 11503 and 11505 within 30 days of the date on which the parties to the hearing on the interim order have submitted the matter, the order shall be dissolved.

Upon service of the accusation the licensee shall have, in addition to the rights granted by this section, all of the rights and privileges available as specified in this chapter. If the licensee requests a hearing on the accusation, the board shall provide the licensee with a hearing within 30 days of the request, unless the licensee stipulates to a later hearing, and a decision within 15 days of the date the decision is received from the administrative law judge, or the board shall nullify the interim order previously issued, unless good cause can be shown by the Division of Medical Quality for a delay.

(g) If an interim order is issued, a written decision shall be prepared within 15 days of the hearing, by the administrative law judge, including findings of fact and a conclusion articulating the connection between the evidence produced at the hearing and the decision reached.

(h) Notwithstanding the fact that interim orders issued pursuant to this section are not issued after a hearing as otherwise required by this chapter, interim orders so issued shall be subject to judicial review pursuant to Section 1094.5 of the Code of Civil Procedure. The relief that may be ordered shall be limited to a stay of the interim order. Interim orders issued pursuant to this section are final interim orders and, if not dissolved pursuant to subdivision (c) or (f), may only be challenged administratively at the hearing on the accusation.

(i) The interim order provided for by this section shall be:

(1) In addition to, and not a limitation on, the authority to seek injunctive relief provided for in the Business and Professions Code.

(2) A limitation on the emergency decision procedure provided in Article 13 (commencing with Section 11460.10) of Chapter 4.5.

SEC. 29.5. Section 11529 of the Government Code is amended to read:

11529. (a) The administrative law judge of the Medical Quality Hearing Panel established pursuant to Section 11371 may issue an interim order suspending a license, imposing drug testing, continuing education, supervision of procedures, limitations on the authority to prescribe, furnish, administer, or dispense controlled substances, or other license restrictions. Interim orders may be issued only if the affidavits in support of the petition show that the licensee has engaged in, or is about to engage in, acts or omissions constituting a violation of the Medical Practice Act or the appropriate practice act governing each allied health profession, or is

unable to practice safely due to a mental or physical condition, and that permitting the licensee to continue to engage in the profession for which the license was issued will endanger the public health, safety, or welfare. The failure to comply with an order issued pursuant to Section 820 of the Business and Professions Code may constitute grounds to issue an interim suspension order under this section.

(b) All orders authorized by this section shall be issued only after a hearing conducted pursuant to subdivision (d), unless it appears from the facts shown by affidavit that serious injury would result to the public before the matter can be heard on notice. Except as provided in subdivision (c), the licensee shall receive at least 15 days' prior notice of the hearing, which notice shall include affidavits and all other information in support of the order.

(c) If an interim order is issued without notice, the administrative law judge who issued the order without notice shall cause the licensee to be notified of the order, including affidavits and all other information in support of the order by a 24-hour delivery service. That notice shall also include the date of the hearing on the order, which shall be conducted in accordance with the requirement of subdivision (d), not later than 20 days from the date of issuance. The order shall be dissolved unless the requirements of subdivision (a) are satisfied.

(d) For the purposes of the hearing conducted pursuant to this section, the licentiate shall, at a minimum, have the following rights:

(1) To be represented by counsel.

(2) To have a record made of the proceedings, copies of which may be obtained by the licentiate upon payment of any reasonable charges associated with the record.

(3) To present written evidence in the form of relevant declarations, affidavits, and documents.

The discretion of the administrative law judge to permit testimony at the hearing conducted pursuant to this section shall be identical to the discretion of a superior court judge to permit testimony at a hearing conducted pursuant to Section 527 of the Code of Civil Procedure.

(4) To present oral argument.

(e) Consistent with the burden and standards of proof applicable to a preliminary injunction entered under Section 527 of the Code of Civil Procedure, the administrative law judge shall grant the interim order if, in the exercise of discretion, the administrative law judge concludes that:

(1) There is a reasonable probability that the petitioner will prevail in the underlying action.

(2) The likelihood of injury to the public in not issuing the order outweighs the likelihood of injury to the licensee in issuing the order.

(f) In all cases in which an interim order is issued, and an accusation is not filed and served pursuant to Sections 11503 and 11505 within 30 days of the date on which the parties to the hearing on the interim order have submitted the matter, the order shall be dissolved.

Upon service of the accusation the licensee shall have, in addition to the rights granted by this section, all of the rights and privileges available as specified in this chapter. If the licensee requests a hearing on the accusation, the board shall provide the licensee with a hearing within 30 days of the request, unless the licensee stipulates to a later hearing, and a decision within 15 days of the date the decision is received from the administrative law judge, or the board shall nullify the interim order previously issued, unless good cause can be shown by the Division of Medical Quality for a delay.

(g) If an interim order is issued, a written decision shall be prepared within 15 days of the hearing, by the administrative law judge, including findings of fact and a conclusion articulating the connection between the evidence produced at the hearing and the decision reached.

(h) Notwithstanding the fact that interim orders issued pursuant to this section are not issued after a hearing as otherwise required by this chapter, interim orders so issued shall be subject to judicial review pursuant to Section 1094.5 of the Code of Civil Procedure. The relief that may be ordered shall be limited to a stay of the interim order. Interim orders issued pursuant to this section are final interim orders and, if not dissolved pursuant to subdivision (c) or (f), may only be challenged administratively at the hearing on the accusation.

(i) The interim order provided for by this section shall be:

(1) In addition to, and not a limitation on, the authority to seek injunctive relief provided for in the Business and Professions Code.

(2) A limitation on the emergency decision procedure provided in Article 13 (commencing with Section 11460.10) of Chapter 4.5.

SEC. 30. Section 12529 of the Government Code, as amended by Section 112 of Chapter 332 of the Statutes of 2012, is amended to read:

12529. (a) There is in the Department of Justice the Health Quality Enforcement Section. The primary responsibility of the section is to investigate and prosecute proceedings against licensees and applicants within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, the Physical Therapy Board of California, or any committee under the jurisdiction of the Medical Board of California.

(b) The Attorney General shall appoint a Senior Assistant Attorney General of the Health Quality Enforcement Section. The Senior Assistant Attorney General of the Health Quality Enforcement Section shall be an attorney in good standing licensed to practice in the State of California, experienced in prosecutorial or administrative disciplinary proceedings and competent in the management and supervision of attorneys performing those functions.

(c) The Attorney General shall ensure that the Health Quality Enforcement Section is staffed with a sufficient number of experienced and able employees that are capable of handling the most complex and varied types of disciplinary actions against the licensees of the boards.

(d) Funding for the Health Quality Enforcement Section shall be budgeted in consultation with the Attorney General from the special funds financing the operations of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, the Physical Therapy Board of California, and the committees under the jurisdiction of the Medical Board of California, with the intent that the expenses be proportionally shared as to services rendered.

SEC. 31. Section 12529 of the Government Code, as amended by Section 113 of Chapter 332 of the Statutes of 2012, is repealed.

SEC. 32. Section 12529.5 of the Government Code, as amended by Section 114 of Chapter 332 of the Statutes of 2012, is amended to read:

12529.5. (a) All complaints or relevant information concerning licensees that are within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, or the Physical Therapy Board of California shall be made available to the Health Quality Enforcement Section.

(b) The Senior Assistant Attorney General of the Health Quality Enforcement Section shall assign attorneys to work on location at the intake unit of the boards described in subdivision (a) to assist in evaluating and screening complaints and to assist in developing uniform standards and procedures for processing complaints.

(c) The Senior Assistant Attorney General or his or her deputy attorneys general shall assist the boards in designing and providing initial and in-service training programs for staff of the boards, including, but not limited to, information collection and investigation.

(d) The determination to bring a disciplinary proceeding against a licensee of the boards shall be made by the executive officer of the boards as appropriate in consultation with the senior assistant.

SEC. 33. Section 12529.5 of the Government Code, as amended by Section 115 of Chapter 332 of the Statutes of 2012, is repealed.

SEC. 34. Section 12529.6 of the Government Code is amended to read:

12529.6. (a) The Legislature finds and declares that the Medical Board of California, by ensuring the quality and safety of medical care, performs one of the most critical functions of state government. Because of the critical importance of the board's public health and safety function, the complexity of cases involving alleged misconduct by physicians and surgeons, and the evidentiary burden in the board's disciplinary cases, the

Legislature finds and declares that using a vertical enforcement and prosecution model for those investigations is in the best interests of the people of California.

(b) Notwithstanding any other provision of law, as of January 1, 2006, each complaint that is referred to a district office of the board for investigation shall be simultaneously and jointly assigned to an investigator and to the deputy attorney general in the Health Quality Enforcement Section responsible for prosecuting the case if the investigation results in the filing of an accusation. The joint assignment of the investigator and the deputy attorney general shall exist for the duration of the disciplinary matter. During the assignment, the investigator so assigned shall, under the direction but not the supervision of the deputy attorney general, be responsible for obtaining the evidence required to permit the Attorney General to advise the board on legal matters such as whether the board should file a formal accusation, dismiss the complaint for a lack of evidence required to meet the applicable burden of proof, or take other appropriate legal action.

(c) The Medical Board of California, the Department of Consumer Affairs, and the Office of the Attorney General shall, if necessary, enter into an interagency agreement to implement this section.

(d) This section does not affect the requirements of Section 12529.5 as applied to the Medical Board of California where complaints that have not been assigned to a field office for investigation are concerned.

(e) It is the intent of the Legislature to enhance the vertical enforcement and prosecution model as set forth in subdivision (a). The Medical Board of California shall do all of the following:

(1) Increase its computer capabilities and compatibilities with the Health Quality Enforcement Section in order to share case information.

(2) Establish and implement a plan to locate its enforcement staff and the staff of the Health Quality Enforcement Section in the same offices, as appropriate, in order to carry out the intent of the vertical enforcement and prosecution model.

(3) Establish and implement a plan to assist in team building between its enforcement staff and the staff of the Health Quality Enforcement Section in order to ensure a common and consistent knowledge base.

SEC. 35. Section 12529.7 of the Government Code is amended to read:

12529.7. By March 1, 2015, the Medical Board of California, in consultation with the Department of Justice and the Department of Consumer Affairs, shall report and make recommendations to the Governor and the Legislature on the vertical enforcement and prosecution model created under Section 12529.6.

SEC. 36. Section 1248.15 of the Health and Safety Code is amended to read:

1248.15. (a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:

(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.

(2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.

(B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.

(C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:

(i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.

(ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

(iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.

(D) In addition to the requirements imposed in subparagraph (C), the outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:

(i) Notify the individual designated by the patient to be notified in case of an emergency.

(ii) Ensure that the mode of transfer is consistent with the patient's medical condition.

(iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.

(iv) Continue to provide appropriate care to the patient until the transfer is effectuated.

(E) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.

(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.

(4) Outpatient settings shall have a system for maintaining clinical records.

(5) Outpatient settings shall have a system for patient care and monitoring procedures.

(6) (A) Outpatient settings shall have a system for quality assessment and improvement.

(B) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.

(C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.

(7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.

(8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.

(9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.

(10) Outpatient settings shall have a written discharge criteria.

(b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.

(c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.

(d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.

(e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.

(f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.

(g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, "conducting a reasonable investigation" means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision.

SEC. 37. Section 830.3 of the Penal Code is amended to read:

830.3. The following persons are peace officers whose authority extends to any place in the state for the purpose of performing their primary duty or when making an arrest pursuant to Section 836 as to any public offense with respect to which there is immediate danger to person or property, or of the escape of the perpetrator of that offense, or pursuant to Section 8597 or 8598 of the Government Code. These peace officers may carry firearms only if authorized and under those terms and conditions as specified by their employing agencies:

(a) Persons employed by the Division of Investigation of the Department of Consumer Affairs and investigators of the Medical Board of California and the Board of Dental Examiners, who are designated by the Director of Consumer Affairs, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 160 of the Business and Professions Code.

(b) Voluntary fire wardens designated by the Director of Forestry and Fire Protection pursuant to Section 4156 of the Public Resources Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 4156 of that code.

(c) Employees of the Department of Motor Vehicles designated in Section 1655 of the Vehicle Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 1655 of that code.

(d) Investigators of the California Horse Racing Board designated by the board, provided that the primary duty of these peace officers shall be the enforcement of Chapter 4 (commencing with Section 19400) of Division 8 of the Business and Professions Code and Chapter 10 (commencing with Section 330) of Title 9 of Part 1 of this code.

(e) The State Fire Marshal and assistant or deputy state fire marshals appointed pursuant to Section 13103 of the Health and Safety Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 13104 of that code.

(f) Inspectors of the food and drug section designated by the chief pursuant to subdivision (a) of Section 106500 of the Health and Safety Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 106500 of that code.

(g) All investigators of the Division of Labor Standards Enforcement designated by the Labor Commissioner,

provided that the primary duty of these peace officers shall be the enforcement of the law as prescribed in Section 95 of the Labor Code.

(h) All investigators of the State Departments of Health Care Services, Public Health, Social Services, Mental Health, and Alcohol and Drug Programs, the Department of Toxic Substances Control, the Office of Statewide Health Planning and Development, and the Public Employees' Retirement System, provided that the primary duty of these peace officers shall be the enforcement of the law relating to the duties of his or her department or office. Notwithstanding any other provision of law, investigators of the Public Employees' Retirement System shall not carry firearms.

(i) The Chief of the Bureau of Fraudulent Claims of the Department of Insurance and those investigators designated by the chief, provided that the primary duty of those investigators shall be the enforcement of Section 550.

(j) Employees of the Department of Housing and Community Development designated under Section 18023 of the Health and Safety Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 18023 of that code.

(k) Investigators of the office of the Controller, provided that the primary duty of these investigators shall be the enforcement of the law relating to the duties of that office. Notwithstanding any other law, except as authorized by the Controller, the peace officers designated pursuant to this subdivision shall not carry firearms.

(l) Investigators of the Department of Business Oversight designated by the Commissioner of Business Oversight, provided that the primary duty of these investigators shall be the enforcement of the provisions of law administered by the Department of Business Oversight. Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(m) Persons employed by the Contractors State License Board designated by the Director of Consumer Affairs pursuant to Section 7011.5 of the Business and Professions Code, provided that the primary duty of these persons shall be the enforcement of the law as that duty is set forth in Section 7011.5, and in Chapter 9 (commencing with Section 7000) of Division 3, of that code. The Director of Consumer Affairs may designate as peace officers not more than 12 persons who shall at the time of their designation be assigned to the special investigations unit of the board. Notwithstanding any other provision of law, the persons designated pursuant to this subdivision shall not carry firearms.

(n) The Chief and coordinators of the Law Enforcement Branch of the Office of Emergency Services.

(o) Investigators of the office of the Secretary of State designated by the Secretary of State, provided that the primary duty of these peace officers shall be the enforcement of the law as prescribed in Chapter 3 (commencing with Section 8200) of Division 1 of Title 2 of, and Section 12172.5 of, the Government Code. Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(p) The Deputy Director for Security designated by Section 8880.38 of the Government Code, and all lottery security personnel assigned to the California State Lottery and designated by the director, provided that the primary duty of any of those peace officers shall be the enforcement of the laws related to assuring the integrity, honesty, and fairness of the operation and administration of the California State Lottery.

(q) Investigators employed by the Investigation Division of the Employment Development Department designated by the director of the department, provided that the primary duty of those peace officers shall be the enforcement of the law as that duty is set forth in Section 317 of the Unemployment Insurance Code.

Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(r) The chief and assistant chief of museum security and safety of the California Science Center, as designated by the executive director pursuant to Section 4108 of the Food and Agricultural Code, provided that the primary duty of those peace officers shall be the enforcement of the law as that duty is set forth in Section 4108 of the Food and Agricultural Code.

(s) Employees of the Franchise Tax Board designated by the board, provided that the primary duty of these peace officers shall be the enforcement of the law as set forth in Chapter 9 (commencing with Section 19701) of Part 10.2 of Division 2 of the Revenue and Taxation Code.

(t) Notwithstanding any other provision of this section, a peace officer authorized by this section shall not be authorized to carry firearms by his or her employing agency until that agency has adopted a policy on the use of deadly force by those peace officers, and until those peace officers have been instructed in the employing agency's policy on the use of deadly force.

Every peace officer authorized pursuant to this section to carry firearms by his or her employing agency shall qualify in the use of the firearms at least every six months.

(u) Investigators of the Department of Managed Health Care designated by the Director of the Department of Managed Health Care, provided that the primary duty of these investigators shall be the enforcement of the provisions of laws administered by the Director of the Department of Managed Health Care. Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(v) The Chief, Deputy Chief, supervising investigators, and investigators of the Office of Protective Services of the State Department of Developmental Services, provided that the primary duty of each of those persons shall be the enforcement of the law relating to the duties of his or her department or office.

(w) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 38. Section 830.3 is added to the Penal Code, to read:

830.3. The following persons are peace officers whose authority extends to any place in the state for the purpose of performing their primary duty or when making an arrest pursuant to Section 836 as to any public offense with respect to which there is immediate danger to person or property, or of the escape of the perpetrator of that offense, or pursuant to Section 8597 or 8598 of the Government Code. These peace officers may carry firearms only if authorized and under those terms and conditions as specified by their employing agencies:

(a) Persons employed by the Division of Investigation of the Department of Consumer Affairs and investigators of the Board of Dental Examiners, who are designated by the Director of Consumer Affairs, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 160 of the Business and Professions Code.

(b) Voluntary fire wardens designated by the Director of Forestry and Fire Protection pursuant to Section 4156 of the Public Resources Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 4156 of that code.

(c) Employees of the Department of Motor Vehicles designated in Section 1655 of the Vehicle Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 1655 of that code.

(d) Investigators of the California Horse Racing Board designated by the board, provided that the primary duty of these peace officers shall be the enforcement of Chapter 4 (commencing with Section 19400) of Division 8 of the Business and Professions Code and Chapter 10 (commencing with Section 330) of Title 9 of Part 1 of this code.

(e) The State Fire Marshal and assistant or deputy state fire marshals appointed pursuant to Section 13103 of the Health and Safety Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 13104 of that code.

(f) Inspectors of the food and drug section designated by the chief pursuant to subdivision (a) of Section 106500 of the Health and Safety Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 106500 of that code.

(g) All investigators of the Division of Labor Standards Enforcement designated by the Labor Commissioner, provided that the primary duty of these peace officers shall be the enforcement of the law as prescribed in Section 95 of the Labor Code.

(h) All investigators of the State Departments of Health Care Services, Public Health, Social Services, Mental Health, and Alcohol and Drug Programs, the Department of Toxic Substances Control, the Office of Statewide

Health Planning and Development, and the Public Employees' Retirement System, provided that the primary duty of these peace officers shall be the enforcement of the law relating to the duties of his or her department or office. Notwithstanding any other provision of law, investigators of the Public Employees' Retirement System shall not carry firearms.

(i) The Chief of the Bureau of Fraudulent Claims of the Department of Insurance and those investigators designated by the chief, provided that the primary duty of those investigators shall be the enforcement of Section 550.

(j) Employees of the Department of Housing and Community Development designated under Section 18023 of the Health and Safety Code, provided that the primary duty of these peace officers shall be the enforcement of the law as that duty is set forth in Section 18023 of that code.

(k) Investigators of the office of the Controller, provided that the primary duty of these investigators shall be the enforcement of the law relating to the duties of that office. Notwithstanding any other law, except as authorized by the Controller, the peace officers designated pursuant to this subdivision shall not carry firearms.

(l) Investigators of the Department of Business Oversight designated by the Commissioner of Business Oversight, provided that the primary duty of these investigators shall be the enforcement of the provisions of law administered by the Department of Business Oversight. Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(m) Persons employed by the Contractors State License Board designated by the Director of Consumer Affairs pursuant to Section 7011.5 of the Business and Professions Code, provided that the primary duty of these persons shall be the enforcement of the law as that duty is set forth in Section 7011.5, and in Chapter 9 (commencing with Section 7000) of Division 3, of that code. The Director of Consumer Affairs may designate as peace officers not more than 12 persons who shall at the time of their designation be assigned to the special investigations unit of the board. Notwithstanding any other provision of law, the persons designated pursuant to this subdivision shall not carry firearms.

(n) The Chief and coordinators of the Law Enforcement Branch of the Office of Emergency Services.

(o) Investigators of the office of the Secretary of State designated by the Secretary of State, provided that the primary duty of these peace officers shall be the enforcement of the law as prescribed in Chapter 3 (commencing with Section 8200) of Division 1 of Title 2 of, and Section 12172.5 of, the Government Code. Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(p) The Deputy Director for Security designated by Section 8880.38 of the Government Code, and all lottery security personnel assigned to the California State Lottery and designated by the director, provided that the primary duty of any of those peace officers shall be the enforcement of the laws related to assuring the integrity, honesty, and fairness of the operation and administration of the California State Lottery.

(q) Investigators employed by the Investigation Division of the Employment Development Department designated by the director of the department, provided that the primary duty of those peace officers shall be the enforcement of the law as that duty is set forth in Section 317 of the Unemployment Insurance Code.

Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(r) The chief and assistant chief of museum security and safety of the California Science Center, as designated by the executive director pursuant to Section 4108 of the Food and Agricultural Code, provided that the primary duty of those peace officers shall be the enforcement of the law as that duty is set forth in Section 4108 of the Food and Agricultural Code.

(s) Employees of the Franchise Tax Board designated by the board, provided that the primary duty of these peace officers shall be the enforcement of the law as set forth in Chapter 9 (commencing with Section 19701) of Part 10.2 of Division 2 of the Revenue and Taxation Code.

(t) Notwithstanding any other provision of this section, a peace officer authorized by this section shall not be authorized to carry firearms by his or her employing agency until that agency has adopted a policy on the use of deadly force by those peace officers, and until those peace officers have been instructed in the employing agency's policy on the use of deadly force.

Every peace officer authorized pursuant to this section to carry firearms by his or her employing agency shall qualify in the use of the firearms at least every six months.

(u) Investigators of the Department of Managed Health Care designated by the Director of the Department of Managed Health Care, provided that the primary duty of these investigators shall be the enforcement of the provisions of laws administered by the Director of the Department of Managed Health Care. Notwithstanding any other provision of law, the peace officers designated pursuant to this subdivision shall not carry firearms.

(v) The Chief, Deputy Chief, supervising investigators, and investigators of the Office of Protective Services of the State Department of Developmental Services, provided that the primary duty of each of those persons shall be the enforcement of the law relating to the duties of his or her department or office.

(w) This section shall become operative July 1, 2014.

SEC. 39. Section 29.5 of this bill incorporates amendments to Section 11529 of the Government Code proposed by both this bill and Senate Bill 670. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2014, (2) each bill amends Section 11529 of the Government Code, and (3) this bill is enacted after Senate Bill 670, in which case Section 29 of this bill shall not become operative.

SEC. 40. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SB 305

California LEGISLATIVE INFORMATION

SB-305 Healing arts: boards. (2013-2014)

ENROLLED SEPTEMBER 12, 2013
PASSED IN SENATE SEPTEMBER 10, 2013
PASSED IN ASSEMBLY SEPTEMBER 09, 2013
AMENDED IN ASSEMBLY SEPTEMBER 06, 2013
AMENDED IN ASSEMBLY SEPTEMBER 03, 2013
AMENDED IN ASSEMBLY AUGUST 05, 2013
AMENDED IN ASSEMBLY JUNE 19, 2013
AMENDED IN ASSEMBLY JUNE 14, 2013
AMENDED IN SENATE APRIL 25, 2013
AMENDED IN SENATE APRIL 15, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

SENATE BILL No. 305

Introduced by Senator Lieu
(Principal coauthor: Assembly Member Gordon)
(Coauthor: Assembly Member Bonilla)

February 15, 2013

An act to amend Sections 1000, 2450, 2450.3, 2530.2, 2531, 2531.06, 2531.75, 2532.6, 2533, 2570.19, 3010.5, 3014.6, 3046, 3056, 3057, 3110, 3685, 3686, 3710, 3716, and 3765 of, and to add Sections 144.5 and 3090.5 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 305, Lieu. Healing arts: boards.

(1) Existing law requires specified regulatory boards within the Department of Consumer Affairs to require an applicant for licensure to furnish to the board a full set of fingerprints in order to conduct a criminal history record check.

This bill would additionally authorize those boards to request and receive from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation and would authorize a local or state agency to provide those records to the board upon request.

(2) The Chiropractic Act, enacted by an initiative measure, provides for the licensure and regulation of chiropractors in this state by the State Board of Chiropractic Examiners. Existing law specifies that the law governing chiropractors is found in the act.

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature as if these provisions were scheduled to be repealed on January 1, 2018. This bill would also make nonsubstantive changes to conform with the Governor's Reorganization Plan No. 2.

(3) Existing law, the Osteopathic Act, provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California.

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature. The bill would require that the review be performed as if these provisions were scheduled to be repealed as of January 1, 2018.

(4) Existing law, the Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act, provides for the licensure and regulation of speech-language pathologists, audiologists, and hearing aid dispensers by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board. The act authorizes the board to appoint an executive officer. Existing law repeals these provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.

The Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act also authorizes the board to refuse to issue, or issue subject to terms and conditions, a license on specified grounds, including, among others, securing a license by fraud or deceit.

This bill would additionally authorize the board to refuse to issue, or issue subject to terms and conditions, a license for a violation of a term or condition of a probationary order of a license or a term or condition of a conditional license issued by the board, as provided. The bill would also delete an obsolete provision and make other technical changes.

(5) Existing law, the Occupational Therapy Practice Act, provides for the licensure and regulation of occupational therapists, as defined, by the California Board of Occupational Therapy. Existing law repeals those provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.

(6) Existing law, the Naturopathic Doctors Act, until January 1, 2014, provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Existing law also specifies that the repeal of the committee subjects it to review by the appropriate policy committees of the Legislature.

This bill would extend the operation of these provisions until January 1, 2018, and make conforming changes.

(7) Existing law, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. The Respiratory Care Act provides for the licensure and regulation of respiratory care practitioners by the Respiratory Care Board of California. Each of those acts authorizes the board to employ an executive officer. Existing law repeals these provisions on January 1, 2014, and subjects the boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the boards to review by the appropriate policy committees of the Legislature.

(8) The Optometry Practice Act prescribes license eligibility requirements, including, but not limited to, not having been convicted of a crime, as specified. The act defines unprofessional conduct to include, committing or soliciting an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of an optometrist. Under the act, the board may take action against a licensee who is charged with unprofessional conduct, and may deny an application for a license if the applicant

has committed an act of unprofessional conduct. Under existing law, commission of any act of sexual abuse, misconduct, or relations with a patient, client, or customer constitutes unprofessional conduct and grounds for disciplinary action against any healing arts licensee, subject to a specified exception for a physician and surgeon.

This bill would add to the license eligibility requirements under the act that the applicant is not currently required to register as a sex offender, as specified. The bill would make conviction of a crime that currently requires a licensee to register as a sex offender unprofessional conduct and would expressly specify that commission of an act of sexual abuse or misconduct, as specified, constitutes unprofessional conduct, subject to an exception for an optometrist treating his or her spouse or person in an equivalent domestic relationship. The bill would also state that those acts of unprofessional conduct shall be considered crimes substantially related to the qualifications, functions, or duties of a licensee. The bill would also expressly specify that the board may revoke a license if the licensee has been found, in an administrative proceeding, as specified, to have been convicted of sexual misconduct or convicted of a crime that currently requires the licensee to register as a sex offender.

(9) The Respiratory Care Act also prohibits a person from engaging in the practice of respiratory care unless he or she is a licensed respiratory care practitioner. However, the act does not prohibit specified acts, including, among others, the performance of respiratory care services in case of an emergency or self-care by a patient.

This bill would additionally authorize the performance of pulmonary function testing by persons who are currently employed by Los Angeles County hospitals and have performed pulmonary function testing for at least 15 years.

This bill would make legislative findings and declarations as to the necessity of a special statute for the persons described above.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 144.5 is added to the Business and Professions Code, to read:

144.5. Notwithstanding any other law, a board described in Section 144 may request, and is authorized to receive, from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. A local or state agency may provide those records to the board upon request.

SEC. 2. Section 1000 of the Business and Professions Code is amended to read:

1000. (a) The law governing practitioners of chiropractic is found in an initiative act entitled "An act prescribing the terms upon which licenses may be issued to practitioners of chiropractic, creating the State Board of Chiropractic Examiners and declaring its powers and duties, prescribing penalties for violation hereof, and repealing all acts and parts of acts inconsistent herewith," adopted by the electors November 7, 1922.

(b) The State Board of Chiropractic Examiners is within the Department of Consumer Affairs.

(c) Notwithstanding any other law, the powers and duties of the State Board of Chiropractic Examiners, as set forth in this article and under the act creating the board, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 3. Section 2450 of the Business and Professions Code is amended to read:

2450. There is a Board of Osteopathic Examiners of the State of California, established by the Osteopathic Act, which shall be known as the Osteopathic Medical Board of California which enforces this chapter relating to persons holding or applying for physician's and surgeon's certificates issued by the Osteopathic Medical Board of California under the Osteopathic Act.

Persons who elect to practice using the term of suffix "M.D.," as provided in Section 2275, shall not be subject to this article, and the Medical Board of California shall enforce the provisions of this chapter relating to persons who made the election.

Notwithstanding any other law, the powers and duties of the Osteopathic Medical Board of California, as set forth in this article and under the Osteopathic Act, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 4. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3. There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, 2018, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the Naturopathic Medicine Committee subject to review by the appropriate policy committees of the Legislature.

SEC. 5. Section 2530.2 of the Business and Professions Code is amended to read:

2530.2. As used in this chapter, unless the context otherwise requires:

(a) "Board" means the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.

(b) "Person" means any individual, partnership, corporation, limited liability company, or other organization or combination thereof, except that only individuals can be licensed under this chapter.

(c) A "speech-language pathologist" is a person who practices speech-language pathology.

(d) The practice of speech-language pathology means all of the following:

(1) The application of principles, methods, instrumental procedures, and noninstrumental procedures for measurement, testing, screening, evaluation, identification, prediction, and counseling related to the development and disorders of speech, voice, language, or swallowing.

(2) The application of principles and methods for preventing, planning, directing, conducting, and supervising programs for habilitating, rehabilitating, ameliorating, managing, or modifying disorders of speech, voice, language, or swallowing in individuals or groups of individuals.

(3) Conducting hearing screenings.

(4) Performing suctioning in connection with the scope of practice described in paragraphs (1) and (2), after compliance with a medical facility's training protocols on suctioning procedures.

(e) (1) Instrumental procedures referred to in subdivision (d) are the use of rigid and flexible endoscopes to observe the pharyngeal and laryngeal areas of the throat in order to observe, collect data, and measure the parameters of communication and swallowing as well as to guide communication and swallowing assessment and therapy.

(2) Nothing in this subdivision shall be construed as a diagnosis. Any observation of an abnormality shall be referred to a physician and surgeon.

(f) A licensed speech-language pathologist shall not perform a flexible fiber optic nasendoscopic procedure unless he or she has received written verification from an otolaryngologist certified by the American Board of Otolaryngology that the speech-language pathologist has performed a minimum of 25 flexible fiber optic nasendoscopic procedures and is competent to perform these procedures. The speech-language pathologist shall have this written verification on file and readily available for inspection upon request by the board. A speech-language pathologist shall pass a flexible fiber optic nasendoscopic instrument only under the direct authorization of an otolaryngologist certified by the American Board of Otolaryngology and the supervision of a physician and surgeon.

(g) A licensed speech-language pathologist shall only perform flexible endoscopic procedures described in subdivision (e) in a setting that requires the facility to have protocols for emergency medical backup procedures, including a physician and surgeon or other appropriate medical professionals being readily available.

(h) "Speech-language pathology aide" means any person meeting the minimum requirements established by the board, who works directly under the supervision of a speech-language pathologist.

(i) (1) "Speech-language pathology assistant" means a person who meets the academic and supervised training requirements set forth by the board and who is approved by the board to assist in the provision of speech-language pathology under the direction and supervision of a speech-language pathologist who shall be responsible for the extent, kind, and quality of the services provided by the speech-language pathology assistant.

(2) The supervising speech-language pathologist employed or contracted for by a public school may hold a valid and current license issued by the board, a valid, current, and professional clear clinical or rehabilitative services credential in language, speech, and hearing issued by the Commission on Teacher Credentialing, or other credential authorizing service in language, speech, and hearing issued by the Commission on Teacher Credentialing that is not issued on the basis of an emergency permit or waiver of requirements. For purposes of this paragraph, a "clear" credential is a credential that is not issued pursuant to a waiver or emergency permit and is as otherwise defined by the Commission on Teacher Credentialing. Nothing in this section referring to credentialed supervising speech-language pathologists expands existing exemptions from licensing pursuant to Section 2530.5.

(j) An "audiologist" is one who practices audiology.

(k) "The practice of audiology" means the application of principles, methods, and procedures of measurement, testing, appraisal, prediction, consultation, counseling, instruction related to auditory, vestibular, and related functions and the modification of communicative disorders involving speech, language, auditory behavior or other aberrant behavior resulting from auditory dysfunction; and the planning, directing, conducting, supervising, or participating in programs of identification of auditory disorders, hearing conservation, cerumen removal, aural habilitation, and rehabilitation, including, hearing aid recommendation and evaluation procedures including, but not limited to, specifying amplification requirements and evaluation of the results thereof, auditory training, and speech reading, and the selling of hearing aids.

(l) A "dispensing audiologist" is a person who is authorized to sell hearing aids pursuant to his or her audiology license.

(m) "Audiology aide" means any person meeting the minimum requirements established by the board. An audiology aid may not perform any function that constitutes the practice of audiology unless he or she is under the supervision of an audiologist. The board may by regulation exempt certain functions performed by an industrial audiology aide from supervision provided that his or her employer has established a set of procedures or protocols that the aide shall follow in performing these functions.

(n) "Medical board" means the Medical Board of California.

(o) A "hearing screening" performed by a speech-language pathologist means a binary puretone screening at a preset intensity level for the purpose of determining if the screened individuals are in need of further medical or audiological evaluation.

(p) "Cerumen removal" means the nonroutine removal of cerumen within the cartilaginous ear canal necessary for access in performance of audiological procedures that shall occur under physician and surgeon supervision. Cerumen removal, as provided by this section, shall only be performed by a licensed audiologist. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but shall include all of the following:

(1) Collaboration on the development of written standardized protocols. The protocols shall include a requirement that the supervised audiologist immediately refer to an appropriate physician any trauma, including skin tears, bleeding, or other pathology of the ear discovered in the process of cerumen removal as defined in this subdivision.

(2) Approval by the supervising physician of the written standardized protocol.

(3) The supervising physician shall be within the general vicinity, as provided by the physician-audiologist protocol, of the supervised audiologist and available by telephone contact at the time of cerumen removal.

(4) A licensed physician and surgeon may not simultaneously supervise more than two audiologists for purposes of cerumen removal.

SEC. 6. Section 2531 of the Business and Professions Code is amended to read:

2531. (a) There is in the Department of Consumer Affairs the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board in which the enforcement and administration of this chapter are vested. The Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board shall consist of nine members, three of whom shall be public members.

(b) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 7. Section 2531.06 of the Business and Professions Code is amended to read:

2531.06. (a) The board is vested with the duties, powers, purposes, responsibilities, and jurisdiction over the licensing and regulation of hearing aid dispensers as provided under Article 8 (commencing with Section 2538.10).

(b) In the performance of the duties and the exercise of the powers vested in the board under this chapter, the board may consult with hearing aid dispenser industry representatives.

(c) For the performance of the duties and the exercise of the powers vested in the board under this chapter, the board shall have possession and control of all records, papers, offices, equipment, supplies, or other property, real or personal, held for the benefit or use by the former Hearing Aid Dispensers Bureau.

(d) All regulations in Division 13.3 (commencing with Section 1399.100) of Title 16 of the California Code of Regulations are continued in existence under the administration of the board until repealed by regulation.

SEC. 8. Section 2531.75 of the Business and Professions Code is amended to read:

2531.75. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(b) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 9. Section 2532.6 of the Business and Professions Code is amended to read:

2532.6. (a) The Legislature recognizes that the education and experience requirements of this chapter constitute only minimal requirements to assure the public of professional competence. The Legislature encourages all professionals licensed and registered by the board under this chapter to regularly engage in continuing professional development and learning that is related and relevant to the professions of speech-language pathology and audiology.

(b) The board shall not renew any license or registration pursuant to this chapter unless the applicant certifies to the board that he or she has completed in the preceding two years not less than the minimum number of continuing professional development hours established by the board pursuant to subdivision (c) for the professional practice authorized by his or her license or registration.

(c) (1) The board shall prescribe the forms utilized for and the number of hours of required continuing professional development for persons licensed or registered under this chapter.

(2) The board shall have the right to audit the records of any applicant to verify the completion of the continuing professional development requirements.

(3) Applicants shall maintain records of completion of required continuing professional development coursework for a minimum of two years and shall make these records available to the board for auditing purposes upon request.

(d) The board shall establish exceptions from the continuing professional development requirements of this section for good cause as defined by the board.

(e) (1) The continuing professional development services shall be obtained from accredited institutions of

higher learning, organizations approved as continuing education providers by either the American Speech-Language Hearing Association or the American Academy of Audiology, the California Medical Association's Institute for Medical Quality Continuing Medical Education Program, or other entities or organizations approved as continuing professional development providers by the board, in its discretion.

(2) No hours shall be credited for any course enrolled in by a licensee that has not first been approved and certified by the board, if the board has sufficient funding and staff resources to implement the approval and certification process.

(3) The continuing professional development services offered by these entities may, but are not required to, utilize pretesting and posttesting or other evaluation techniques to measure and demonstrate improved professional learning and competency.

(4) An accredited institution of higher learning, an organization approved as continuing education providers by either the American Speech-Language Hearing Association or the American Academy of Audiology, and the California Medical Association's Institute for Medical Quality Continuing Education Program shall be exempt from any application or registration fees that the board may charge for continuing education providers.

(5) Unless a course offered by entities listed in paragraph (4) meets the requirements established by the board, the course may not be credited towards the continuing professional development requirements for license renewal.

(6) The licensee shall be responsible for obtaining the required course completion documents for courses offered by entities specified in paragraph (1).

(f) The board, by regulation, shall fund the administration of this section through professional development services provider and licensing fees to be deposited in the Speech-Language Pathology and Audiology Board Fund. The fees related to the administration of this section shall be sufficient to meet, but shall not exceed, the costs of administering the corresponding provisions of this section.

(g) The continuing professional development requirements adopted by the board shall comply with any guidelines for mandatory continuing education established by the Department of Consumer Affairs.

SEC. 10. Section 2533 of the Business and Professions Code is amended to read:

2533. The board may refuse to issue, or issue subject to terms and conditions, a license on the grounds specified in Section 480, or may suspend, revoke, or impose terms and conditions upon the license of any licensee for any of the following:

(a) Conviction of a crime substantially related to the qualifications, functions, and duties of a speech-language pathologist or audiologist or hearing aid dispenser, as the case may be. The record of the conviction shall be conclusive evidence thereof.

(b) Securing a license by fraud or deceit.

(c) (1) The use or administering to himself or herself of any controlled substance.

(2) The use of any of the dangerous drugs specified in Section 4022, or of alcoholic beverages, to the extent or in a manner as to be dangerous or injurious to the licensee, to any other person, or to the public, or to the extent that the use impairs the ability of the licensee to practice speech-language pathology or audiology safely.

(3) More than one misdemeanor or any felony involving the use, consumption, or self-administration of any of the substances referred to in this section.

(4) Any combination of paragraph (1), (2), or (3).

The record of the conviction shall be conclusive evidence of unprofessional conduct.

(d) Advertising in violation of Section 17500. Advertising an academic degree that was not validly awarded or earned under the laws of this state or the applicable jurisdiction in which it was issued is deemed to constitute a violation of Section 17500.

(e) Committing a dishonest or fraudulent act that is substantially related to the qualifications, functions, or

duties of a licensee.

(f) Incompetence, gross negligence, or repeated negligent acts.

(g) Other acts that have endangered or are likely to endanger the health, welfare, and safety of the public.

(h) Use by a hearing aid dispenser of the term "doctor" or "physician" or "clinic" or "audiologist," or any derivation thereof, except as authorized by law.

(i) The use, or causing the use, of any advertising or promotional literature in a manner that has the capacity or tendency to mislead or deceive purchasers or prospective purchasers.

(j) Any cause that would be grounds for denial of an application for a license.

(k) Violation of Section 1689.6 or 1793.02 of the Civil Code.

(l) Violation of a term or condition of a probationary order of a license issued by the board pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(m) Violation of a term or condition of a conditional license issued by the board pursuant to this section.

SEC. 11. Section 2570.19 of the Business and Professions Code is amended to read:

2570.19. (a) There is hereby created a California Board of Occupational Therapy, hereafter referred to as the board. The board shall enforce and administer this chapter.

(b) The members of the board shall consist of the following:

(1) Three occupational therapists who shall have practiced occupational therapy for five years.

(2) One occupational therapy assistant who shall have assisted in the practice of occupational therapy for five years.

(3) Three public members who shall not be licentiates of the board, of any other board under this division, or of any board referred to in Section 1000 or 3600.

(c) The Governor shall appoint the three occupational therapists and one occupational therapy assistant to be members of the board. The Governor, the Senate Committee on Rules, and the Speaker of the Assembly shall each appoint a public member. Not more than one member of the board shall be appointed from the full-time faculty of any university, college, or other educational institution.

(d) All members shall be residents of California at the time of their appointment. The occupational therapist and occupational therapy assistant members shall have been engaged in rendering occupational therapy services to the public, teaching, or research in occupational therapy for at least five years preceding their appointments.

(e) The public members may not be or have ever been occupational therapists or occupational therapy assistants or in training to become occupational therapists or occupational therapy assistants. The public members may not be related to, or have a household member who is, an occupational therapist or an occupational therapy assistant, and may not have had, within two years of the appointment, a substantial financial interest in a person regulated by the board.

(f) The Governor shall appoint two board members for a term of one year, two board members for a term of two years, and one board member for a term of three years. Appointments made thereafter shall be for four-year terms, but no person shall be appointed to serve more than two consecutive terms. Terms shall begin on the first day of the calendar year and end on the last day of the calendar year or until successors are appointed, except for the first appointed members who shall serve through the last calendar day of the year in which they are appointed, before commencing the terms prescribed by this section. Vacancies shall be filled by appointment for the unexpired term. The board shall annually elect one of its members as president.

(g) The board shall meet and hold at least one regular meeting annually in the Cities of Sacramento, Los Angeles, and San Francisco. The board may convene from time to time until its business is concluded. Special meetings of the board may be held at any time and place designated by the board.

(h) Notice of each meeting of the board shall be given in accordance with the Bagley-Keene Open Meeting Act

(Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

(i) Members of the board shall receive no compensation for their services, but shall be entitled to reasonable travel and other expenses incurred in the execution of their powers and duties in accordance with Section 103.

(j) The appointing power shall have the power to remove any member of the board from office for neglect of any duty imposed by state law, for incompetency, or for unprofessional or dishonorable conduct.

(k) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 12. Section 3010.5 of the Business and Professions Code is amended to read:

3010.5. (a) There is in the Department of Consumer Affairs a State Board of Optometry in which the enforcement of this chapter is vested. The board consists of 11 members, five of whom shall be public members.

Six members of the board shall constitute a quorum.

(b) The board shall, with respect to conducting investigations, inquiries, and disciplinary actions and proceedings, have the authority previously vested in the board as created pursuant to Section 3010. The board may enforce any disciplinary actions undertaken by that board.

(c) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 13. Section 3014.6 of the Business and Professions Code is amended to read:

3014.6. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(b) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 14. Section 3046 of the Business and Professions Code is amended to read:

3046. In order to obtain a license to practice optometry in California, an applicant shall have graduated from an accredited school of optometry, passed the required examinations for licensure, not have met any of the grounds for denial established in Section 480, and not be currently required to register as a sex offender pursuant to Section 290 of the Penal Code. The proceedings under this section shall be in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 15. Section 3056 of the Business and Professions Code is amended to read:

3056. (a) The board may issue a license to practice optometry to a person who meets all of the following qualifications:

(1) Has a degree as a doctor of optometry issued by an accredited school or college of optometry.

(2) Is currently licensed in another state.

(3) Is currently a full-time faculty member of an accredited California school or college of optometry and has served in that capacity for a period of at least five continuous years.

(4) Has attained, at an accredited California school or college of optometry, the academic rank of professor, associate professor, or clinical professor, except that the status of adjunct or affiliated faculty member shall

not be deemed sufficient.

(5) Has successfully passed the board's jurisprudence examination.

(6) Is in good standing, with no past or pending malpractice awards or judicial or administrative actions.

(7) Has met the minimum continuing education requirements set forth in Section 3059 for the current and preceding year.

(8) Has met the requirements of Section 3041.3 regarding the use of therapeutic pharmaceutical agents under subdivision (e) of Section 3041.

(9) Has never had his or her license to practice optometry revoked or suspended.

(10) (A) Is not subject to denial based on any of the grounds listed in Section 480.

(B) Is not currently required to register as a sex offender pursuant to Section 290 of the Penal Code.

(11) Pays an application fee in an amount equal to the application fee prescribed by the board pursuant to Section 3152.

(12) Files an application on a form prescribed by the board.

(b) Any license issued pursuant to this section shall expire as provided in Section 3146, and may be renewed as provided in this chapter, subject to the same conditions as other licenses issued under this chapter.

(c) The term "in good standing," as used in this section, means that a person under this section:

(1) Is not currently under investigation nor has been charged with an offense for any act substantially related to the practice of optometry by any public agency, nor entered into any consent agreement or subject to an administrative decision that contains conditions placed by an agency upon a person's professional conduct or practice, including any voluntary surrender of license, nor been the subject of an adverse judgment resulting from the practice of optometry that the board determines constitutes evidence of a pattern of incompetence or negligence.

(2) Has no physical or mental impairment related to drugs or alcohol, and has not been found mentally incompetent by a physician so that the person is unable to undertake the practice of optometry in a manner consistent with the safety of a patient or the public.

SEC. 16. Section 3057 of the Business and Professions Code is amended to read:

3057. (a) The board may issue a license to practice optometry to a person who meets all of the following requirements:

(1) Has a degree as a doctor of optometry issued by an accredited school or college of optometry.

(2) Has successfully passed the licensing examination for an optometric license in another state.

(3) Submits proof that he or she is licensed in good standing as of the date of application in every state where he or she holds a license, including compliance with continuing education requirements.

(4) Submits proof that he or she has been in active practice in a state in which he or she is licensed for a total of at least 5,000 hours in five of the seven consecutive years immediately preceding the date of his or her application under this section.

(5) Is not subject to disciplinary action as set forth in subdivision (h) of Section 3110. If the person has been subject to disciplinary action, the board shall review that action to determine if it presents sufficient evidence of a violation of this chapter to warrant the submission of additional information from the person or the denial of the application for licensure.

(6) Has furnished a signed release allowing the disclosure of information from the Healthcare Integrity and Protection Data Bank and, if applicable, the verification of registration status with the federal Drug Enforcement Administration. The board shall review this information to determine if it presents sufficient evidence of a violation of this chapter to warrant the submission of additional information from the person or the denial of the application for licensure.

(7) Has never had his or her license to practice optometry revoked or suspended.

(8) (A) Is not subject to denial of an application for licensure based on any of the grounds listed in Section 480.

(B) Is not currently required to register as a sex offender pursuant to Section 290 of the Penal Code.

(9) Has met the minimum continuing education requirements set forth in Section 3059 for the current and preceding year.

(10) Has met the certification requirements of Section 3041.3 to use therapeutic pharmaceutical agents under subdivision (e) of Section 3041.

(11) Submits any other information as specified by the board to the extent it is required for licensure by examination under this chapter.

(12) Files an application on a form prescribed by the board, with an acknowledgment by the person executed under penalty of perjury and automatic forfeiture of license, of the following:

(A) That the information provided by the person to the board is true and correct, to the best of his or her knowledge and belief.

(B) That the person has not been convicted of an offense involving conduct that would violate Section 810.

(13) Pays an application fee in an amount equal to the application fee prescribed pursuant to subdivision (a) of Section 3152.

(14) Has successfully passed the board's jurisprudence examination.

(b) If the board finds that the competency of a candidate for licensure pursuant to this section is in question, the board may require the passage of a written, practical, or clinical exam or completion of additional continuing education or coursework.

(c) In cases where the person establishes, to the board's satisfaction, that he or she has been displaced by a federally declared emergency and cannot relocate to his or her state of practice within a reasonable time without economic hardship, the board is authorized to do both of the following:

(1) Approve an application where the person's time in active practice is less than that specified in paragraph (4) of subdivision (a), if a sufficient period in active practice can be verified by the board and all other requirements of subdivision (a) are satisfied by the person.

(2) Reduce or waive the fees required by paragraph (13) of subdivision (a).

(d) Any license issued pursuant to this section shall expire as provided in Section 3146, and may be renewed as provided in this chapter, subject to the same conditions as other licenses issued under this chapter.

(e) The term "in good standing," as used in this section, means that a person under this section:

(1) Is not currently under investigation nor has been charged with an offense for any act substantially related to the practice of optometry by any public agency, nor entered into any consent agreement or subject to an administrative decision that contains conditions placed by an agency upon a person's professional conduct or practice, including any voluntary surrender of license, nor been the subject of an adverse judgment resulting from the practice of optometry that the board determines constitutes evidence of a pattern of incompetence or negligence.

(2) Has no physical or mental impairment related to drugs or alcohol, and has not been found mentally incompetent by a physician so that the person is unable to undertake the practice of optometry in a manner consistent with the safety of a patient or the public.

SEC. 17. Section 3090.5 is added to the Business and Professions Code, to read:

3090.5. The board may revoke a license issued to a licensee upon a decision, made in a proceeding as provided in Section 3092, that contains a finding of fact of either of the following:

(a) The licensee has engaged in an act of sexual abuse, misconduct, or relations with a patient, as described in paragraph (2) of subdivision (m) of Section 3110.

(b) The licensee has been convicted of a crime described in paragraph (3) of subdivision (m) of Section 3110.

SEC. 18. Section 3110 of the Business and Professions Code is amended to read:

3110. The board may take action against any licensee who is charged with unprofessional conduct, and may deny an application for a license if the applicant has committed unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

(a) Violating or attempting to violate, directly or indirectly assisting in or abetting the violation of, or conspiring to violate any provision of this chapter or any of the rules and regulations adopted by the board pursuant to this chapter.

(b) Gross negligence.

(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions.

(d) Incompetence.

(e) The commission of fraud, misrepresentation, or any act involving dishonesty or corruption, that is substantially related to the qualifications, functions, or duties of an optometrist.

(f) Any action or conduct that would have warranted the denial of a license.

(g) The use of advertising relating to optometry that violates Section 651 or 17500.

(h) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action against a health care professional license by another state or territory of the United States, by any other governmental agency, or by another California health care professional licensing board. A certified copy of the decision or judgment shall be conclusive evidence of that action.

(i) Procuring his or her license by fraud, misrepresentation, or mistake.

(j) Making or giving any false statement or information in connection with the application for issuance of a license.

(k) Conviction of a felony or of any offense substantially related to the qualifications, functions, and duties of an optometrist, in which event the record of the conviction shall be conclusive evidence thereof.

(l) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022, or using alcoholic beverages to the extent, or in a manner, as to be dangerous or injurious to the person applying for a license or holding a license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a license to conduct with safety to the public the practice authorized by the license, or the conviction of a misdemeanor or felony involving the use, consumption, or self administration of any of the substances referred to in this subdivision, or any combination thereof.

(m) (1) Committing or soliciting an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of an optometrist.

(2) Committing any act of sexual abuse, misconduct, or relations with a patient. The commission of and conviction for any act of sexual abuse, sexual misconduct, or attempted sexual misconduct, whether or not with a patient, shall be considered a crime substantially related to the qualifications, functions, or duties of a licensee. This paragraph shall not apply to sexual contact between any person licensed under this chapter and his or her spouse or person in an equivalent domestic relationship when that licensee provides optometry treatment to his or her spouse or person in an equivalent domestic relationship.

(3) Conviction of a crime that currently requires the person to register as a sex offender pursuant to Section 290 of the Penal Code. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. A conviction described in this paragraph shall be considered a crime substantially related to the qualifications, functions, or duties of a licensee.

(n) Repeated acts of excessive prescribing, furnishing or administering of controlled substances or dangerous drugs specified in Section 4022, or repeated acts of excessive treatment.

(o) Repeated acts of excessive use of diagnostic or therapeutic procedures, or repeated acts of excessive use of diagnostic or treatment facilities.

(p) The prescribing, furnishing, or administering of controlled substances or drugs specified in Section 4022, or treatment without a good faith prior examination of the patient and optometric reason.

(q) The failure to maintain adequate and accurate records relating to the provision of services to his or her patients.

(r) Performing, or holding oneself out as being able to perform, or offering to perform, any professional services beyond the scope of the license authorized by this chapter.

(s) The practice of optometry without a valid, unrevoked, unexpired license.

(t) The employing, directly or indirectly, of any suspended or unlicensed optometrist to perform any work for which an optometry license is required.

(u) Permitting another person to use the licensee's optometry license for any purpose.

(v) Altering with fraudulent intent a license issued by the board, or using a fraudulently altered license, permit certification or any registration issued by the board.

(w) Except for good cause, the knowing failure to protect patients by failing to follow infection control guidelines of the board, thereby risking transmission of blood borne infectious diseases from optometrist to patient, from patient to patient, or from patient to optometrist. In administering this subdivision, the board shall consider the standards, regulations, and guidelines of the State Department of Health Services developed pursuant to Section 1250.11 of the Health and Safety Code and the standards, guidelines, and regulations pursuant to the California Occupational Safety and Health Act of 1973 (Part 1 (commencing with Section 6300) of Division 5 of the Labor Code) for preventing the transmission of HIV, hepatitis B, and other blood borne pathogens in health care settings. As necessary, the board may consult with the Medical Board of California, the Board of Podiatric Medicine, the Board of Registered Nursing, and the Board of Vocational Nursing and Psychiatric Technicians, to encourage appropriate consistency in the implementation of this subdivision.

(x) Failure or refusal to comply with a request for the clinical records of a patient, that is accompanied by that patient's written authorization for release of records to the board, within 15 days of receiving the request and authorization, unless the licensee is unable to provide the documents within this time period for good cause.

(y) Failure to refer a patient to an appropriate physician in either of the following circumstances:

(1) Where an examination of the eyes indicates a substantial likelihood of any pathology that requires the attention of that physician.

(2) As required by subdivision (c) of Section 3041.

SEC. 19. Section 3685 of the Business and Professions Code is amended to read:

3685. Notwithstanding any other law, the repeal of this chapter renders the committee subject to review by the appropriate policy committees of the Legislature.

SEC. 20. Section 3686 of the Business and Professions Code is amended to read:

3686. This chapter shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 21. Section 3710 of the Business and Professions Code is amended to read:

3710. (a) The Respiratory Care Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

(b) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees

of the Legislature.

SEC. 22. Section 3716 of the Business and Professions Code is amended to read:

3716. The board may employ an executive officer exempt from civil service and, subject to the provisions of law relating to civil service, clerical assistants and, except as provided in Section 159.5, other employees as it may deem necessary to carry out its powers and duties.

This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 23. Section 3765 of the Business and Professions Code is amended to read:

3765. This act does not prohibit any of the following activities:

(a) The performance of respiratory care that is an integral part of the program of study by students enrolled in approved respiratory therapy training programs.

(b) Self-care by the patient or the gratuitous care by a friend or member of the family who does not represent or hold himself or herself out to be a respiratory care practitioner licensed under the provisions of this chapter.

(c) The respiratory care practitioner from performing advances in the art and techniques of respiratory care learned through formal or specialized training.

(d) The performance of respiratory care in an emergency situation by paramedical personnel who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their specialty.

(e) Respiratory care services in case of an emergency. "Emergency," as used in this subdivision, includes an epidemic or public disaster.

(f) Persons from engaging in cardiopulmonary research.

(g) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.

(h) The performance by a person employed by a home medical device retail facility or by a home health agency licensed by the State Department of Public Health of specific, limited, and basic respiratory care or respiratory care related services that have been authorized by the board.

(i) The performance of pulmonary function testing by persons who are currently employed by Los Angeles County hospitals and have performed pulmonary function testing for at least 15 years.

SEC. 24. The Legislature finds and declares that a special law, as set forth in Section 18 of this act, is necessary and that a general law cannot be made applicable within the meaning of Section 16 of Article IV of the California Constitution because of the unique circumstances relating to persons who are currently employed by Los Angeles County hospitals and have performed pulmonary function testing for at least 15 years.

SB 809

California LEGISLATIVE INFORMATION

SB-809 Controlled substances: reporting. (2013-2014)

ENROLLED SEPTEMBER 12, 2013
PASSED IN SENATE SEPTEMBER 10, 2013
PASSED IN ASSEMBLY SEPTEMBER 09, 2013
AMENDED IN ASSEMBLY SEPTEMBER 03, 2013
AMENDED IN ASSEMBLY AUGUST 05, 2013
AMENDED IN ASSEMBLY JUNE 26, 2013
AMENDED IN SENATE MAY 28, 2013
AMENDED IN SENATE MAY 24, 2013
AMENDED IN SENATE MAY 14, 2013
AMENDED IN SENATE MAY 01, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

SENATE BILL No. 809

Introduced by Senators DeSaulnier and Steinberg
(Coauthors: Senators Hancock, Lieu, Pavley, and Price)
(Coauthor: Assembly Member Blumenfield)

February 22, 2013

An act to add Sections 208, 209, and 2196.8 to the Business and Professions Code, and to amend Sections 11164.1, 11165, and 11165.1 of, and to add Section 11165.5 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 809, DeSaulnier. Controlled substances: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would, beginning April 1, 2014, require an annual fee of $6 to be assessed on specified licensees, including licensees authorized to prescribe, order, administer, furnish, or dispense controlled substances, and require the regulating agency of each of those licensees to bill and collect that fee at the time of license renewal. The bill would authorize the Department of Consumer Affairs to reduce, by regulation, that fee to the reasonable cost of operating and maintaining CURES for the purpose of regulating those licensees, if the reasonable regulatory cost is less than $6 per licensee. The bill would require the proceeds of the fee to be deposited into the CURES Fund for the support of CURES, as specified. The bill would also permit specified insurers, health care service plans, qualified manufacturers, and other donors to voluntarily contribute to the CURES Fund, as described.

(2) Existing law requires the Medical Board of California to periodically develop and disseminate information and educational materials regarding various subjects, including pain management techniques, to each licensed physician and surgeon and to each general acute care hospital in California.

This bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information relating to CURES.

(3) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require, by January 1, 2016, or upon receipt of a federal Drug Enforcement Administration registration, whichever occurs later, health care practitioners authorized to prescribe, order, administer, furnish, or dispense controlled substances, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under their care. The bill would require the Department of Justice, in conjunction with the Department of Consumer Affairs and certain licensing boards, to, among other things, develop a streamlined application and approval process to provide access to the CURES database for licensed health care practitioners and pharmacists. The bill would make other related and conforming changes.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable preventive, investigative, and educational tool for health care providers, regulatory agencies, educational researchers, and law enforcement. Recent budget cuts to the Attorney General's Division of Law Enforcement have resulted in insufficient funding to support CURES and its Prescription Drug Monitoring Program (PDMP). The CURES PDMP is necessary to ensure health care professionals have the necessary data to make informed treatment decisions and to allow law enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.

(b) Each year CURES responds to more than 800,000 requests from practitioners and pharmacists regarding all of the following:

(1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.

(2) Helping practitioners make prescribing decisions.

(3) Helping reduce misuse, abuse, and trafficking of those drugs.

(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund the operation of CURES which seeks to mitigate those deleterious effects and serve as a tool for ensuring safe patient care, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

(d) The following goals are critical to increase the effectiveness and functionality of CURES:

(1) Upgrading the CURES PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.

(2) Upgrading the CURES PDMP in California so that it is capable of operating in conjunction with all national prescription drug monitoring programs.

(3) Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.

(4) Upgrading the CURES PDMP so that it is capable of accepting the reporting of electronic prescription data, thereby enabling more reliable, complete, and timely prescription monitoring.

SEC. 2. Section 208 is added to the Business and Professions Code, to read:

208. (a) Beginning April 1, 2014, a CURES fee of six dollars ($6) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than six dollars ($6) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Wholesalers and nonresident wholesalers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(3) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(4) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the California Board of Podiatric Medicine to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

SEC. 3. Section 209 is added to the Business and Professions Code, to read:

209. The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES

Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that he or she is applying for licensure or renewing his or her license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to order reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

SEC. 4. Section 2196.8 is added to the Business and Professions Code, to read:

2196.8. The board shall periodically develop and disseminate information and educational material regarding assessing a patient's risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Public Health, the boards and committees specified in subdivision (d) of Section 208, and the Department of Justice in developing the materials to be distributed pursuant to this section.

SEC. 5. Section 11164.1 of the Health and Safety Code is amended to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

SEC. 6. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any

information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

SEC. 7. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before January 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data

contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

SEC. 8. Section 11165.5 is added to the Health and Safety Code, to read:

11165.5. (a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

(b) For purposes of this section, the following definitions apply:

(1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers' compensation insurance, as defined in Section 109 of the Insurance Code.

(4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

TAB 9

This Page has
been intentionally
left blank

TAB 10

Osteopathic Medical Board

Future Agenda Items

Agenda Item	Requestor

TAB 11

Osteopathic Medical Board

Future Meeting Dates

Date	Place	Time
January 23, 2014 (Tentative)	Sacramento	10am-5pm

**Please note that all meetings should be held in the best interest of the Board. Meetings in resorts or vacation areas should not be made. Using Conference areas that do not require contracts and or payment is the best option for the Board. No overnight travel. If an employee chooses a mode of transportation which is more costly than another mode, a Cost Comparison form must be completed. Reimbursement by the State will be made at the lesser of the two costs. Taxi Service should be used for trips within but not over a 10-mile radius. Receipts are required for taxi expenses of $10.00 and over. Tips are not reimbursable.*

Canadian Guideline
for
Safe and Effective Use of Opioids
for
Chronic Non-Cancer Pain

http://nationalpaincentre.mcmaster.ca/opioid

PRACTICE TOOLKIT

Michael G. DeGroote National Pain Centre

The **Michael G. DeGroote National Pain Centre (MGD NPC)** was established in 2010 through a generous gift from Michael G. DeGroote. The centre draws on McMaster's expertise in evidence-based medicine to identify, collate, review, revise, update and develop clinical practice guidelines for the treatment of chronic pain. Guidelines will then be disseminated, using best practice techniques of knowledge translation.

Mission

The mission of the MGD NPC is to improve the management of pain through the dissemination of best practice information.

The Canadian Guideline

As its first major activity, the Michael G. DeGroote National Pain Centre at McMaster University has accepted responsibility for stewardship of the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* (the *Canadian Guideline*). The Canadian Guideline was developed by the National Opioid Use Guidelines Group (NOUGG), a subcommittee of the Federation of Medical Regulatory Authorities of Canada (FMRAC). This stewardship will include updating of the guideline as new evidence becomes available and continuing knowledge transfer to practice. The mission of the centre also includes further updating and development of other guidelines for the treatment of chronic non-cancer pain (CNCP), including a wide range of treatment modalities. McMaster will foster collaboration and partnerships for knowledge transfer and exchange, building on the partnerships and networks established by NOUGG.

Michael G. DeGroote
National Pain
Centre

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

**Note: Use the bookmark icon*  *located on the left hand side to navigate through this document.*

If the bookmarks still do not appear, go to view, click on navigation panel and then bookmarks.

e-PRACTICE TOOLS

OPIOID MANAGER
RECOMMENDATIONS ROADMAP
RECOMMENDATION HIGHLIGHTS
LIST OF RECOMMENDATIONS

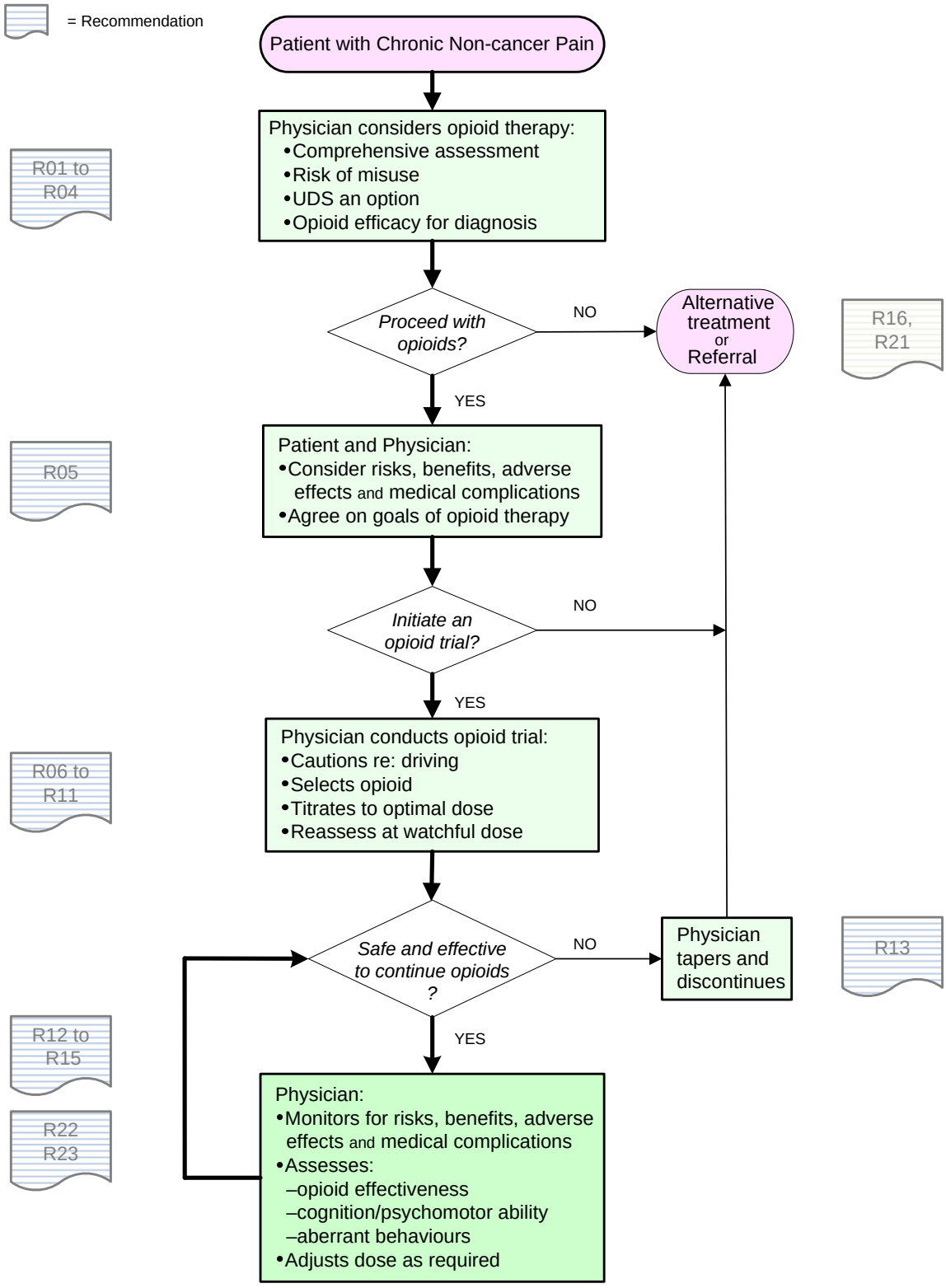
TOOLS TO USE BEFORE YOU PRESCRIBE OPIOIDS
Opioid Efficacy
Alcohol/Substance Use Screen
Opioid Risk Tool
Urine Drug Screening
Adverse Effects of Opioids
Opioid Medical Complications
Opioid Risks
Patient Handout
Sample Opioid Treatment Agreement
Benzodiazepine Tapering
Benzodiazepine Equivalent Table

TOOLS TO SELECT THE RIGHT OPIOID AND TITRATE EFFECTIVELY
Stepped Approach to Opioid Selection
Selecting Opioids: Safety Issues
Initial Dose/Titration
Optimal Dose/Watchful Dose
Brief Pain Inventory
Aberrant Drug Behaviours

TOOLS TO MONITOR FOR SAFETY AND EFFECTIVENESS
Oral Opioid Conversion
SOAPP®-R and COMM®

OPIOID TAPERING

Recommendations Roadmap



Recommendation Highlights

1. What should I do before prescribing an opioid?

- ✓ Complete a thorough assessment to understand the pain problem to make an informed decision about opioids as a reasonable treatment choice.
- ✓ Consider screening tools to help identify patients at risk of opioid misuse or addiction.
- ✓ Manage expectations by setting function-improvement and pain-reduction goals with the patient — these become the outcomes for measuring opioid effectiveness.
- ✓ Ensure informed consent by reviewing with the patient: potential benefits, risks, side effects, and complications of opioid therapy.

2. How do I titrate the opioid dose?

- ✓ Start with a low dose, increase gradually and monitor "**opioid effectiveness,"** i.e., an improvement in function or a reduction in pain intensity of at least 30%.
- ✓ Track the daily dose in morphine equivalents and flag the "**watchful dose."** i.e., over 200 mg morphine or equivalent per day – most patients can be effectively managed below this. If you determine the dose required is beyond the watchful dose: reassess the pain problem to ensure opioids are the right therapy, reassess risk of misuse, and increase monitoring vigilance.
- ✓ Recognize the **"optimal dose"** is reached with a BALANCE of three factors:
  1) **effectiveness**: improved function or at least 30% reduction in pain intensity
  2) **plateauing**: effectiveness plateaus—increasing the dose yields negligible benefit, and
  3) **adverse effects/complications**: adverse effects or complications are manageable.

3. What should I do to ensure patient safety?

- ✓ Use the function-improvement and pain-reduction goals set with the patient to monitor opioid effectiveness — structured assessment tools could also help.
- ✓ Watch for aberrant drug-related behaviours that could signal opioid misuse — tools can help.
- ✓ Assess factors that could impair cognition and psychomotor ability, possibly making driving unsafe.
- ✓ Use available consultation as needed, e.g., pain condition unresponsive; opioid misuse or addiction suspected; special populations — pregnant, psychiatric co-morbid conditions, elderly, or adolescent.
- ✓ Collaborate with pharmacists to improve patient education and safety.

4. When do I stop the patient's opioids?

- ✓ Stop or switch opioids when side effects or risks are unacceptable or opioid effectiveness is insufficient.
- ✓ Discontinue opioids with a tapering protocol — avoid sedative-hypnotic drugs, especially benzodiazepines, during the taper.

List of Recommendations

Cluster 1: Deciding to Initiate Opioid Therapy

R01	Before initiating opioid therapy, ensure comprehensive documentation of the patient's pain condition, general medical condition and psychosocial history (Grade C), psychiatric status, and substance use history. (Grade B).	***Comprehensive assessment***
R02	Before initiating opioid therapy, consider using a screening tool to determine the patient's risk for opioid addiction. (Grade B).	***Addiction-risk screening***
R03	When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C).	***Urine drug screening***
R04	Before initiating opioid therapy, consider the evidence related to effectiveness in patients with chronic non-cancer pain. (Grade A).	***Opioid efficacy***
R05	Before initiating opioid therapy, ensure informed consent by explaining potential benefits, adverse effects, complications and risks (Grade B). A treatment agreement may be helpful, particularly for patients not well known to the physician or at higher risk for opioid misuse. (Grade C).	***Risks, adverse effects, complications***
R06	For patients taking benzodiazepines, particularly for elderly patients, consider a trial of tapering (Grade B). If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. (Grade C).	***Benzodiazepine tapering***

Cluster 2: Conducting an Opioid Trial

R07	During dosage titration in a trial of opioid therapy, advise the patient to avoid driving a motor vehicle until a stable dosage is established and it is certain the opioid does not cause sedation (Grade C); and when taking opioids with alcohol, benzodiazepines, or other sedating drugs. (Grade B).	***Titration and driving***
R08	During an opioid trial, select the most appropriate opioid for trial therapy using a stepped approach, and consider safety. (Grade C).	***Stepped opioid selection***
R09	When conducting a trial of opioid therapy, start with a low dosage, increase dosage gradually and monitor opioid effectiveness until optimal dose is attained. (Grade C).	***Optimal dose***
R10	Chronic non-cancer pain can be managed effectively in most patients with dosages at or below 200 mg/day of morphine or equivalent (Grade A). Consideration of a higher dosage requires careful reassessment of the pain and of risk for misuse, and frequent monitoring with evidence of improved patient outcomes. (Grade C).	***Watchful dose***
R11	When initiating a trial of opioid therapy for patients at higher risk for misuse, prescribe only for well-defined somatic or neuropathic pain conditions (Grade A), start with lower doses and titrate in small-dose increments (Grade B), and monitor closely for signs of aberrant drug-related behaviors. (Grade C).	***Risk: opioid misuse***

OVER ➡

Cluster 3: Monitoring Long-Term Opioid Therapy (LTOT)

R12	When monitoring a patient on long-term therapy, ask about and observe for opioid effectiveness, adverse effects or medical complications, and aberrant drug-related behaviours. (Grade C).	***Monitoring LTOT***
R13	For patients experiencing unacceptable adverse effects or insufficient opioid effectiveness from one particular opioid, try prescribing a different opioid or discontinuing therapy. (Grade B).	***Switching or Discontinuing opioids***
R14	When assessing safety to drive in patients on long-term opioid therapy, consider factors that could impair cognition and psychomotor ability, such as a consistently severe pain rating, disordered sleep, and concomitant medications that increase sedation. (Grade C).	***LTOT and driving***
R15	For patients receiving opioids for a prolonged period who may not have had an appropriate trial of therapy, take steps to ensure that long-term therapy is warranted and dose is optimal. (Grade C).	***Revisiting opioid trial steps***
R16	When referring patients for consultation, communicate and clarify roles and expectations between primary-care physicians and consultants for continuity of care and for effective and safe use of opioids. (Grade C).	***Collaborative care***

Cluster 4: Treating Specific Populations with Long-Term Opioid Therapy

R17	Opioid therapy for elderly patients can be safe and effective (Grade B) with appropriate precautions, including lower starting doses, slower titration, longer dosing interval, more frequent monitoring, and tapering of benzodiazepines. (Grade C).	***Elderly patients***
R18	Opioids present hazards for adolescents (Grade B). A trial of opioid therapy may be considered for adolescent patients with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed, risk of opioid misuse is assessed as low, close monitoring is available, and consultation, if feasible, is included in the treatment plan. (Grade C).	***Adolescent patients***
R19	Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible. (Grade B).	***Pregnant patients***
R20	Patients with a psychiatric diagnosis are at greater risk for adverse effects from opioid treatment. Usually in these patients, opioids should be reserved for well-defined somatic or neuropathic pain conditions. Titrate more slowly and monitor closely; seek consultation where feasible. (Grade B).	***Co-morbid psychiatric diagnoses***

Cluster 5: Managing Opioid Misuse and Addiction in CNCP Patients

R21	For patients with chronic non-cancer pain who are addicted to opioids, three treatment options should be considered: methadone or buprenorphine treatment (Grade A), structured opioid therapy (Grade B), or abstinence-based treatment (Grade C). Consultation or shared care, where available, can assist in selecting and implementing the best treatment option. (Grade C).	***Addiction treatment options***
R22	To reduce prescription fraud, physicians should take precautions when issuing prescriptions and work collaboratively with pharmacists. (Grade C).	***Prescription fraud***
R23	Be prepared with an approach for dealing with patients who disagree with their opioid prescription or exhibit unacceptable behaviour. (Grade C).	***Patient unacceptable behaviour***
R24	Acute or urgent health care facilities should develop policies to provide guidance on prescribing opioids for chronic pain to avoid contributing to opioid misuse or diversion. (Grade C).	***Acute care opioid prescribing policy***

Tools to Use Before You Prescribe Opioids

Opioid Efficacy
Alcohol/Substance Use Screen
Opioid Risk Tool
Urine Drug Screening
Adverse Effects of Opioids
Opioid Medical Complications
Opioid Risks
Patient Handout
Sample Opioid Treatment Agreement
Benzodiazepine Tapering
Benzodiazepine Equivalent Table

Evidence of Opioid Efficacy

Examples of CNCP conditions for which opioids *were shown to be effective* in placebo-controlled trials*		Examples of CNCP conditions that *have NOT been studied* in placebo-controlled trials
Tramadol only	**Weak or strong opioid**	
Fibromyalgia	• Diabetic neuropathy • Peripheral neuropathy • Postherpetic neuralgia • Phantom limb pain • Spinal cord injury with pain below the level of injury • Lumbar radiculopathy • Osteoarthritis • Rheumatoid arthritis • Low-back pain • Neck pain	• Headache • Irritable bowel syndrome • Pelvic pain • Temporomandibular joint dysfunction • Atypical facial pain • Non-cardiac chest pain • Lyme disease • Whiplash • Repetitive strain Injury

*A limitation of these trials was that the duration of opioid therapy was a maximum of three months.

SEE GUIDELINE, PART B, RECOMMENDATION 4

Alcohol / Substance Use Screen

Interview Guide for **Alcohol Consumption**

1. Maximum number of drinks* consumed on any one day in past 1-3 months
2. Number of drinks per week
3. Previous alcohol problem
4. Attendance at treatment program for alcohol
5. Family history of alcohol or drug problem

Low-Risk Drinking Guidelines[1]
(no more than 2 standard drinks on any one day)
Women: up to 9 standard drinks a week.
Men: up to 14 standard drinks a week.
Patients who exceed the Low-Risk Drinking Guidelines are considered at-risk for acute problems such as trauma, and/or chronic problems such as depression and hypertension.

Standard drink = 13.6 gm alcohol
= 1 bottle beer (12 oz, 5% alcohol)
= 5 oz/142 ml glass wine (12% alcohol)
(5 standard drinks in 750 ml bottle)
= 1.5 oz spirits (e.g., vodka, scotch, 40% alcohol)
(18 standard drinks in 26 oz bottle 40% alcohol)
Note: Higher alcohol beers and coolers have more alcohol that one standard drink

1. Source: *Centre for Addiction and Mental Health (CAMH)*

CAGE Questionnaire

"CAGE" = acronym formed from the italicized words in the questionnaire (cut-annoyed-guilty-eye).
The CAGE is a simple screening questionnaire to ID potential problems with alcohol.
Two "yes" responses is considered positive for males; one "yes" is considered positive for females.

Note: This test will only be scored correctly if you answer each one of the questions. Check the one response to each item that best describes how you have felt and behaved over your whole life.

1. Have you ever felt you should cut down on your drinking? __Yes __No
2. Have people annoyed you by criticising your drinking? __Yes __No
3. Have you ever felt bad or guilty about your drinking? __Yes __No
4. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (eye-opener)? __Yes __No

Interview Guide for **Substance Use**

1. Cannabis	number of joints per day, week
2. Cocaine	any use in the past year
3. OTC Drugs	especially sedating antihistamines
4. Opioids	• In past year, use of opioids from any source: e.g. OTC (T#1), prescriptions from other physicians, borrowed from friends/family, buying on the street • How much, how often • Crushing or injecting oral tablets • Opioid withdrawal symptoms: myalgias, GI symptoms, insomnia, dysphoria • Previous opioid problem • Attendance at treatment program for opioid addiction (e.g., methadone)
5. Benzo-diazepines	Amount, frequency, source

SEE GUIDELINE, PART B, RECOMMENDATION 1

Opioid Risk Tool

Item	Mark each box that applies	Item score if female	Item score if male
1. Family History of Substance Abuse:			
Alcohol	[ ]	1	3
Illegal Drugs	[ ]	2	3
Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse:			
Alcohol	[ ]	3	3
Illegal Drugs	[ ]	4	4
Prescription Drugs	[ ]	5	5
3. Age (mark box if 16-45)	[ ]	1	1
4. History of Preadolescent Sexual Abuse	[ ]	3	0
5. Psychological Disease			
Attention Deficit Disorder, Obsessive-Compulsive Disorder, or Bipolar, Schizophrenia	[ ]	2	2
Depression	[ ]	1	1
Total		____	____
Total Score Risk Category: Low Risk: 0 to 3 Moderate Risk: 4 to 7 High Risk: 8 and above			

Attribution:
By Lynn R. Webster, MD; Medical Director of Lifetree Medical, Inc., Salt Lake City, UT 84106

Website: http://www.lifetreeresearch.com/media/articles/ORT.pdf

SEE GUIDELINE, PART B, RECOMMENDATION 2

Urine Drug Screening

1. Interpreting Unexpected Results of Urine Drug Screens

	Unexpected Result	Possible Explanations	Actions for the Physician
1	UDS *negative* for prescribed opioid.	• False negative. • Non-compliance. • Diversion.	• Repeat test using chromatography; specify the drug of interest (e.g. oxycodone often missed by immunoassay). • Take a detailed history of the patient's medication use for the preceding 7 days (e.g., could learn that patient ran out several days prior to test) • Ask patient if they've given the drug to others. • Monitor compliance with pill counts.
2	UDS *positive* for non-prescribed opioid or benzodiazepines.	• False positive. • Patient acquired opioids from other sources (double-doctoring, street).	• Repeat UDS regularly. • Ask the patient if they accessed opioids from other sources. • Assess for opioid misuse/addiction (See Guideline, Part B, Recommendation 12). • Review/revise treatment agreement
3	UDS *positive* for illicit drugs (e.g., cocaine, cannabis).	• False positive. • Patient is occasional user or addicted to the illicit drug. • Cannabis is positive for patients taking dronabinol (Marinol®), THC:CBD (Sativex®) or using medical marijuana.	• Repeat UDS regularly. • Assess for abuse/addiction and refer for addiction treatment as appropriate • Ask about medical prescription of dronabinol, THC:CBD or medical marijuana access program.
4	Urine creatinine is lower than 2-3 mmol/liter.	• Patient added water to sample.	• Repeat UDS • Consider supervised collection or temperature testing • Take a detailed history of the patient's medication use for the preceding 7 days • Review/revise treatment agreement.
5	Urine sample is cold.	• Delay in handling sample (urine cools within minutes). • Patient added water to sample.	• Repeat UDS, consider supervised collection or temperature testing • Take a detailed history of the patient's medication use for the preceding 7 days • Review/revise treatment agreement.

2. Immunoassay versus Chromatography for Detection of Opioid Use

Immunoassay	Chromatography
• Does not differentiate between various opioids	Differentiates: codeine, morphine, oxycodone, hydrocodone, hydromorphone, heroin (monoacetylmorphine).
• Will show false positives: Poppy seeds, quinolone antibiotics.	Does not react to poppy seeds.
• Often misses semi-synthetic and synthetic opioids, e.g., oxycodone, methadone, fentanyl.	More accurate for semi-synthetic and synthetic opioids.

SEE GUIDELINE, PART B, RECOMMENDATION 3

OVER ➡

3. Detection Times for Immunoassay and Chromatography

	Number of days drug is detectable	
Drug	**Immunoassay**	**Chromatography**
Benzodiazepines (regular use)	• 20+ days for regular diazepam use. • Immunoassay does not distinguish different benzodiazepines. • Intermediate-acting benzodiazepines such as clonazepam are often undetected.	Not usually used for benzodiazepines.
Cannabis	20+	Not used for cannabis.
Cocaine + metabolite	3-7	1-2
Codeine	2-5	1-2 (Codeine metabolized to morphine.)
Hydrocodone	2-5	1-2
Hydromorphone	2-5	1-2
Meperidine	1 (often missed)	1
Morphine	2-5	1-2: Morphine can be metabolized to hydromorphone
Oxycodone	Often missed	1-2

Source: Adapted from Brands 1998.

SEE GUIDELINE, PART B, RECOMMENDATION 3

Adverse Effects of Opioids

Note: From randomized trials, excluding enrichment design trials, results show a clinically important difference (Diff>10%) and are statistically significant (P<0.05).

Adverse effect	Number of Studies	Incidence in Opioid Group	Incidence in Placebo Group	Difference (95% CI)
Nausea	38	28%	9%	17% (13% to 21%) P<0.00001
Constipation	37	26%	7%	20% (15% to 25%) P<0.00001
Somnolence/drowsiness	30	24%	7%	14% (10% to 18%) P<0.00001
Dizziness/vertigo	33	18%	5%	12% (9% to 16%) P<0.00001
Dry-skin/ itching/ pruritus	25	15%	2%	10% (5% to 15%) P<0.0001
Vomiting	23	15%	3%	11% (7% to 16%) P<0.00001

SEE GUIDELINE, PART B, RECOMMENDATION 5

Opioid Medical Complications

Information about medical complications associated with LTOT is reported in *nonrandomized* trials (RCTs are short-term: 3 months). There is no evidence regarding the frequency of medical complications, the relationship between length of time on opioids and occurrence of medical complications, or whether the complications are permanent or transient.

Patients should be informed about potential long-term use medical complications such as **neuroendocrine** (hypogonadism and amenorrhea), **sleep apnea** (central sleep apnea or worsening of obstructive sleep apnea), and **opioid-induced hyperalgesia**.

1.3.1 Neuroendocrine Abnormalities

Neuroendocrine abnormalities and **erectile dysfunction** can be experienced with LTOT (Ballantyne 2003, Daniell 2006). One recently published randomized trial found that the incidence of sexual dysfunction after morphine happened in 11% (Khoromi 2007). However, two other randomized trials suggested that patients taking opioid medications reported better sexual function, which was likely an improvement of wellbeing (Arkinstall 1995, Watson 2003). In summary, in the short term, the patient may notice improvement in sexual function (as a consequence of improved analgesia), but in the long term, opioids may cause neuroendocrine dysfunction.

1.3.2 Sleep Apnea

Opioids can aggravate not just **central sleep apnea**, but frequently also significantly aggravate **obstructive sleep apnea**. High opioid doses may contribute to sleep movement disorders including myoclonus and sometimes choreiform movement, and in combination with benzodiazepines and other drugs may significantly contribute to oxygen desaturation (Zgierska 2007, Mogri 2008, Farney 2003). Consider a sleep study for patients using high-dose opioids, opioid in combination with other sedating drugs, elderly patients, obese patients, and patients with somnolence.

1.3.3 Opioid-induced Hyperalgesia (OIH)

OIH is a paradoxical hyperalgesia resulting from LTOT. It is characterized by pain sensitivity (hyperalgesia and allodynia) in the absence of overt opioid withdrawal. It is distinct from tolerance in that pain extends beyond the area of initial complaint. It is alsoknown as opioid neurotoxicity

SEE GUIDELINE, PART B, RECOMMENDATION 5

Opioid Risks

RISK	Actions for the Physician	Information for the Patient	Directions for the Patient and Family
OVERDOSE	• Start with a low dose, titrate gradually, and monitor frequently (see Initial Dose/Titration). • Be cautious when prescribing benzodiazepines • For patients at higher risk of overdose*, ♦Initial dose should not exceed 50% of the suggested initial dose, and dose increments should be more gradual (see Initial Dose/Titration). ♦Consider a 3-day "tolerance check:" contact the patient 3 days after starting the opioid to check for signs of oversedation.	• Opioids are safe over the long term, BUT can be dangerous when starting or increasing a dose. • Overdose means thinking and breathing slows down — this could result in brain damage, trauma, and death. • Mixing opioids with alcohol or sedating drugs greatly increases the risk of overdose.	• *Contact a physician on early signs of overdose: slurred or drawling speech, emotional lability, ataxia, "nodding off" during conversation or activity.* • *Avoid mixing prescribed opioids with alcohol or sedating drugs.* • *Avoid driving a vehicle or operating equipment/heavy machinery until a stable dose is reached.* • *If you interrupt your medication schedule for three days or more for any reason, do not resume taking it without consulting a physician.*
DIVERSION	Ask questions about the following to determine risk of opioid diversion: • History of alcohol or substance abuse (patient and/or household member) • Transient or unstable housing • Vulnerability and dependence on caregivers	• Sharing prescribed medication with others is illegal, and could harm the other person. • While the patient's opioid dose is safe, it may be dangerous for other people. • Adolescents may abuse prescription opioids and sometimes pilfer drugs from the family medicine cabinet	• *Do not give your prescribed medication to any other person: This is illegal, and the drug could harm the other person.* • *Store your medication in a secure place with limited access to guard against others' (e.g., adolescents) illicit use.* • *Inform your physician if you feel your medication is insecure, or if you feel any pressure about sharing.*
ADDICTION	Use appropriate screening tools to determine risk of addiction.	• Addiction means that a person uses the drug to "get high," and cannot control the urge to take the drug. • However, most patients do not get high from taking opioids, and addiction is unlikely if addiction risk factors are low: those at greatest risk have a history of addiction. • Withdrawal symptoms can occur in any patient taking opioids regularly: they do not indicate addiction.	*Do not let unfounded fears of addiction stop you from taking your medication. Take your medication strictly as prescribed and do not stop the medication without informing a doctor.*
WITHDRAWAL	If a decision is made to discontinue opioid therapy, the opioids should be tapered under medical supervision (see Opioid Tapering).	• Opioid withdrawal symptoms are flu-like, e.g., nausea, diarrhea, and chills. • Withdrawal is not dangerous but it can be very uncomfortable. • Withdrawal can occur in any patient who takes opioids regularly, and it does not mean that the patient is addicted.	*Do not abruptly discontinue your medication, as this can cause uncomfortable withdrawal symptoms.*

OVER ➡

SEE GUIDELINE, PART B, RECOMMENDATION 5

Opioid Risks

* Patients at higher risk of opioid overdose are those with:

1. **Renal or hepatic impairment***:* Caution is advised, because opioids are metabolized in the liver and excreted through the renal system (Tegeder 1999, Foral 2007). Morphine is contraindicated in renal insufficiency.
2. **Chronic obstructive pulmonary disease (COPD) and sleep apnea***:* Opioid use may be a risk factor for central sleep apnea (Mogri 2008). Tolerance to the respiratory depressant effects of opioids develops slowly and incompletely, putting COPD patients at risk for respiratory depression with a higher dose increase.
3. **Sleep disorders***:* Sleep disorders, including insomnia and daytime sleepiness, are common among opioid users (Zgierska 2007). They may reflect the effects of pain, or the sedating effects of opioids, or concurrent depression.
4. **Cognitive impairment***:* Opioids should be avoided in cognitively impaired patients who live alone, unless ongoing medication supervision can be arranged.

SEE GUIDELINE, PART B, RECOMMENDATION 5

Sample Opioid Treatment Agreement

I, *(name)*_____ understand that I am receiving opioid medication from Dr. _____to treat my pain condition.

I agree to the following:

1. I will not seek opioid medications from another physician. Only Dr. _____ will prescribe opioids for me.

2. I will not take opioid medications in larger amounts or more frequently than is prescribed by Dr. _____

3. I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else.

4. I will not use over-the-counter opioid medications such as 222's and Tylenol® No. 1.

5. I understand that if my prescription runs out early for any reason (for example, if I lose the medication, or take more than prescribed), Dr. _____ will not prescribe extra medications for me; I will have to wait until the next prescription is due.

6. I will fill my prescriptions at one pharmacy of my choice; pharmacy name:
_____

7. I will store my medication in a secured location.

I understand that if I break these conditions, Dr. _____ may choose to cease writing opioid prescriptions for me.

_____ _____

Patient signature *Date*

Source: Kahan 2006.

SEE GUIDELINE, PART B, RECOMMENDATION 5

Benzodiazepine Tapering

1. BENEFITS of Benzodiazepine Tapering

- Lower the risk of future adverse drug-related risks such as falls.
- Increased alertness and energy.

2. APPROACH to Tapering

- Taper slowly: slow tapers are more likely to be successful than fast tapers.
- Use scheduled rather than p.r.n. doses.
- Halt or reverse taper if severe anxiety or depression occurs.
- Schedule follow-up visits q. 1–4 weeks depending on the patient's response to taper.
- At each visit, ask patient about the benefits of tapering (e.g., increased energy, increased alertness).

3. PROTOCOL for Outpatient Benzodiazepine Tapering

3.1 Initiation

- Can taper with a longer-acting agent, e.g., diazepam/clonazepam, or taper with agent that patient is taking. (Diazepam can cause prolonged sedation in elderly and those with liver impairment.)
- Insufficient evidence to strongly support the use of one particular benzodiazepine for tapering.
- Convert to equivalent dose in divided doses (see equivalence table below).
- Adjust initial dose according to symptoms (equivalence table is approximate).

3.2 Decreasing the Dose

- Taper by no more than 5 mg diazepam equivalent/week.
- Adjust rate of taper according to symptoms.
- Slow the pace of the taper once dose is below 20 mg of diazepam equivalent (e.g., 1–2 mg/week).
- Rx: dispense daily, 2x weekly, or weekly depending on dose and patient reliability.

3.3 Another Approach

Taper according to the proportional dose remaining: Taper by 10% of the dose every 1–2 weeks until the dose is at 20% of the original dose; then taper by 5% every 2–4 weeks.

Source: Adapted from Kahan 2002

SEE GUIDELINE, PART B, RECOMMENDATION 6

Benzodiazepine Equivalent Table

Source: Adapted from Kalvik 1995; Canadian Pharmacists Association 1999.

Benzodiazepine	Equivalent to 5 mg diazepam (mg) *
Alprazolam (Xanax®)**	0.5
Bromazepam (Lectopam®)	3–6
Chlordiazepoxide (Librium®)	10–25
Clonazepam (Rivotril®)	0.5–1
Clorazepate (Tranxene®)	7.5
Flurazepam (Dalmane®)	15
Lorazepam (Ativan®)	0.5–1
Nitrazepam (Mogadon®)	5–10
Oxazepam (Serax®)	15
Temazepam (Restoril®)	10–15
Triazolam (Halcion®)**	0.25

* Equivalences are approximate. Careful monitoring is required to avoid over-sedation, particularly in older adults and those with impaired hepatic metabolism.

**Equivalency uncertain.

SEE GUIDELINE, PART B, RECOMMENDATION 6

Tools to Select the Right Opioid and Titrate Effectively

Stepped Approach to Opioid Selection

The most appropriate drug for an opioid trial depends on the patient's clinical profile and individual circumstances.

Stepped Approach to Opioid Selection

Mild-to-Moderate Pain

First-line for Mild-to-Moderate Pain:
codeine or tramadol

Second-line for Mild-to-Moderate Pain:
morphine, oxycodone or hydromorphone

Severe Pain

First-line for Severe Pain:
morphine, oxycodone or hydromorphone

Second-line for Severe Pain:
fentanyl

Third-line for Severe Pain:
methadone

SEE GUIDELINE, PART B, RECOMMENDATION 8

Selecting Opioids: Safety Issues

Note: This table highlights safety issues for specific agents; for comprehensive information, prescribers should consult the individual drug monographs.

Agent	Safety Issues
Codeine	1) Use with caution for breast-feeding women. 2) Lower risk of overdose and addiction than stronger opioids.
Tramadol	1) Associated with seizures in patients at high seizure risk, or when combined with medications that increase serotonin levels, e.g., SSRIs. 2) Lower risk of overdose and addiction than stronger opioids.
Morphine	Avoid for patients with renal dysfunction:
Oxycodone Hydromorphone Hydrocodone	Use with caution for patients at higher risk for opioid misuse and addiction.
Fentanyl	1) Before starting fentanyl, obtain a complete history of-opioid use within the last 2 weeks to ensure the patient is fully opioid tolerant. 2) Do not switch from codeine to fentanyl regardless of the codeine dose, as some codeine users may have little or no opioid tolerance. 3) Maintain the initial dose for at least 6 days: use extra caution with patients at higher risk for overdose. 5) Advise the patient as follows: • Be alert for signs of overdose, e.g., slurred/drawling speech, emotionally labile, ataxia, nodding off during conversation/activity; if detected, remove patch and seek medical help. • Avoid external heat, e.g., heating pad, hot tub • Apply strictly as prescribed • Dispose of patches securely.
Methadone	Using methadone to treat pain requires a written Health Canada exemption.
Meperidine (Demerol)	Not recommended for use in CNCP.
Acetaminophen-opioid combinations	Use with caution to avoid acetaminophen toxicity. Heavy drinkers should be advised to use acetaminophen with extra caution.

Other Formulations/ Preparations : Safety Issues	
CR formulations	Titrate with caution to avoid overdose and misuse: each CR tablet can contain a much higher opioid dose than IR formulations, and can easily be converted to IR by biting or crushing the tablet.
Parenteral opioids	Parenteral opioids are not recommended for use in CNCP: parenteral route has higher risk of overdose, abuse and addiction, and infection.

SEE GUIDELINE, PART B, RECOMMENDATION 8

Initial Dose / Titration

Opioid	Initial dose	Minimum time interval for increase	Suggested dose increase	Minimum daily Dose before converting IR to CR
Codeine (alone or in combination with acetaminophen or ASA)	15-30 mg q.4 h. as required	7 days	15-30 mg/day up to maximum of 600 mg/day (acetaminophen dose should not exceed 3.2 grams/day)	100 mg daily
CR Codeine	50 mg q.12 h.	2 days	50 mg/day up to maximum of 300 mg q.12 h.	NA
Tramadol (37.5 mg) + acetaminophen (325 mg)	1 tablet q.4-6 h. as needed up to 4/day	7 days	1-2 tab q. 4-6 h. as needed up to maximum 8 tablets/day	3 tablets
CR Tramadol	a) Zytram XL®: 150 mg q. 24 h. b) Tridural™: 100 mg q. 24 h. c) Ralivia™: 100 mg q. 24 h.	a) 7 days b) 2 days c) 5 days	Maximum doses: a) 400 mg/day b) 300 mg/day c) 300 mg/day	NA
IR Morphine	• 5-10 mg q. 4 h. as needed • maximum 40 mg/day	7 days	5-10 mg/day	20-30 mg
CR Morphine	• 10-30 mg q.12 h. • Kadian®: q. 24 h. Kadian® should not be started in opioid-naïve patients	Minimum 2 days, recommended: 14 days	5-10 mg/day	NA
IR Oxycodone	• 5-10 mg q. 6 h. as needed • maximum 30 mg/day	7 days	5 mg/day	20 mg
CR Oxycodone	• 10-20 mg q.12 h. • maximum 30 mg/day	Minimum 2 days, recommended: 14 days	10 mg/day	NA
IR Hydromorphone	• 1-2 mg q. 4-6 h. as needed • maximum 8 mg/day	7 days	1-2 mg/day	6 mg
CR Hydromorphone	• 3 mg q. 12 h. • maximum 9 mg/day	Minimum 2 days, recommended: 14 days	2-4 mg/day	NA

Modified from Weaver 2007 with information from the e-CPS (Canadian Pharmacists Association, 2008)

Note: The table is based on oral dosing for chronic non-cancer pain. Brand names are shown if there are some distinct features about specific formulations.
Reference to brand names as examples does not imply endorsement of any of these products.

ASA: acetylsalicylic acid, CR = controlled release, IR = immediate release, NA = not applicable

SEE GUIDELINE, PART B, RECOMMENDATION 9

Optimal Dose / Watchful Dose

Optimal Dose: is reached with a BALANCE of three factors:

1) **Effectiveness**: improved function or at least 30% reduction in pain intensity
2) **Plateauing**: effectiveness plateaus—increasing the dose yields negligible benefit, and
3) **Adverse effects/complications**: adverse effects or complications are manageable.

Measuring Opioid Effectiveness

Assessing *FUNCTION* Change

The patient's progress in reaching agreed-on goals is an important indicator of function change. Self-report can be prompted by asking about work, household activity, mood, walking ability, sleep, and social activities. For an example of a structured assessment tool frequently used in trials, see Brief Pain Inventory.

Assessing *PAIN* Change

A 30% or greater reduction in pain intensity is considered clinically significant (Farrar 2001).

Change in pain intensity can be assessed using an 11-point (0–10) numeric rating scale (NRS). With each dose increase, the patient should be asked to estimate the pain intensity: a desirable response is a reduction in pain intensity (e.g., from 9/10 [baseline] to 6/10 [endpoint]) and a longer duration of analgesia per dose.

Example of assessing change in pain intensity:

1. Determine the ***raw change*** in the NRS score:
   baseline – endpoint, e.g., 9 – 6 = 3

2. Determine the ***percent change***:

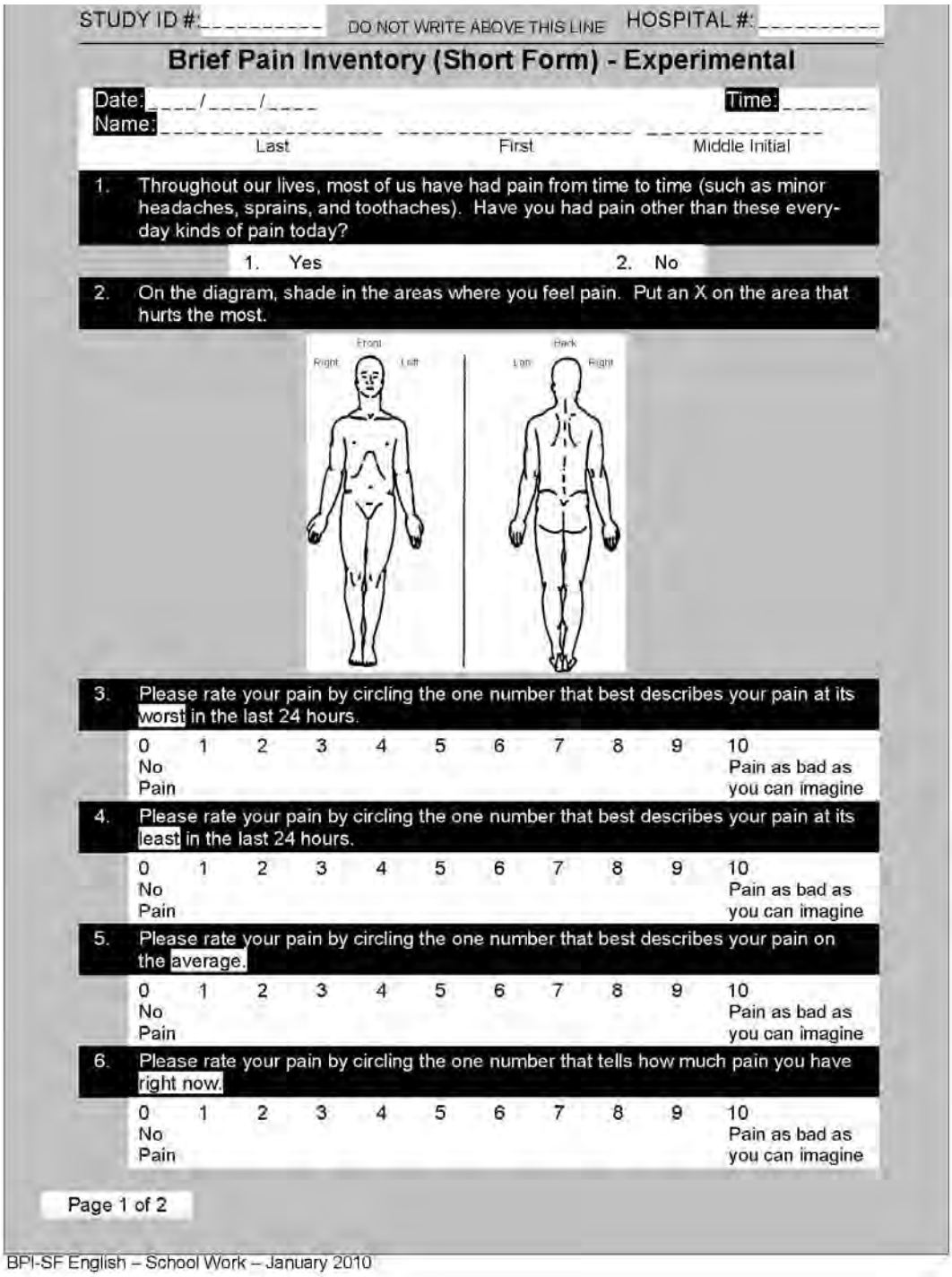
$$\frac{\text{raw change}}{\text{baseline}} \times 100, \text{ e.g., } \frac{3}{9} \times 100 = 33\%$$

Watchful Dose

Watchful Dose = morphine or equivalent dose exceeding 200 mg/day.
See Guideline, Part B, Recommendation 10 for guidance on a watchful dose.

SEE GUIDELINE, PART B, RECOMMENDATION 9

Brief Pain Inventory©



STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #:_____

Brief Pain Inventory (Short Form) - Experimental

Date: ____/____/____ Time: _____

Name: _____ _____ _____

Last First Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

Front Back

Right Left Left Right

3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

Page 1 of 2

BPI-SF English – School Work – January 2010

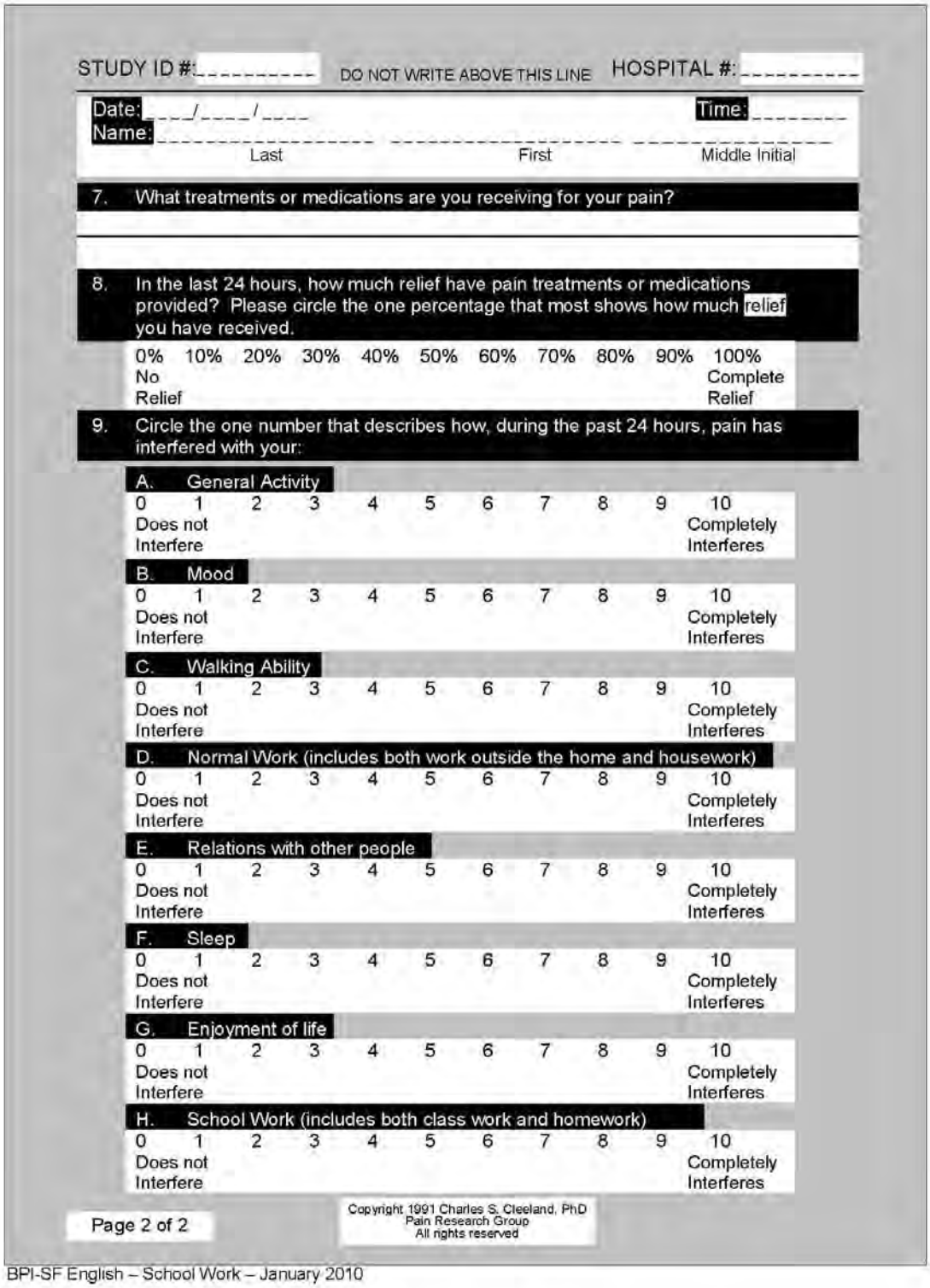
Brief Pain Inventory©: Cleeland CS. Measurement of pain by subjective report. In: Chapman CR, Loeser JD, editors. Issues in Pain Measurement. New York: Raven Press; pp. 391-403, 1989. Advances in Pain Research and Therapy; Vol. 12.

NOTE: For further information about using the BPI and to obtain copies for clinical use:
www.mdanderson.org/departments/prg > Symptom Assessment Tools > The Brief Pain Inventory (BPI).

OVER ➡

SEE GUIDELINE, PART B, RECOMMENDATION 9

Brief Pain Inventory©



STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #:_____

Date:____/____/____ Time:_____

Name:_____ _____ _____

Last First Middle Initial

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

B. Mood

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

C. Walking Ability

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

E. Relations with other people

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

F. Sleep

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

G. Enjoyment of life

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

H. School Work (includes both class work and homework)

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

Page 2 of 2

BPI-SF English – School Work – January 2010

SEE GUIDELINE, PART B, RECOMMENDATION 9

Aberrant Drug-Related Behaviours Indicative of Opioid Misuse

(Modified from Passik 2004)

Note: * = behaviours more indicative of addiction than the others

Indicator	Examples
*Altering the route of delivery	• Injecting, biting or crushing oral formulations
*Accessing opioids from other sources	• Taking the drug from friends or relatives • Purchasing the drug from the "street" • Double-doctoring
Unsanctioned use	• Multiple unauthorized dose escalations • Binge rather than scheduled use
Drug seeking	• Recurrent prescription losses • Aggressive complaining about the need for higher doses • Harassing staff for faxed scripts or fit-in appointments • Nothing else "works"
Repeated withdrawal symptoms	• Marked dysphoria, myalgias, GI symptoms, craving
Accompanying conditions	• Currently addicted to alcohol, cocaine, cannabis or other drugs • Underlying mood or anxiety disorders not responsive to treatment
Social features	• Deteriorating or poor social function • Concern expressed by family members
Views on the opioid medication	• Sometimes acknowledges being addicted • Strong resistance to tapering or switching opioids • May admit to mood-leveling effect • May acknowledge distressing withdrawal symptoms

SEE GUIDELINE, PART B, RECOMMENDATION 11 AND RECOMMENDATION 12

OVER ➡

RESOURCES for Aberrant Drug-Related Behaviours

Tools used to assist in identifying aberrant drug-related behaviours:

- *Addiction Behaviors Checklist* (ABC): In 2006, Wu, Compton et al. also developed and tested the ABC, a 20-item instrument designed to identify problematic drug-use in chronic pain patients treated with opioids (Wu 2006).
- *Current Opioid Misuse Measure* (COMM®): In 2007, Butler et al. developed and demonstrated the potential for a brief and easy-to-administer 17-item questionnaire, the COMM®, to identify aberrant drug-related behaviours (Butler 2007). (See SOAPP®-R and COMM®.)
- *Patient Assessment and Documentation Tool* (PADT): developed by Passik et al. 2004, Clin Ther. This instrument focuses on key outcomes and provides a consistent way to document progress in pain management therapy over time. Items assess four domains: pain relief, patient functioning, adverse events, and drug-related behaviors.
- *Prescription Drug Use Questionnaire* (PDUQ): In 1998, Compton et al. developed and piloted the *PDUQ* for screening for addiction in chronic pain patients receiving opioids (Compton 1998). This is a 42-item interview to assess abuse/misuse for pain patients.
- *Prescription Opioid Therapy Questionnaire* (POTQ): In 2004, Michna et al. developed and tested the POTQ, an 11-item scale where the provider answers "yes" or "no" to questions indicative of misuse of opioids (Michna 2004).
- *Screener and Opioid Assessment for Patients with Pain* (SOAPP®-R). In 2004, Butler et al. developed the SOAPP® instrument (Butler 2004). In 2008 they published the revised SOAPP®-R, a 24-item self-report questionnaire that may also be useful for identifying risk of aberrant behaviours (Butler 2008). (See SOAPP®-R and COMM®.)

SEE GUIDELINE, PART B, RECOMMENDATION 11 AND RECOMMENDATION 12

Tools to Monitor for Safety and Effectiveness

Oral Opioid Conversion
SOAPP®-R and COMM®

Oral Opioid Analgesic Conversion Table

- The table is based on oral dosing for chronic non-cancer pain.
- The figures are based on the Compendium of Pharmaceutical & Specialties (2008) and a systematic review by Pereira (2001). Wide ranges have been reported in the literature.
- These equivalences refer to analgesic strength of oral opioids, and not psychoactive effects or effectiveness in relieving withdrawal symptoms.

1. Equivalence to oral morphine 30 mg:

	Equivalence to oral morphine 30 mg:	To convert to oral morphine equivalent multiply by:	To convert from oral morphine multiply by:
Morphine	30 mg	1	1
Codeine	200 mg	0.15	6.67
Oxycodone	20 mg	1.5	0.667
Hydromorphone	6 mg	5	0.2
Meperidine	300 mg	0.1	10
Methadone and tramadol	Morphine dose equivalence not reliably established.		

2. Equivalence between oral morphine and transdermal fentanyl:

Transdermal fentanyl[l]	60–134 mg morphine = 25mcg/h 135–179 mg = 37 mcg/h 180–224 mg = 50 mcg/h 225–269 mg = 62 mcg/h 270–314 mg = 75 mcg/h 315–359 mg = 87 mcg/h 360–404 mg = 100 mcg/h

[l]Formulations include 12, 25, 50, 75 and 100 ucg/hour patches, but the 12 ucg/hour patch is generally used for dose adjustment rather than initiation of fentanyl treatment.

SEE GUIDELINE, PART B, RECOMMENDATION 13

1. SOAPP®-R

Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R)

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	☺	☺	☺	☺	☺
2. How often have you felt a need for higher doses of medication to treat your pain?	☺	☺	☺	☺	☺
3. How often have you felt impatient with your doctors?	☺	☺	☺	☺	☺
4. How often have you felt that things are just too overwhelming that you can't handle them?	☺	☺	☺	☺	☺
5. How often is there tension in the home?	☺	☺	☺	☺	☺
6. How often have you counted pain pills to see how many are remaining?	☺	☺	☺	☺	☺
7. How often have you been concerned that people will judge you for taking pain medication?	☺	☺	☺	☺	☺
8. How often do you feel bored?	☺	☺	☺	☺	☺
9. How often have you taken more pain medication than you were supposed to?	☺	☺	☺	☺	☺
10. How often have you worried about being left alone?	☺	☺	☺	☺	☺
11. How often have you felt a craving for medication?	☺	☺	☺	☺	☺
12. How often have others expressed concern over your use of medication?	☺	☺	☺	☺	☺

NOTE: For further information and to obtain copies for clinical use:
http://www.painedu.org/registration.asp?target=terms

SEE GUIDELINE, PART B, RECOMMENDATION 12

…*SOAPP® page 2* OVER ➡

SOAPP®-R,

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

SEE GUIDELINE, PART B, RECOMMENDATION 12

OVER ➡

2. COMM®

Current Opioid Misuse Measure (COMM)®

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

PainEDU.org

NOTE: For further information and to obtain copies for clinical use:
http://www.painedu.org/registration.asp?target=terms

SEE GUIDELINE, PART B, RECOMMENDATION 12

…*COMM® page 2* OVER ➡

2. COMM®…

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

SEE GUIDELINE, PART B, RECOMMENDATION 12

Opioid Tapering

Opioid Tapering

1.PRECAUTIONS for Outpatient Opioid Tapering

1) **Pregnancy**: Severe, acute opioid withdrawal is associated with premature labour and spontaneous abortion.
2) **Unstable medical and psychiatric conditions that can be worsened by anxiety**: While opioid withdrawal does not have serious medical consequences, it can cause significant anxiety and insomnia.
3) **Addiction to opioids obtained from multiple doctors or "the street:"** Outpatient tapering is unlikely to succeed if patient regularly accesses opioids from other sources; such patients are usually best managed in an opioid agonist treatment program (methadone or buprenorphine).
4) **Concurrent medications**: Avoid sedative-hypnotic drugs, especially benzodiazepines, during the taper.

2. OPIOID TAPERING PROTOCOL

2.1 Before Initiation

1) Emphasize the goal of tapering is to make the patient feel better: to reduce pain intensity and to improve mood and function.
2) Have a detailed treatment agreement.
3) Be prepared to provide frequent follow-up visits and supportive counselling.

2.2 Type of Opioid, Schedule, Dispensing Interval

1) Use controlled-release morphine if feasible (see 2.3 below).
2) Prescribe scheduled doses (not p.r.n.).
3) Prescribe at frequent dispensing intervals (daily, alternate days, weekly; depending on patient's degree of control over opioid use). Do not refill if patient runs out.
4) Keep daily schedule the same for as long as possible (e.g., t.i.d.).

2.3. Rate of the Taper

1) The rate of the taper can vary from 10% of the total daily dose every day, to 10% of the total daily dose every 1–2 weeks.
2) Slower tapers are recommended for patients who are anxious about tapering, may be psychologically dependent on opioids, have co-morbid cardio-respiratory conditions, or express a preference for a slow taper.
3) Once one-third of the original dose is reached, slow the taper to one-half or less of the previous rate.
4) Hold the dose when appropriate: The dose should be held or increased if the patient experiences severe withdrawal symptoms, a significant worsening of pain or mood, or reduced function during the taper.

2.4 Switching to Morphine

1) Consider switching to morphine if the patient might be dependent on oxycodone or hydromorphone.
2) Calculate equivalent dose of morphine (see Oral Opioid Analgesic Conversion Table).
3) Start patient on one-half this dose (tolerance to one opioid is not fully transferred to another opioid).
4) Adjust dose up or down as necessary to relieve withdrawal symptoms without inducing sedation.

2.5 Monitoring during the Taper

1) Schedule frequent visits during the taper (e.g. weekly).
2) At each visit, ask about pain status, withdrawal symptoms and possible benefits of the taper: reduced pain and improved mood, energy level and alertness.
3) Use urine drug screening to assess compliance.

2.6 Completing the Taper

1) Tapers can usually be completed between 2–3 weeks and 3–4 months.
2) Patients who are unable to complete the taper may be maintained at a lower dose if their mood and functioning improve and they follow the treatment agreement.

SEE GUIDELINE, PART B, RECOMMENDATION 13

OPIOID MANAGER

The Opioid Manager is designed to be used as a point of care tool for providers prescribing opioids for chronic non cancer pain. It condenses key elements from the Canadian Opioid Guideline and can be used as a chart insert.

A Before You Write the First Script

Patient Name: _____

Pain Diagnosis: _____

Date of Onset: _____

Goals decided with patient:

_____

_____

_____

_____

_____

_____

_____

Initiation Checklist

	Y	N	Date
Are opioids indicated for this pain condition			
Explained potential benefits			
Explained adverse effects			
Explained risks			
Patient given information sheet			
Signed treatment agreement (as needed)			
Urine drug screening (as needed)			

Opioid Risk Tool

By Lynn R. Webster MD

Item (circle all that apply)	**Item score if female**	**Item score if male**
1. Family History of Substance Abuse:		
Alcohol	1	3
Illegal Drugs	2	3
Prescription Drugs	4	4
2. Personal History of Substance Abuse:		
Alcohol	3	3
Illegal Drugs	4	4
Prescription Drugs	5	5
3. Age (mark box if 16-45)	1	1
4. History of Preadolescent Sexual Abuse	3	0
5. Psychological Disease Attention Deficit Disorder, Obsessive-Compulsive Disorder, or Bipolar, Schizophrenia	2	2
Depression	1	1
Total		

Total Score Risk Category:
Low Risk: 0 to 3, Moderate Risk: 4 to 7, High Risk: 8 and above

Overdose Risk

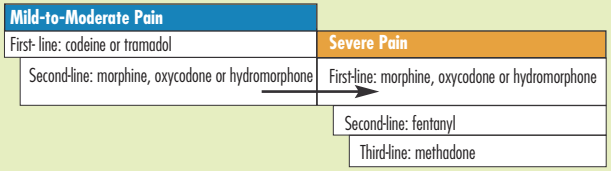
Patient Factors
- Elderly
- On benzodiazepines
- Renal impairment
- Hepatic impairment
- COPD
- Sleep apnea
- Sleep disorders
- Cognitive impairment

Provider Factors
- Incomplete assessments
- Rapid titration
- Combining opioids and sedating drugs
- Failure to monitor dosing
- Insufficient information given to patient and/or relatives

Opioid Factors
- Codeine & Tramadol - lower risk
- CR formulations - higher doses than IR

Prevention
- Assess for Risk Factors
- Educate patients /families about risks & prevention
- Start low, titrate gradually, monitor frequently
- Careful with benzodiazepines
- Higher risk of overdose - reduce initial dose by 50%; titrate gradually
- Avoid parenteral routes
- Adolescents; elderly - may need consultation
- Watch for Misuse

Stepped Approach to Opioid Selection



B Initiation Trial

A closely monitored trial of opioid therapy is recommended before deciding whether a patient is prescribed opioids for long term use.

Suggested Initial Dose and Titration (Modified from Weaver M., 2007 and the e-CPS, 2008) Notes: The table is based on oral dosing for CNCP. Brand names are shown if there are some distinct features about specific formulations. Reference to brand names as examples does not imply endorsement of any of these products. CR = controlled release, IR = immediate release, NA = not applicable, ASA: Acetylsalicylic Acid

Opioid	Initial dose	Minimum time interval for increase	Suggested dose increase	Minimum daily dose before converting IR to CR
Codeine (alone or in combination with acetaminophen or ASA)	15-30 mg q.4 h. as required	7 days	15-30 mg/day up to maximum of 600 mg/day (acetaminophen dose should not exceed 3.2 grams/day)	100 mg
CR Codeine	50 mg q.12 h.	2 days	50 mg/day up to maximum of 300 mg q.12 h.	NA
Tramadol (37.5 mg) + acetaminophen (325 mg)	1 tablet q.4-6 h. as needed up to 4/day	7 days	1-2 tab q. 4-6 h. as needed up to maximum 8 tablets/day	3 tablets
CR Tramadol	a) Zytram XL®: 150 mg q. 24 h. b) Tridural™: 100 mg q. 24 h. c) Ralivia™: 100 mg q. 24 h.	a) 7 days b) 2 days c) 5 days	Maximum doses: a) 400 mg/day b) 300 mg/day c) 300 mg/day	NA
IR Morphine	5-10 mg q. 4 h. as needed maximum 40 mg/day	7 days	5-10 mg/day	20-30 mg
CR Morphine	10-30 mg q.12 h. Kadian®: q.24 h. Kadian® should not be started in opioid-naïve patients	Minimum 2 days, recommended: 14 days	5-10 mg/day	NA
IR Oxycodone	5-10 mg q. 6 h. as needed maximum 30 mg/day	7 days	5 mg/day	20 mg
CR Oxycodone	10-20 mg q.12 h. maximum 30 mg/day	Minimum 2 days, recommended: 14 days	10 mg/day	NA
IR Hydromorphone	1-2 mg q. 4-6 h. as needed maximum 8 mg/day	7 days	1-2 mg/day	6 mg
CR Hydromorphone	3 mg q. 12 h. maximum 9 mg/day	Minimum 2 days, recommended: 14 days	2-4 mg/day	NA

Initiation Trial Chart

Date	D / M / Y	D / M / Y	D / M / Y	D / M / Y
Opioid prescribed				
Daily dose				
Daily morphine equivalent				
More than 200 (Watchful Dose > than 200)				
Less than 200				
Goals achieved → Yes, No, Partially				
Pain intensity				
Functional status → Improved, No Change, Worsened				
Adverse effects: Nausea				
Constipation				
Drowsiness				
Dizziness/Vertigo				
Dry skin/Pruritis				
Vomiting				
Other?				
Complications? (Reviewed: Y/N)				
Aberrant Behaviour (Reviewed: Y/N)				
Urine Drug Screening (Y/N)				
Other Medications				

0 = None
1 = Limits ADLs
2 = Prevents ADLs

To access the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-cancer Pain and to download the Opioid Manager visit **http://nationalpaincentre.mcmaster.ca/opioid/**

Feb 2011

C Maintenance & Monitoring

Morphine Equivalence Table

Opioid	Equivalent Doses (mg)	Conversion to MEQ
Morphine	30	1
Codeine	200	0.15
Oxycodone	20	1.5
Hydromorphone	6	5
Meperidine	300	0.1
Methadone & Tramadol	Dose Equivalents unreliable	
Transdermal fentanyl	60 – 134 mg morphine = 25 mcg/h 135 – 179 mg = 37 mcg/h 180 – 224 mg = 50 mcg/h 225 – 269 mg = 62 mcg/h 270 – 314 mg = 75 mcg/h 315 – 359 mg = 87 mcg/h 360 – 404 mg = 100 mcg/h	

Switching Opioids:	
If previous opioid dose was:	**Then, SUGGESTED new opioid dose is:**
High	50% or less of previous opioid (converted to morphine equivalent)
Moderate or low	60-75% of the previous opioid (converted to morphine equivalent)

Maintenance & Monitoring Chart

Date	D / M / Y	D / M / Y	D / M / Y	D / M / Y	D / M / Y	D / M / Y
Opioid prescribed						
Daily dose						
Daily morphine equivalent						
More than 200 (Watchful Dose > than 200)						
Less than 200						
Goals achieved → Yes, No, Partially						
Pain intensity						
Functional status → Improved, No Change, Worsened						
Adverse effects: Nausea						
Constipation						
Drowsiness						
Dizziness/Vertigo						
Dry skin/Pruritis						
Vomiting						
Other?						
Complications? (Reviewed: Y/N)						
Aberrant Behaviour (Reviewed: Y/N)						
Urine Drug Screening (Y/N)						
Other Medications						

0 = None
1 = Limits ADLs
2 = Prevents ADLs

D When is it time to Decrease the dose or Stop the Opioid completely?

When to stop opioids	Examples and Considerations
Pain Condition Resolved	Patient receives definitive treatment for condition. A trial of tapering is warranted to determine if the original pain condition has resolved.
Risks Outweighs Benefits	Overdose risk has increased. Clear evidence of diversion. Aberrant drug related behaviours have become apparent.
Adverse Effects Outweighs Benefits	Adverse effects impairs functioning below baseline level. Patient does not tolerate adverse effects.
Medical Complications	Medical complications have arisen (e.g. hypogonadism, sleep apnea, opioid induced hyperalgesia)
Opioid Not Effective	**Opioid effectiveness = improved function or at least 30% reduction in pain intensity** Pain and function remains unresponsive. Opioid being used to regulate mood rather than pain control. Periodic dose tapering or cessation of therapy should be considered to confirm opioid therapy effectiveness.

How to Stop – the essentials

How do I stop? The opioid should be tapered rather than abruptly discontinued.

How long will it take to stop the opioid? Tapers can usually be completed between 2 weeks to 4 months.

When do I need to be more cautious when tapering? Pregnancy:
Severe, acute opioid withdrawal has been associated with premature labour and spontaneous abortion.

How do I decrease the dose?
Decrease the dose by no more than 10% of the total daily dose every 1-2 weeks. Once one-third of the original dose is reached, decrease by 5% every 2-4 weeks. Avoid sedative-hypnotic drugs, especially benzodiazepines, during the taper.

Aberrant Drug Related Behaviour (Modified by Passik,Kirsh et al 2002).

Indicator	Examples
*Altering the route of delivery	• Injecting, biting or crushing oral formulations
*Accessing opioids from other sources	• Taking the drug from friends or relatives • Purchasing the drug from the "street" • Double-doctoring
Unsanctioned use	• Multiple unauthorized dose escalations • Binge rather than scheduled use
Drug seeking	• Recurrent prescription losses • Aggressive complaining about the need for higher doses • Harassing staff for faxed scripts or fit-in appointments • Nothing else "works"
Repeated withdrawal symptoms	• Marked dysphoria, myalgias, GI symptoms, craving
Accompanying conditions	• Currently addicted to alcohol, cocaine, cannabis or other drugs • Underlying mood or anxiety disorders not responsive to treatment
Social features	• Deteriorating or poor social function • Concern expressed by family members
Views on the opioid medication	• Sometimes acknowledges being addicted • Strong resistance to tapering or switching opioids • May admit to mood-leveling effect • May acknowledge distressing withdrawal symptoms

* = behaviours more indicative of addiction than the others.

7. **The medication the doctor prescribes for you can be very dangerous to others.**

- ► Your body will get used to the dose your doctor sets for you but this same dose can be very dangerous to others.
- ► You have reached your proper dose slowly, but someone who is not used to the medication could have a serious reaction, including death — don't give your medication to anyone else – it is illegal and could harm them.
- ► Keep you medication securely stored at home — the bathroom medicine cabinet is *not* a safe place; research has shown that others, particularly teenagers might help themselves to these drugs from friends or relatives.

Canadian Guideline:
http://nationalpaincentre.mcmaster.ca/opioid

Patient Information

What you need to know about taking Opioids

Opioids are a group of similar medications that are used to help with pain — there is more than one type of opioid and they have different names for example, Percocet®, OxyContin®, Tylenol® No. 2, Tramacet®.

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

Messages for Patients Taking Opioids

1. **Opioids are used to improve your ability to be active and reduce pain.**
   - ► You and your doctor will set goals and ensure the medication is effective in achieving the goals, e.g. improving your ability to do the things you did before pain prevented you.
   - ► If you seem to benefit from the pain medication, your doctor will see you for follow-up visits to assess pain relief, any side effects, and your ability to meet your set activity goals.
2. **There are side effects from opioids, but they can be mostly controlled with increasing your dose slowly.**
   - ► Common side effects include: nausea (28% of patients report it), constipation (26%), drowsiness (24%), dizziness (18%), dry-skin/itching (15%) and vomiting (15%).
   - ► Side effects can be minimized by slowly increasing the dose of the drug and by using anti-nausea drugs and bowel stimulants.
3. **Your doctor will ask you questions and discuss any concerns with you about your possibility of developing addiction.**
   - ► Addiction means that a person uses the drug to "get high," and cannot control the urge to take the drug.
   - ► Most patients do not "get high" from taking opioids, and addiction is unlikely if your risk for addiction is low: those at greatest risk have a history of addiction with alcohol or other drugs.
4. **Opioids can help but they do have risks — these can be managed by working cooperatively with your doctor.**
   - ► Take the medication as your doctor prescribed it.
   - ► Don't drive while your dose is being gradually increased or if the medication is making you sleepy or feel confused.
   - ► Only one doctor should be prescribing opioid medication for you — don't obtain this medication from another doctor unless both are aware that you have two prescriptions for opioids.
   - ► Don't take opioids from someone else or share your medication with others.
   - ► You may be asked for a urine sample — this will help to show all the drugs you are taking and ensure a combination is not placing you at risk.
   - ► Your doctor will give you a prescription for the amount of medication that will last until your next appointment — keep your prescription safe and use the medications as instructed — if you run out too soon or lose your prescription your doctor will not likely provide another.
   - ► If you cannot follow these precautions it may not be safe for your doctor to prescribe opioid medication for you.
5. **If you stop taking your medication abruptly, you will experience a withdrawal reaction.**
   - ► Withdrawal symptoms do not mean you are addicted — just that you stopped the drug too quickly — your doctor will direct you on how to slowly stop this medication so you won't have this experience.
   - ► Opioid withdrawal symptoms are flu-like, e.g., nausea, diarrhea, and chills.
   - ► Withdrawal is not dangerous but it can be very uncomfortable.
   - ► If you interrupt your medication schedule for three days or more for any reason, do not resume taking it without consulting a doctor.
6. **Overdose from opioids is uncommon, but you and your family should be aware of the signs.**
   - ► Opioids are safe over the long term, BUT can be dangerous when starting or increasing a dose.
   - ► Overdose means thinking and breathing slows down — this could result in brain damage, trauma, and death.
   - ► Mixing opioids with alcohol or sedating drugs such as pills to help anxiety or sleeping, greatly increases the risk of overdose.
   - ► You and your family should be aware of signs of overdose — contact a doctor if you notice: slurred or drawling speech, becoming upset or crying easily, poor balance or, "nodding off" during conversation or activity.

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

Part A: Executive Summary and Background
Part B: Recommendations for Practice

PART A

— Executive Summary and Background —

Published by the
National Opioid Use Guideline Group (NOUGG)
a collaboration of:

Federation of Medical Regulatory Authorities of Canada
College of Physicians & Surgeons of British Columbia
College of Physicians & Surgeons of Alberta
College of Physicians and Surgeons of Saskatchewan
College of Physicians & Surgeons of Manitoba
College of Physicians and Surgeons of Ontario
Collège des médecins du Québec
College of Physicians and Surgeons of New Brunswick
College of Physicians and Surgeons of Nova Scotia
College of Physicians and Surgeons of Prince Edward Island
College of Physicians and Surgeons of Newfoundland and Labrador
Government of Nunavut
Yukon Medical Council

April 30 2010 Version 4.5

http://nationalpaincentre.mcmaster.ca/opioid/

Acknowledgements

The following individuals are gratefully acknowledged for their contribution to the inception, development, review, revision, and publication of the *Canadian Guideline***.**

Research Group

Dr. Andrea Furlan
Dr. Meldon Kahan
Dr. Angela Mailis-Gagnon
Ms Emma Irvin
Dr. Luis Chaparro
Dr. Anita Srivastava

National Opioid Use Guideline Group (NOUGG)

Ms Rhoda Reardon (Co-chair)
Mr. Clarence Weppler (Co-chair)
Dr. Angela Carol
Ms Connie Côté
Dr. Patricia DeMaio
Dr. Lindy Lee
Dr. Fleur-Ange Lefebvre
Dr. Don Ling
Dr. Cameron Little
Dr. Bill Pope
Dre. Carole Santerre
Dr. Ed Schollenberg
Dr. Said Secerbegovic
Dr. Karen Shaw
Mr. Doug Spitzig
Dr. Janet Wright
Dr. Robbert Vroom
Dr. Robert Young
Dr. Anna Ziomek

National Advisory Panel (NAP)

Ms Lori Adler
Dr. John F. Anderson
Ms Catherine Biggs
Dr. Aline Boulanger
Dr. Robert James Boyd
Dr. Norman Buckley
Dr. Peter Butt
Dr. Michel Cauchon
Dr. John Clark
Dr. John Collingwood
Ms Lynn Cooper
Dr. Ann Crabtree
Dr. Etienne de Medicis
Dr. Ted Findlay
Dr. Ian Forster
Dr. John Fraser
Dr. Brian Goldman
Dr. Allan Gordon
Dr. Neil Hagen
Dr. Lydia Hatcher
Dr. Phillipa Hawley
Dr. Howard Intrater
Dr. Margaret Jin
Dr. Roman Jovey
Dr. Milan Khara
Dr. Brian Knight
Dr. Jill Konkin
Mr. James Krempien
Dr. Roger Ladouceur
Dr. Andre Lalonde
Dr. Vernon Lappi
Dr. Lindy Lee
Dr. Joël Loiselle
Dr. Mary Lynch
Dr. David MacPherson
Dr. David Marsh
Dr. Gary Mazowita
Dr. Gordon McFadden
Dr. Patricia K. Morley-Forster
Dr. Murray Opdahl
Dr. R. Keith Phillips
Dr. Saifee Rashiq
Mr. Loren Regier
Dr. Toomas Sauks
Dr. Roger Shick
Dr. Chris Spanswick
Dr. Paul Taenzer
Dr. Eldon Tunks
Dr. Preston Zuliani

Table of Contents

NOTES:

- Throughout this document, *Canadian Guideline* (italicized) refers to "Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-cancer Pain."
- Numbering of Tables and Figures
  Tables and Figures are numbered to correspond with the associated section in Part A, and the associated recommendation in Part B, e.g.,
  - Table A-10.3 is located in Part A, section 10.3.
  - Table B-12.1 is located in Part B, under Recommendation 12.
- Acronyms used in Part A:
  CNCP = chronic non-cancer pain
  CPG = clinical practice guideline
  CPSO = College of Physicians and Surgeons of Ontario
  CPSA = College of Physicians & Surgeons of Alberta
  FMRAC = Federation of Medical Regulatory Authorities of Canada
  MRA = medical regulatory authority
  NAP = National Advisory Panel
  NOUGG = National Opioid Use Guideline Group
  RCT = randomized controlled trial.
- The complete reference list is located in Part B.

Executive Summary

Impetus for the *Canadian Guideline*

Canadian medical regulatory authorities undertook guideline development in response to:

1) physicians and other stakeholders seeking guidance regarding safe and effective use of opioids
2) a growing concern about opioid misuse creating patient and public safety issues, and
3) the lack of systematically developed national guidelines on opioid use for CNCP.

In November 2007, the **National Opioid Use Guideline Group** (NOUGG) formed under the umbrella of the Federation of Medical Regulatory Authorities of Canada (FMRAC) with support and/or representation from all provincial and territorial medical regulatory authorities (MRA). NOUGG's aim was to oversee the development and implementation of a guideline *to assist physicians in managing patients with CNCP by prescribing opioids in a safe and effective manner.* To achieve its aim, NOUGG established objectives:

1) develop a national guideline for safe and effective opioid use for CNCP that relies on the best available evidence and expert opinion consensus
2) develop and implement a knowledge-transfer strategy that ensures transition of the national guideline to practice as a useful decision-making tool for physicians who treat CNCP patients
3) evaluate the transfer of knowledge impact on practice
4) find a permanent home for the national guideline to ensure currency and ongoing transfer of evidence to practice
5) report on the project as a model for MRAs national collaboration.

NOUGG Principles

NOUGG's work in developing the "Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-cancer Pain" (*Canadian Guideline*) was shaped by the following principles and values.

- **Treatment of pain:** Patients deserve to have their chronic pain treated. Opioids can be a useful and appropriate treatment option. Harms associated with opioid use can be reduced when 1) drugs are prescribed and monitored with knowledge of the patient's history and risks, 2) patients understand potential benefits and harms and participate in reducing harms, and 3) clinicians assess outcomes for both effectiveness and harms.
- **Evidence**: Effective national guideline development requires rigorous methods to 1) search, appraise, and synthesize the best available evidence, and 2) create a national consensus of expert opinion to provide guidance where evidence is not available or insufficient.
- **Collaboration**: Collaboration among Canadian physician organizations and other key stakeholders is central to the development and implementation.
- **Autonomy**: The *Canadian Guideline* will be free from commercial bias from the pharmaceutical industry and any other commercial entities.
- **Clinician and Patient Input**: Practicing physicians from multiple disciplines, other healthcare providers, and patients all have defined roles in the formulation and ongoing evaluation.
- **Practice Improvement**: The *Canadian Guideline* is intended to educate/inform clinicians and to assist and guide practice decisions. Although MRAs oversaw the development, it is not intended for use as a standard of practice.
- **Implementation**: An implementation strategy will incorporate evidence-based principles of knowledge transfer and continuing professional development.
- **Practice Resources**: User-friendly resources, freely accessible to all, will enhance implementation to practice.

NOUGG Resources

NOUGG assembled key resources to meet its objectives.

A **Research Group** comprising a physician/epidemiologist, four physician-researchers, and a research librarian was responsible for the literature review, quality appraisal, evidence summary, and the first draft of recommendations. A **National Advisory Panel** (NAP) comprising 49 individuals was structured to reach consensus and advise on recommendations. Recruitment criteria included representation from across Canada, the target audience, other healthcare providers, patients with CNCP, clinical expertise, and academia. NAP used a Modified Delphi technique to reach consensus on recommendations for practice, and also provided open-ended narrative comment used in iterative revision.

The **National Faculty** comprising approximately 35 people (representing 9 provinces, 1 territory, and 8 national associations) held their inaugural meeting in June 2009 with a goal to guide and assist NOUGG with implementing the *Canadian Guideline* to practice.

NOUGG Outputs

In total, 6,580 studies were identified from the literature; from this search, 184 met inclusion criteria and were used to create 49 draft recommendations. The National Advisory Panel critically examined these 49 recommendations. With their direction, consensus was built to finalize 24 practice recommendations that were organized into five clusters:

1. Deciding to Initiate Opioid Therapy
2. Conducting an Opioid Trial
3. Monitoring Long-Term Opioid Therapy (LTOT)
4. Treating Specific Populations with LTOT
5. Managing Opioid Misuse and Addiction in CNCP Patients.

The *Canadian Guideline* includes tools intended to assist busy clinicians in decision making.

Throughout development, NOUGG engaged with various academics to find a permanent home for the *Canadian Guideline.* McMaster University's Michael G. DeGroote National Pain Centre assumed responsibility for keeping the *Canadian Guideline* current, working collaboratively with national partners and alerting clinicians to new evidence.

NOUGG's Message to Users

The number of patients with CNCP is significant and growing. Responsibility for care of these patients should rest with primary-care providers who use consultation/referral for specialized input selectively. With this in mind, the intent of the *Canadian Guideline* is to improve comfort and confidence in using opioids for CNCP among clinicians, particularly primary-care providers, while preserving patient and public safety. To achieve these ends, recommendations and practice tools are both supported by the best available evidence or expert opinion consensus, and also feasible in day-to-day practice.

Funding

All funding to support the development of the *Canadian Guideline* was provided by Canadian medical regulatory authorities and the Federation of Medical Regulatory Authorities of Canada. The Canadian Institute of Health Research (CIHR) provided a one-time grant to support two meetings of the National Faculty who are focused on implementation. The project received no funding from commercial organizations.

Part A: *Canadian Guideline* Background

1. Core Concepts

Many contributors engaged in developing the *Canadian Guideline*:

- Canadian medical regulatory authorities were responsible for the initiation and oversight.
- A Research Group searched, appraised, and synthesized the evidence into recommendations.
- A National Advisory Panel reviewed, critiqued, and reached consensus on the recommendations.
- A National Faculty continues to assist with building a plan for active implementation.
- McMaster University created the Michael G. DeGroote National Pain Centre that will assume responsibility for keeping the *Canadian Guideline* current, working collaboratively with national partners and alerting clinicians about new evidence.

Through the countless hours of research, writing, reviewing, revising, discussing, and debating that culminated in this *Canadian Guideline*, the notion of a common ground at times seemed elusive. Even though the landscape of chronic non-cancer pain management appeared to be characterized more by differences of opinion and divergent views than consensus, a common ground that contributors *do* share emerged from this collaborative process. It seemed a fitting beginning to describe the core concepts that represent contributor's values and beliefs:

1. Patients with chronic pain have a right to be treated.
2. Opioids can be an effective treatment for chronic non-cancer pain (CNCP) and should be considered.
3. Opioids are not indicated in all CNCP conditions, and medication alone is often insufficient to manage CNCP; other effective treatments should also be considered.
4. Opioid use does present risks and potential harms — prescribers and dispensers have an obligation to assess risks and minimize harms.
5. Not enough is known about the long-term benefits, risks, and side effects of opioid therapy; more research is needed in these areas.
6. Many clinicians can play a role in managing CNCP; patient care is improved with good communication and collaboration between clinicians across disciplines within primary care, and between primary care and specialty care.
7. Guidelines are necessary but not sufficient to change practice — guidelines need to be actively implemented to practice and supported with useful, easy-to-use tools.
8. Across Canada, systemic barriers exist that could reduce *Canadian Guideline* compliance. Implementation efforts should include raising awareness with multiple-system stakeholders about the role they can play in improving the effectiveness and safety of opioid prescribing.
9. Guidelines provide information and recommendations but are not to be considered training manuals. Some recommendations in the *Canadian Guideline* may require some clinicians to acquire specific knowledge and skills.
10. Overdose, addiction, and opioid diversion are problems associated with opioid use — striking a balance between effective treatment of chronic pain and preventing harms is a challenge.
11. Patients have an important role to play in ensuring opioids are used safely. Implementation should include education of patients and the general public about the potential benefits and harms of opioids and their role in using opioids safely and effectively.

2. Funding

All funding to support the development of the *Canadian Guideline* was provided by Canadian medical regulatory authorities and the Federation of Medical Regulatory Authorities of Canada. The Canadian Institute of Health Research (CIHR) provided a one-time grant to support two meetings of the National Faculty who are focused on implementation. The project received no funding from commercial organizations.

3. Scope

The *Canadian Guideline* is intended to assist physicians with decisions to initiate appropriate trials of opioid therapy for patients with chronic non-cancer pain, to monitor long-term opioid therapy, and to detect and respond appropriately to situations of opioid misuse including addiction. It was not designed to serve as a standard of care nor as a training manual.

The document addresses safe and effective prescribing of opioids for CNCP (defined as pain that persists for more than six months) in male and female adolescents and adults. The target audience is primary-care physicians and medical and surgical specialists who manage patients with CNCP. Pharmacists, nurses, and dentists may also find it useful. The scope does not include using opioids for acute pain and end-of-life pain, or CNCP treatment modalities and approaches other than opioids.

4. Limitations

The *Canadian Guideline* is constrained by the paucity of evidence to support most of the topics where recommendations for practice were considered necessary and relevant. This required a heavy reliance on the opinion and expertise of the National Advisory Panel to develop recommendations. The literature searches for observational studies used broad terms and might have missed relevant studies. Of the 184 studies used to support the recommendations, only 62 were randomized trials; the remaining were observational studies. Given that the quality of the observational studies was not formally assessed, the grading system of the Canadian Task Force on Preventive Health Care (CTFPHC) was adapted (Woolf 1990).

Another limitation of the published evidence was that functional outcomes studied were predominantly “activity of daily living” and “quality of life” — other important outcomes such as return to work, productivity, and cognitive impairment were rarely reported. Potential long-term complications of opioid use (hypogonadism, opioid-induced hyperalgesia, addiction) cannot be ruled out even if the recommendations are strictly followed.

It addresses only one modality for managing CNCP — opioid therapy, and it does not discuss or provide guidance about selecting other options.

An attempt was made to maintain national perspective but NAP pointed out numerous instances where recommendations were dependent on access to resources not available in all parts of Canada (e.g., access to pain or addiction specialists, multi-disciplinary pain management teams, prescription-monitoring databases).

In spite of its narrow focus, it is a lengthy and detailed document, and will need to be translated into feasible and practical tools for day-to-day use by busy practitioners. Screening tools, e.g., the Opioid Risk Tool, are only valid when the patient’s reporting is accurate.

Finally, the group overseeing guideline development (NOUGG) represents medical regulatory authorities, and this could create concern that the *Canadian Guideline* will be used as a standard of practice rather than for its intended purpose as advice to assist physicians.

5. *Canadian Guideline* Inception

In 2000, the College of Physicians and Surgeons of Ontario (CPSO) released "Evidence-based Recommendations for Medical Management of Chronic Non-Malignant Pain," which was accepted by the Ontario Guidelines Advisory Committee as its recommended guideline for chronic pain management. This document was completed by a CPSO-appointed task force of physicians with expertise in pain management. The topics included chronic headache, migraines, neuropathic pain, opioid management for chronic non-malignant pain, and chronic musculoskeletal pain. In 2007, the task force co-chairs recommended updating the 2000 guideline. It was agreed that completing a methodologically rigorous update of all the sub-topics in the 2000 guideline was beyond the resources and the scope of the College's mandate. However, CPSO agreed that one section, the use of opioids for chronic non-malignant pain, presented a pressing problem in practice and should be revised and further developed.

At the same time, other Canadian medical regulatory authorities (MRAs) were meeting to discuss issues of common interest and it became evident that Colleges across Canada shared the need to provide physicians with guidance on prescribing opioids for CNCP. In response, Canadian MRAs created the **National Opioid Use Guideline Group** (NOUGG) to oversee the development and implementation of a guideline for safe and effective opioid use for CNCP. NOUGG is a unique collaboration of MRAs with the active support and/or representation from **all provincial Colleges, Yukon Medical Council**, **Government of Nunavut,** and the **Federation of Medical Regulatory Authorities of Canada** (FMRAC). See Appendix A-1 for NOUGG members.

NOUGG's primary aim was *to assist physicians in managing patients with CNCP by prescribing opioids in a safe and effective manner.* Three key goals were to:

- facilitate development of a national evidence-based guideline
- implement the guideline to clinical practice, and
- find a permanent home for the guideline to ensure the evidence remains current and useful.

From the outset, NOUGG grappled with the notion that creating clinical practice guidelines (CPG) is a task traditionally, and probably best, left to researchers, academics, and clinicians. MRAs do, however, have a central mandate to regulate the practice of medicine in the pubic interest that includes a responsibility to provide guidance and contribute to ensuring the quality of practice.

At its annual June 2008 meeting, FMRAC discussed the regulators' role in creating CPGs, citing NOUGG's work as a case in point. It was reasoned that, ideally, CPGs are created by clinical/research groups, but the topic of opioid prescribing met the requisites of a "special case," in that:

- No academic body can be clearly identified to take responsibility.
- The topic extends beyond clinical care into other areas, e.g., criminality, professional conduct.
- Societal impacts are significant.
- MRAs have a unique role to play in implementation.
- Membership or other stakeholders are requesting MRAs participation.

With the FMRAC meeting confirmation, NOUGG's work began. Two NOUGG co-chairs convened monthly meetings to facilitate and oversee the development and implementation.

6. Players Involved in Development

Three groups were involved in developing the *Canadian Guideline*: National Opioid Use Guideline Group (NOUGG), Research Group, and National Advisory Panel (NAP).

6.1 National Opioid Use Guideline Group

NOUGG is a task-specific group convened with the assistance and support of FMRAC. It was formed in November 2007 with support and/or representation from all provincial medical regulatory authorities and subsequently the Medical Council of Yukon and the Government of Nunavut. NOUGG's role was to oversee the development and implementation of a guideline. The regulatory bodies and FMRAC appointed the Group members, and two co-chairs were selected. FMRAC provided funding over a 12-month period to support work of the two co-chairs. For NOUGG members, see Appendix A-1.

6.2 Research Group

The Research group comprised six members: a physician/epidemiologist, four physician-researchers, and a research librarian. It was responsible for the literature review, quality appraisal, evidence summary, and the first draft of recommendations for practice. Two physician-researchers were previous members of the CPSO task force responsible for the predecessor guideline, "Evidence-based Recommendations for Medical Management of Chronic Non-Malignant Pain." The physician/epidemiologist, research librarian, and one physician-researcher were secured from the Institute for Work & Health, which has a systematic review program of research that includes the Cochrane Back Review Group. NOUGG approached IWH, and they agreed to contribute their expertise to oversee the systematic review process from literature search to data extraction. See Appendix A-2 for Research Group members and for information on the Institute for Work & Health.

6.3 National Advisory Panel

NAP is a group of 49 individuals from across Canada who were invited in September 2008 to participate in the *Canadian Guideline* development. They were identified by NOUGG members, using common selection criteria to ensure the group included a wide cross-section of medical expertise, patient perspectives, other healthcare providers, and geographic representation. NAP's role was to review draft materials prepared by the Research Group and, using a Modified Delphi technique, reach consensus on recommendations for practice. In addition, NAP members provided extensive narrative comment that was organized by theme and used in iterative revision. See Section A-11 for a more detailed explanation of NAP and Appendix A-3 for members.

7. Epidemiology of Chronic Non-cancer Pain (CNCP)

CNCP is a major problem in modern society. The negative effects on quality of life and productivity have an immense social and economic impact.

Chronic pain in persons older than 65 years of age is a significant problem for Canada. A recently published study (Ramage-Morin 2009) used data from 1) the Health Institutions and Household components of the "National Population Health Survey" (NPHS; Statistics Canada 1994/1995 through 2002/2003) and 2) the 2005 "Canadian Community Health Survey" (CCHS). Thirty-eight percent of institutionalized seniors experienced pain on a regular basis, compared with 27% of seniors living in households. In both populations, rates were higher for women than men. Given the fact that Canada's population is aging, chronic pain promises to become an even larger problem in the near future.

Osteoarthritis affects 3 million (1 in 10) Canadians. It affects men and women in equal numbers. Most people develop osteoarthritis after the age of 45, but it can occur at any age (www.arthritis.ca).

The Canadian Pain Society (CPS) has suggested that up to 1 million Canadians live with neuropathic pain (Moulin 2007). This is based on an estimate of the prevalence of 8.2% chronic neuropathic pain in the general population (Torrance 2006).

The "Canadian Chronic Pain Study II" (CCPS-II) was set to study the prevalence of chronic pain by conducting a general population computer-assisted telephone interview. The response rate was only 20%, and they found the prevalence of chronic pain to be 25% of the respondents (Boulanger 2007). In comparison with the CCPS-I, the prevalence of chronic pain was 29% in 2001.

Low-back pain is among the most common causes of CNCP, and there are no studies conducted in Canada to examine its prevalence. A recent national survey conducted in the United States showed that 15% reported "back pain on most days for at least one month in the past year" (Ricci 2006).

In a United Kingdom study, 46.5% of the general population reported chronic pain; low-back problems and arthritis were the leading causes (Elliott 1999).

A recent epidemiological study in Denmark found that CNCP had a prevalence of 19%, and 12% of those who had CNCP (corresponding to 130,000 adults or 3% of Denmark's population) used opioid medications regularly (Eriksen 2004).

It is reasonable to conclude that CNCP affects substantial and growing numbers of the Canadian population. Not all treatment approaches have been well studied, but opioids are a modality that has been shown to be effective in reducing intensity of pain in many of these chronic pain conditions.

8. Need for a Guideline on Opioid Use and for CNCP

Canadian medical regulatory authorities undertook guideline development in response to:

1) physicians and other stakeholders seeking guidance regarding safe and effective use of opioids
2) a growing concern about opioid misuse creating patient and public safety issues, and
3) the lack of systematically developed national guidelines on opioid use for CNCP.

8.1 Need for Guidance regarding Safe and Effective Opioid Use

Medical regulators, through various interactions with physician members and other stakeholders, recognized a growing need for guidance on opioid use for CNCP. The College of Physicians and Surgeons of Ontario, in 2007, completed an environmental scan to better understand needs in the area of chronic pain treatment — and their findings resonated with regulators across Canada. The environmental scan gathered information through multiple methods — surveys, key informant interviews, and focus groups:

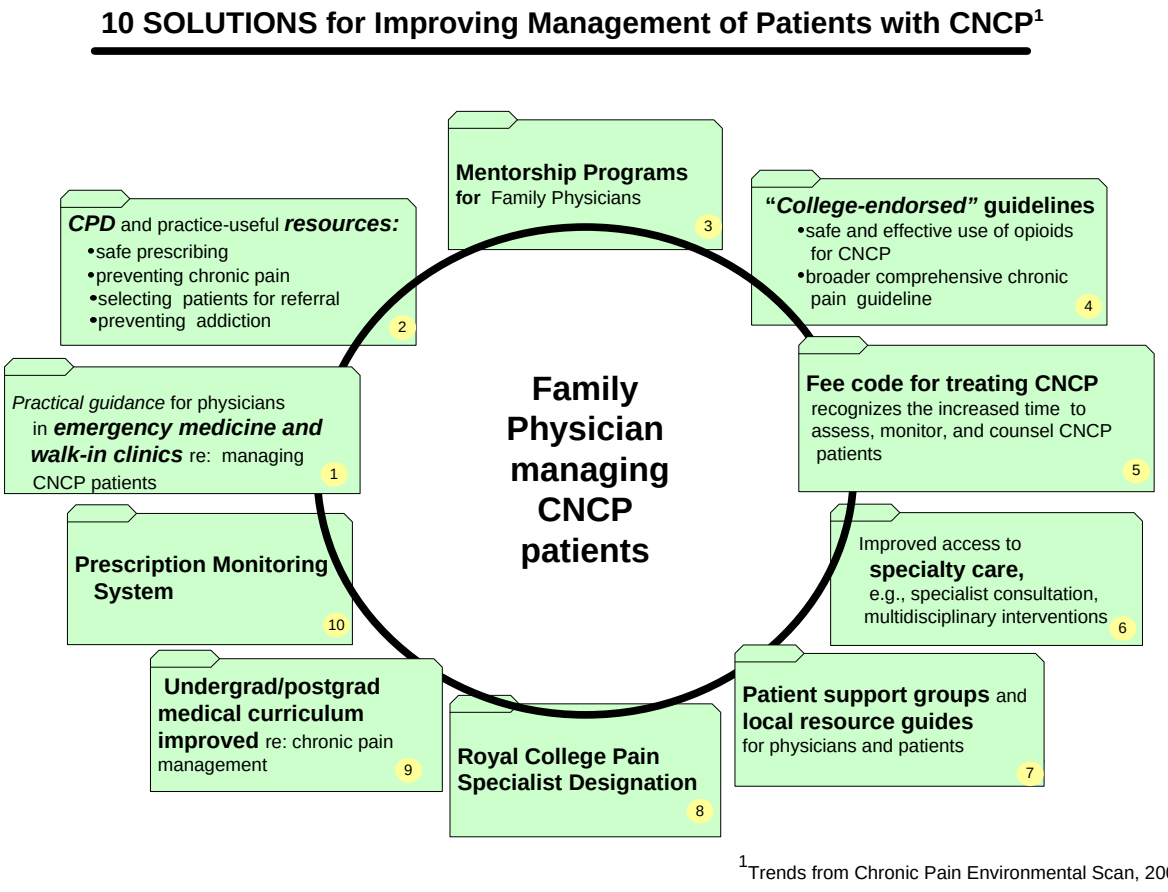
1) key informant interviews with three teams of chronic-pain researchers (Ontario, Alberta, and international)
2) key informant interviews with medical professional practice leaders in pain and addiction
3) focus groups with two multidisciplinary chronic pain treatment teams
4) focus groups with nurses and pharmacists
5) consumer consultation using two focus groups and one-on-one interviews:
   - focus group 1: self-identified chronic-pain sufferers recruited at a public information session
   - focus group 2: consumer-support group for chronic-pain sufferers
   - one-on-one interviews: chronic-pain sufferers recruited from an inner-city pain clinic
6) survey of a network of approximately 175 family physicians identified by peers as "educationally influential"
7) survey of approximately 50 physicians who work with CPSO in the quality management division, completing peer-assessments with family practitioners.

Results for each data-gathering method were qualitatively analyzed for trends. These trends were organized into a model that depicts the potential solutions that should result in an ideal system for CNCP management (see Figure A-8.1). The most common input from physicians centered on the need for guidance about prescribing opioids safely. Physicians expressed their fears and uncertainty in light of "mixed messages from educators, pain specialists, and the College" and highlighted the need for clear, evidence-based practice guidance to assist with managing chronic-pain patients without fear of exposing themselves or their patients to unnecessary risk.

More recently, Wenghofer et al. completed a random survey of 658 primary-care physicians in Ontario. This study found:

- only 44% of physicians reported opioid prescribing to be satisfying
- 57% agreed that "many patients become addicted to opioids"
- 58% had at least one patient with an opioid-related adverse event in the past year, and
- another 58% had concerns about the opioid use of one or more patients (Wenghofer 2009 in press).

Figure A-8.1 10 Solutions to Improving Management of CNCP



[1]Trends from Chronic Pain Environmental Scan, 2007

CPD = continuing professional development.

8.2. Concerns regarding Patient and Public Safety Risks from Opioid Misuse

Medical regulators and others are concerned about 1) patient and public safety regarding opioid misuse and 2) disturbing prescribing trends emerging in the past decade in Canada.

Canada's recorded prescription-opioid consumption increased by about 50% between 2000 and 2004 (International Narcotics Control Board 2006); the rate of increase for this period is greater than that of the United States. Canada is currently the world's third-largest opioid analgesic consumer per capita (overall consumption includes use of opioids for acute and palliative pain) (International Narcotics Control Board 2009). In Ontario, oxycodone prescriptions rose by 850% from 1991 to 2007, from 23 prescriptions/1000 individuals per year to 197/1000 per year, and the average amount per prescription of long-acting oxycodone increased from 1830 mg to 2280 mg (Dhalla 2009). In other words, more patients are receiving opioids in larger quantities.

The increase in opioid prescribing has been accompanied by simultaneous increases in abuse, serious injuries, and overdose deaths among individuals taking these drugs (Kuehn 2007). From 1991 to 2004 in Ontario, the mortality rate due to unintentional opioid overdose increased from 13.7/million to 27.2/million/year, more than double the mortality rate from HIV (12/million) (Dhalla 2009). Studies have documented a major increase in prescription-opioid misuse and addiction throughout North America. For example, a prospective Canadian study found that illicit opioid users are more likely to use prescription opioids than heroin (Fischer 2006).

It has been argued that legitimate prescribers bear little direct responsibility for this, because overdose deaths and addiction arise primarily from drug diversion. However, a recent study (Dhalla 2009) showed that of 1095 overdose deaths in Ontario, 56% of patients had been given an opioid prescription within four weeks before death. In a study of opioid-dependent patients admitted to the Centre for Addiction and Mental Health in Toronto, 37% received their opioid from physician prescriptions, 26% from both a prescription and "the street," and only 21% entirely from the street (Sproule 2009). A United States national study found that, of 1408 patients entering treatment of opioid abuse, 79% of male and 85% of female patients were first exposed to opioids through a prescription to treat pain (Cicero 2008). Furthermore, the total amount of diverted opioids is directly related to the total amount of prescribed opioids (Dasgupta 2006).

8.3 Lack of a Systematically Developed National Guideline on Opioids and CNCP

Although consensus statements existed and other jurisdictions had published guidelines on chronic pain management and opioid use, no single Canadian guideline existed that used a combination of 1) systematic methods for searching and appraising the literature and 2) a consensus process that included clinicians from multiple disciplines and specialties along with patients.

9. Implementation to Practice

From its inception, NOUGG viewed developing the guideline as only the first step, and articulated an additional goal: *Develop and implement a knowledge transfer strategy that ensures the guideline moves into practice as a useful decision-making tool for physicians treating patients with chronic non-cancer pain.*

An effective implementation plan would ensure that clinicians can easily apply the recommendations in demanding day-to-day practice environments. NOUGG created the National Faculty to guide and assist with moving the recommendations to practice. Individuals were selected from across the country, based on matching one or more of the following criteria:

- involvement in physician, inter-professional or patient education
- focus/interest in the topic of chronic pain and opioid use for CNCP
- contribution of relevant materials, teaching resources, or expertise (e.g., continuing professional development, knowledge transfer, guideline implementation)
- connection to some knowledge-to-practice infrastructure, and
- *Canadian Guideline* "ambassador" potential.

At the June 2009 inaugural meeting[1], participants (representing 9 provinces, 1 territory, and 8 national associations) agreed on a set of goals:

1) define **targeted outcomes for implementation** to promote safe and effective use of opioids for CNCP
2) develop an **implementation strategy** considering multiple audiences
3) contribute to creating a **funding plan** for implementing to practice, and
4) define **strategies to evaluate impact** of the *Canadian Guideline.*

The Michael G. DeGroote National Pain Centre (along with ongoing responsibility for the *Canadian Guideline*) will coordinate continuing activities initiated by the National Faculty to ensure the *Canadian Guideline* improves practice and patient outcomes.

10. Literature Search Methods

Development of this *Canadian Guideline* relied on the 2006 meta-analysis by Furlan et al. "Opioids for chronic non-cancer pain: a meta-analysis of effectiveness and side effects" (Furlan 2006). In addition, three new literature searches were completed:

- **Search One:** Search for randomized controlled trials (RCT) published since May 2006 to update the Furlan meta-analysis.
- **Search Two:** Search for additional literature (multiple designs) that answered questions about the treatment of CNCP with opioids and managing the patient with problematic opioid use.
- **Search Three:** Search for additional literature (multiple designs) that answered questions about long-term outcomes of opioid use.

[1] Sponsored by Canadian Institute of Health Research (CIHR).

10.1 Description of Literature Search One

For details of the original Furlan meta-analysis search (Furlan 2006), see http://www.cmaj.ca/cgi/data/174/11/1589/DC1/1 and http://www.cmaj.ca/cgi/data/174/11/1589/DC1/10

The following bibliographic data sources were used to update the review to July 2009:

- *Cochrane Central Register of Controlled Trials* (CENTRAL) 2009
- MEDLINE (OVID) from 2005 to July 2009 (same strategy as the 2006 review)
- EMBASE from 2005 to July 2009 (same strategy as the 2006 review)
- reference lists of retrieved articles
- **a**rticles forwarded by the National Advisory Panel.

Search strategies for MEDLINE and EMBASE are available (see Appendix A-4 Literature Search Strategies). A research librarian ran the electronic searches and coordinated the data entry into Reference Manager® 11, removing all duplicates.

10.1.1 Relevance Screening for Search One

Three CPSO research associates independently reviewed the titles and abstracts using the following criteria: 1) not a letter, editorial or short commentary (usually less than three pages in length); 2) focus of the article is not dealing with surgical pain, 3) article is not dealing with cancer pain, 4) population studied had chronic non-cancer pain, and 5) focus is on opioids. Studies that passed the relevance screen were forwarded to the Research Group for inclusion/exclusion criteria screening.

10.1.2 Inclusion/Exclusion Screening for Search One

Text of full articles was obtained for studies that passed the relevance screening. Two Research Group members independently reviewed these studies and applied inclusion/exclusion criteria as follows:

1. *Study characteristics:* Included RCTs published in English, French, Portuguese, or Spanish (languages that could be read by Research Group members). Excluded studies published only as abstracts.
2. *Study population:* Included adults (>18 years) with CNCP (defined as pain that persists for more than six months) including neuropathic pain, osteoarthritis, rheumatoid arthritis, fibromyalgia, and back and musculoskeletal pain. Excluded migraines, dental pain, ischemic pain due to vascular disease and abdominal pains (e.g., chronic pancreatitis, kidney stones) because these conditions are not usually classified as CNCP.
3. *Types of intervention:* Included any opioid administered by oral, transdermal, transmucosal or rectal route for seven days or more. Opioids were classified as weak (propoxyphene, codeine, tramadol, hydrocodone) or strong (oxycodone, morphine, fentanyl, hydromorphone or buprenorphine). Excluded methadone.
4. *Types of comparison group:* Included placebo or other analgesics. Excluded comparisons of different opioids.
5. *Outcomes*: Quantifying pain (intensity or relief), function, and side effects.

For Search One, two reviewers reviewed selected titles, abstracts, and full texts and determined the articles for inclusion. If consensus could not be achieved, a third reviewer was consulted. On some occasions, authors of the randomized trials were contacted to obtain more details that were not reported in the publication.

10.1.3 Methodological Quality Screen for Search One

The same two Research Group members completed an independent appraisal of methodological quality on studies admitted after inclusion/exclusion screening. Where needed, they reached consensus through discussion. Reviewers were not blinded with respect to authors, institution and journal because they were familiar with the literature. In cases of disagreement, a third reviewer was consulted. Each study was scored from 0 to 5 with the instrument developed by Jadad and colleagues (Jadad 1996). The instrument includes three questions about randomization methods, double-blinding, and number of withdrawals. Studies scoring 3, 4, or 5 were considered to be of high quality; scoring 0, 1, or 2, of low quality. Study scores were recorded in a Microsoft Excel® spreadsheet (see Appendix B-13, Part B).

10.1.4 Data extraction and synthesis for Search One

Research Group members extracted the data from the high quality studies using Microsoft Excel®. Meta-analyses and meta-regression were conducted using Comprehensive Meta-Analysis© software, with calculations of effect sizes for pain relief and functional outcomes.

Effect Size: Cohen's three levels (Cohen 1988) were used and adapted to a scale developed by the Cochrane Back Review Group (Furlan 2009):

- Small = ES <0.5 = Mean difference less than 10% of the scale (e.g., <10mm on a 100mm visual analog scale).
- Medium = ES from 0.5 to <0.8 = Mean difference 10 to 20% of the scale.
- Large = ES ≥0.8 = Mean difference >20% of the scale.

For side effects, all meta-analyses were done using RevMan 5[2] using risk differences. Statistical heterogeneity was tested by Q test (chi-square) reported as I^2 (higher values indicate higher heterogeneity).

All meta-analyses were conducted using a random effects model. Sub-groups were decided *a priori* to assess the variations in effect sizes. Clinical significance of side effects was considered when the incidence was 10% or higher in the opioid or reference group.

10.2 Description of Literature Search Two and Search Three

Search Two was conducted to find articles that could be useful in drafting the recommendations on the treatment of CNCP with opioids and managing the patient with problematic opioid use. Search Three was conducted to understand the effects of prolonged opioid use. These searches were not limited to RCTs. (See Appendix A-5 Flowchart of Literature Review Process and Appendix A-4: Literature Search Strategies.)

The following bibliographic data sources were used:

- *Cochrane Central Register of Controlled Trials* (CENTRAL) 2009
- MEDLINE (OVID) from 1950 to July 2009
- EMBASE from 1982 to July 2009
- reference lists of retrieved articles
- articles forwarded by the National Advisory Panel.

[2] Review Manager (RevMan) [Computer program]. Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008.

10.2.1 Relevance Screen for Search Two and Search Three

A CPSO research associate independently reviewed the titles and abstracts using the following criteria: 1) not a letter, editorial or short commentary (usually less than three pages in length), 2) population studied has chronic non-cancer pain, 3) focus on opioids, and 4) focus on addiction.

10.2.2 Inclusion/Exclusion Screen for Search Two and Search Three

From the titles and abstracts that passed the relevance screen, text of full articles was obtained, and two out of four Research Group members applied inclusion criteria:

1. *Study characteristics:* Included any study design with primary data collection, conducted in humans, with no language restriction. Studies could be experimental (e.g., clinical trials), observational (e.g., cohort, case-control, cross-sectional) or descriptive (e.g., before-and-after, case series, case reports). Studies published in a language other than English were judged for inclusion/exclusion, based on the English abstract.
2. *Study population:* Included adults (>18 years) with CNCP (defined as pain that persists for more than six months) including neuropathic pain, osteoarthritis, rheumatoid arthritis, fibromyalgia, and back and musculoskeletal pain. Excluded acute pain, post-surgical pain, or experimental pain in healthy volunteers. In some circumstances, a study in a population with cancer pain could be included if information could be extrapolated to non-cancer pain.
3. *Types of intervention:* Included any opioid administered by oral, transdermal, transmucosal or rectal route for pain for seven days or more. Studies of methadone were included.
4. *Useful Topics:* Included topics deemed to be of value in drafting the recommendations on the treatment of CNCP with opioids and managing the patient with problematic opioid use:
   - dose of opioids to achieve maximum benefits with minimum adverse events
   - urine drug screening
   - initiation, titration and tapering of opioids
   - assessments and monitoring during treatment with opioids
   - frequency of follow-up
   - identification of patients at risk for medical complications, overdose, misuse or addiction
   - recommendations for practice regarding screening, management, follow-up
   - approaches to dealing with conflicts with patients
   - treating chronic pain patients in acute care settings
   - mechanisms to prevent prescription fraud
   - use of opioids and driving
   - identifying patients at risk of opioid addiction
   - managing an opioid addicted patient with chronic pain
   - tapering and stopping opioids or other drugs, e.g., benzodiazepines
   - dealing with challenging or threatening patients
   - long-term outcomes of opioid use.

For Searches Two and Three, four reviewers worked in pairs to select articles for inclusion. When in doubt, a third reviewer from the other pair was consulted.

10.2.3 Additional Strategies for Search Two and Search Three

All included and excluded studies from Search One were also evaluated by two reviewers against the list of useful topics developed for inclusion of studies in the Searches Two and Three.

10.2.4. Methodological Quality Screen for Searches Two and Three

Observational studies were not assessed for methodological quality due to lack of resources to fund experts in epidemiological methods necessary to complete the more complex and subjective review required.

10.3 Using Extracted Evidence to Develop Recommendations for Practice

10.3.1. Recommendation Development Process

The Research Group provided methodological and clinical expertise in the area of chronic pain and addiction medicine. They summarized evidence from the studies and drafted 49 initial recommendations that each included a discussion and related evidence. An iterative course of action ensued, using a Modified Delphi technique with the National Advisory Panel (NAP), to produce final recommendations. NAP member identities were blind to the Research Group and each other until the last round of review.

NAP received material via email and responded using an on-line survey tool to rate their opinion on relevance, feasibility, clarity, and their degree of agreement with each recommendation. They also provided open-ended narrative comments.

Consensus was defined as 80% of NAP members supporting a recommendation. Recommendations that did not receive this level of consensus were revised using feedback provided by NAP and re-rated in the next round. With each round of review, each NAP member received a complete transcript of all written comments made by NAP in the previous round.

While participation rates declined as the Modified Delphi progressed, the portion of NAP members involved remained high throughout, as summarized in Table A-10.3.1. A drop in the last two rounds could have been due to Panel fatigue, or related to the H1N1 pandemic occurring in Canada at the time. Consensus on recommendations resulted after four rounds of electronic review and rating, culminating with a final telephone and web-assisted meeting.

Table A-10.3.1 National Advisory Panel Participation in Modified Delphi Process

Round	Number of Recommendations Under Review	Panelists Participating
1	49	84%
2	20	80%
3	4	65%
4	2	60%

10.3.2 Recommendation Grading

The evidence-grading system was adapted from the Canadian Task Force on Preventive Health Care (CTFPHC) (Woolf 1990); see Table A-10.3.2. A single recommendation statement can be supported by one, two, or three different grades of evidence.

Each recommendation includes a key word, recommendation statement, discussion, and evidence summary. References may be provided in both the discussion and evidence summary. There are two types of references used: those that 1) provide direct or indirect support for the recommendation statement and 2) provide contextual information.

If a reference supported ***directly***, the recommendation statement was graded consistent with the study design of that reference, i.e., "A" or "B." (See Table A-10.3.2)
If a reference supported ***indirectly***, the recommendation statement was graded to reflect the primary source driving the recommendation.

- Example 1: a RCT informed the recommendation but the recommendation is graded "B" or "C" (rather than "A") — this is because the recommendation statement is not directly extracted from the main hypothesis of the RCT.
- Example 2: references are graded "B" in the evidence summary, but the recommendation statement is graded "C" — this is because expert opinion from NAP was the predominant driver of the recommendation statement, even though some of the recommendation's concepts were backed by the studies mentioned in the evidence summary.
- Example 3: a reference conflicts with the recommendation, and the recommendation statement is graded "C" — this reflects NAP expert opinion assessing the evidence as weak or not generalizable.

Table A-10.3.2 Recommendation Grading

CTFPHC Evidence Grading System*	***Canadian Guideline* Recommendation Grading**
I. –Evidence from RCTs	**Grade A**: Recommendations are supported by evidence from RCT(s).
II – 1 Evidence from controlled trial(s) without randomization. II – 2 Evidence from cohort or case-control analytic studies, preferably from more than one centre or research group. II – 3 Evidence from comparisons between times or places with or without the intervention; dramatic results from uncontrolled studies could be included here.	**Grade B**: Recommendations are supported by: • Evidence from controlled trial(s) without randomization, or, • Evidence from cohort or case-control analytic studies, preferably from more than one centre or research group, or • Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could be included here.
III – Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees.	**Grade C**: Recommendations are supported by consensus opinion of the National Advisory Panel.

*(Woolf 1990).

11. National Advisory Panel (NAP) Consultation

11.1 Need for the National Advisory Panel

The available evidence on safe and effective use of opioids for managing CNCP was necessary but not sufficient to create practical clinical guidance. Clinical expertise was also required. In response to this need, NOUGG created a process to capture expert opinion through consultation with a variety of experts and stakeholders. NOUGG's intent was to create a well-balanced advisory panel so that multiple perspectives and experience were included in feedback for the developing guideline. Participation and selection requirements included:

- Representation from:
  - —across Canada
  - —the target audience (family physicians and other physicians who manage CNCP)
  - —other healthcare providers who work with physicians in using opioids to manage CNCP (e.g., pharmacists, nurses, psychologists)
  - —patients with CNCP.
- Specific relevant expertise: clinical focus in pain and/or addictions, research, or teaching in pain and/or addictions.

11.2 Establishing NAP

MRAs participating in NOUGG invited potential participants from their jurisdiction (see Appendix A-6 for selection criteria).The College of Physicians & Surgeons of Alberta (CPSA), on behalf of NOUGG, coordinated NAP activities. A total of 49 individuals agreed to participate on the Panel. All NAP members returned a signed conflict of interest disclosure to CPSA. (See Appendix A-7 for a copy of the form, and Appendix A-3 for NAP members and their declared competing interests.)

11.3 NAP Consultation Process

Throughout the initiative, NOUGG's process for NAP consultation was transparent. Before the consultation started, all NAP members received background information describing the NOUGG initiative, the rationale for MRA's involvement, the approach for guideline development, the role of the panel, and NOUGG's intent to pursue implementation strategies that included knowledge transfer and evaluation.

For the consultation process details, see Table A-11.3.

Table A-11.3 NAP Consultation Tasks and Outcomes

	Material Provided to NAP	NAP Task	Outcomes
First Consultation Oct 2008	Background, methods, evidence summary from RCTs and references.	Task: Respond to the following questions: 1) What questions do you have after reviewing the enclosed document with background and context for the draft guideline? 2) What clarifications would be helpful in the document? 3) Are there any references missing that should have been considered for Section A of G*uideline*?	75% of Panel members (37 individuals) responded. •Constructive comments on how to improve description of methods. •Suggestions of other relevant literature. •CPSA summarized all NAP feedback for submission to the Research Group (Note: NAP responders not identified).
Modified Delphi Round 1 Mar "09	49 draft practice recommendations with discussion notes and evidence summaries.	Modified Delphi Process used; see Appendix A-8. Task: using an electronic survey tool: 1) rate opinion on clarity, feasibility and agreement for each of 49 recommendations (See Appendix A-9 for detail) 2) provide narrative feedback.	84% of Panel members (41 individuals) responded. •**29/49** recommendations supported by consensus. •**20/49** recommendations unsupported. •Qualitative analysis of narrative feedback organized into specific themes and used to revise unsupported recommendations.
Modified Delphi R2 R3 June 2009	•Individual responses and NAP aggregate response from Round 1. •For each of the 21[3] revised recommendations: -original recommendation -revised recommendation -NAP feedback from Round 1, organized into themes.	Task: using an electronic survey tool: 1) rate opinion on clarity, feasibility and agreement for 21 revised recommendations 2) provide narrative feedback.	80% of Panel members (40[4] individuals) responded. •**9/21** recommendations supported by consensus. •**12/21** recommendations unsupported. •Three grade C-only recommendations eliminated. •Narrative feedback organized in themes and used to revise (some merged) unsupported recommendations for NAP Modified Delphi Round 3.
Modified Delphi R3 Nov 2009	•Substantively revised G*uideline* including: -20 supported recommendations -4 recommendations that required voting •NAP feedback from Round 2, organized into themes.	Task: using an electronic survey tool: 1) rate opinion on clarity, feasibility and agreement for 4 revised recommendations 2) provide narrative feedback.	65% of Panel members (32 individuals) responded. •**2/4** recommendations supported by consensus. •**2/4** recommendations unsupported. •Narrative feedback organized in themes and used to revise 2 unsupported recommendations for NAP Modified Delphi Round 4.
Modified Delphi R4 Dec 2009	•2 recommendations that required voting •NAP feedback from Round 2, organized into themes.	Task: •Participate in a real time virtual meeting to address topics/issues identified by NAP members. •Agree on core concepts for Guideline. •Final 2 recommendations approved.	60% of Panel members (29 individuals) responded. •2/**2** recommendations supported by consensus.

[3] One of the 20 unsupported recommendations from previous round had been split into 2 recommendations.
[4] Includes one partially completed response.

11.4 Overview: Revising with NAP Input

NAP input included quantitative and qualitative data.

- Quantitative data, i.e., the scoring of degree of support for a given recommendation, was used to identify recommendations targeted for revision.
- Qualitative data, i.e., narrative comment from NAP members, guided the evolution of the recommendations at both macro and micro levels. At the macro level, dominant themes in NAP feedback influenced revisions. See Table A-11.4 for a summary of themes and resulting modifications.

11.4.1 NAP Feedback at the Macro Level

Table A-11.4 NAP-Response Dominant Themes and Modifications

No.	Dominant Theme	*Canadian Guideline* Modification
1	Background/Methods section too long; methods section confusing, grading system not clear.	•Part A streamlined; Methods section revised with more detailed information moved to Appendix. •Grading system and insertion of grades in recommendation statements clarified.
2	*Guideline* lacks a clear opening, stating purpose and fundamental position on opioids and pain.	• Executive summary written.
3	*Guideline* too long; too many recommendations: redundancy and overlap.	•49 recommendations reduced to 24. • 8 clusters reduced to 5.
4	*Guideline* too "universal," i.e., too often directed physicians toward actions that "should" or "must" always be followed: • this creates an unnecessary burden, especially on family physicians, making them even **less likely** to use opioids for CNCP – this runs contrary to *Guideline* goal of increasing prescriber comfort and confidence in using opioids for this population •in some cases the "universal" approach assumed access to resources inaccessible across the country.	•Recommendations modified to provide latitude for prescriber judgment. •More "how to" guidance provided without the indication of "must" or "should", e.g., urine drug screening, use of screening tools, use if treatment agreements, seeking consultation, selecting opioids.
5	*Guideline* too "addiction-focused;" concern that it included recommendations more appropriate in an addiction guideline than a CNCP guideline.	•More focus on preventing misuse and screening for risk. •Addiction management recommendations merged into a single recommendation that provides information about treatment options (see Recommendation 21, Part B).
6	•Confusing and inappropriate use of terminology, e.g., dependence and addiction. •Glossary and appendices need greater clarity.	•Terms clarified and used consistently. •Glossary clarified with the majority of definitions referenced. •Appendices culled. •Professional editor engaged.

11.4.2 NAP Feedback at the Micro Level

Panelist's comments were organized into themes, preserving the comments in their entirety. Strong themes were incorporated into recommendation revisions, and individual suggestions were used where possible to add useful detail and clarity.

In a few cases, the Panel's comments were polarized. This was observed most often where there was a lack of evidence and the recommendation was advocating a specific approach. Modifications were made in these cases to reflect the range of clinical opinion. This is illustrated in the urine drug screening recommendation (Recommendation 3) that carries forward the opposing views and provides the prescriber with decision-making options.

12. Updating

The Michael G. DeGroote National Pain Centre at McMaster University accepted responsibility for stewardship of the *Canadian Guideline*. This will include updating as new evidence becomes available and continuing knowledge transfer to practice. The mission of the Centre also includes further updating and development of guidelines for the treatment of CNCP, including a wide range of treatment modalities. McMaster will foster collaboration and partnerships for knowledge transfer and exchange, building on the partnerships and networks established by NOUGG.

13. Comparison with Other Guidelines

There are numerous other clinical practice guidelines that address the management of CNCP with opioids. In preparation for developing the *Canadian Guideline*, searches in MEDLINE and www.guideline.gov up to February 2009 were conducted with 15 relevant guidelines selected for a detailed evaluation. This evaluation determined that most guidelines were either focused on a specific health problem (fibromyalgia, neuropathic pain, osteoarthritis, low-back pain) or were out-of-date.

Three current guidelines are similar to the *Canadian Guideline* in terms of scope, population, development, sponsorship, recommendations, and presentation.

When work began on the *Canadian Guideline*, only one of these was published — the American Society of the Interventional Pain Physicians guideline, originally published in 2006 (Trescot 2006) and updated in 2008 (Trescot 2008): however, the target audience was interventional pain specialists.

In 2009, when the *Canadian Guideline* development was well underway, two other similar guidelines were published. The guideline of the American Pain Society/American Academy of Pain Medicine (Chou 2009) has additional recommendations not included in the *Canadian Guideline*: treatment of breakthrough pain, management of side effects, selection of short-acting versus long-acting preparations, special issues with methadone, and awareness of state laws. The Utah Department of Health guideline (Utah Department of Health 2009) is in fact a compilation of recommendations from six other guidelines on the management of CNCP with opioids. There are no major discrepancies between the Utah and the *Canadian Guideline*.

14. Topics for Future Research

Questions remain that cannot be confidently answered by the currently published randomized trials and that require appropriately designed studies of long-term opioid use for CNCP. Topics include:

1. Alternative routes of administration: There is a need for more information on efficacy and risk/benefits of intramuscular, subcutaneous, transdermal, rectal, and infusion routes of administration of opioids for CNCP.
2. Opioids compared with non-opioid drugs: There is a need for well-designed equivalence and non-inferiority trials to assess the relative effectiveness and risk-to-benefit ratios of opioids compared with non-opioid drugs.
3. Various clinical diagnoses: Most of the RCTs on opioids for CNCP have concerned musculoskeletal pain and neuropathic pain. There is limited literature on treating fibromyalgia pain and chronic headache with opioids other than tramadol, and no useful literature on opioids for chronic visceral pain.
4. Long-term follow-up: CNCP is a long-term disorder, but the RCTs included in the current systematic review had fairly short follow-up periods, e.g., six weeks. Well-designed long-term studies are needed to clarify: a) the proportion of CNCP patients for whom opioids remain effective over months or years, and b) the potential over extended timeframes for developing opioid tolerance; hyperalgesia; loss of efficacy; complications such as hypogonadism, sexual dysfunction, or central sleep apnea; or probability of developing opioid misuse.
5. Assessment of opioid misuse: There is a need for more well-designed trials of sufficient duration, with appropriate measures to identify prevalence and risks of opioid-related problems such as addiction.
6. Populations with co-morbidities: There is a need for more trials dealing with safe and appropriate management of chronic pain where there is significant co-morbidity, e.g., pain in the elderly or psychiatric co-morbidity.
7. Impact of research sponsorship: The majority of the randomized trials included in the systematic review were funded by the pharmaceutical industry. However, there was not sufficient information in these studies to determine if pharmaceutical industry funding might introduce publication bias. It is not known if there were small or unfavourable studies that were not submitted for publication.
8. Genetic Factors: There is a need for trials regarding the influence of genetic factors in opioid metabolism, analgesic response, incidence of side effects and predisposition to misuse and addiction.

Appendix A-1: National Opioid Use Guideline Group (NOUGG)

Medical Regulatory Authority	Representative(s)
Federation of Medical Regulatory Authorities of Canada	• Dr. Fleur-Ange Lefebvre, PhD, Executive Director and CEO • Ms Connie Côté, Director, Professional Affairs
College of Physicians & Surgeons of British Columbia	Dr. Robbert Vroom, Deputy Registrar
College of Physicians & Surgeons of Alberta	• Mr. Clarence Weppler, Manager-Physician Prescribing Practices • Dr. Janet Wright, Assistant Registrar
College of Physicians and Surgeons of Saskatchewan	• Mr. Doug Spitzig, Consultant Pharmacist, Prescription Review Program • Dr. Karen Shaw, Deputy Registrar
College of Physicians & Surgeons of Manitoba	• Dr. Lindy Lee, Family Physician • Dr. Bill Pope, Registrar • Dr. Anna Ziomek, Assistant Registrar
College of Physicians and Surgeons of Ontario	• Ms Rhoda Reardon, Manager (A), Research and Evaluation • Dr. Angela Carol, Family Physician; Medical Officer, Quality Management Division
Collège des médecins du Québec	Dre. Carole Santerre, Inspector, Practice Improvement Division
College of Physicians and Surgeons of PEI	Dr. Don Ling, Family Physician; President of Council
College of Physicians and Surgeons of Nova Scotia	Dr. Cameron Little, Registrar
College of Physicians and Surgeons of New Brunswick	Dr. Ed Schollenberg, Registrar
College of Physicians and Surgeons of Newfoundland and Labrador	Dr. Robert Young, Registrar
Yukon Medical Council	Dr. Said Secerbegovic, Family Physician; member of Council
Government of Nunavut	Dr. Patricia DeMaio, Family Physician

Appendix A-2: Research Group

Name and Research Group Role	Title	Disclosure of Competing Interests
Andrea Furlan Physician-Epidemiologist, Systematic Review Lead	Assistant Professor, Department of Medicine, University of Toronto Associate Scientist, Institute for Work & Health Editorial Board, Cochrane Back Review Group Medical Staff, Toronto Rehabilitation Institute	None.
Meldon Kahan Physician-Researcher	Associate Professor, Department of Family and Community Medicine, University of Toronto	Schering-Plough: Unrestricted research and educational grant and stipends.
Angela Mailis-Gagnon Physician-Researcher	Director, Comprehensive Pain Program, Toronto Western Hospital Professor, Department of Medicine, University of Toronto	Pfizer: Advisory Board Member and unrestricted grant to fund a research fellow; Boehringer Ingelheim: Advisory Board Member.
Anita Srivastava Physician-Researcher	Assistant Professor & Staff Physician, St. Joseph's Health Centre, Department of Family and Community Medicine, University of Toronto	Schering-Plough: Honorarium re: buprenorphine educational course development.
Luis Chaparro Physician-Researcher	Clinical Fellow, Comprehensive Pain Program, Toronto Western Hospital, University Health Network	None.
Emma Irvin Research Librarian	Director, Research Operations Institute for Work & Health, Toronto	None.

Institute for Work & Health
The Institute for Work & Health (IWH) is an independent, not-for-profit research organization based in Toronto, Ontario. Its mission is to conduct and share research that protects and improves the health of working people and is valued by policy-makers, workers and workplaces, clinicians, and health and safety professionals.

The Institute operates with support from the Ontario Workplace Safety and Insurance Board (WSIB). In addition to this core funding, IWH scientists are also awarded competitive grants from funding agencies across North America.

Appendix A-3: National Advisory Panel (NAP)

Name	Title	Disclosure of Competing Interests
Ms. Lori Adler	Outreach Program Coordinator College of Nurses of Ontario Toronto ON	
Dr. John F. Anderson	Senior Research Fellow Centre for Addictions Research of B.C. Victoria BC	
Ms. Catherine Biggs	Clinical Pharmacist Orofacial Pain and Medicine Clinic Edmonton AB	
Dr. Aline Boulanger	Director, Pain Clinic, CHUM (HD) and Sacre-Coeur Hospital Montreal QC	Conferences for Pfizer, Purdue, Janssen-Ortho, Bayer, Merck, Valeant, Paladin, Biovail, and Wyeth (> $5000 annually)
Dr. Robert James Boyd	Professor and Head, Family Medicine, University of Manitoba Winnipeg MB	
Dr. Norman Buckley	Professor and Chair, Department of Anesthesia, McMaster University Hamilton ON	PI or Co-investigator – Purdue, Pfizer, Janssen-Ortho, Abbott
Dr. Peter Butt	Associate Professor, Department of Family Medicine University of Saskatchewan Saskatoon SK	
Dr. Michel Cauchon	Professeur Médecine Familiale Université Laval Laval QC	
Dr. Alexander J. Clark	Medical Director, Chronic Pain Centre Calgary Pain Program Alberta Health Services Calgary, AB	PI or Co-investigator – Pfizer, Purdue, AstraZeneca and Bayer Consultant or Honoraria (>$5000 annually) – Pfizer, Biovail and College of Physicians & Surgeons of Alberta
Dr. John Collingwood	Family Physician St. John's NL	
Ms. Lynn Cooper	President, Canadian Pain Coalition Kitchener ON	
Dr. Ann Crabtree	Consulting Physician, Calgary Health Region Chronic Pain Centre Calgary AB	
Dr. Etienne de Medicis	Professeur d'enseignement cliniquie agrege, Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke QC	PI or Co-investigator – Pfizer and Purdue
Dr. Ted Findlay	Consultant physician, Regional Pain Program, Alberta Health Services Calgary AB	
Dr. Ian Forster	Medical Director, Lifemark Health Edmonton AB	Consultant or Honoraria (>$5000 annually) -Valiant, Purdue Pharma and Janssen-Ortho stock shareholder (>$5000) -Pfizer, Biovail and Paladin

…continued

…Appendix A-3: NAP Members, continued

Name	Title	Disclosure of Competing Interests
Dr. John Fraser	Family Physician North End Community Health Centre Halifax NS	
Dr. Brian Goldman	Staff Emergency Physician Mount Sinai Hospital Toronto ON	Consultant or Honoraria (>$5000 annually) – Purdue and Paladin
Dr. Allan Gordon	Neurologist and Director Wasser Pain Management Centre Toronto ON	PI or Co-investigator – Canadian Institutes of Health Research, Purdue Pharma, Pfizer, Merck and Paladin. Consultant or Honoraria (>$5000 annually – Pfizer, Purdue Pharma and Janssen-Ortho
Dr. Neil Hagen	Professor and Head Division of Palliative Medicine, University of Calgary Calgary AB	Research support in trials of a non-opioid analgesic, approximately $100,000 over two years for WEX Pharmaceuticals
Dr. Lydia Hatcher	Family Physician Family Wellness Place Mount Pearl NL	PI or Co-investigator – Purdue Consultant or Honoraria (>$5000 annually) – Purdue and Janssen-Ortho
Dr. Phillipa Hawley	Palliative Medicine Specialist B.C. Cancer Agency Vancouver BC	
Dr. Howard Intrater	Medical Director Pain Clinic, Health Sciences Centre Winnipeg MB	Consultant or Honoraria (<$5000 annually) – Janssen-Ortho, Purdue, Valeant and Medtronic
Dr. Margaret Jin	Clinical Pharmacist Hamilton Family Health Team Hamilton ON	
Dr. Roman Jovey	Program Medical Director, CPM Centres for Pain Management Physician Director, Addictions & Concurrent Disorders Centre Credit Valley Hospital Mississauga ON	Consultant or Honoraria (>$5000 annually) for Biovail, Janssen-Ortho, Glaxo-Smith-Kline, Merck-Frost, Nycomed, Pfizer, Paladin, Purdue, Sanofi-Aventis and Valeant
Dr. Milan Khara	Clinical Director, Tobacco Dependence Clinic, Vancouver Coastal Health, Addiction Services Clinical Assistant Professor, Faculty of Medicine, University of British Columbia Vancouver BC	PI or Co-investigator – Pfizer, Johnson & Johnson (smoking cessation products only) Consultant or Honoraria (>$5000 annually) – Pfizer, Johnson & Johnson (smoking cessation products only)
Dr. Brian Knight	Anesthesiologist, Misericordia Hospital Edmonton AB	Consultant or Honoraria (>$5000 annually) – Purdue
Dr. Jill Konkin	Associate Dean, Rural and Regional Health Faculty of Medicine and Dentistry University of Alberta Edmonton AB	
Mr. James Krempien	Complaints Director Alberta College of Pharmacists Edmonton AB	

…continued

…Appendix A-3: NAP Members, continued

Name	Title	Disclosure of Competing Interests
Dr. Roger Ladouceur	Médecin responsable du Plan d'autogestion du Développement professionnel continu Collège des médecins du Québec Montreal QC	
Dr. Andre Lalonde	Expert Clinicien Hôpital de Sacre-Coeur Laval QC	Consultant or Honoraria (>$5000 annually) – Pfizer, Purdue, Biovail, Paladin, Valeant, Boehringer, Lilly and Merck
Dr. Vernon Lappi	Director, Medical Services, Workers' Compensation Board of Alberta Edmonton AB	
Dr. Lindy Lee	Medical Director, Health Sciences Centre Addiction Unit Winnipeg MB	
Dr. Joël Loiselle	Anesthesiologist, St. Boniface Hospital, and Chronic Pain and Palliative Care Consultant Winnipeg Regional Health Authority Winnipeg MB	$10,000 for research support from the University of Manitoba Consultant or Honoraria (<$5000 annually) – Purdue Pharma
Dr. Mary Lynch	Director Pain Management Unit Capital District Health Authority Halifax NS	Co-investigator on a tramadol study in PHN with Purdue
Dr. David MacPherson	Assistant Professor, Family Medicine Queens University Kingston ON	
Dr. David Marsh	Medical Director, Addiction, HIV/AIDS, Aboriginal Health Services Vancouver Coastal Health Vancouver BC	Advisory Board Member for Schering Canada
Dr. Gary Mazowita	Chair, Family and Community Medicine Providence Health Centre Vancouver BC	
Dr. Gordon McFadden	Physician, Dr. Gordon R. McFadden Inc., Burnaby BC	
Dr. Patricia K. Morley-Forster	Medical Director, Pain Management Program, St. Joseph's Health Care London ON	Co-investigator ($820,000) for Neuropathic Pain Registry, Multi-centre Honoraria ($6,000 for 4 talks) – Pfizer Financial/Material Support ($200,000) – grant from Purdue for operating costs of Pain Clinic
Dr. Murray Opdahl	Medical Director Saskatoon Chronic Pain Centre Saskatoon SK	Pain management consults for Worker's Compensation Board and Saskatchewan Government Insurance Speak regarding pain management and receive honoraria from Purdue, Janssen-Ortho and Pfizer

…continued

…Appendix A-3: NAP Members, continued

Name	Title	Disclosure of Competing Interests
Dr. R. Keith Phillips	Assistant Clinical Professor Department of Family Practice, University of British Columbia Nanaimo BC	PI for hepatitis C treatment with Hoffman - La Roche.
Dr. Saifee Rashiq	Director, Division of Pain Medicine, University of Alberta Edmonton AB	PI or Co-investigator – Purdue, Janssen-Ortho, AstraZeneca, WCB Alberta
Mr. Loren Regier	Pharmacist, Saskatoon Health Region Saskatoon SK	
Dr. Toomas Sauks	Family Physician Owen Sound ON	Consultant or honoraria (>$5000 annually) – College of Physicians and Surgeons of Ontario
Dr. Roger Shick	Physician Leader, St. Paul's Pain Centre, St. Paul's Hospital Vancouver BC	
Dr. Chris Spanswick	Medical Leader, Regional Pain Program Calgary AB	
Dr. Paul Taenzer	Specialist/Clinical Psychologist, Regional Pain Program Calgary, AB	
Dr. Eldon Tunks	Emeritus Professor Psychiatry McMaster University Regional Rehabilitation Center Hamilton Health Sciences Hamilton ON	
Dr. Preston Zuliani	President, College of Physicians and Surgeons of Ontario, and Family Physician St. Catherines ON	

Appendix A-4: Literature Search Strategies

(1a) Search strategy in MEDLINE

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. Randomized Controlled Trials/
4. Random Allocation/
5. Double-Blind Method/
6. Single-Blind Method/
7. or/1-6
8. Animal/ not Human/
9. 7 not 8
10. clinical trial.pt.
11. explode Clinical Trials/
12. (clinic$ adj25 trial$).tw.
13. ((singl$ or doubl$ or trebl$ or tripl$) adj(mask$ or blind$)).tw.
14. Placebos/
15. placebo$.tw.
16. random$.tw.
17. Research Design/
18. (latin adj square).tw.
19. or/10-18
20. 19 not 8
21. 20 not 9
22. Comparative Study/
23. explode Evaluation Studies/
24. Follow-Up Studies/
25. Prospective Studies/
26. (control$ or prospectiv$ or volunteer$).tw.
27. Cross-Over Studies/
28. or/22-27
29. 28 not 8
30. 29 not (9 or 21)
31. 9 or 21 or 30
32. PAIN/pc, dt, rh, th [Prevention & Control, Drug Therapy, Rehabilitation, Therapy]
33. Chronic Disease/dt, pc, rh, th [Drug Therapy, Prevention & Control, Rehabilitation, Therapy]
34. (chronic adj3 pain).mp
35. Low Back Pain/
36. (low adj back adj pain).mp
37. or/ 32-36
38. exp Analgesics, opioid/
39. Codeine.mp.
40. Fentanyl.mp.
41. Hydrocodone.mp.
42. Hydromorphone.mp.
43. Levorphanol.mp.
44. Meperidine.mp.
45. Morphine.mp.
46. Oxycodone.mp.
47. Oxymorphone.mp.
48. Pentazocine.mp.
49. Propoxyphene.mp.
50. Sufentanil.mp.
51. Tramadol.mp
52. or/ 38-51
53. Or/ 39-51
54. 31 and 37 and 53

(1b) Search in EMBASE

1. Randomized Controlled Trial/
2. (random: adj2 control: trial:).mp.
3. 1 or 2
4. control: clinical trial:.mp.
5. (control: adj2 trial:).mp.
6. 4 or 5
7. randomization/
8. random: allocation:.mp.
9. (random: adj2 allocation:).mp.
10. 8 or 9
11. Double Blind Procedure/
12. double-blind method:.mp.
13. Single Blind Procedure/
14. single-blind method:.mp.
15. or/1-14
16. limit 15 to (amphibia or ape or bird or cat or cattle or chicken or dog or "ducks and geese" or fish or "frogs and toads" or goat or guinea pig or "hamsters and gerbils" or horse or monkey or mouse or "pigeons and doves" or "rabbits and hares" or rat or reptile or sheep or swine)
17. exp animal/
18. 15 and 17
19. 16 or 18
20. limit 15 to human
21. 20 not 19
22. Clinical Trial/
23. exp clinical trial/
24. (clinic: adj25 trial:).tw.
25. ((singl: or doubl: or trebl: or tripl:) adj (mask: or blind:)).tw.
26. PLACEBO/
27. placebo:.mp.
28. random:.tw.
29. methodology/
30. latin square design/
31. (latin adj square).tw.
32. or/22-31
33. 32 not 19
34. Comparative Study/
35. evaluation/
36. follow up/
37. prospective study/
38. (control: or prospectiv: or volunteer:).tw.
39. Crossover Procedure/
40. or/34-39
41. 40 not 19
42. 21 or 33 or 41
43. Pain/pc, rh, dt, th [Prevention, Rehabilitation, Drug Therapy, Therapy]Chronic Disease/pc, rh, dt, th [Prevention, Rehabilitation, Drug Therapy, Therapy]
44. (chronic adj3 pain).mp.
45. Low Back Pain/
46. (low adj back adj pain).mp.
47. or/43-47
48. exp Narcotic Analgesic Agent/
49. Codeine.mp.
50. Fentanyl.mp.
51. Hydromorphone.mp.
52. Levorphanol.mp.
53. Meperidine.mp.
54. Morphine.mp.
55. Oxycodone.mp.
56. Oxymorphone.mp.
57. Pentazocine.mp.
58. Propoxyphene.mp.
59. Tramadol.mp.sufentanil.mp
60. Tramadol.mp
61. or/49-63
62. or/50-63
63. 64 not 65
64. 65 not 49
65. 42 and 48 and 65

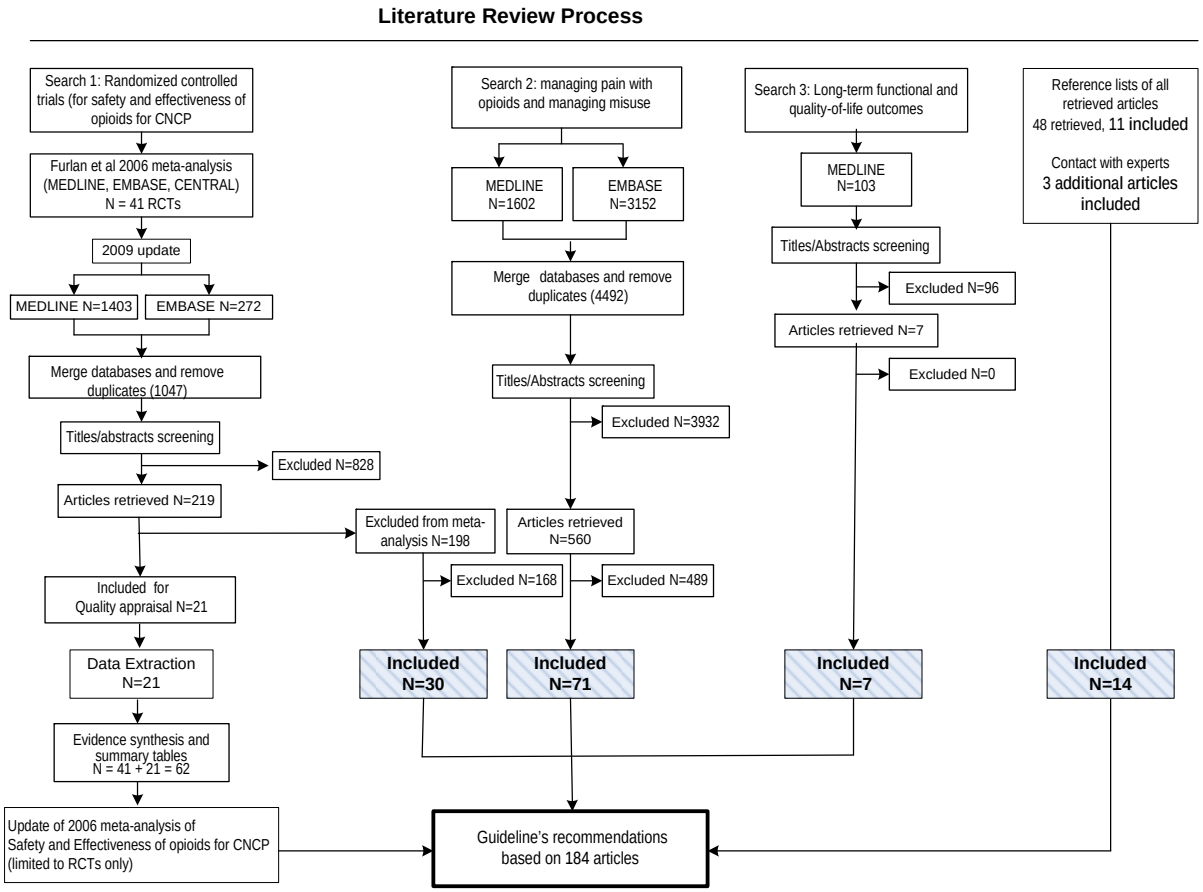
(2) Searches for EMBASE and MEDLINE

1. narcotics/
2. exp Analgesics, Opioid/
3. morphine/
4. codeine/
5. fentanyl/
6. hydromorphone.mp.
7. (levorphanol or meperidine or oxymorphone or pentazocine or propoxyphene or sufentanil or tramadol).mp.
8. hydrocodone.mp.
9. tramacet/
10. 57-27-2.rn.
11. oxycodone/
12. 76-42-6.rn.
13. Buprenorphine/
14. prescription opioid$.mp.
15. or/1-14
16. pain/
17. pain clinics/
18. 16 or 17
19. exp Risk Assessment/
20. substance-related disorders/
21. screening.mp.
22. psychoactive effect$.mp.
23. misuse.mp.
24. dependence.mp.
25. abuse liability.mp.
26. risk factor$.mp.
27. urine drug screening.mp.
28. clinical feature$.mp.
29. substance abuse detection/
30. opioid-related disorders/
31. substance abuse detection/
32. crime/
33. drug.mp. and narcotic control/
34. street drugs/
35. substance withdrawal syndrome/
36. methadone/
37. or/19-36
38. 15 and 18 and 37

(3) Search strategy in MEDLINE

1. randomized controlled trial/
2. Random Allocation/
3. Double-Blind Method/
4. Single-Blind Method/
5. Research Design/
6. Comparative Study/
7. exp Evaluation Studies/
8. Follow-Up Studies/
9. Prospective Studies/
10. Cross-Over Studies/
11. or/1-10
12. exp Chronic Disease/pc, dt, th, rh [Prevention & Control, Drug Therapy, Therapy, Rehabilitation]
13. exp Pain/th, rh, dt, pc [Therapy, Rehabilitation, Drug Therapy, Prevention & Control]
14. (chronic adj5 pain).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. exp Analgesics, Opioid/
16. Opioid-Related Disorders/
17. "Quality of Life"/
20. or/12-14
21. or/16-17
22. 11 and 20 and 15 and 21

Appendix A-5: Flowchart of Literature Review Process



Appendix A-6: NOUGG Criteria for Recruiting NAP Members

Organizations participating in NOUGG applied criteria to select advisory panel members included the following:

1. Include those who are physician "influencers" within the province/territory.
2. Include those whose endorsement and assistance with implementation could help identify barriers and contribute to the *Canadian Guideline's* successful implementation to practice.
3. Invite individuals who bring their own perspectives but who are fundamentally committed to blending research evidence and expert consensus in creating practice guidance.
4. Include a range of expertise and perspective (a single panel member might contribute more than one perspective):
   - *Family physicians* – predominant group targeted as the end-user for the *Canadian Guideline*
   - *Focused practice physicians* – pain and/or addictions.
   - *Other health disciplines* who work with physicians when opioids for CNCP are prescribed, e.g., pharmacists and nurses.
   - *Opinion Leaders* – broadly defined as those within the province/territory who others look to for guidance or as models.
   - *Academia* – researchers and teachers who bring a focus on the evidence.
   - *Other relevant stakeholders* who have a distinct role in this area and who are seen as critical to successful implementation of the *Canadian Guideline*.

Appendix A-7: Disclosure of Conflict of Interest Form

National Opioid Use Guideline Group (NOUGG)
Disclosure of Conflict of Interest

COMPLETION OF THIS DISCLOSURE IS MANDATORY FOR ALL EXPERTS PARTICIPATING IN THE NOUGG GUIDELINE DEVELOPMENT PROCESS

The National Opioid Use Guidelines Group wants to ensure balance, independence, impartiality and scientific rigor in the review of the guideline by experts from across the country. All experts are asked to disclose any real or apparent conflict(s) of interest in the past two years that may have a direct bearing on the subject matter of the guidelines. This pertains to relationships with pharmaceutical companies who may manufacture or distribute pharmaceutical products containing opioids or used in the treatment and management of pain, and to work done on behalf of third parties such as insurance companies or workers compensation agencies.

The intent of this disclosure is not to prevent any reviewer from participating in the process but rather to be transparent about any conflicts so that users of the guidelines can form their own judgment to determine the possible existence of bias in review of the guidelines.

The final guideline will include the names of the expert panel members and their disclosures of conflicts of interest.

Name: _____

Address: _____

Email: _____

A. ☐ I have no actual or potential conflict of interest

OR

B. ☐ I have/had financial interest/arrangement or affiliation with the following organizations that could be perceived as a possible or apparent conflict of interest. *(Please list the name of the organization(s) and the nature of your relationship. Please include: Grant or Research support, consultant or Honoraria, shareholding or any other financial or material support.)*

Affiliation/Financial Interest	Name of Organization(s)
Grant or Research Support (PI or Co investigator; any amount)	
Consultant or Honoraria (>$5000 annually)	
Stock Shareholder (>$5000)	
Other Financial/Material Support (>$5000 annually)	
Other	

Signature: _____ Date: _____

Appendix A-8: Modified Delphi Process used in NAP Consultation Rounds 2 to 4

Before Round 1 of the modified Delphi process, all NAP members received the following description of methodology:

1. Through structured responses, NAP members are requested to indicate their degree of support for draft recommendations. A "N/A" response offers an option for NAP members not able to give an opinion about a specific statement.
2. The evidence grade for recommendations lacking Grade A or Grade B evidence will be considered Grade C if NAP reaches consensus.
3. The definition of consensus for this Modified Delphi process is:
   80% of National Advisory Panel respondents indicate that they Agree or Strongly Agree with the statement "I support this recommendation."
4. Results from the Modified Delphi process will identify:
   1) recommendations the NAP supports by consensus, and
   2) recommendations that require further consultation with NAP.
5. Following NOUGG analysis of all NAP replies, each respondent will receive a comparison of their own individual feedback and the aggregate NAP responses.
6. The Modified Delphi process will be used in subsequent guideline rounds as required.
7. After Round 2 of the Modified Delphi process, recommendations based on Grade C evidence only and failing to reach consensus will be eliminated. However, recommendations based on Grade A and/or B evidence that fail to achieve consensus will undergo further revision for consideration by NAP in a third round.

Appendix A-9: NAP Electronic Response Survey Tool

To capture NAP feedback, CPSA used a web-based electronic-response tool developed using SurveyMonkey®.

Electronic responses (using a Likert scale) were required to three statements for each recommendation:

1) This recommendation is clear.
2) It would be feasible for me to follow this recommendation in my usual practice setting.
3) I support this recommendation.

Likert scale:

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree
- N/A (offered an option for NAP members not able to give an opinion).

In addition, NAP members had the option of providing open-ended comments or information they would like to add. Members were requested to comment if they felt a recommendation lacked clarity or was not feasible. If they did not support a recommendation, respondents were requested to provide their rationale and identify what changes would be necessary for them to support

Scoring Consensus:
Consensus for a recommendation was predefined as at least 80% of responders indicating they agreed or strongly agreed with the statement "I support this recommendation".
Note: NAP members responding to a statement using "N/A," were removed from the denominator calculating consensus.

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

Part A: Executive Summary and Background
Part B: Recommendations for Practice

PART B

— Recommendations for Practice —

Published by the
National Opioid Use Guideline Group (NOUGG)
a collaboration of:

Federation of Medical Regulatory Authorities of Canada
College of Physicians & Surgeons of British Columbia
College of Physicians & Surgeons of Alberta
College of Physicians and Surgeons of Saskatchewan
College of Physicians & Surgeons of Manitoba
College of Physicians and Surgeons of Ontario
Collège des médecins du Québec
College of Physicians and Surgeons of New Brunswick
College of Physicians and Surgeons of Nova Scotia
College of Physicians and Surgeons of Prince Edward Island
College of Physicians and Surgeons of Newfoundland and Labrador
Government of Nunavut
Yukon Medical Council

April 30 2010 Version 5.6

http://nationalpaincentre.mcmaster.ca/opioid/

Acknowledgements

The following individuals are gratefully acknowledged for their contribution to the inception, development, review, revision, and publication of the *Canadian Guideline*.

Research Group

Dr. Andrea Furlan
Dr. Meldon Kahan
Dr. Angela Mailis-Gagnon
Ms Emma Irvin
Dr. Luis Chaparro
Dr. Anita Srivastava

National Opioid Use Guideline Group (NOUGG)

Ms Rhoda Reardon (Co-chair)
Mr. Clarence Weppler (Co-chair)
Dr. Angela Carol
Ms Connie Côté
Dr. Patricia DeMaio
Dr. Lindy Lee
Dr. Fleur-Ange Lefebvre
Dr. Don Ling
Dr. Cameron Little
Dr. Bill Pope
Dre. Carole Santerre
Dr. Ed Schollenberg
Dr. Said Secerbegovic
Dr. Karen Shaw
Mr. Doug Spitzig
Dr. Janet Wright
Dr. Robbert Vroom
Dr. Robert Young
Dr. Anna Ziomek

National Advisory Panel (NAP)

Ms Lori Adler
Dr. John F. Anderson
Ms Catherine Biggs
Dr. Aline Boulanger
Dr. Robert James Boyd
Dr. Norman Buckley
Dr. Peter Butt
Dr. Michel Cauchon
Dr. John Clark
Dr. John Collingwood
Ms Lynn Cooper
Dr. Ann Crabtree
Dr. Etienne de Medicis
Dr. Ted Findlay
Dr. Ian Forster
Dr. John Fraser
Dr. Brian Goldman
Dr. Allan Gordon
Dr. Neil Hagen
Dr. Lydia Hatcher
Dr. Phillipa Hawley
Dr. Howard Intrater
Dr. Margaret Jin
Dr. Roman Jovey
Dr. Milan Khara
Dr. Brian Knight
Dr. Jill Konkin
Mr. James Krempien
Dr. Roger Ladouceur
Dr. Andre Lalonde
Dr. Vernon Lappi
Dr. Lindy Lee
Dr. Joël Loiselle
Dr. Mary Lynch
Dr. David MacPherson
Dr. David Marsh
Dr. Gary Mazowita
Dr. Gordon McFadden
Dr. Patricia K. Morley-Forster
Dr. Murray Opdahl
Dr. R. Keith Phillips
Dr. Saifee Rashiq
Mr. Loren Regier
Dr. Toomas Sauks
Dr. Roger Shick
Dr. Chris Spanswick
Dr. Paul Taenzer
Dr. Eldon Tunks
Dr. Preston Zuliani

Part B: Table of Contents

List of Figures and Tables

NOTES:

- Numbering of Tables and Figures
  Tables and Figures are numbered to correspond with the associated section in Part A, and the associated recommendation in Part B, e.g.,
  - Table A-11.1 is located in Part A, section 11.1.
  - Table B-12.1 is located in Part B, under Recommendation 12.

- Individual Recommendations
  For Part B, the recommendations are organized into three sections: Recommendation Statement, Discussion, and Summary of Peer-Reviewed Evidence. For recommendations with Grade-C only support, the "Summary of Peer-Reviewed Evidence" is omitted.

- Acronyms used in Part B:
  CNCP = chronic non-cancer pain
  CPG = clinical practice guideline
  CR = controlled release
  FDA = Food and Drug Administration
  IR = immediate release
  LTOT = long-term opioid therapy
  MEQ = morphine equivalent
  NA = not applicable
  NRS = numeric rating scale
  OIH = Opioid-induced Hyperalgesia
  ORT = Opioid Risk Tool
  PDI = pain disability index
  RCT = randomized controlled trial
  UDS = urine drug screening

SUMMARY of RECOMMENDATIONS

Cluster 1: Deciding to Initiate Opioid Therapy

No.	Recommendation	Keyword
R01	Before initiating opioid therapy, ensure comprehensive documentation of the patient's pain condition, general medical condition and psychosocial history (Grade C), psychiatric status, and substance use history. (Grade B).	*Comprehensive assessment*
R02	Before initiating opioid therapy, consider using a screening tool to determine the patient's risk for opioid addiction. (Grade B).	*Addiction-risk screening*
R03	When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C).	*Urine drug screening*
R04	Before initiating opioid therapy, consider the evidence related to effectiveness in patients with chronic non-cancer pain. (Grade A).	*Opioid efficacy*
R05	Before initiating opioid therapy, ensure informed consent by explaining potential benefits, adverse effects, complications and risks (Grade B). A treatment agreement may be helpful, particularly for patients not well known to the physician or at higher risk for opioid misuse. (Grade C).	*Risks, adverse effects, complications*
R06	For patients taking benzodiazepines, particularly for elderly patients, consider a trial of tapering (Grade B). If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. (Grade C).	*Benzodiazepine tapering*

Cluster 2: Conducting an Opioid Trial

R07	During dosage titration in a trial of opioid therapy, advise the patient to avoid driving a motor vehicle until a stable dosage is established and it is certain the opioid does not cause sedation (Grade C); and when taking opioids with alcohol, benzodiazepines, or other sedating drugs. (Grade B).	*Titration and driving*
R08	During an opioid trial, select the most appropriate opioid for trial therapy using a stepped approach, and consider safety. (Grade C).	*Stepped opioid selection*
R09	When conducting a trial of opioid therapy, start with a low dosage, increase dosage gradually and monitor opioid effectiveness until optimal dose is attained. (Grade C).	*Optimal dose*
R10	Chronic non-cancer pain can be managed effectively in most patients with dosages at or below 200 mg/day of morphine or equivalent (Grade A). Consideration of a higher dosage requires careful reassessment of the pain and of risk for misuse, and frequent monitoring with evidence of improved patient outcomes. (Grade C).	*Watchful dose*
R11	When initiating a trial of opioid therapy for patients at higher risk for misuse, prescribe only for well-defined somatic or neuropathic pain conditions (Grade A), start with lower doses and titrate in small-dose increments (Grade B), and monitor closely for signs of aberrant drug-related behaviors. (Grade C).	*Risk: opioid misuse*

Cluster 3: Monitoring Long-Term Opioid Therapy (LTOT)

No.	Recommendation	Keyword
R12	When monitoring a patient on long-term therapy, ask about and observe for opioid effectiveness, adverse effects or medical complications, and aberrant drug-related behaviours. (Grade C).	*Monitoring LTOT*
R13	For patients experiencing unacceptable adverse effects or insufficient opioid effectiveness from one particular opioid, try prescribing a different opioid or discontinuing therapy. (Grade B).	*Switching or discontinuing opioids*
R14	When assessing safety to drive in patients on long-term opioid therapy, consider factors that could impair cognition and psychomotor ability, such as a consistently severe pain rating, disordered sleep, and concomitant medications that increase sedation. (Grade C).	*LTOT and driving*
R15	For patients receiving opioids for a prolonged period who may not have had an appropriate trial of therapy, take steps to ensure that long-term therapy is warranted and dose is optimal. (Grade C).	*Revisiting opioid trial steps*
R16	When referring patients for consultation, communicate and clarify roles and expectations between primary-care physicians and consultants for continuity of care and for effective and safe use of opioids. (Grade C).	*Collaborative care*

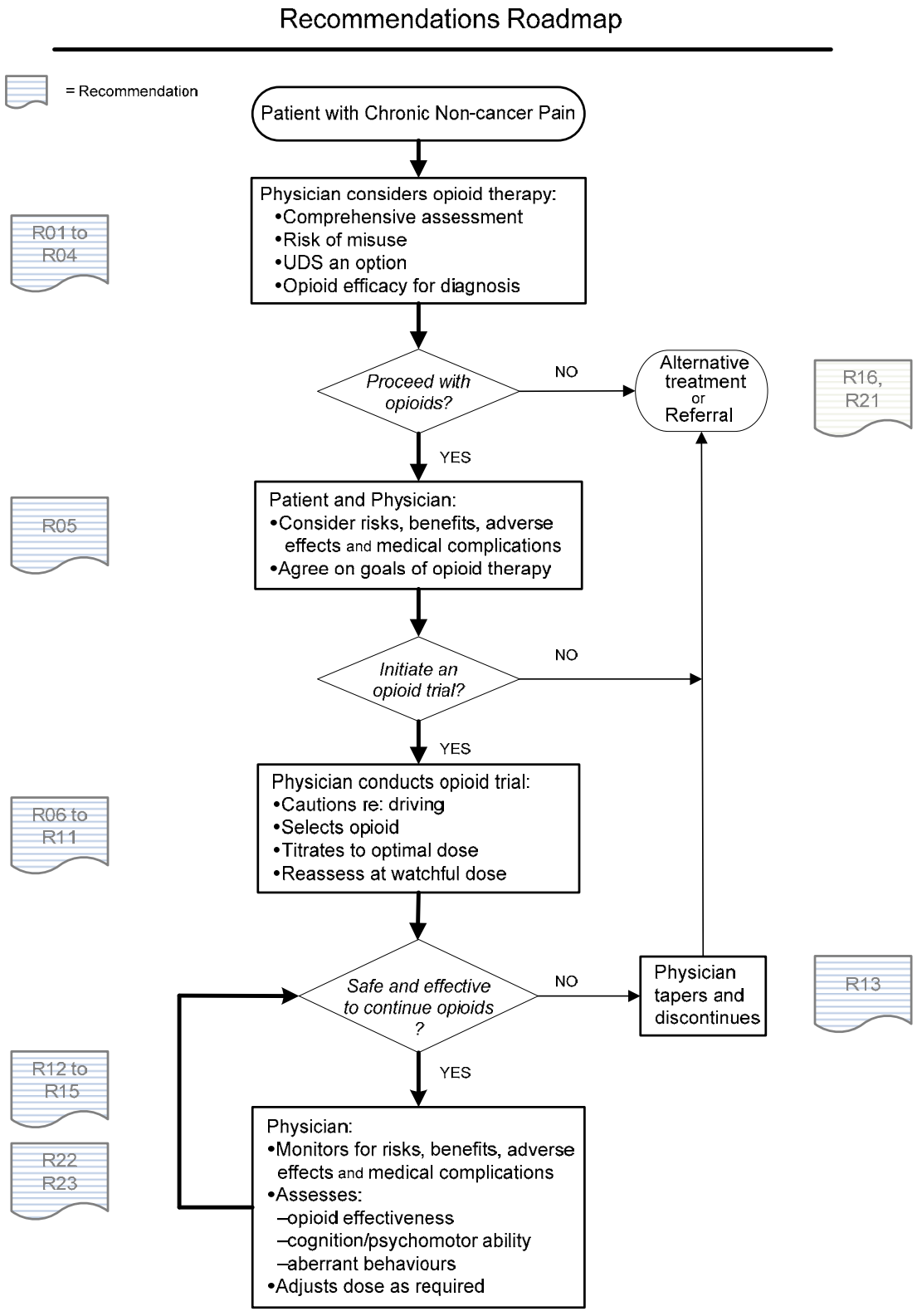
Cluster 4: Treating Specific Populations with Long-Term Opioid Therapy

R17	Opioid therapy for elderly patients can be safe and effective (Grade B) with appropriate precautions, including lower starting doses, slower titration, longer dosing interval, more frequent monitoring, and tapering of benzodiazepines. (Grade C).	*Elderly patients*
R18	Opioids present hazards for adolescents (Grade B). A trial of opioid therapy may be considered for adolescent patients with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed, risk of opioid misuse is assessed as low, close monitoring is available, and consultation, if feasible, is included in the treatment plan. (Grade C).	*Adolescent patients*
R19	Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible. (Grade B).	*Pregnant patients*
R20	Patients with a psychiatric diagnosis are at greater risk for adverse effects from opioid treatment. Usually in these patients, opioids should be reserved for well-defined somatic or neuropathic pain conditions. Titrate more slowly and monitor closely; seek consultation where feasible. (Grade B).	*Co-morbid psychiatric diagnoses*

Cluster 5: Managing Opioid Misuse and Addiction in CNCP Patients

No.	Recommendation	Keyword
R21	For patients with chronic non-cancer pain who are addicted to opioids, three treatment options should be considered: methadone or buprenorphine treatment (Grade A), structured opioid therapy (Grade B), or abstinence-based treatment (Grade C). Consultation or shared care, where available, can assist in selecting and implementing the best treatment option. (Grade C).	*Addiction treatment options*
R22	To reduce prescription fraud, physicians should take precautions when issuing prescriptions and work collaboratively with pharmacists. (Grade C).	*Prescription fraud*
R23	Be prepared with an approach for dealing with patients who disagree with their opioid prescription or exhibit unacceptable behaviour. (Grade C).	*Patient unacceptable behaviour*
R24	Acute or urgent health care facilities should develop policies to provide guidance on prescribing opioids for chronic pain to avoid contributing to opioid misuse or diversion. (Grade C).	*Acute care opioid prescribing policy*

Figure 01. Recommendations Roadmap



Canadian Guideline RECOMMENDATIONS

Cluster 1: Deciding to Initiate Opioid Therapy

R01	Recommendation Statement

R01	Before initiating opioid therapy, ensure comprehensive documentation of the patient's pain condition, general medical condition and psychosocial history (Grade C), psychiatric status, and substance use history. (Grade B).	***Comprehensive assessment***

R01 Discussion

1. Comprehensive Knowledge of the Patient

1.1 Pain Condition

Comprehensive knowledge of the patient's pain condition includes:

- thorough history and physical examination to determine the type, cause and nature of the pain, including questions about past investigations and interventions for pain including medication trials
- estimate of the pain intensity and the functional impairment that arises from it (impact of pain on work, school, home and leisure activities)
- diagnosis.

1.2 General Medical and Psychosocial History

- General medical history includes questions about general physical health, emotional health, and medication use.
- Psychosocial history includes information regarding: living arrangements, family/social support, family obligations, work status.

1.3 Psychiatric Status

Psychiatric status includes information regarding:

- the patient's current and past history of psychiatric disorders and treatments; (also see Recommendation 20 for more details about prescribing options for patients with psychiatric disorders)
- family history of psychiatric disorders.

1.4 Substance Use History

Substance use history includes questions about:

- current, past, and family history of substance use, abuse, and addiction (alcohol, marijuana, tobacco, benzodiazepines, opioids, cocaine, amphetamines, barbiturates, hallucinogens, and solvents), and
- any attendance at a treatment program for addiction. (See Appendix B-1 for tools and interview guides to assist in taking a substance use history.)

2. Documentation

Maintain detailed records documenting the assessment of the patient, treatment plan, discussion of risks and benefits, informed consent, opioids prescribed, and outcomes.

…continued

R01 Summary of Peer-Reviewed Evidence

1. Opioid addiction is estimated to have an overall prevalence of 3.3% in patients receiving opioids for CNCP, with a wide variation between clinics and regions. Aberrant drug-related behaviours have a much higher prevalence. The major risk factor for addiction is a current or past history of addiction.

The prevalence of aberrant drug-related behaviours and addiction among patients on LTOT is not certain. In a recent systematic review of 67 studies (Fishbain 2008), the prevalence of clinically diagnosed opioid abuse or addiction was reported as 3.3% in those studies that included patients with a history of substance abuse. The prevalence of aberrant drug-related behaviours was 11.5% (range 0–44%). The percent of urine drug screens with illicit drugs present was 14.5%, while the percent of urine drug screens with a non-prescribed opioid or no opioid present (suggesting possibly diversion) was 20.4%.

The corresponding figures were much lower for studies that excluded patients with a history of substance abuse, confirming that a past history is an important risk factor for the development of abuse or addiction. Other risk factors have been identified in individual studies, such as anxiety disorders, post-traumatic stress disorder and personality disorders (Wilsey 2008).

This review (Fishbain 2008) and the studies on which it is based have several limitations. There was no breakdown of the types of clinics studied or the dates of the study (evidence suggests the incidence of opioid addiction is increasing). The diagnosis of addiction is dependent on the clinician's judgment—aberrant drug-related behaviours and urine drug screen results are only a proxy measure of addiction. Aberrant drug-related behaviours could indicate opioid addiction but they also might reflect inadequately treated pain, or abuse of non-opioid drugs, e.g., cocaine.

The prevalence of aberrant drug-related behaviours appears to vary widely between regions and clinics. One study of two primary-care clinics found a prevalence of opioid aberrant drug-related behaviours of 24% and 31% (Reid 2002), while another found a prevalence of 7% among depressed primary-care patients (Roeloffs 2002). Specialty medical or surgical clinics, which tend to follow older patients with organic pain conditions, have found low rates of opioid aberrant drug-related behaviours (Mahowald 2005). There are also striking regional variations.

It is difficult to generalize from these studies, as they 1) were usually based in a specific clinic setting, 2) are limited by selection biases, and 3) often used proxy measures for addiction (drug-seeking behaviours) rather than comprehensive patient assessment.

2. The prevalence of problematic substance use, including opioids, non-opioid substances and alcohol, is higher among patients on long-term opioid therapy for CNCP than in the general population.

One large nationally representative cross-sectional survey of over 9,000 subjects found that the prevalence of problematic substance use was higher among those on prescribed opioids than among non-opioid users (Edlund 2007). This included problematic use of alcohol and non-opioid substances as well as opioids. Controlling for co-morbid mental disorders, the association with non-opioid substances disappeared, suggesting that the higher prevalence of mental disorders in opioid users mediates their higher risk for problematic substance use.

R02 Recommendation Statement

R02	Before initiating opioid therapy, consider using a screening tool to determine the patient's risk for opioid addiction. (Grade B).	***Addiction-risk screening***

R02 Discussion

A comprehensive history when considering opioids for CNCP includes a thorough review of the patient's alcohol and other substance use. This history is important in assessing the patient's risk for opioid misuse or addiction and various screening tools can help with this determination. Most of the screening tools have not been studied in depth, validated, or been compared to each other but the Opioid Risk Tool (ORT) is widely used (see Appendix B-2: ORT).

The ORT provides a scoring mechanism that translates the patient's responses into a low, moderate or high risk categorization. It relies on identifying personal or family history of alcohol and substance abuse as well as personal psychiatric history.

See Appendix B-1 for examples of interview guides and assessment tools that may be used to supplement a comprehensive history of alcohol and substance use.

R02 Summary of Peer-Reviewed Evidence

1. Some screening questionnaires for risk of opioid misuse and abuse have demonstrated high sensitivity and specificity. However, samples used were small and unrepresentative.

The Opioid Risk Tool, in a preliminary study (Webster 2005), demonstrated high sensitivity and specificity for predicting individuals presenting to a pain clinic who were at risk for developing aberrant behaviors related to their opioid use. The ORT assessed personal and family history of substance abuse, age, history of preadolescent sexual abuse, depression, and other psychiatric history and categorized patients as low, moderate or high risk.

A systematic review of predictors for opioid misuse concluded that none of the screening tools can be recommended with confidence, because the samples were small and unrepresentative (Turk 2008). A personal history of abuse of illicit drugs or alcohol remains the strongest predictor of opioid misuse and abuse.

R03 Recommendation Statement

R03	When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C).	***Urine drug screening***

R03 Discussion

In the context of using opioids for treating CNCP, UDS can be used to as a tool for: 1) setting a baseline measure of substance use that may help assess risk for addiction, and 2) ongoing monitoring of the patient's compliance with opioids prescribed. However, opinions regarding UDS utility vary.

1. Types of Urine Drug Screening (UDS)

1.1 Point-of-care Testing

For point-of-care (POC) testing, the urine sample is collected and tested at the physician's office/clinic.

- POC test kits are available for purchase; urine dipsticks are required.
- Results are immediate, but it tends to be less sensitive and specific than laboratory tests.

1.2 Laboratory Testing

For laboratory testing, the urine sample is collected at physician's office/clinic and sent to a laboratory for testing.

There are two types of laboratory tests: immunoassay and chromatography (see Appendix B-3 for a comparison and overview of detection time).

- Province health plans vary in funding UDS; some provide immunoassays for classes of drugs (opioids, cocaine, benzodiazepines, cannabis) or one single drug at a time (e.g., oxycodone, methadone)
- Immunoassay detects drugs for a longer time than chromatography (5–7 days compared to 1–2 days) but does not distinguish between different types of opioids and often misses semi-synthetic or synthetic opioids such as oxycodone or meperidine.
- Chromatography is more expensive and requires specification of the drug(s) to be identified e.g., oxycodone, morphine, codeine, hydromorphone (alternatively can indicate: "full screen" or "broad spectrum screen").

2. Clinical Usefulness of UDS

2.1 Baseline Measure of Risk

UDS can be helpful in establishing the reliability of a patient's reported substance use. Some clinicians believe that UDS should be used routinely to establish baseline information regardless how well the patient is known to the prescriber. They believe a universal approach will eventually "de-stigmatize" UDS and increase prescriber confidence in using opioids. Other clinicians point out that UDS, whether point-of-care or laboratory-completed, is costly, not available in all parts of Canada, and that routine use adds an unnecessary burden to the system. These clinicians believe that UDS should be used selectively with patients who may be at risk for misuse.

…continued

R03 Discussion…continued

2.2 Monitoring for Compliance

During an opioid trial or after a patient is established on LTOT, UDS can be useful in detecting unauthorized drug use, non-compliance, and diversion (Adams 2001, Brown 2006). There is evidence that urine drug screening reduces substance use in LTOT patients (Manchikanti 2004, Manchikanti 2006.)

There is no compelling evidence to guide physicians on identifying CNCP patients who should have UDS or how often. In deciding whether to order a baseline UDS, and how often to use screening to monitor patients, consider:

- patient's risk for opioid misuse and addiction
- aberrant drug-related behaviours
- availability of UDS.

3. Conducting Urine Drug Screening

3.1 Prior to Ordering the Test

- Take a detailed history of the patient's medication use for the preceding 7 days.
- Inform patients that the UDS is not meant to "catch" or punish patients but to improve the safety and effectiveness of LTOT.
- Tell the patient what results are expected from appropriate opioid use and ask the patient if anything else might show up. (This gives the patient the opportunity to inform the prescriber about changes in their use of the prescribed drug or illicit drug use).
- If using a treatment agreement, add the requirement of UDS to the treatment agreement (see Recommendation 5).

3.2 Sample Collection and Preventing Tampering

3.2.1. Sample Dilution

The most common and easiest form of tampering is diluting the urine sample with water. Supervised sample collection makes tampering more difficult, but is a costly use of staff time and patients may find it demeaning. Use supervision if the patient is known to have tampered with a sample.

3.2.2 Sample Temperature

The temperature of the sample can be used to detect tampering because water added to a sample usually varies from body temperature. Temperature-test strips can be used, but they are costly, and must be read within minutes because the sample cools rapidly.

3.2.3. Creatinine Level

A urine creatinine of less than 2–3 mmol/liter is non-physiologic and suggests dilution. Most laboratories can test creatinine level.

4. Interpreting Unexpected Results of UDS

UDS can assist clinical decision-making but should not be considered definitive. Two examples illustrate this: 1) a patient who is diverting prescribed opioids might take a small amount of the prescribed drug so the UDS will be positive; 2) for cocaine there is a relatively short window of detection, so binge cocaine use could be missed.

R03 Discussion…continued

Table B-3.1 reviews some common unexpected results and provides a range of possible reasons and some potential actions. In some cases the physician may find it useful to review unexpected results with the laboratory or a physician experienced in interpreting UDS. Prescribers who are unfamiliar with using UDS should take steps to increase knowledge and skill by seeking out an appropriate educational resource or observership.

Table B-3.1 Interpreting Unexpected Results of Urine Drug Screens

	Unexpected Result	Possible Explanations	Actions for the Physician
1	UDS *negative* for prescribed opioid.	• False negative. • Non-compliance. • Diversion.	• Repeat test using chromatography; specify the drug of interest (e.g. oxycodone often missed by immunoassay). • Take a detailed history of the patient's medication use for the preceding 7 days (e.g., could learn that patient ran out several days prior to test) • Ask patient if they've given the drug to others. • Monitor compliance with pill counts.
2	UDS *positive* for non-prescribed opioid or benzodiazepines.	• False positive. • Patient acquired opioids from other sources (double-doctoring, "street").	• Repeat UDS regularly. • Ask the patient if they accessed opioids from other sources. • Assess for opioid misuse/addiction (See Recommendation 12). • Review/revise treatment agreement
3	UDS *positive* for illicit drugs (e.g., cocaine, cannabis).	• False positive. • Patient is occasional user or addicted to the illicit drug. • Cannabis is positive for patients taking dronabinol (Marinol®), THC:CBD (Sativex®) or using medical marijuana.	• Repeat UDS regularly. • Assess for abuse/addiction and refer for addiction treatment as appropriate • Ask about medical prescription of dronabinol, THC:CBD or medical marijuana access program.
4	Urine creatinine is lower than 2-3 mmol/liter.	• Patient added water to sample.	• Repeat UDS • Consider supervised collection or temperature testing • Take a detailed history of the patient's medication use for the preceding 7 days • Review/revise treatment agreement.
5	Urine sample is cold.	• Delay in handling sample (urine cools within minutes). • Patient added water to sample.	• Repeat UDS, consider supervised collection or temperature testing • Take a detailed history of the patient's medication use for the preceding 7 days • Review/revise treatment agreement.

R03 Summary of Peer-Reviewed Evidence

1. Urine drug screening and other forms of adherence monitoring may reduce rates of substance abuse.

Urine drug screens are an important but underutilized therapeutic tool. Currently, only a small percentage of physicians prescribing opioids for pain are utilizing UDS as a clinical tool: in one study only 8% of physicians utilized UDS (Adams 2001). Another study found only 7% used UDS before initiating opioids and 15% used UDS once patients were on long-term treatment (Bhamb 2006).

Yet, UDS can have value in both detecting substance abuse and in reducing it. In one study (Manchikanti 2004) of patients on stable doses of opioids, 16% were found to have evidence of illicit drug use, and the use of random UDS was found to decrease the amount of illicit drug use. Another evaluation of the same group of patients (Manchikanti 2006) found that a combination of UDS, treatment agreements, pill counts, and education reduced substance abuse by 50%.

R04 Recommendation Statement

R04	Before initiating opioid therapy, consider the evidence related to effectiveness in patients with chronic non-cancer pain. (Grade A).	***Opioid efficacy***

R04 Discussion

The systematic review update (see Part A, 10: Literature Search Methods) completed to support this guideline examined the effectiveness of opioids for CNCP. A summary of findings includes:

- Opioids were more effective than placebo for pain and function, irrespective of the type of opioid (strong or weak) or mechanism of pain (nociceptive or neuropathic).
- The effect sizes of opioids over placebo were medium[1] for pain and small for function. In other words, opioids work better for pain than for function.
- One opioid (tramadol) was effective for fibromyalgia for pain and function; however there were only two randomized trials, and the effects sizes were small for both pain and function.

Table B-4.1 Evidence of Opioid Efficacy

Examples of CNCP conditions for which opioids *were shown to be effective* in placebo-controlled trials*		**Examples of CNCP conditions that *have NOT been studied* in placebo-controlled trials**
Tramadol only	**Weak or strong opioid**	
Fibromyalgia	• Diabetic neuropathy • Peripheral neuropathy • Postherpetic neuralgia • Phantom limb pain • Spinal cord injury with pain below the level of injury • Lumbar radiculopathy • Osteoarthritis • Rheumatoid arthritis • Low-back pain • Neck pain	• Headache • Irritable bowel syndrome • Pelvic pain • Temporomandibular joint dysfunction • Atypical facial pain • Non-cardiac chest pain • Lyme disease • Whiplash • Repetitive strain Injury

*A limitation of these trials was that the duration of opioid therapy was a maximum of three months.

1. Nociceptive pain of musculoskeletal origin (e.g., osteoarthritis, low-back pain, neck pain)
Opioids showed only small to moderate benefits for nociceptive pain in improving function and relieving pain (Furlan 2006, Furlan unpublished 2010, Nuesch 2009). If opioids are required, patients generally respond to moderate doses. Acetaminophen, NSAIDs and non-pharmacological treatments are often effective for patients with low back pain and other common musculoskeletal problems.

…continued

[1] For effect size, most authors use Cohen's three levels,(REF Cohen, & REF 2009 Updated Method Guideline)
Small: • Mean difference less than 10% of the scale (e.g., <10mm on a 100 mm VAS).
• ES <0.5.
Medium: • Mean difference 10 to 20% of the scale.
• ES from 0.5 to <0.8.
Large • Mean difference >20% of the scale.
• ES ≥ 0.8.

R04 Discussion… continued

2. Neuropathic pain

Opioids showed only small to moderate benefits for neuropathic pain (Furlan 2006, Furlan 2009, Eisenberg 2005). Patients with neuropathic pain may require higher opioid doses, in combination with tricyclic antidepressants (Khoromi 2007) or anticonvulsants (Gilron 2005).

3. Migraine, tension headache, functional GI problems

Opioids are usually not indicated for migraine or tension headaches, or for patients with functional gastro-intestinal problems such as irritable bowel syndrome (Bigal 2009).

4. Widespread soft tissue pain

The benefit of the weak opioid tramadol for fibromyalgia was small. Other pain-relief options should be considered.

R04 Summary of Peer-Reviewed Evidence

The updated systematic review of opioids for CNCP included 62 randomized trials (see Appendix B-13). Opioids were compared to placebos in 47 randomized trials. The effect size for improvement in pain was medium (0.58 95% confidence interval [CI]: 0.48 to 0.67, extracted from 47 RCTs). For functional outcomes, the effect size was small (0.34 95% CI: 0.25 to 0.43, extracted from 31 RCTs) (Furlan unpublished 2010).

1. Nociceptive pain and osteoarthritis.

The meta-analysis of 31 randomized trials of opioids for nociceptive pain showed a medium-effect size for pain relief outcomes (0.60 95% CI: 0.49 to 0.72, extracted from 31 trials), and small for functional outcomes (0.38 95% CI: 0.26 to 0.49, extracted from 21 trials) (Furlan unpublished 2010).

A recently published Cochrane review of opioids for osteoarthritis showed that the small-to-moderate beneficial effects of non-tramadol opioids are outweighed by large increases in the risk of adverse events. They concluded that non-tramadol opioids should therefore not be routinely used, even if osteoarthritic pain is severe (Nuesch 2009).

2. Neuropathic pain.

The meta-analysis of 13 randomized trials of opioids for neuropathic pain showed a medium effect size for pain relief outcomes (0.56 95% CI: 0.38 to 0.73, extracted from 13 trials), and small for functional outcomes (0.24 95% CI: 0.09 to 0.39, extracted from 7 trials) (Furlan unpublished 2010).

A fixed-effects model meta-analysis of 6 randomized trials of opioids for neuropathic pain showed mean post-treatment visual analog scale scores of pain intensity after opioids to be 14 units lower on a scale from 0 to 100 than after placebo (95% CI: −18 to −10; P<.001) (Eisenberg 2005).

3. Widespread soft tissue pain.

There are no randomized trials of strong opioids for fibromyalgia. There are two randomized trials of the weak opioid, tramadol for fibromyalgia. They showed small benefits in reducing pain (Russell 2000, Bennett 2003). The EULAR (European League Against Rheumatism) guidelines for the treatment of fibromyalgia recommend tramadol but not strong opioids (Carville 2008).

R05 Recommendation Statement

R05	Before initiating opioid therapy, ensure informed consent by explaining potential benefits, adverse effects, complications and risks (Grade B). A treatment agreement may be helpful, particularly for patients not well known to the physician or at higher risk for opioid misuse. (Grade C).

Risks, adverse effects, complications

R05 Discussion

1. Informed Consent

A discussion about potential benefits, adverse effects, complications, and risks helps the physician and patient make a joint decision on whether to proceed with opioid therapy. (See Appendix B-4 for opioid information for patients).

1.1 Goal Setting: Potential Benefits and Patient Expectations

Before starting opioids, the physician should ensure the patient's expectations are realistic. The goal of opioid therapy for *chronic* non-cancer pain is rarely the elimination of pain, but rather an improvement in function or a reduction of pain intensity by at least 30%. Before starting opioids, a discussion with the patient about specific goals related to pain reduction and functional improvement should address any unrealistic expectations. These agreed-on goals should be documented in the patient's record; they are critical in determining that opioids are effective and should be monitored over time.

1.2 Adverse Effects

The most common adverse effects are listed in Table B-5.1.

Table B-5.1 Adverse Effects of Opioids

Note: From randomized trials, excluding enrichment design trials, results show a clinically important difference (Diff>10%) and are statistically significant (P<0.05).

Adverse effect	Number of Studies	Incidence in Opioid Group	Incidence in Placebo Group	Difference (95% CI)
Nausea	38	28%	9%	17% (13% to 21%) P<0.00001
Constipation	37	26%	7%	20% (15% to 25%) P<0.00001
Somnolence/drowsiness	30	24%	7%	14% (10% to 18%) P<0.00001
Dizziness/vertigo	33	18%	5%	12% (9% to 16%) P<0.00001
Dry-skin/ itching/ pruritus	25	15%	2%	10% (5% to 15%) P<0.0001
Vomiting	23	15%	3%	11% (7% to 16%) P<0.00001

Adverse effects where the difference was not clinically important (Diff <10%) and/or not statistically significant (P>=0.05) include: dry-mouth, headache, sexual dysfunction, hot flushes, loss of appetite, abdominal pain, fatigue, sleeplessness/insomnia, sweating, blurred vision/confusion, muscle contractions, diarrhea, ataxia, edema, difficulty urinating, restless legs, application site reaction, heart burn, anxiety, weakness.

…continued

R05 Discussion… continued

1.3 Medical Complications

Information about medical complications associated with LTOT is reported in *non-randomized* trials (RCTs are short-term: 3 months). There is no evidence regarding the frequency of medical complications, the relationship between length of time on opioids and occurrence of medical complications, or whether the complications are permanent or transient. Patients should be informed about potential long-term use medical complications such as **neuroendocrine** (hypogonadism and amenorrhea), **sleep apnea** (central sleep apnea or worsening of obstructive sleep apnea), and **opioid-induced hyperalgesia**.

1.3.1 Neuroendocrine Abnormalities

Neuroendocrine abnormalities and **erectile dysfunction** can be experienced with LTOT (Ballantyne 2003, Daniell 2006). One recently published randomized trial found that the incidence of sexual dysfunction after morphine happened in 11% (Khoromi 2007). However, two other randomized trials suggested that patients taking opioid medications reported better sexual function, which was likely an improvement of well-being (Arkinstall 1995, Watson 2003). In summary, in the short term, the patient may notice improvement in sexual function (as a consequence of improved analgesia), but in the long term, opioids may cause neuroendocrine dysfunction.

1.3.2 Sleep Apnea

Opioids can aggravate not just **central sleep apnea**, but frequently also significantly aggravate **obstructive sleep apnea**. High opioid doses may contribute to sleep movement disorders including myoclonus and sometimes choreiform movement, and in combination with benzodiazepines and other drugs may significantly contribute to oxygen desaturation (Zgierska 2007, Mogri 2008, Farney 2003). Consider a sleep study for patients using high-dose opioids, opioid in combination with other sedating drugs, elderly patients, obese patients, and patients with somnolence.

1.3.3 Opioid-induced Hyperalgesia (OIH)

OIH is a paradoxical hyperalgesia resulting from LTOT. It is characterized by pain sensitivity (hyperalgesia and allodynia) in the absence of overt opioid withdrawal. It is distinct from tolerance in that pain extends beyond the area of initial complaint. It is also known as opioid neurotoxicity or opioid-induced pain sensitivity (OIPS) (Chu 2006, Ballantyne 2003).

1.4 Risks

Explain the potential risks of opioid therapy and provide reassurance on how the risks can be managed. See Table B-5.2.

…continued

Table B-5.2 Opioid Risks

	Actions for the Physician	Information for the Patient	Directions for the Patient and Family
1. Risk: OVERDOSE	• Start with a low dose, titrate gradually, and monitor frequently. See Table B-9.1: Opioid Suggested Initial Dose and Titration. • Be cautious when prescribing benzodiazepines (see Recommendation 06). • For patients at higher risk of overdose*, —initial dose should not exceed 50% of the suggested initial dose, and dose increments should be more gradual (See Table B-9.1). —consider a 3-day "tolerance check:" contact the patient 3 days after starting the opioid to check for signs of oversedation.	• Opioids are safe over the long term, BUT can be dangerous when starting or increasing a dose. • Overdose means thinking and breathing slows down — this could result in brain damage, trauma, and death. • Mixing opioids with alcohol or sedating drugs greatly increases the risk of overdose.	• *Contact a physician on early signs of overdose: slurred or drawling speech, emotional lability, ataxia, "nodding off" during conversation or activity.* • *Avoid mixing prescribed opioids with alcohol or sedating drugs.* • *Avoid driving a vehicle or operating equipment/heavy machinery until a stable dose is reached.* • *If you interrupt your medication schedule for three days or more for any reason, do not resume taking it without consulting a physician.*
2. Risk: DIVERSION	Ask questions about the following to determine risk of opioid diversion: • History of alcohol or substance abuse (patient and/or household member) • Transient or unstable housing • Vulnerability and dependence on caregivers	• Sharing prescribed medication with others is illegal, and could harm the other person. • While the patient's opioid dose is safe, it may be dangerous for other people. • Adolescents may abuse prescription opioids and sometimes pilfer drugs from the family medicine cabinet	• *Do not give your prescribed medication to any other person: This is illegal, and the drug could harm the other person.* • *Store your medication in a secure place with limited access to guard against others' (e.g., adolescents) illicit use.* • *Inform your physician if you feel your medication is insecure, or if you feel any pressure about sharing.*

Table B-5.2 Opioid Risks…*continued*

	Actions for the Physician	Information for the Patient	Directions for the Patient and Family
3. Risk: ADDICTION	Use appropriate screening tools to determine risk of addiction.	• Addiction means that a person uses the drug to "get high," and cannot control the urge to take the drug. • However, most patients do not get high from taking opioids, and addiction is unlikely if addiction risk factors are low: those at greatest risk have a history of addiction. • Withdrawal symptoms can occur in any patient taking opioids regularly: they do not indicate addiction.	*Do not let unfounded fears of addiction stop you from taking your medication. Take your medication strictly as prescribed and do not stop the medication without informing a doctor.*
4. Risk: WITHDRAWAL	If a decision is made to discontinue opioid therapy, the opioids should be tapered under medical supervision (see Appendix B-12).	• Opioid withdrawal symptoms are flu-like, e.g., nausea, diarrhea, and chills. • Withdrawal is not dangerous but it can be very uncomfortable. • Withdrawal can occur in any patient who takes opioids regularly, and it does not mean that the patient is addicted.	*Do not abruptly discontinue your medication, as this can cause uncomfortable withdrawal symptoms.*

* Patients at higher risk of opioid overdose are those with:

1. **Renal or hepatic impairment***:* Caution is advised, because opioids are metabolized in the liver and excreted through the renal system (Tegeder 1999, Foral 2007). Morphine is contraindicated in renal insufficiency.
2. **Chronic obstructive pulmonary disease (COPD) and sleep apnea***:* Opioid use may be a risk factor for central sleep apnea (Mogri 2008). Tolerance to the respiratory depressant effects of opioids develops slowly and incompletely, putting COPD patients at risk for respiratory depression with a higher dose increase.
3. **Sleep disorders***:* Sleep disorders, including insomnia and daytime sleepiness, are common among opioid users (Zgierska 2007). They may reflect the effects of pain, or the sedating effects of opioids, or concurrent depression.
4. **Cognitive impairment***:* Opioids should be avoided in cognitively impaired patients who live alone, unless ongoing medication supervision can be arranged.

R05 Discussion… continued

2. Treatment Agreement / Contract

Contracts are widely used in the long-term administration of potentially abusable substances. These agreements are intended to improve adherence and to enhance the therapeutic relationship by initiating an alliance between the patient and the physician. A contract is defined as an "explicit bilateral commitment to a well-defined course of action." Responsible parties in the contract usually have a clearly stated understanding of their individual obligations.

Contracts attempt to improve treatment through disseminating information, facilitating an agreed-on course, and enhancing adherence. The treatment agreement often includes clear descriptions of medication use and abuse, as well as the consequences for violating the contract.

2.1 Treatments Agreements: Oral or Written

- Written treatment agreements are chosen particularly for patients the physician does not know well, or who are at higher risk for misuse. A written agreement is usually signed by both patient and physician, with a copy provided to the patient.
- Oral treatment agreements should be documented in the patient's chart.

2.2 Treatments Agreement Contents

The agreement usually outlines responsibilities and boundaries for both the patient and physician. (See Appendix B-5 for an example of a treatment agreement.) For example, a treatment agreement typically includes the following:

- states that the patient:
  - —will not give opioids to others
  - —will not receive opioids from other sources
  - —will store the medication in a safe place
  - —will comply with scheduled visits and consultations
  - —will provide urine samples for drug screens when requested
- states that the physician:
  - —will not normally refill the prescription ahead of schedule if the patient runs out
  - —may cease opioid prescribing if the patient does not abide by the agreement.
- identifies one single prescribing physician: All physicians involved in the patient's care should agree on a designated prescribing physician, and whenever possible, identify an alternate physician to continue prescribing a patient's medication in the event that the primary prescribing physician is unavailable.
- identifies one dispensing pharmacy.

R05 Summary of Peer-Reviewed Evidence

1. Non-randomized trials describe medical complications.

1.1 Hypogonadism

Opioids influence the hypothalamic-pituitary-adrenal axis and the hypothalamic-pituitary-gonadal axis. Morphine has been reported to cause a strong, progressive decline in the plasma cortisol level in adults. Opioids interfere with the modulation of hormonal release, including an increase in prolactin and a decrease in luteinizing hormone, follicle-stimulating hormone, testosterone, and estrogen. Testosterone depletion has been demonstrated in heroin addicts and in patients receiving methadone maintenance therapy. The collective effects of the hormonal changes may lead to decreased libido, aggression, and drive; amenorrhea or irregular menses; and galactorrhea (Ballantyne 2003).

…continued

R05 Summary of Peer-Reviewed Evidence…continued

Most randomized trials reviewed did not inquire about sexual dysfunction. The few studies that did so were of too short duration to allow for the development of any endocrinological abnormalities. In these studies, the authors inquired about sexual activity by using the Pain Disability Index (PDI). This index consists of 7 self-reported disability subscales, one of which refers to sexual activity; each scale is graded from 0 to 10, where 0 = no disability and 10 = total disability. This scale is not adequate to validly identify sexual dysfunction. Only two studies give a specific score on the dimension of sexual activity. In the first study using this measure (Arkinstall 1995), with 46 patients randomly assigned to receive CR codeine or placebo, the PDI score for the "sexual activity" subscale was 4.1 and 6.3, respectively. In the other (Watson 2003), which involved 45 patients, the score was 3.4 for controlled-release oxycodone and 4.5 for placebo. Both studies, therefore, suggested that patients taking opioid medications reported better sexual function than those taking placebo.

However, the PDI is a patient-rated global rating of function, does not measure variables such as libido, sexual dysfunction or gonadal function, or opportunity for sexual activity, and by itself cannot be used to estimate risk of hypogonadism. It is more likely that improvement of well-being secondary to better pain control by the use of opioids, accounted for this reported positive result in those studies.

One recently published trial (Khoromi 2007) found that the incidence of sexual dysfunction after morphine happened in 11% (of 28 completers of the study, out of 55 randomized), 0% in the nortriptyline group, 4% in the combination (morphine plus nortryptiline) and 0% in the placebo group. It is not possible to draw conclusions about the differences among these four groups because 1) this information is drawn from the completers of the study, and 2) these subgroup analyses do not have statistical power to detect any meaningful difference. Nevertheless, it was interesting to note that most recent studies are starting to ask participants about sexual dysfunction as a possible adverse event from opioids.

1.2 Sleep apnea

Patients on long-term sustained-release opioids show a distinctive pattern of sleep-disordered breathing that is different from the disturbances usually observed in subjects with obstructive sleep apnea (OSA). The oxygen desaturation is more severe and respiratory disturbances are long during NREM sleep (Farney 2003). In another study, even a short-term ingestion of opioid analgesic precipitated central sleep apnea in patients with chronic pain receiving long-term opioid therapy (Mogri 2008). There is also evidence that opioids may complicate underlying sleep apnea and make continuous positive airway pressure (CPAP) therapy less effective (Mogri 2008).

1.3 Opioid-induced hyperalgesia

Many studies were conducted in healthy volunteers with experimental pain, opioid addicts on methadone program and on perioperative exposures to opioids. There is one prospective study conducted on chronic pain patients (low-back pain) after one month of oral morphine therapy (Chu 2006). These authors showed evidence for the development of analgesic tolerance and OIH using a cold pressor test and experimental heat pain to measure pain sensitivity.

…continued

R05 Summary of Peer-Reviewed Evidence…continued

2. Evidence for Treatment Agreements

Overall, there is evidence to support the use of treatment agreements, although from non-randomized studies (Arnold 2006). One small study found that treatment agreements improve compliance (Fishman 2000), while another found that primary-care physicians were more willing to prescribe opioids to patients if the pain-medicine physician also signed an agreement ("trilateral contract") (Fishman 2002).

R06 Recommendation Statement

R06	For patients taking benzodiazepines, particularly for elderly patients, consider a trial of tapering (Grade B). If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. (Grade C).	***Benzodiazepine tapering***

R06 Discussion

The combination of opioids and benzodiazepines increases the risk of sedation, overdose, and diminished function in all patients, especially as age advances. (See also Recommendation 17 for prescribing cautions for the elderly). Opioids should be prescribed more slowly and at lower doses for patients on benzodiazepine treatment.

A successful trial of **benzodiazepine tapering** can mean either a dose reduction or elimination of benzodiazepines. (See Appendix B-6 for a description of benzodiazepine tapering approach.) Benzodiazepine tapering is feasible in a primary-care setting, and it is associated with improved health outcomes. Tapering benzodiazepines may not be indicated in situations such as moderate to severe anxiety, panic disorder, seizures, and spasticity.

R06 Summary of Peer-Reviewed Evidence

1. There is evidence that benzodiazepines increase opioid toxicity and risk of overdose.

Concurrent prescribing of opioids and benzodiazepines is common. Cross-sectional studies suggest that pain patients may be more likely to be prescribed opioids and to receive higher doses if they abuse alcohol, are on benzodiazepines, or are depressed (Hermos 2004, Sullivan 2005). Most opioid overdoses involve multiple drugs in addition to opioids (Mirakbari 2003); benzodiazepines and alcohol are most commonly implicated. The serum concentration of opioids is lower in mixed overdoses than in pure overdoses, suggesting that other drugs significantly lower the lethal opioid dose (Cone 2004).

2. There is evidence that benzodiazepines can be successfully tapered in a primary-care setting, with improved health outcomes.

Several controlled trials have demonstrated that benzodiazepine tapering can be done in a primary-care setting. Tapering has been shown to be successful both in patients with anxiety disorders and with insomnia (Baillargeon 2003, Gosselin 2006). An observational study documented reduced symptoms of depression in methadone patients who were tapered off benzodiazepines and started on antidepressant therapy (Schreiber 2008). Tapering is more effective when combined with cognitive-behavioural therapy, but can be successful without formal CBT (Baillargeon 2003, Gosselin 2006, Vicens 2006). A significant number of older patients are willing to attempt benzodiazepine tapering (Cook 2007). Patients being tapered for insomnia have decreased sleep time but improved quality of sleep post-taper (Morin 2004). Controlled trials have found that psychiatric symptoms (panic disorder, GAD) do not worsen with tapering, and may improve (Moroz 1999, Gosselin 2006). For an approach to benzodiazepine tapering, see Appendix B-6.

Cluster 2: Conducting an Opioid Trial

R07 Recommendation Statement

R07	During dosage titration in a trial of opioid therapy, advise the patient to avoid driving a motor vehicle until a stable dosage is established and it is certain the opioid does not cause sedation (Grade C); and when taking opioids with alcohol, benzodiazepines, or other sedating drugs. (Grade B).	***Titration and driving***

R07 Discussion

During an opioid trial titration, patients should be advised that opioids could cause cognitive effects that could impair their ability to drive. This caution is even more important in patients taking alcohol, benzodiazepines, or other sedating drugs with their opioids. For more details about opioids and driving, see Recommendation 14.

A "pharmacologically stable dose" is one that produces a fairly steady plasma level; it is established when the *total daily dose* is fixed for at least two weeks *and*:

1) frequency is scheduled and spread throughout the day
   AND/OR
2) at least 70% of the prescribed opioid is controlled release.

R07 Summary of Peer-Reviewed Evidence

1. Patients who undergo a significant increase in the dose of narcotic experience significant cognitive impairment.

Bruera et al. reported on 40 patients with cancer pain: 20 had no change in narcotic dose (stable dose) and 20 had undergone an increase of more than 30% in dose (increased dose group). Cognitive changes were observed only in the increased dose group (Bruera 1989).

2. In a population receiving both narcotics and benzodiazepines, the cognitive impairment noted was found to be more likely due to benzodiazepines than to narcotics.

Hendler et al. compared three groups of patients: benzodiazepines alone, narcotics alone, and both benzodiazepine and narcotics. They found that narcotics did not impair cognitive functioning, memory or performance on visual and motor-perceptual tasks, however, cognitive impairment was much more apparent in patients receiving benzodiazepines (Hendler 1980).

R08 Recommendation Statement

R08	During an opioid trial, select the most appropriate opioid for trial therapy using a stepped approach, and consider safety. (Grade C).	***Stepped opioid selection***

R08 Discussion

The most appropriate drug for an opioid trial depends on the patient's clinical profile and individual circumstances. The following tables have been prepared to assist prescribers in selecting the most appropriate opioid.

Table B-8.1 Stepped Approach to Opioid Selection

Mild-to-Moderate Pain		
First-line for Mild-to-Moderate Pain: codeine or tramadol		
	Severe Pain	
Second-line for Mild-to-Moderate Pain: morphine, oxycodone or hydromorphone	*First-line for Severe Pain*: morphine, oxycodone or hydromorphone	
	Second-line for Severe Pain: fentanyl	
		Third-line for Severe Pain: methadone

…continued

Table B-8.2 Safety Issues to Consider When Selecting Opioids

Note: This table highlights safety issues for specific agents; for comprehensive information, prescribers should consult the individual drug monographs.

Agent	Safety Issues
Codeine	1) Use with caution for breast-feeding women: some rapidly convert codeine to morphine, placing the infant at risk of morphine toxicity. (See Recommendation 19.) 2) Lower risk of overdose and addiction than stronger opioids. (See Supporting Evidence item 1.)
Tramadol	1) Associated with seizures in patients at high seizure risk, or when combined with medications that increase serotonin levels, e.g., SSRIs. 2) Lower risk of overdose and addiction than stronger opioids. (See Supporting Evidence item 1.)
Morphine	Avoid for patients with renal dysfunction: an active metabolite of morphine (M-6 glucoronide) can accumulate to toxic levels in patients with renal impairment. (See Supporting Evidence item 2.)
Oxycodone, Hydromorphone, Hydrocodone	Use with caution for patients at higher risk for opioid misuse and addiction: experimental studies and surveys of drug users suggest that oxycodone, hydromorphone and hydrocodone may have a higher abuse liability than morphine. (See Supporting Evidence item 3.)
Fentanyl	1) Before starting fentanyl, obtain a complete history of-opioid use within the last 2 weeks to ensure the patient is fully opioid tolerant. Tolerance can be assumed if the patient is on a moderate, stable dose of a strong opioid, i.e., a total daily dose of at least 60–90 mg/day morphine equivalence daily for at least 2 weeks. This dose should be scheduled rather than p.r.n. (at least b.i.d. for CR or q.i.d. for IR). See Supporting Evidence item 4.) 2) Do not switch from codeine to fentanyl regardless of the codeine dose, as some codeine users may have little or no opioid tolerance. 3) Maintain the initial dose for at least 6 days: use extra caution with patients at higher risk for overdose, e.g., elderly, patients on benzodiazepines. 4) Advise the patient as follows: • Be alert for signs of overdose: (e.g. slurred or drawling speech, emotionally labile, ataxia, nodding off during conversation or activity) if detected, remove the patch and seek medical attention. • Apply as prescribed: do not apply more than one patch at a time or change more often than directed. • Avoid heat sources such as heating pads, electric blankets, saunas, heated waterbeds, hot baths, sunbathing. • Dispose of patches securely: a used patch contains large amount of fentanyl and could be dangerous to others. e.g., children or abusers could “recycle” by cutting into small pieces and sucking the pieces.
Methadone	Use methadone to treat pain only if holding a written Health Canada exemption. Titration is hazardous due to its very long half life leading to bio-accumulation. (See Supporting Evidence item 5.)

…continued

Table B-8.2 Safety Issues to Consider When Selecting Opioids… continued

Agent	Safety Issues
Meperidine (Demerol®)	Not recommended for use in CNCP: a) oral meperidine has poor bioavailability and is less effective than codeine, and b) normeperidine can accumulate with frequent use of parenteral doses of meperidine, causing seizures and delirium. (See Supporting Evidence item 6.)
Acetaminophen-opioid combinations	Use with caution to avoid acetaminophen toxicity. FDA (U.S.) recommends a maximum daily dose of 3.2 grams acetaminophen for adults = 10 tablets/day for opioid/ acetaminophen combinations. The manufacturer recommends a lower dose for tramadol/acetaminophen (8 tablets/day). (See Supporting Evidence item 7.) Heavy drinkers should be advised to use acetaminophen with extra caution.

Table B-8.3 Other Formulations and Preparations

Formulation/ Preparation	Safety Issues
CR formulations	Titrate with caution to avoid overdose and misuse: each CR tablet can contain a much higher opioid dose than IR formulations, and can easily be converted to IR by biting or crushing the tablet. (See Supporting Evidence item 8.)
Parenteral opioids	Parenteral opioids are not recommended for use in CNCP: parenteral route has higher risk of overdose, abuse and addiction, and infection.

R08 Supporting Evidence

1. Codeine and Tramadol

1.1 Codeine and tramadol may have a lower abuse risk than more potent opioids.

Codeine has a lower risk of abuse and addiction than stronger opioids. For example, one national U.S. study found that codeine and other low potency opioids have low ratios of abuse to prescription use, relative to oxycodone, hydromorphone and hydrocodone. Abuse rates were measured from Drug Abuse Warning Network data (Dasgupta 2006). Tramadol also has a low risk of addiction, and experimental studies suggest that it has fewer psychoactive effects than other opioids (Preston 1991, Cicero 2005).

2. Morphine

2.1 Morphine can cause toxicity in patients with renal dysfunction.

For example, one cross-sectional study demonstrated that M-6 glucoronide, an active metabolite of morphine, accumulated in the serum of patients with renal dysfunction when morphine was administered orally or subcutaneously. The degree of accumulation was related to the morphine dose and the extent of renal impairment (Peterson 1990).

3. Oxycodone, Hydromorphone and Hydrocodone

3.1 There is evidence that oxycodone and hydromorphone have a higher abuse liability than other opioids. This is based on phase-2 studies, patient surveys, and studies of treatment programs.

One study found that prescription opioid misusers ranked controlled-release oxycodone, and immediate-release hydromorphone and oxycodone as the most desirable of 14 different opioid formulations. The study used a validated opioid attractiveness scale (Butler 2006). A national surveillance study of addiction experts, law enforcement agencies and poison control centers identified hydrocodone and both immediate-release and controlled-release oxycodone as by far the most commonly abused opioids in the United States (Cicero 2007).

Only a few controlled studies have been conducted comparing opioids on their abuse liability. Two placebo-controlled studies compared the psychoactive effects of oral morphine to oral oxycodone in non-drug abusing volunteers. The studies found that oxycodone had greater reinforcing effects at equi-analgesic doses to morphine (Zacny 2003, Zacny 2007). Another controlled trial found that oxycodone, hydromorphone and hydrocodone had equivalent abuse liability (Walsh 2008). The clinical significance of these studies for chronic pain patients is not certain because volunteers may experience different psychoactive effects than actual pain patients (Lamb 1991).

It is also possible that the prevalence of oxycodone abuse may simply reflect its popularity as an opioid analgesic. In an analysis of data from the Drug Abuse Warning Network, oxycodone, hydromorphone and morphine had similar rates of overdoses and other events after controlling for the potency of the opioid and the amounts prescribed in kg (Dasgupta 2006).

4. Fentanyl

4.1 Fentanyl can cause significant cognitive impairment in non-tolerant opioid patients.

Experimental studies in volunteers have found that cognitive impairment caused by acute intravenous fentanyl administration was greater than that caused by moderate doses of alcohol (Zacny 1992, Schneider 1999). …*continued*

R08 Supporting Evidence, 4. Fentanyl…continued

4.2 Fentanyl has contributed to numerous overdose deaths.

Fentanyl was a contributing cause in 100 overdose deaths in Ontario between 2002 and 2004. In 54 of the deaths, fentanyl intoxication was the sole cause of death. Deaths occurred from both therapeutic and illicit use (Martin 2006).

Fentanyl-laced heroin appeared simultaneously in various parts of the United States, beginning in 2005. In Chicago, in the first half of 2006, 55 drug overdose cases (resulting in 12 deaths) have been attributed to fentanyl-laced heroin (Fodale 2008). Fentanyl toxicity is related in 92% of fentanyl-related deaths and is attributed partially due to cytochrome P450 3A4*1B and 3A5*3 variant alleles, resulting in variable fentanyl metabolism: the homozygous CYP3A5*3 have impaired metabolism of fentanyl (Fodale 2008). In July 2005, the FDA issued a public health advisory calling attention to an increase in the number of fentanyl patch-related overdoses and deaths, particularly among patients ignoring the product's boxed warnings and instruction for use (Federal Drug Administration 2007).

4.3 CNCP patients on codeine at risk for overdose when switched to fentanyl.

Up to 10% of Caucasians lack the enzyme CYP450 2D6 that converts codeine to morphine and therefore when switching from codeine to fentanyl, regardless of the codeine dose, caution is required as patients may have little or no opioid tolerance (Tyndale 1997, Romach 2000, Howard 2002).

5. Methadone

5.1 Methadone for pain is more effective than placebo, but has not been shown to be more effective than other opioids.

Sandoval (2005) conducted a systematic review of methadone for CNCP. The review included 21 studies (1 small randomized trial, 13 case reports, and 7 case series) and concluded that pain improvements were meaningful in 59% of the patients in the uncontrolled studies. The randomized trial demonstrated a statistically significant improvement in pain for methadone (20 mg/day) compared to placebo. Side effects were considered minor. One controlled trial found no difference in analgesic efficacy between morphine and methadone in cancer patients with respect to pain management (Bruera 2004). A similar trial found no difference between methadone, oral morphine and transdermal fentanyl 25 ucg/hour, although methadone titration was more difficult (Mercadante 2005).

5.2 Physicians must hold an exemption from Health Canada before prescribing methadone for pain.

Methadone has been associated with numerous overdose deaths in pain patients. Methadone analgesic use has increased sharply in the US, with a seven-fold rise from 1997 to 2004 (Sims 2007). This has been accompanied by a 17-fold increase in methadone overdose deaths (Shields 2007, Sims, 2007). Federal law requires that a physician hold a written exemption from Health Canada before prescribing methadone for analgesia. The specific process to apply for a methadone exemption varies by jurisdiction, and may include submission of a letter of support from the applicable medical regulatory authority before Health Canada will provide a methadone exemption. A physician may be able to receive an exemption to prescribe methadone under various circumstances, including if "mentored" by an experienced methadone prescriber. Physicians should confirm the methadone prescribing requirements of the jurisdiction where they practice.

…continued

R08 Supporting Evidence…continued

6. Meperidine (Demerol®)

6.1 Repeated parenteral doses of meperidine are associated with adverse neurological events.

In one study of hospitalized patients receiving parenteral meperidine, 14% had neurological adverse events such as confusion or seizures. The risk of an adverse event was associated with the cumulative meperidine dose, renal insufficiency, and benzodiazepine use (Seifert 2004).

7. Acetaminophen-opioid Combinations

7.1 Acetaminophen is a common cause of hepatotoxicity; risk increases with alcohol use.

Acetaminophen toxicity causes the majority of cases of acute liver failure in the U.S., (Krenzelok 2009, Amar 2007). Sub-clinical liver toxicity has been shown to occur even with doses below 4 gm/day (Krenzelok 2009, Arundel and Lewis 244-54). To reduce toxicity, the FDA in the U.S. revised their maximum daily acetaminophen dose downward, from 4 gm/day to 3.2 gm/day. Alcohol competes for the same metabolic pathway as acetaminophen so heavy drinkers are at higher risk for toxicity. Chronic alcohol use is an independent risk factor for mortality in acetaminophen poisoning (Schmidt 2002).

8. CR Formulations

8.1 CR opioids are available in high-dose formulations which increase their risk of abuse and overdose.

CR opioids contain much higher opioid doses than acetaminophen-opioid combinations (e.g., one OxyContin® 80 mg tab = 16 Percocet® tablets). This increases the risk of both overdose and addiction. Controlled experimental studies indicate that the psychoactive effects of an opioid are dose related (Lamas 1994). Studies using non-drug-abusing volunteers have found dose-related reinforcing psychoactive effects with oral doses of 5, 10, and 20 mg of hydrocodone, and 10, 20, and 30 mg of oxycodone (Zacny 2003, 2005).

CR opioids can easily be converted to IR by crushing or biting the tablet. The outer layer of the OxyContin® tablet (but not other Contin tablets) is an IR formulation, containing 1/3 of the total dose.

R09 Recommendation Statement

R09	When conducting a trial of opioid therapy, start with a low dosage, increase dosage gradually and monitor opioid effectiveness until optimal dose is attained. (Grade C).	***Optimal dose***

R09 Discussion

1. Optimal Dose

1.1 Dose: Initial and Incremental

The object of the trial is to determine the optimal dose, i.e., a dose that will improve function or reduce pain intensity by at least 30% without causing major adverse effects or complications. It is recommended to start the opioid trial with a low dose and increase the dose in small quantities. Opioids produce a graded analgesic response: the patient experiences the greatest benefits at lower doses and a plateauing of analgesic response at higher doses. Therefore, slow titration 1) avoids unnecessarily high doses, and 2) reduces the risk of sedation and overdose as it ensures that a dose increase does not exceed the patient's tolerance. (Consider a three-day "tolerance check" for elderly and other high-risk patients: the nurse, physician, or pharmacist calls the patient/family three days after starting the prescription to check for any signs of sedation.) See Table B-9.1 for opioid suggested initial dose and titration.

1.2 Attaining Optimal Dose

The **optimal dose** is reached with a BALANCE of three factors:
1) **effectiveness**: improved function or at least 30% reduction in pain intensity
2) **plateauing**: effectiveness plateaus—increasing the dose yields negligible benefit, and
3) **adverse effects/complications**: adverse effects or complications are manageable.

1.3 Watchful Dose

Watchful Dose = morphine or equivalent dose exceeding 200 mg/day. See Recommendation 10 for guidance on a watchful dose.

2. Measuring Opioid Effectiveness

Opioid effectiveness = improved function or at least 30% reduction in pain intensity.

During an opioid trial, schedule patient visits frequently (e.g., 2–4 weeks) to assess for changes in pain intensity and function.

2.1 Assessing Function Change

The patient's progress in reaching agreed-on goals is an important indicator of function change. Self-report can be prompted by asking about work, household activity, mood, walking ability, sleep, and social activities. For an example of a structured assessment tool frequently used in trials, see Appendix B-9: Brief Pain Inventory©.

2.2 Assessing Pain Change

A 30% or greater reduction in pain intensity is considered clinically significant (Farrar 2001).

Change in pain intensity can be assessed using an 11-point (0–10) numeric rating scale (NRS). With each dose increase, the patient should be asked to estimate the pain intensity: a desirable response is a reduction in pain intensity (e.g., from 9/10 [baseline] to 6/10 [endpoint]) and a longer duration of analgesia per dose.

…continued

R09 Discussion, Assessing Pain Change… continued

Example of assessing change in pain intensity:

1. Determine the ***raw change*** in the NRS score:
   baseline – endpoint, e.g., 9 – 6 = 3

2. Determine the ***percent change***:
   $\frac{\text{raw change}}{\text{baseline}}$ x 100, e.g., $\frac{3}{9}$ x 100 = 33%

3. Monitoring for Adverse Effects, Medical Complications, Compliance, and Risks

3.1 Adverse Effects and Medical Complications

See Recommendation 5 for potential adverse effects, medical complications, and risks.

3.2 Compliance

Compliance is indicated when the patient takes the opioids as prescribed and shows no signs of misuse or aberrant drug-related behaviours.

4. Ending Titration

Titration ends when 1) the optimal dose is attained, or the 2) trial is considered a "failed trial."

The following circumstances could indicate a failed trial:

1) The patient experiences insufficient analgesia after two or three dose increases and/or unacceptable adverse effects and/or medical complications (see Recommendation 13).
2) There are indications of misuse or addiction (see Recommendation 12).

5. Documenting the Trial

It is important to record all aspects of the opioid trial in the patient's chart. Details regarding dose, frequency, opioid effectiveness, adverse effects, medical complications, goal attainment, and compliance are crucial in evaluating the opioid trial outcome.

For documentation templates, see Appendix B-7.

R09 Summary of Peer-Reviewed Evidence

1. Clinically important change for numerical pain scale (NRS)

"On average, a reduction of approximately two points or a reduction of approximately 30% in the PI-NRS represented a clinically important difference. The relationship between percent change and the PGIC was also consistent regardless of baseline pain, while higher baseline scores required larger raw changes to represent a clinically important difference" (Farrar 2001).

Table B-9.1 Opioid Suggested Initial Dose and Titration

Modified from Weaver 2007 with information from the e-CPS (Canadian Pharmacists Association, 2008)

Note: The table is based on oral dosing for chronic non-cancer pain. Brand names are shown if there are some distinct features about specific formulations. Reference to brand names as examples does not imply endorsement of any of these products.

ASA: acetylsalicylic acid, CR = controlled release, IR = immediate release, NA = not applicable

Opioid	Initial dose	Minimum time interval for increase	Suggested dose increase	Minimum daily dose before converting IR to CR
Codeine (alone or in combination with acetaminophen or ASA)	15-30 mg q.4 h. as required	7 days	15-30 mg/day up to maximum of 600 mg/day (acetaminophen dose should not exceed 3.2 grams/day)	100 mg daily
CR Codeine	50 mg q.12 h.	2 days	50 mg/day up to maximum of 300 mg q.12 h.	NA
Tramadol (37.5 mg) + acetaminophen (325 mg)	1 tablet q.4-6 h. as needed up to 4/day	7 days	1-2 tab q. 4-6 h. as needed up to maximum 8 tablets/day	3 tablets
CR Tramadol	a) Zytram XL®: 150 mg q. 24 h. b) Tridural™: 100 mg q. 24 h. c) Ralivia™: 100 mg q. 24 h.	a) 7 days b) 2 days c) 5 days	Maximum doses: a) 400 mg/day b) 300 mg/day c) 300 mg/day	NA
IR Morphine	• 5-10 mg q. 4 h. as needed • maximum 40 mg/day	7 days	5-10 mg/day	20-30 mg
CR Morphine	• 10-30 mg q.12 h. • Kadian®: q. 24 h. Kadian® should not be started in opioid-naïve patients	Minimum 2 days, recommended: 14 days	5-10 mg/day	NA
IR Oxycodone	• 5-10 mg q. 6 h. as needed • maximum 30 mg/day	7 days	5 mg/day	20 mg
CR Oxycodone	• 10-20 mg q.12 h. • maximum 30 mg/day	Minimum 2 days, recommended: 14 days	10 mg/day	NA
IR Hydromorphone	• 1-2 mg q. 4-6 h. as needed • maximum 8 mg/day	7 days	1-2 mg/day	6 mg
CR Hydromorphone	• 3 mg q. 12 h. • maximum 9 mg/day	Minimum 2 days, recommended: 14 days	2-4 mg/day	NA

R10 Recommendation Statement

R10	Chronic non-cancer pain can be managed effectively in most patients with dosages at or below 200 mg/day of morphine or equivalent (Grade A). Consideration of a higher dosage requires careful reassessment of the pain and of risk for misuse, and frequent monitoring with evidence of improved patient outcomes. (Grade C).

Watchful dose

R10 Discussion

Watchful Dose = morphine or equivalent dose exceeding 200 mg/day.

Some patients may require higher doses of opioids (e.g., patients who are benefiting from opioids but have developed tolerance), but based on existing RCTs, the majority of patients with CNCP will respond at doses up to the equivalent of 200 mg/day of morphine.

1. Considerations before Dose Exceeds 200 mg/day

Before prescribing over 200 mg/day, consider:

1. Reassessment of the pain problem:
   - Is diagnosis(es) accurate?
   - Is opioid effective for the patient's diagnosis(es)? (See Recommendation 4 for an overview of evidence of opioid efficacy.)
   - Is further investigation and/or consultation required?
   - Are non-opioid treatment options available?
   - Is there an inadequately treated mental health disorder?
2. Patient's response to opioids:
   - Has the patient shown appropriate opioid effectiveness (i.e., improved function or at least 30% reduction in pain intensity) in response to the dose increases to date? (Opioids have a graded response with the greatest benefit at the lowest doses.) If response has been insignificant, continuing to increase the dose will be futile. Switching or discontinuing the opioid could be considered.
   - Are there indications of increased medical complications and adverse effects? Some complications, i.e., opioid-induced hyperalgesia, cognitive impairment (attentional performance) and hypogonadism occur more frequently with higher doses (also see Recommendation 5).
3. Risk of misuse:
   - Is there any indication of aberrant drug-related behaviours?

2. Monitoring Doses Exceeding 200 mg/day

If prescribing over 200 mg/day, monitor patients more frequently for opioid effectiveness, medical complications, adverse effects and risks.

R10 Summary of Peer-Reviewed Evidence

1. Evidence of effectiveness and adverse effects from randomized controlled trials.

The systematic review update described in Part A: Literature Search Methods included 62 randomized trials, of which 25 employed a titration or fixed scheme to achieve optimal analgesia (Furlan unpublished 2010). The maximum, minimum, and average daily doses of morphine equivalents are shown in Table B-10.1 below.

Randomized trials of tramadol or codeine are not shown Table B-10.1 because there is a maximum pre-established daily dose of 400 and 600 mg respectively. Elderly patients (>75 years of age) should receive maximum of 300 mg of tramadol per day (Pascual 2007). Trials of transdermal fentanyl are not shown because they are not recommended for opioid-naïve patients, and it is commonly used as a second-line opioid; therefore the usual doses of transdermal fentanyl are dependent on the doses of the first-line opioid. In many cases patients with extremely high doses of other opioids are switched to transdermal fentanyl in an attempt to decrease the adverse effects and improve analgesia. Trials of transdermal buprenorphine were excluded because the conversion rate to morphine equivalent is not well established.

Table B-10.1 Morphine Equivalents for Strong Opioids used in Randomized Controlled Trials

MEQ= morphine equivalent, NR = not reported.

Drug	Pain type	MEQ Minimum	MEQ Average	MEQ Maximum	N studies
CR oxycodone	Nociceptive	20	65.7	146.7	6
	Neuropathic	40	81.3	173.3	3
Dihydrocodeine	Nociceptive	No Studies	No Studies	No Studies	0
	Neuropathic	NR	24	NR	1
CR morphine	Nociceptive	25	56.8	120	2
	Neuropathic	28.75	91.7	202.5	5
Oxymorphone	Nociceptive	30	219.2	420	3
	Neuropathic	No Studies	No Studies	No Studies	0

2. Concerns regarding high daily dose of opioids from observational studies.

The potential for adverse psychological and physical effects, the potential for misuse, and questionable efficacy are all factors that should be considered in limiting the dose and increasing the frequency of follow-up visits. Some studies reported safety concerns or questionable efficacy of higher daily doses of opioids.

Rowbotham and Lindsey reported on a long-term open label study where study patients were discouraged from exceeding a total of 360 mg/day MEQ. Twenty-nine patients entered the study, and interestingly there was a sex difference with men reaching both a higher dose (282 compared to 150 mg/day), and showing greater dose escalation (Rowbotham 2007).

2.1. Hypogonadism related to higher daily dose.

In 2003, Rajagopal and Bruera studied 20 male patients with cancer-related chronic pain who were disease-free for at least one year and all patients were consuming at least 200 mg/day MEQ. They found marked central hypogonadism and sexual dysfunction in this population (Rajagopal 2003). They reported on a case of a cancer survivor who showed improvement in sexual function after reduction of chronic high-dose MEQ daily dose from 690 mg to 20 mg (Rajagopal 2003).

…continued

R10 Summary of Peer-Reviewed Evidence…continued

2.2. Poor outcomes in population receiving higher daily dose.

Rome et al. reported the outcomes of a chronic non-cancer pain rehabilitation program according to opioid use status at admission (Rome 2004). They stratified the participants into non-opioid group (n=221), low dose (<41 mg/day) opioid users (n=71), and high dose (>41 mg/day, average 137.48 mg/day) opioid users (n=64). The outcomes at discharge showed that patients taking higher doses reported significantly greater catastrophizing and greater pain severity than the non-opioid group. There were no significant pre-treatment differences between the groups regarding demographics, pain duration, treatment completion or all outcome variables including pain severity.

Two recently published studies conducted in the workers' compensation population showed similar results. Webster et al. showed that mean disability duration, mean medical costs, risk of surgery and late opioid use increased with higher MEQ amounts. Those who received more than 450 mg were on average disabled 69 days longer than those who received no opioids (Webster 2007). Franklin et al. showed a statistically significant correlation that the receipt of more than 150 mg/day of morphine equivalent doses was associated with doubling of one-year disability risk (Franklin 2008).

2.3 Adverse events more commonly observed at higher daily doses.

Pascual et al. reported on an open-label study of the safety and effectiveness of long-term therapy with extended-release tramadol in the management of 919 patients with non-malignant pain (Pascual 2007). Adverse events were noted to begin more commonly at average daily doses of 300–399 mg/day or > 400 mg, than at lower doses. Two patients experienced seizures during the study (one serious and one non-serious), and both events occurred at a dose of 400 mg/day.

In a randomized trial of morphine compared to placebo for patients with neuropathic pain, attentional performance was assessed with the "d2-test", measuring vigilance over a 20-minute time period. The dose of morphine was titrated to at least 70 mg/day and at highest 300 mg/day. The results showed that the reduction of attention during morphine compared to placebo was more pronounced when a high dosage was taken (attentional deficit and dose: r = 0:73, P <0:05) (Huse 2001).

2.4 Conflicting evidence regarding the dose relationship between opioids and sleep apnea.

Walker et al. report on a retrospective study comparing 60 patients taking chronic opioids with 60 patients not taking opioids to determine the effect of opioid dose on breathing patterns during sleep. After controlling for BMI, age, sex, there was a dose-response relationship between morphine-equivalent dose and apnea-hypopnea, obstructive apnea, hypopnea and central apnea indexes. They concluded that there is a dose-dependent relationship between chronic opioid use and the development of a peculiar pattern of respiration consisting of central sleep apnea and ataxic breathing (Walker 2007).

One observational study of chronic pain patients on opioid therapy was designed to assess whether a dose relationship exists between methadone, non-methadone opioids, benzodiazepines and the indices measuring sleep apnea. They included all consecutive (392) patients on around-the-clock opioid therapy for at least 6 months with a stable dose for at least 4 weeks. Available data were analyzed on 140 patients. The apnea-hypopnea index was abnormal (≥5 per hour) in 75% of patients (39% had obstructive sleep apnea, 4% had sleep apnea of indeterminate type, 24% had central sleep apnea, and 8% had both central and obstructive sleep apnea); 25% had no sleep apnea. They found a direct relationship between the apnea-hypopnea index and the daily dosage of methadone (P = 0.002) but not to other around-the-clock opioids. They concluded that sleep-disordered breathing was common in chronic pain patients on opioids. The dose-response relationship of sleep apnea to methadone and benzodiazepines calls for increased vigilance (Webster 2008). …*continued*

R10 Summary of Peer-Reviewed Evidence…continued

Another study reported on 6 cases of patients receiving opioids for CNCP for more than 6 months referred to a sleep study because of excessive daytime sleepiness (Allatar 2009). All six cases had a diagnosis of central sleep apnea. Three patients also had obstructive sleep apnea. The opioid doses were 120, 230, 262, 300 (two) and 420 MEQ per day.

2.5 Opioid-induced hyperalgesia related to higher daily doses.

Cohen conducted a study on 355 patients on a steady regimen of opioids who volunteered to receive a standardized subcutaneous injection of lidocaine prior to a full dose of local anesthetic for a scheduled interventional procedure. Before and after the injection, they were asked to rate pain and unpleasantness. Subjects were stratified into 6 groups based on the dose of opioids they were taking. A group of 27 volunteers who had no pain and no analgesics were also injected. Both opioid dose and duration of treatment directly correlated with pain intensity and unpleasantness scores. Baseline pain intensity and female genders were also predictive of responses. The results of this study are in agreement with experimental studies of enhanced pain perception in subjects receiving opioid therapy (Cohen 2008).

3. Evidence from other systematic reviews, opinion papers, and clinical practice guidelines.

In a recent review, Ballantyne and Mao indicated that doses higher than 180 mg of MEQ/day have not been validated in clinical trials and should be considered excessive (Ballantyne 2003).

In a recent editorial in JAMA, McLellan and Turner call for physician responsibility in prescribing opioids because of the direct relationship between amount of prescriptions and public health threats from prescription diversion. They advise physicians that opioid doses should be re-evaluated regularly because analgesic response has been shown to wane at longer intervals (McLellan 2008).

The 2009 "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (The American Pain Society and American Academy of Pain Medicine) proposed by panel consensus, a reasonable definition for high-dose opioid therapy as >200 mg daily of oral morphine (Chou 2009).

4. Opioid-receptor genotype associated with higher opioid dose required to achieve pain relief.

Analgesic efficacy of mu-acting drugs has been linked to the 118>G single nucleotide polymorphism (SNP) of OPRM1, the gene encoding the mu-1 receptor. The frequency of the variant G allele varies from 10% to 48% depending on the population studied. Studies conducted in cancer pain show that patients carrying the GG (homozygous variant) genotype require much higher opioid doses to achieve pain relief. In AA patients the daily morphine dose was 112 mg, in AG patients the dose was 132 mg and in GG patients the dose was 216 mg. All three groups achieved the same pain relief (Reynolds 2008.).

R11 Recommendation Statement

R11	When initiating a trial of opioid therapy for patients at higher risk for misuse, prescribe only for well-defined somatic or neuropathic pain conditions (Grade A), start with lower doses and titrate in small-dose increments (Grade B), and monitor closely for signs of aberrant drug-related behaviors. (Grade C).

Risk: opioid misuse

R11 Discussion

1. Indicators of Patients at Higher Risk of Opioid Misuse

The following factors could indicate patients at higher risk of opioid misuse:

1) history of alcohol or substance abuse (patient and/or family)
2) uncertain security in the home (e.g., living in a boarding home with minimal protection for possessions), and
3) past aberrant drug-related behaviours (see Recommendation 12).

For patients at higher risk of misuse, ensure that:

1) opioids have shown to be effective for the patient's diagnosis(es) (See Recommendation 4 for an overview of evidence of opioid efficacy), and
2) all other available treatment options have been exhausted.

2. Titration for Patients with Higher Risk of Opioid Misuse

In these higher-risk cases, start the titration at lower doses, increase in smaller quantities, and monitor more frequently. Careful opioid prescribing will limit both diversion and misuse of prescribed medications. Also, since the euphoric effects of opioids are dose-related, minimizing the dose may reduce the risk of opioid misuse by reducing patients' exposure to the reinforcing psychoactive effects of opioids.

A further precaution could include prescribing at frequent dispensing intervals, e.g., daily, alternate days, twice per week, or every 1–2 weeks.

3. Monitoring Patients with Higher Risk of Opioid Misuse

Extra cautions could include:

1) asking the patient to bring their medication for pill counts and to explain any discrepancies, and
2) using screening tools to check for aberrant drug-related behaviours (see Appendix B-10).

R11 Summary of Peer-Reviewed Evidence

1. Prescribing strong opioids has increased substantially in many regions throughout North America. This has been accompanied by a major increase in prescription opioid misuse and addiction.

Evidence from multiple sources suggests that North America is witnessing a major increase in prescription opioid misuse and addiction. For example, the Drug Abuse Warning Network in the United States has documented a seven-fold increase in emergency department visits and overdose deaths related to oxycodone (Gilson 2004, Paulozzi 2006). Increases in opioid abuse were also documented by the Purdue-sponsored RADARS system using addiction experts as key informants (Cicero 2005). A prospective Canadian study found that illicit opioid users are more likely to use prescription opioids than heroin (Fischer 2006). In the United States, the number of prescription opioid users entering addiction treatment rose from 14,000 in 1994 to 60,000 in 2004 (Maxwell 2006).

2. Physicians' prescriptions are a significant source of abused opioids.

Hall et al. conducted a population-based, observational study of unintended pharmaceutical overdose fatalities in West Virginia. Of the 295 decedents, opioid analgesics were taken by 275 (93.2%), of whom only 122 (44.4%) had ever been prescribed these drugs. Pharmaceutical diversion was associated with 186 (63.1%) deaths, while 63 (21.4%) were accompanied by evidence of doctor shopping (Hall 2008).

In studies of patients admitted to a treatment program for prescription opioid addiction, physicians' prescriptions were a common source of opioids (Brands 2004, Passik 2004, Rosenblum 2007). Most had also received opioids from friends, family or dealers, although it is not known how many of these non-medical sources had received their opioids from physicians' prescriptions.

In 2006, Dasgupta et al. published a study using national data from the Drug Abuse Warning Network (DAWN). They showed that the non-medical use of prescription analgesics was directly associated with the potency-adjusted total amount of opioids in prescriptive use. This data suggests that non-medical use of opioids is predictable based on potency and extent of prescriptive use (Dasgupta 2006).

3. The reinforcing psychoactive effects of opioids are dose-related.

In a retrospective case-control study, opioid-dependent patients had much higher ratings of euphoria on their first exposure to opioids for chronic pain than controls who were not opioid dependent (Bieber 2008). This suggests that a subgroup of patients experience euphoria when prescribed opioids and this group is at greater risk for becoming dependent on them. Controlled studies in healthy volunteers have demonstrated that the cognitive and euphoric effects of opioids are dose related, both in non-drug using volunteers and in former opioid addicts (Zacny 2003, Lamb 1991).

Cluster 3: Monitoring Long-Term Opioid Therapy (LTOT)

R12 Recommendation Statement

R12	When monitoring a patient on long-term therapy, ask about and observe for opioid effectiveness, adverse effects or medical complications, and aberrant drug-related behaviours. (Grade C).	***Monitoring LTOT***

R12 Discussion

1. Opioid Effectiveness (improved function or at least 30% reduction in pain intensity)

1.1 Evaluate change in pain intensity; see Recommendation 9.
1.2 Ask about progress in reaching agreed-on goals, an important indicator of function change. Self-report can be prompted by asking about work, household activity, mood, walking ability, sleep, and social activities. For an example of a structured assessment tool frequently used in trials, see Appendix B-9: Brief Pain Inventory©.
1.3 If opioid therapy is not effective consider switching opioids or discontinuing (see Recommendation 13).

2. Adverse Effects and Medical Complications

2.1 More common adverse effects include nausea, constipation, drowsiness, dizziness/vertigo, dry-skin/itching/pruritus, and vomiting.
2.2 Medical complications include neuroendocrine abnormalities and erectile dysfunction, sleep apnea and opioid-induced hyperalgesia.
2.3 See Recommendation 5 for detailed information about adverse effects and medical complications.

3. Aberrant Drug-related Behaviours

3.1 Aberrant drug-related behaviours have been divided into three groups (Passik 2004):
- escalating the dose (e.g., requesting higher doses, running out early)
- altering the route of delivery (e.g., biting, crushing controlled-release tablets, snorting or injecting oral tablets), and
- engaging in illegal activities (e.g., multiple doctoring, prescription fraud, buying, selling and stealing drugs). See Appendix B-10 for more information on detecting aberrant drug-related behaviours.

3.2 Tools designed to recognize aberrant drug-related behaviours may be useful in determining a patient's misuse of opioids. See Appendix B-11 for available tools including two examples, SOAPP®-R and COMM®.

4. Physician-Pharmacist Collaboration

4.1 A complete prescription history in one location can facilitate monitoring and support physician-pharmacist collaboration. Physicians can enable this by encouraging patients to select a single pharmacy to have prescriptions filled.

4.2 Pharmacists, through their multiple interactions with the patient, can:
- reinforce patient education about safe, appropriate use of opioids
- observe for behaviours or adverse effects that should be communicated to the physician (Also see Recommendation 14, LTOT and driving.)
- alert physicians to concerns about potential misuse (Also see Recommendation 22, Prescription fraud.).

R13 Recommendation Statement

R13	For patients experiencing unacceptable adverse effects or insufficient opioid effectiveness from one particular opioid, try prescribing a different opioid or discontinuing therapy. (Grade B).	***Switching or discontinuing opioids***

R13 Discussion

1. Switching Opioids

Because of unpredictable and incomplete cross-tolerance from one opioid to another, **suggested** initial doses of the new opioid are as follows:

If previous opioid dose was:	Then, **SUGGESTED** new opioid dose is:
• High	50% or less of previous opioid (converted to morphine equivalent)
• Moderate or low	60–75% of the previous opioid (converted to morphine equivalent)

If switching to fentanyl, see Appendix B-8.1: Oral Opioid Analgesic Conversion Table.
There is no evidence to support the practice of combining different types of opioids.

2. Discontinuing Opioids

Opioids should be tapered and discontinued if the patient's pain remains unresponsive after a trial of several different opioids. Patients who receive high opioid doses and remain incapacitated by pain should be considered treatment failures, even if the opioid "takes the edge off" the pain.

Patients sometimes report improvements in mood and pain reduction with tapering. The reason for this is not fully understood. With higher opioid doses, patients might experience withdrawal at the end of a dosing interval, which could heighten pain perception ("withdrawal-mediated pain"). Opioid tapering might relieve these withdrawal symptoms, thus decreasing pain perception. LTOT is known to cause hyperalgesia or pain sensitization, and lowering the opioid dose could reset the patient's pain threshold (Baron 2006) — or it could be that patients' mood and energy level improve with opioid tapering, so they do not focus on their pain as much.

The opioid should be tapered rather than abruptly discontinued. See Appendix B-12 for an opioid tapering protocol.

R13 Summary of Peer-Reviewed Evidence

1. Observational and uncontrolled studies have demonstrated that patients who have not responded to one opioid will sometimes respond when switched to a different opioid.

In 2004, Quigley conducted a Cochrane review on opioid switching to improve pain relief and drug tolerability. They found no randomized control trials. They included 23 case reports, 15 retrospective studies/audits and 14 prospective uncontrolled studies. The majority of the reports used morphine as first-line opioid and methadone as the most frequently used second-line opioid. All reports, apart from one, concluded that opioid switching is a useful clinical maneuver for improving pain control and/or reducing opioid-related side effects.

Quigley also concluded that more studies are needed to determine which opioid should be used first-line or second-line, and more research is needed to standardize conversion ratios when switching from one opioid to another.

…continued

R13 Summary of Peer-Reviewed Evidence…continued

2. Several observational studies have demonstrated that for patients with severe pain on high opioid doses, tapering results in improved reduced pain and improved mood.

Baron reported on a retrospective study of patients undergoing detoxification from high-dose opioids prescribed to treat an underlying chronic pain condition that had not resolved in the year prior. All patients were converted to ibuprofen to manage pain, with a subgroup treated with buprenorphine during detoxification. Self-reports for pain scores were taken at first evaluation, follow-up visits, and termination. Twenty-one of 23 patients reported a significant decrease in pain after detoxification, suggesting that high-dose opioids may contribute to pain sensitization via opioid-induced hyperalgesia, decreasing patient pain threshold and potentially masking resolution of the pre-existing pain condition (Baron 2006).

One study was conducted on over 356 patients with persistent pain and disability who attended a three-week cognitive behavioural program. Patients on opioids were tapered off. Pain decreased, and mood and functioning improved from baseline to discharge; the degree of improvement was the same in patients tapered off opioids as in patients who were not on opioids at baseline (Rome 2004).

One randomized trial demonstrated that patients attending an outpatient multidisciplinary pain program had improved pain ratings, psychological well-being, sleep and functioning, while their need for immediate-release opioid was also reduced (Becker 2000). Another study found that after a brief detoxification period, patients with both chronic pain and opioid dependence also report improved pain scores (Miller 2006).

Another trial reported success with opioid tapering, whether the tapering schedule was patient controlled reduction or staff controlled cocktail (Ralphs 1994). In both groups, 55% of the sample remained abstinent from opioids at six months.

One study demonstrated that multidisciplinary pain rehabilitation treatment incorporating analgesic medication withdrawal is associated with significant clinical improvements in physical and emotional functioning (Crisostomo 2008). A study on patients with fibromyalgia had similar results (Hooten 2007).

There are several limitations to these studies. The length of follow-up was short, up to six months. It is not known whether the outcomes were due to the tapering or to the psychological interventions the patients received. Nor is it known why tapering might improve pain perception.

R14 Recommendation Statement

R14	When assessing safety to drive in patients on long-term opioid therapy, consider factors that could impair cognition and psychomotor ability, such as a consistently severe pain rating, disordered sleep, and concomitant medications that increase sedation. (Grade C).	***LTOT and driving***

R14 Discussion

Physicians should assess cognitive and psychomotor ability because these functions are essential for driving a motor vehicle. Some factors, **in combination with opioids**, threaten these functions, e.g.,

- consistent severe pain rating (i.e., >7/10 most of the time)
- sleep disorder (chronic poor sleep, sleep apnea) and/or daytime somnolence
- pre-existing medical conditions that result in cognitive decline
- concomitant medications that increase sedation, such as benzodiazepines and anticholinergics, tricyclic antidepressants, anticonvulsants, antihistamines, breakthrough pain medication.

Requirements regarding a physician's duty to report a patient as unsafe to drive vary by province. Prescribers have an obligation to be aware of their provincial legislation about reporting concerns regarding the patient's ability to drive safely. A useful resource is "Determining Medical Fitness to Operate Motor Vehicles." (Canadian Medical Association 2009).

Also see Recommendation 7 for titration and driving.

R14 Summary of Peer-Reviewed Evidence

1. Pain itself affects cognitive function.

A recent review by Seminowicz and Davis showed that there is evidence that chronic pain can impair cognitive abilities. One possible mechanism for this effect is based on cortical plasticity and involves impairment of brain function. Another possible mechanism, not exclusive of the first, is based on the concept of limited processing capacity, whereby ongoing pain demands attention and limits the amount of resources available for task performance. Several studies have reported an association between chronic pain and hypervigilance (Seminowicz 2007).

Eccleston suggested that there is competition for attentional resources, reflected in attenuated task performance when a task is very demanding and pain is high (Eccleston 1996).

2. Associations between opioid use and impaired driving.

The evidence for association between opioid use and impaired driving is sparse, heterogeneous, and of poor quality. Some authors attempted to summarize this literature; however, no firm conclusions can be made because of the problems with the primary studies, and because of flaws in the reviews themselves.

Fishbain et al. conducted a systematic review of epidemiological evidence of an association of opioid use and intoxicated driving (6 studies), motor vehicle accidents (MVA) (9 studies) and MVA fatalities (10 studies). The authors concluded that opioids do not appear to be associated with intoxicated driving, MVA, and MVA fatalities (Fishbain 2003). However, there were many flaws in the studies included in this review; also the methods to compare the prevalence rates among the various studies were subject to bias.

…continued

R14 Summary of Peer-reviewed Evidence…continued

Another systematic review by the same author included 41 studies of opioid dependent/tolerant patients and evaluated the following outcomes: psychomotor abilities; cognitive function; effect of opioid dosing on psychomotor abilities; motor vehicle driving violations and MVAs; and driving impairment as measured in driving simulators and off/on road driving. This review concluded that opioids do not impair driving-related skills. However, the majority of the studies included in this review included populations on methadone for addiction, or healthy volunteers. Only five studies were conducted in a population with CNCP. It is known that pain itself interferes with psychomotor and cognitive function; therefore it is difficult to generalize the results of this review to the population for which this guideline is recommended (Fishbain 2003).

R15 Recommendation Statement

R15	For patients receiving opioids for a prolonged period who may not have had an appropriate trial of therapy, take steps to ensure that long-term therapy is warranted and dose is optimal. (Grade C).	***Revisiting opioid trial steps***

R15 Discussion

Not all patients on opioid therapy have progressed through the recommended steps of an opioid trial to determine an optimal dose (see Recommendation 9 for optimal dose). This situation can arise from various circumstances, e.g., when a patient on LTOT transfers from one doctor to another, or when a patient has inadvertently transitioned from receiving opioids for an acute condition to prolonged use. For these patients, the prescribing physician should review steps for an appropriate opioid trial and schedule follow-up visits to ensure all of the following have been addressed and documented:

1) pain condition diagnosis
2) risk screening
3) goal setting
4) informed consent
5) appropriateness of opioid selected and dose, and
6) opioid effectiveness.

1. Diagnosis

- Confirm the patient has a pain condition for which opioids have been shown to be effective (see Recommendation 4).

2. Screening

- Ensure that the patient's risk for misuse, overdose and addiction has been determined (see Recommendations 1 and 2).
- Screen for aberrant drug-related behaviours (see Recommendation 12).
- Consider usefulness of urine drug screening (see Recommendation 3).

3. Goal Setting

- Ensure the patient's expectations are realistic.
- Discuss specific goals related to pain reduction and function improvement.
- Document agreed-on goals in the patient's record; (they are critical in determining that opioids are effective)

4. Informed Consent

- Review potential benefits, potential adverse effects, medical complications, and risks (see Recommendation 5).
- Consider using a treatment agreement (see Recommendation 5).

5. Opioid Selection and Dose

- Confirm the most appropriate opioid has been selected (see Recommendation 8).
- Review dose — if above daily 200 mg of morphine equivalent, confirm that the patient's pain condition warrants the dose (see Recommendation 10).
- Taper or switch opioid as required.

6. Opioid Effectiveness

- Confirm that LTOT is providing significant benefit, i.e., the patient is experiencing an improvement in function or a reduction of pain intensity by at least 30% (see Recommendation 9).
- Taper or switch opioid as required.

R16 Recommendation Statement

R16	When referring patients for consultation, communicate and clarify roles and expectations between primary-care physicians and consultants for continuity of care and for effective and safe use of opioids. (Grade C).	***Collaborative care***

R16 Discussion

Options for external assistance include consultation with physicians with expertise in pain management or addiction, referral for treatment intervention, and shared-care models. Once a primary-care physician seeks outside help, successful management of the CNCP patient depends on clear detailed communication and collaboration between all healthcare providers.

1. Referral for Consultation

1.1 Expertise in Pain Management

1. Primary-care physicians seek consultation with physicians experienced in pain management for a variety of reasons, e.g.,
   - co-morbid conditions
   - uncertain diagnosis
   - uncertainty about the need for opioids or the dose
   - problematic adverse effects and/or medical complications
   - significant risk of overdose.
2. Clear communications *from* the primary-care physician *to* the consultant include:
   - details describing the patient's pain condition
   - actions undertaken to manage the pain and results, and
   - specific requested action(s) for the consultant (e.g., confirm diagnosis, screen for risks or misuse, review and advise on need for opioids and dose).
3. Clear communications *from* the consultant *to* the primary-care physician include:
   - specific details in response to the request(s) for action
   - clarification of any continuing role in directing care, e.g., if consultant initiates opioids, specification of responsibility for continued prescribing and monitoring the trial.

1.2 Expertise in Addictions

1. Primary-care physicians seek consultation with physicians experienced in addictions when one or more of the following are present:
   - The patient has exhibited aberrant drug-related behaviours.
   - The physician has concerns regarding illicit drug use.
   - There is apparent addiction to opioids.
2. Clear communications *from* the primary-care physician *to* the consultant include:
   - details describing the patient's pain condition
   - concerns regarding opioid misuse and/or addiction, and
   - specific requested action(s) for the consultant (e.g., confirm misuse or addiction and advise on treatment options.)
3. Clear communications *from* the consultant *to* the primary-care physician include:
   - recommended treatment
   - clarification of respective continuing roles in directing ongoing care.

2. Referral for Treatment Intervention

2.1 Multidisciplinary Pain Program

Patients on opioids who continue to have severe pain and pain-related disability appear to have better outcomes when managed by a multidisciplinary pain clinic. There are, however, significant variations in multidisciplinary pain programs: different treatment modalities, diagnostic approaches, healthcare providers, and diverse treatment philosophies regarding the use of opioids for CNCP. In addition, access to multidisciplinary pain programs is very limited in most parts of Canada, and many are not publicly funded.

The referring physician should understand the program's goals and postdischarge support available. Ideally, these programs would support primary-care physicians through:

- regular written and telephone communication during the treatment phase
- ongoing follow-up
- facilitation of referrals for counseling and addiction treatment as warranted.

2.2 Addiction Treatment Program

Addiction physicians and psychiatrists usually work in formal inpatient or outpatient treatment programs, or in community or hospital-based clinics. In most cases they directly provide detoxification or methadone treatment when appropriate.

3. Shared-Care Models

Examples of shared-care models vary but they do represent another form of information and knowledge sharing. These models could benefit primary-care physicians and their CNCP patients, and also use specialty expertise to the best advantage. Two examples are:

- Collaboration between primary-care physicians in developing and delivering a care plan for a particular patient seen by both physicians.
- A mentorship approach where primary-care physicians can access specialty opinion about case management, often with the goal of increasing the primary-care physician's knowledge, skills, and expertise in managing particular patient groups.

R16 Summary of Peer-Reviewed Evidence

1. Primary-care management of complex-pain patients on opioids is not as effective as ongoing involvement by a multidisciplinary clinic, even when the primary-care physician has been advised by a pain medicine physician.

In one randomized trial, CNCP patients managed by a multidisciplinary pain clinic had reduced pain intensity and decreased short-acting opioid use, whereas patients managed by their primary-care physician with a consultant's recommendations had no reduced pain intensity and a slight decrease in opioid use. Waiting-list controls actually deteriorated (Becker 2000).

2. Access to multidisciplinary pain programs is very limited.

Pain clinics in Canada vary widely in the types of care providers available, methods, funding, location, and waiting lists (Peng 2007).

Clinics located in academic science centres or publically funded facilities have much longer waiting lists than pain clinics funded by third parties (e.g., workers compensation systems or motor vehicle insurers). The types of patients may vary: hospital-based clinics see more complex patients with significant co-morbidities and more patients with cancer or neuropathic pains (Catchlove 1988), while non-hospital pain clinics and third-party funded clinics may see more musculoskeletal problems (facial pains, headaches, back and neck pain). Access to multidisciplinary pain programs is also variable based on funding, as some of the more intense pain programs are accessible only to those with third-party funding (Peng 2007).

Cluster 4: Treating Specific Populations with LTOT

R17 Recommendation Statement

R17	Opioid therapy for elderly patients can be safe and effective (Grade B) with appropriate precautions, including lower starting doses, slower titration, longer dosing interval, more frequent monitoring, and tapering of benzodiazepines. (Grade C).	***Elderly patients***

R17 Discussion

1. Opioids Safe and Effective for the Elderly

Opioid therapy may be underutilized in the elderly. Older patients may be less likely than younger patients to complain of pain or to accept opioid analgesics because they fear addiction; they associate opioids (particularly morphine) with severe or terminal illness, and they fear that complaining about pain may lead to investigations or hospitalization (Robinson 2007). Also, some physicians are reluctant to prescribe opioids for elderly patients.

While older patients are less likely to complain about pain, they appear to have the same pain thresholds as younger patients. It is known that elderly patients have comparable pain levels to younger ones, and that the dose of morphine necessary to achieve pain VAS[2] <4 is not significantly affected by age (Wilder-Smith 2005).

Opioids are generally safe in the elderly if carefully titrated. As a class, opioids cause less organ toxicity than NSAIDs, and in single-dose studies, they appear to cause less cognitive impairment than benzodiazepines (Hanks 1995). Clinics caring for elderly patients with well-defined pain conditions have found very low rates of abuse and addiction (Ytterberg 1998, Mahowald 2005).

2. Risks for the Elderly

2.1 Risks for the Elderly

1. Overdose**:** Several pharmacokinetic factors put the elderly at higher risk for opioid overdose than younger patients, including lower serum binding, lower stroke volume (slows liver metabolism), and greater sensitivity to the psychoactive and respiratory effects of opioids; (Freye 2004, Wilder-Smith 2005).
2. Oversedation: A high proportion of elderly patients on opioids are also on benzodiazepines and other psychotropic medications (Hartikainen 2005), increasing the risk of sedation.

2.2 Reducing Risks for the Elderly

1. Educate the patient and caregiver about signs of overdose, e.g., slurred or drawling speech, emotional lability, ataxia, "nodding off" during conversation or activity (see Table B-5.2: Opioid Risks).
2. Avoid opioids in cognitively impaired patients living alone, unless ongoing medication supervision can be organized.
3. Consider a three-day "tolerance check:" contact the patient three days after starting the prescription to check for any signs of sedation.
4. Monitor renal function (creatinine and creatinine clearance) (Pergolizzi 2008).

…continued

[2] Visual Analog Scale

R17 Discussion… continued

3. Prescribing Cautions for the Elderly

Suggested prescribing recommendations for the elderly are as follows:

1. Start initial titration at no more than 50% of the suggested initial dose for adults, and lengthen the time interval between dose increases. (See Table B-9.1: Opioid Suggested Initial Dose and Titration.)
2. Among strong opioids, oxycodone and hydromorphone may be preferred over oral morphine for the elderly because they are less likely to cause constipation and sedation (Clark 2004).
3. Controlled-release (CR) formulations are recommended for the elderly for reasons of compliance even though there is no evidence CR formulations are more effective than immediate-release (IR) formulations. However, for breakthrough pain or activity-related pain, IR formulations can be used (Pergolizzi 2008).
4. Morphine solutions are preferable to tablets in some situations, e.g., patients with swallowing problems, or patients requiring less than 5 mg morphine per tablet (Pergolizzi 2008).
5. For elderly patients on benzodiazepines, try to taper the benzodiazepine dose to reduce the risk of falls and cognitive impairment.

R17 Summary of Peer-Reviewed Evidence

1. Evidence suggests that many elderly patients who might benefit from opioid therapy are not receiving it.

A national Canadian survey documented that 29% of Canadian adults experienced chronic pain, with increasing frequency in elderly patients (Moulin 2002). Although most of these patients had moderate to severe pain that interfered with function, only 7% were receiving opioids stronger than codeine. In a study of 83,000 patients in 12 primary-care clinics in Wisconsin, only 201 patients were receiving opioid therapy for chronic pain (Adams 2001). Another survey found that up to 35% of primary-care physicians in Canada would never prescribe opioids even for moderate to severe chronic pain (Morley-Forster 2003). Solomon et al. described prescription opioid use among elderly with arthritis and low back pain. They found that elderly patients most commonly receive weak opioids, and rarely strong opioids (Solomon 2006).

2. Controlled-release opioids are preferred for the elderly for reasons of compliance.

"Consensus Statement of an International Expert Panel with Focus on the Six Clinically Most Often Used World Health Organization Step III Opioids" recommends a preference for sustained-release preparations because they increase patient compliance, as dosing frequency can be reduced. Patients should also be prescribed short-acting analgesics for the treatment of breakthrough pain. This recommendation is despite the fact that there is no evidence to support the use of long-acting analgesics over short-acting analgesics (Pergolizzi 2008).

3. Morphine solutions may be used in some situations.

The consensus statement of the International Expert Panel recommends that morphine solutions are a better option than tablets for p.r.n. (as needed) use. If the patient is frail and/or elderly, a low dose, e.g., 5 mg 4-hourly (or less), will help to reduce the likelihood of drowsiness, confusion or unsteadiness (Pergolizzi 2008).

R18 Recommendation Statement

R18	Opioids present hazards for adolescents (Grade B). A trial of opioid therapy may be considered for adolescent patients with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed, risk of opioid misuse is assessed as low, close monitoring is available, and consultation, if feasible, is included in the treatment plan. (Grade C).	***Adolescent patients***

R18 Discussion

1. Opioids Hazardous for Adolescents

Non-medical use (misuse) of opioids is more common among adolescents, and may be a risk factor for future opioid addiction. Among adolescents, risk factors for opioid misuse include poor academic performance; higher risk-taking levels; major depression; and regular use of alcohol, cannabis, and nicotine (Schepis 2008).

Misuse and overdose are the greatest risks for adolescents. To reduce these risks:

1. Educate the patient and family: Explain the risks of abuse and overdose carefully to the patient and (if feasible) the family. Emphasize the risks of taking extra doses or giving opioids to friends.
2. Whenever feasible, seek consultation with a healthcare provider experienced in treating adolescents (e.g., social worker, pediatrician, psychiatrist, psychologist, physician with expertise in pain management and/or addictions) before placing an adolescent on LTOT.

2. Prescribing Cautions for Adolescents

1. Titrate more slowly; try to avoid opioids that are commonly abused in the local community.
2. Avoid benzodiazepines if possible.
3. Use structured opioid therapy (see Recommendation 21), with a specific treatment agreement, conservative dosing, frequent dispensing, monitoring for aberrant behaviours, and urine drug screening.
4. Consider tapering the opioid if the patient does not experience opioid effectiveness: improved function or at least 30% reduction in pain intensity. See Appendix B-12 for a tapering protocol.

R18 Summary of Peer-Reviewed Evidence

1. Non-medical use of opioids is common among adolescents, and may be a risk factor for future opioid addiction.

In 2007, researchers from the Centre for Addiction and Mental Health in Toronto ON released the "Ontario Student Drug Use and Health Survey." They found that 21% of Ontario students in grades 7 to 12 report using prescription opioid pain relievers such as Tylenol® No. 3 and Percocet® for non-medical purposes; almost 72% report obtaining the drugs from home. In addition, among all drugs asked about, OxyContin® was the only drug to show a significant, but small, increase in non-medical use since the last survey (2% of students reported using it in 2007, representing about 18,100 students, compared to 1% in 2005) (Adlaf 2006).

One study from Michigan documented that 12% of high-school students had used opioids in the past year (Boyd 2006). Another study documented that the risk of developing prescription drug abuse and dependence later is correlated with the age of first exposure to opioids (McCabe 2007).

Among adolescents, risk factors for opioid misuse include poor academic performance; higher risk-taking levels; major depression; and regular use of alcohol, cannabis, and nicotine (Schepis 2008).

R19 Recommendation Statement

R19	Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible. (Grade B).	***Pregnant patients***

R19 Discussion

In general, pregnant patients are advised to discontinue all medications because drug effects on the fetus are often unknown.

1. Opioids During Pregnancy

Pregnant patients with CNCP on LTOT should be tapered to the lowest effective dose and discontinued if possible. Slow tapering is essential, as opioid withdrawal can cause uterine smooth muscle irritability, and is associated with premature labour and spontaneous abortion.

- If the patient has CNCP and is also addicted to prescription opioids, methadone treatment is recommended.
- During pregnancy and lactation:
  —Tramadol is not recommended
  —Safety of fentanyl has not been established.
- Where feasible, the treating physician should consider seeking consultation with a physician with expertise in pain, addictions, and pregnancy.

2. Delivery and Postpartum Cautions

Babies born to mothers who used daily opioids during their pregnancy should be delivered in a hospital with appropriate resources to deliver and care for the infant postpartum.

2.1 Neonatal Abstinence Syndrome (NAS)

Regular opioid use for CNCP during pregnancy is associated with a neonatal abstinence syndrome. These babies should be delivered in a hospital prepared to identify and treat the syndrome. NAS:

- usually begins 1–3 days after delivery, and can last for several weeks
- is characterized by poor feeding, irritability, sweating, and vomiting
- has a clinical presentation similar to other neonatal illnesses such as sepsis, hypoglycemia, and hypocalcemia
- is treated with comfort measures and with small doses of morphine, and
- has no long-term sequelae.

2.2 Codeine and Breast Feeding

Some women rapidly metabolize codeine to morphine, placing the neonate at risk for fatal opioid toxicity.

- If prescribing codeine for postoperative pain for women who are breast feeding:
  —Use small doses and limit the prescription to four days supply.
  —Advise the mother to:
  - Watch for signs of CNS depression in the baby, e.g., poor feeding and limpness
  - Contact a physician if she notes any signs of opioid toxicity (e.g., sedation); this should prompt an urgent assessment of the baby.
- NSAIDS and acetaminophen-oxycodone medications are alternatives to codeine.

…continued

R19 Summary of Peer-Reviewed Evidence

1. There is evidence that regular, scheduled opioid use for CNCP during pregnancy is associated with a neonatal abstinence syndrome.

In a study on 13 pregnant women on opioids for chronic pain, 5 of the neonates had neonatal abstinence syndrome (Hadi 2006).

2. Codeine use in breast-feeding women has been associated with fatal opioid toxicity in the neonate.

Codeine is converted to morphine by the cytochrome P450 system. Some patients are rapid converters, resulting in accumulation of morphine in the breast milk (Madadi 2008). There have been several case reports of neonatal toxicity due to morphine accumulation. The key clinical features were: for the baby, not waking up to feed and limpness; and for the mother, signs of sedation and other signs of toxicity. Symptoms were worse by the fourth day (Madadi 2009).

3. Pregnant women addicted to opioids have improved obstetrical and neonatal outcomes when on methadone treatment.

A number of studies have demonstrated that methadone treatment reduces the risk of premature labour, low birth weight and neonatal mortality in heroin-dependent pregnant women (Blinick 1976, Kaltenbach 1998, Kandall 1999, Wang 1999).

R20 Recommendation Statement

R20	Patients with a psychiatric diagnosis are at greater risk for adverse effects from opioid treatment. Usually in these patients, opioids should be reserved for well-defined somatic or neuropathic pain conditions. Titrate more slowly and monitor closely; seek consultation where feasible. (Grade B).	***Co-morbid psychiatric diagnoses***

R20 Discussion

1. Extra Considerations for CNCP Patients with Co-morbid Psychiatric Conditions

CNCP patients with psychiatric disorders are more likely to receive opioids than CNCP patients *without* psychiatric disorders (Sullivan 2005, Breckenridge 2003, Fishbain 2004). Yet evidence suggests that patients with depression or anxiety are less likely to benefit from opioids, due to a diminished response to opioids or an enhanced perception of pain, or both (Wasan 2005, Levenson 2008, Riley 2008).

In patients with active psychiatric disorders affecting pain perception, opioids should, in most cases, be reserved for well-defined somatic or neuropathic pain conditions. For example, fibromyalgia patients have a high prevalence of depression and anxiety, and a nociceptive or neuropathic cause for fibromyalgia pain has not been found. Opioids have little effect on functional status of these patients, in particular, strong opioids; (see Recommendation 4).

2. Increased Risks with Co-morbid Psychiatric Conditions

1. Substance Abuse: Patients with psychiatric disorders have a higher prevalence of substance abuse (Becker 2008, Edlund 2007, Sullivan 2006, Manchikanti 2007, Wilsey 2008).
2. Sedation and Falls: Opioids increase the risk of sedation and falls in patients on psychotropic drugs, and they increase the lethality of overdose and suicide attempts (Voaklander 2008).
3. Overdose: Patients with psychiatric disgnoses are frequently on benzodiazepines, and concurrent benzodiazepine use is a common feature in opioid overdoses (White 1999, Cone 2003, Burns 2004, Man 2004).
4. Depression: Opioid use is associated with a higher prevalence of depression.

3. Prescribing Cautions for Co-morbid Psychiatric Conditions

1. Titrate more slowly in CNCP patients with co-morbid psychiatric disorders.
2. Consultation with a psychiatrist might be advisable for patients on LTOT who have a concurrent psychiatric illness, particularly if the illness has not fully responded to treatment. They may be able to comment on a) the role of the illness on the patient's pain perception, and b) the advisability of benzodiazepine tapering.
3. Use structured opioid therapy (see Recommendation 21), with a specific treatment agreement, conservative dosing, frequent dispensing, and monitoring for aberrant drug-related behaviours.
4. Closely monitor the patient's mood and functioning.
5. Consider tapering if opioid effectiveness is inadequate (opioid effectiveness = improved function or at least 30% reduction in pain intensity). Short-term studies have documented improvements in mood and pain with opioid tapering (see Appendix B-12 for a tapering protocol).

…continued

R20 Summary of Peer-Reviewed Evidence

1. Need for careful patient selection, cautious opioid prescribing, and opioid tapering when indicated:

1.1 Patients on chronic opioid therapy have a higher prevalence of depression and other psychiatric conditions than the general population.

A large population-based study found that self-reported regular opioid use was strongly associated with both mood and anxiety disorders (Sullivan 2005).

Another study found that patients with low back pain who were receiving opioids were more likely to be depressed than those receiving only NSAIDs (Breckenridge 2003). Other studies have had similar results (Fishbain 2004).

1.2 Patients with anxiety or depression may have diminished analgesic response to opioid therapy, and/or a heightened perception of pain.

One study found that depressed patients with discogenic back pain had diminished analgesic response to opioids (Wasan 2005).

Another study of patients with sickle cell disease found that the severity of pain, functional disability and use of opioids were correlated with the patient's depression and anxiety. The association held for both crisis days and non-crisis days, and even after controlling for hemoglobin type (Levenson 2008). In a recent review of the literature, the most consistent finding is that depression and anxiety are associated with increased risk for drug abuse and decreased opioid efficacy (Riley 2008).

1.3 Opioid tapering is associated with improved mood and pain intensity.

For more details see Recommendation 13.

In one study, patients attending a multidisciplinary pain program were classified into no opioid, low-dose opioid or high-dose opioid groups. Both opioid groups had higher depression scores than the non-opioid group. The opioid groups were tapered off their medication. By six months, all groups improved in mood and function. Interestingly, all three groups had similar mood ratings at six months, even though the opioid group had more depression at baseline (Townsend 2008).

2. Need for monitoring of substance use and mood:

2.1 Patients on LTOT who have psychiatric disorders are more at risk for substance misuse and dependence than patients on LTOT without psychiatric disorders.

A large national cross-sectional survey (United States) found that depression, panic disorder, social phobia and agoraphobia were associated with non-medical use of prescription opioids (Becker 2008). Another cross-sectional survey found higher rates of opioid misuse and problematic drug use among patients on opioid therapy; these rates were mediated by higher rates of psychiatric disorders (Edlund 2007). An earlier study had similar results (Sullivan 2006). A study of 500 chronic pain patients on opioids documented that anxiety and depression was associated with significantly higher rates of opioid abuse and illicit drug use (Manchikanti 2007). A study of chronic pain patients presenting to the emergency department for prescription refills documented that a) a high proportion (81%) were abusing their opioids, and b) of these, a high proportion had depression and anxiety (Wilsey 2008).

…continued

R20 Summary of Peer-Reviewed Evidence…continued

2.2 Patients on LTOT are at higher risk for completed suicide.

One case control study found that patients on chronic opioid therapy are at greater risk for suicide than control patients (Voaklander 2008). This likely reflects the association between depression and opioid use for chronic pain. Nonetheless, it indicates that physicians should assess their patients for depression and suicidal ideation, and opioids should be dispensed in small amounts for patients at risk.

Cluster 5: Managing Opioid Misuse and Addiction in CNCP Patients

R21 Recommendation Statement

R21	For patients with chronic non-cancer pain who are addicted to opioids, three treatment options should be considered: methadone or buprenorphine treatment (Grade A), structured opioid therapy (Grade B), or abstinence-based treatment (Grade C). Consultation or shared care, where available, can assist in selecting and implementing the best treatment option. (Grade C).

Addiction treatment options

R21 Discussion

Where feasible, a physician with expertise in pain management and/or addiction can help select and implement the most appropriate care plan for CNCP patients who are addicted to opioids.

1. Options for Treatment

Three treatment options for the opioid-addicted patient with CNCP are:
1) methadone or buprenorphine treatment
2) structured opioid therapy
3) abstinence-based treatment.

2. Treatment with Methadone and Buprenorphine

2.1. Methadone Treatment

1. Indications for methadone treatment are any of the following:
   - a failed trial of structured opioid therapy
   - using opioids by injection, snorting, or crushing tablets
   - accessing opioids from multiple physicians or from the "street"
   - addiction to opioids and to other drugs/substances, e.g., alcohol, cocaine.
2. Methadone is effective for the treatment of opioid addiction in the presence of CNCP.
   - Methadone maintenance treatment involves daily supervised dispensing, urine drug screening, and counseling.
   - To obtain an exemption to prescribe methadone for opioid addiction, physicians should check with their provincial regulating body for direction.
   - The patient should be expected to consent to open communication between the methadone provider and the primary-care physician (include in treatment agreement).
   - Primary-care physicians and methadone providers should inform each other of newly diagnosed health conditions for the patient and long-term prescribing of other medications, particularly opioids and benzodiazepines.

2.2 Buprenorphine Treatment

1. Indications for buprenorphine treatment are similar to those for methadone treatment; buprenorphine treatment could be preferred over methadone for:
   - patients who are at higher risk of methadone toxicity (e.g., elderly, benzodiazepine users)
   - adolescents and young adults
   - patients in communities where methadone treatment is unavailable.
2. Buprenorphine is a safe and effective treatment for patients with a dual diagnosis of CNCP and opioid addiction.
   - Physicians should be aware of provincial regulatory guidelines regarding buprenorphine prescribing and training requirements.
   - Buprenorphine (buprenorphine and buprenorphine-naloxone are being used interchangeably) is a partial mu opioid agonist with a long duration of action. It is a well-established treatment, with good supporting evidence for the treatment of opioid addiction (West 2000; Mattick 2008).

…continued

R21 Discussion…continued

3. Structured Opioid Therapy (SOT)

Structured opioid therapy has been shown to improve outcomes in patients who have exhibited aberrant drug-related behaviours (see Recommendation 12). SOT is the use of opioids (other than methadone or buprenorphine) to treat CNCP with specific controls in place, including patient education, a written treatment agreement, agreed-on dispensing intervals, and frequent monitoring.

3.1 Indications for a Structured Opioid Therapy Trial

An ideal candidate for a SOT trial would be an opioid-addicted patient with CNCP who:

1) has a well-defined somatic or neuropathic pain condition for which opioids have been shown to be effective. (See Recommendation 4 for a review of evidence of opioid efficacy.)
2) is well-known to the physician
3) is not currently addicted to cocaine, alcohol or other drugs
4) is not, to the physician's knowledge, accessing opioids from other sources, injecting or crushing oral opioids, or diverting the opioid.

3.2 Treatment Agreement Specifications

A written treatment agreement is strongly recommended. It should specify controls relating to prescribing and monitoring, and outline expectations of patient compliance with referral for consultation or treatment programs, e.g., pain management and/or addiction consultation or programs.

3.3 Opioid Selection and Prescribing

1. Selection:
   - It may be advisable to switch patients to a different opioid (see Recommendation 13).
   - Avoid oxycodone and hydromorphone, if possible.
2. Dose: It is advisable to keep below 200 mg morphine equivalent.
3. Dispensing intervals: e.g., daily, bi-weekly or weekly dispensing interval, with no early prescription refills).

3.4 Monitoring Structured Opioid Therapy

Frequent monitoring is required; it could include:

1) urine drug screening (see Recommendation 3)
2) pill and patch count, and
3) evaluation for significant opioid effectiveness (i.e., improved function or at least 30% reduction in pain intensity, see Recommendation 9).

3.5 Failed Trial

If a) opioid effectiveness is not achieved, or b) the patient is not compliant, consider the SOT a failed trial. Taper and refer for opioid agonist treatment or abstinence-based treatment.

4. Abstinence-Based Treatment

- Abstinence-based treatment can be a patient preference or used when methadone or buprenorphine treatment is not available.
- Abstinence-based treatment begins with medically assisted withdrawal management, using clonidine, or tapering doses of methadone, buprenorphine or other opioids.
- This should be immediately followed by formal addiction treatment (inpatient or outpatient).
- Patients should be strongly cautioned that 1) they have lost their tolerance to opioids after as little as a week or two of abstinence, and 2) they are at risk for overdose if they relapse to their original opioid dose (Strang 2003).

R21 Summary of Peer-Reviewed Evidence

1. Structured opioid therapy has been shown to improve outcomes in patients who have exhibited aberrant drug-related behaviours.

Several observational studies have documented improved outcomes in patients receiving structured opioid therapy. In one study, 85 patients on opioids were referred to a primary-care, multidisciplinary disease management program operated by internists, pharmacists and a psychiatrist. Patients received monthly structured assessments, pain contracts, medication titration and monitoring for substance misuse. Twenty-seven patients (32%) were identified as misusers; 15 of these dropped out of the program because they were not prescribed opioids. Those who remained in the program improved pain, depression and disability scores (Chelminski 2005).

Wiedemer (2007) prospectively evaluated a structured opioid renewal clinic operated by a nurse practitioner and clinical pharmacist. About half of the 335 patients referred to the clinic had aberrant drug-related behaviours. The clinic used random urine drug screening, treatment agreements, frequent visits, and pill counts. Only small quantities were dispensed. Of the patients with aberrant baseline behaviours, 45% complied with the treatment agreement and their aberrant behaviours resolved, 38% dropped out of treatment, 13% were referred to addiction treatment, and 4% were weaned off opioids.

A retrospective evaluation of a clinic that performed careful adherence monitoring through urine drug screens and pill counts documented a 50% reduction in cases of opioid abuse (double doctoring or dealing), from 18% to 9% (Manchikanti 2006).

Currie et al. (2003) conducted an evaluation of an outpatient treatment program for 44 chronic pain patients, most of whom had opioid addiction. The clinic provided counseling and close medication supervision, with a tapering protocol using scheduled, long-acting opioids. Half the patients were able to taper completely off opioids and most were able to reduce their opioids (Currie 2003). The patients reported improvements in pain and mood.

These studies suggest that structured opioid therapy can result in increased compliance with the treatment agreement and increased referrals for addiction treatment. These results are promising but the evidence in support of structured opioid therapy is not as strong as the supporting evidence for buprenorphine and methadone therapy for opioid addiction. Also, the clinics using structured opioid therapy were well staffed by nurse practitioners, pharmacists and therapists; it might be difficult for primary-care physicians to undertake this form of treatment. Therefore, we suggest that structured opioid therapy be reserved for patients who meet the criteria listed above – unlikely to be accessing opioids from other sources, altering the route of delivery or diverting.

2. Methadone is effective for the treatment of opioid addiction in patients with CNCP.

Farre et al. conducted a meta-analysis of 13 randomized, double-blinded trials. They showed that higher doses of methadone were more effective than low doses in reduction of illicit opioid use. They concluded that oral methadone at doses of 50 mg/day or higher is the drug of choice for opioid addiction (Farre 2002).

One study found that methadone patients with opioid addiction who also had pain (n=103) had similar substance-related outcomes to those methadone patients in the group without significant pain (n=97). Compared to patients who did not report pain at baseline, patients with pain showed similar reductions in heroin, alcohol, cocaine and illicit prescription sedative use and greater reductions in illicit prescription opioid use. At 1-year follow-up, there was no significant difference in past 30 day use of heroin, cocaine, alcohol, illicit prescription sedative or opioid use between patients with and without pain at baseline (Ilgen 2006).

…continued

R21 Summary of Peer-Reviewed Evidence…continued

3. Patients who "successfully" completed inpatient detoxification were more likely than other patients to have died within a year. The explanation may be loss of tolerance.

Strang et al. followed up patients who received inpatient opiate detoxification, and looked for evidence of increased mortality, and investigated the distinctive characteristics of patients who died. To test whether loss of tolerance increased the risk of overdose, they grouped the patients into three categories, according to their opiate tolerance at the point of leaving treatment: 43 "still tolerant" (ST) patients who failed to complete detoxification; 57 "reduced tolerance" (RT) patients who completed the prescribed phase of detoxification but who prematurely left the treatment program; and 37 "lost tolerance" (LT) patients who completed the detoxification and also completed the inpatient treatment program. The three overdose deaths that occurred within four months after treatment were all from the LT group; the two deaths unrelated to overdose (although both these patients had relapsed) were one LT patient with end stage renal failure and one RT patient with Clostridium welchii infection; no deaths occurred in the ST group (Strang 2003).

4. Buprenorphine is a safe and effective treatment for patients with a dual diagnosis of CNCP and opioid addiction.

A review study found that there was some evidence for the use of buprenorphine in the treatment of CNCP (it largely reviewed trials that used the transdermal preparation) and that it was well tolerated in elderly patients (Johnson 2005).

Myers et al. 2005 state that the "introduction of buprenorphine management has the potential to greatly improve the treatment of chronic pain in patients with a history of addiction to opioids or with a family history of addictive disorders" (Myers 2005).

5. There is evidence from several studies for the safety and effectiveness of buprenorphine use in primary care.

Controlled trials have demonstrated that buprenorphine maintenance treatment is safe and effective when prescribed in primary care settings (O'Connor 1998, Fiellin 2002, Caplehorn 2003, Gibson 2003, Lintzeris 2004, Simoens 2005, Stein 2005, Barry 2007, Mintzer 2007, Moore 2007). Physicians providing office-based opioid agonist treatment report high levels of satisfaction, although they would like better access to counseling and other social services (Becker 2006).

R22 Recommendation Statement

R22	To reduce prescription fraud, physicians should take precautions when issuing prescriptions and work collaboratively with pharmacists. (Grade C).	***Prescription fraud***

R22 Discussion

1. Taking Precautions

In issuing prescriptions, physicians should take the following precautions, which are considered to reduce opioid misuse:

1. Fax prescriptions directly to the pharmacy.
2. If using a paper prescription pad:
    - Use carbon copies or numbered prescription pads.
    - Write the prescription in words and numbers.
    - Draw lines through unused portions of the prescription.
    - Keep blank prescription pads secure.
3. If using desk-top prescription printing, it is especially important to write a clear signature and not use a scribbled initial.
4. If using fax or electronic transmission of the prescription (in jurisdictions that permit it) ensure confidentiality, confirm destination, and retain copies.
5. Promote patient's use of a single dispensing pharmacy.

2. Accessing Drug Databases

If available, physicians and pharmacists should access electronic prescription databases that provide information about patient prescription history.

3. Collaborating

Greater collaboration with other healthcare providers can also contribute to reduction in prescription fraud.

1. Pharmacists are often in a position to alert physicians to possible opioid misuse, e.g., double-doctoring, potential diversion or prescription fraud. Pharmacists are considered part of the patient's "circle of care;" special consent is not required to speak with the pharmacist.
2. If double-doctoring is suspected, expect the patient to consent to a consultation with the "other" prescriber(s), or taper the opioid dose and discontinue**.** Note: The prescribing physician may contact the "other" physician(s) without the patient's consent if the patient is considered to be at significant risk of overdose.

R23 Recommendation Statement

R23	Be prepared with an approach for dealing with patients who disagree with their opioid prescription or exhibit unacceptable behaviour. (Grade C).	***Patient unacceptable behaviour***

R23 Discussion

1. Patient Disagreement with the Opioid Prescription

Opioid prescribing is a common source of conflict between patients and physicians. Physicians can minimize conflicts through the following actions:

1. Use treatment agreements routinely.
2. Provide explanations for changes in prescribing, e.g.,
   - The prescribing is consistent with existing guidelines.
   - The change is intended to help, not penalize, the patients, e.g., it is meant to reduce the pain and improve mood, activity, and safety.
3. Book a longer appointment to allow for more time to provide education and explanations.
4. Arrange consultations: patients may accept a "team decision" more readily than an individual one.
5. Document verbal agreements and past discussions.

2. Patient Unacceptable Behaviour

Physicians are strongly advised to acquaint themselves with applicable legislation and their provincial regulatory body's policies/guidelines regarding standards and termination of the physician-patient relationship. It is important to know the obligations to the patient, staff, and society if illegal patient activities are suspected.

2.1 Aberrant Drug-related Behaviours

Behaviours that stem from opioid addiction, such as aggressively demanding higher opioid doses or double-doctoring, often resolve when the physician ceases prescribing and refers the patient to addiction treatment. If the patient refuses to accept treatment referral and continues to demand opioids, the physician may consider discharging the patient from the practice.

2.2 Non-violent Offences

If a patient has committed a non-violent offence, such as altering a script, the physician is not obliged to contact the police. The physician should assess the patient for opioid addiction, and (in most instances) cease prescribing opioids and refer the patient for formal treatment.

2.3 Threatened or Actual Violence

The physician could contact the police if the patient has, for example:

- threatened violence and there is perceived danger
- committed violence against clinic staff and other patients, or
- vandalized or stolen property.

R24 Recommendation Statement

R24	Acute or urgent health care facilities should develop policies to provide guidance on prescribing opioids for chronic pain to avoid contributing to opioid misuse or diversion. (Grade C).	***Acute-care opioid prescribing policy***

R24 Discussion

Physicians providing care in acute/urgent healthcare facilities need to respond appropriately to patients with pain and to those who are seeking drugs for misuse or diversion. An opioid-prescribing policy, which takes the local community needs into account, could serve to:

1. Provide a framework to facilitate a consistent response from all physicians. (Note: inconsistent policy application can encourage drug seekers "targeting" liberal prescribers.
2. Act as a deterrent for individuals attempting to obtain opioids for diversion or misuse.

Patients with pain are routinely seen in acute/urgent healthcare facilities (e.g., emergency departments and walk-in clinics). Physicians assessing and treating these patients need to distinguish between pain that is acute, originating from an injury or other mechanism, or chronic. This is complicated by various scenarios:

- Some patients have chronic *recurrent* pain and may present in an "acute" episode of a chronic pain condition.
- Patients who are abusing or addicted to opioids or who are drug diverters may visit these settings specifically in an attempt to obtain opioids.
- Patients report they are on LTOT, have run out of their medication, are unable to access their usual care provider, and ask for a temporary prescription: they could be from another area, province, or country.

The following topics are suggested to assist physicians in creating an opioid-prescribing policy:

1. **Development**: Participation by all physicians providing care in the acute/urgent healthcare setting can be useful in addressing the issues and promoting adherence.
2. **Policy Availability**: The policy could be posted in the waiting area of the facility, and/or available as a handout, to provide patients with information in advance of seeing the physician.
3. **Legislation**: The policy should comply with provincial legislation about opioid prescribing, and accessing and sharing patient information.
4. **Opioid Prescribing:** The policy should outline circumstances for prescribing and not prescribing. For example, for patients who report they are established on opioids with another prescriber, but have run out, a policy could include requirements and limits of issuing a prescription, such as:
    - Contact must be made with the prescribing physician or dispensing pharmacist.
    - Number of doses prescribed is limited to last until the next business day.
    - Dose is amount that the physician feels is appropriate, given the patient's underlying pain condition, even if that dose is considerably less than what the patient reports receiving.
    - The facility prescribes once only for patients who have run out.
    - A record of the visit is sent to the primary-care physician.
5. **Suspected Opioid Addiction**: The policy could indicate a response to patients who appear addicted to opioids, e.g., provide information about addiction resources for treatment.

APPENDIX

Appendix B-1: Examples of Tools for Assessing Alcohol and other Substance Use

Appendix B-1.1: Interview Guide for Alcohol Consumption

1. Maximum number of drinks* consumed on any one day in past 1–3 months
2. Number of drinks per week
3. Previous alcohol problem
4. Attendance at treatment program for alcohol
5. Family history of alcohol or drug problem

* Standard drink = 1 bottle beer (12 oz, 5%)
= 5 oz glass wine (5 standard drinks in 750 ml wine bottle)
= 1.5 oz liquor (vodka, scotch) (18 standard drinks in 26 oz bottle 40% alcohol)

Low-Risk Drinking Guidelines[1]

(no more than 2 standard drinks on any one day)
Women: up to 9 standard drinks a week.
Men: up to 14 standard drinks a week.

Patients who exceed the Low-Risk Drinking Guidelines are considered at-risk for acute problems such as trauma, and/or chronic problems such as depression and hypertension.

[1] Source: Centre for Addiction and Mental Health (CAMH) 2004.

Appendix B-1.2: Interview Guide for Substance Use

1. **Cannabis**: number of joints per day, week
2. **Cocaine:** any use in the past year
3. **Over the counter drugs**: especially sedating antihistamines
4. **Opioids:**
   - In past year, use of opioids from any source: e.g., OTC (Tylenol® No. 1), prescriptions from other physicians, borrowed from friends/family, buying from the street
   - How much, how often
   - Crushing or injecting oral tablets
   - Opioid withdrawal symptoms: myalgias, GI symptoms, insomnia, dysphoria
   - Previous opioid problem
   - Attendance at treatment program for opioid addiction (e.g., methadone)
5. **Benzodiazepines**: Amount, frequency, source

Appendix B-1.3: CAGE Questionnaire

"CAGE" is an acronym formed from the italicized words in the questionnaire (cut-annoyed-guilty-eye).

The CAGE is a simple screening questionnaire to id potential problems with alcohol.
Two "yes" responses is considered positive for males; one "yes" is considered positive for females.

CAGE Questionnaire

Please note: This test will only be scored correctly if you answer each one of the questions. Please check the one response to each item that best describes how you have felt and behaved over your whole life.

1. Have you ever felt you should *cut* down on your drinking?
__Yes
__No
2. Have people *annoyed* you by criticising your drinking?
__Yes
__No
3. Have you ever felt bad or *guilty* about your drinking?
__Yes
__No
4. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (*eye*-opener)?
__Yes
__No

For more detail:
Go to: http://lib.adai.washington.edu/instruments/ and enter CAGE in the search box. Under Description, click "more"

Appendix B-2: Opioid Risk Tool

Opioid Risk Tool

Item	Mark each box that applies	Item score if female	Item score if male
1. Family History of Substance Abuse:			
Alcohol	[ ]	1	3
Illegal Drugs	[ ]	2	3
Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse:			
Alcohol	[ ]	3	3
Illegal Drugs	[ ]	4	4
Prescription Drugs	[ ]	5	5
3. Age (mark box if 16-45)	[ ]	1	1
4. History of Preadolescent Sexual Abuse	[ ]	3	0
5. Psychological Disease			
Attention Deficit Disorder, Obsessive-Compulsive Disorder, or Bipolar, Schizophrenia	[ ]	2	2
Depression	[ ]	1	1
Total		____	____
Total Score Risk Category: Low Risk: 0 to 3 Moderate Risk: 4 to 7 High Risk: 8 and above			

Attribution:
By Lynn R. Webster, MD; Medical Director of Lifetree Medical, Inc.
Salt Lake City, UT 84106

Appendix B-3: Urine Drug Screening (UDS)

Table B Appendix 3.1 Immunoassay versus Chromatography for Detection of Opioid Use

Immunoassay	Chromatography
• Does not differentiate between various opioids	Differentiates: codeine, morphine, oxycodone, hydrocodone, hydromorphone, heroin (monoacetylmorphine).
• Will show false positives: Poppy seeds, quinolone antibiotics.	Does not react to poppy seeds.
•Often misses semi-synthetic and synthetic opioids, e.g., oxycodone, methadone, fentanyl.	More accurate for semi-synthetic and synthetic opioids.

Table B Appendix 3.2 Detection Times for Immunoassay and Chromatography

	Number of days drug is detectable	
Drug	**Immunoassay**	**Chromatography**
Benzodiazepines (regular use)	• 20+ days for regular diazepam use. • Immunoassay does not distinguish different benzodiazepines. • Intermediate-acting benzodiazepines such as clonazepam are often undetected.	Not usually used for benzodiazepines.
Cannabis	20+	Not used for cannabis.
Cocaine + metabolite	3–7	1–2
Codeine	2–5	1–2 (Codeine metabolized to morphine.)
Hydrocodone	2–5	1–2
Hydromorphone	2–5	1–2
Meperidine	1 (often missed)	1
Morphine	2–5	1–2: Morphine can be metabolized to hydromorphone
Oxycodone	Often missed	1–2

Source: Adapted from Brands 1998.

Appendix B-4: Opioid Information for Patients

NOTE: These messages could be used to create patient education materials.

Messages for Patients Taking Opioids

Opioids are a group of similar medications that are used to help with pain — there is more than one type of opioid and they have different names for example, Percocet®, OxyContin®, Tylenol® No. 2, Tramacet®.

1. Opioids are used to improve your ability to be active and reduce pain.

- ▶ You and your doctor will set goals and ensure the medication is effective in achieving the goals, e.g. improving your ability to do the things you did before pain prevented you.
- ▶ If you seem to benefit from the pain medication, your doctor will see you for follow-up visits to assess pain relief, any adverse effects, and your ability to meet your set activity goals.

2. There are side effects from opioids, but they can be mostly controlled with increasing your dose slowly.

- ▶ Common side effects include: nausea (28% of patients report it), constipation (26%), drowsiness (24%), dizziness (18%), dry-skin/itching (15%), and vomiting (15%).
- ▶ Side effects can be minimized by slowly increasing the dose of the drug and by using anti-nausea drugs and bowel stimulants.

3. Your doctor will ask you questions and discuss any concerns with you about your possibility of developing addiction.

- ▶ Addiction means that a person uses the drug to "get high," and cannot control the urge to take the drug.
- ▶ Most patients do not "get high" from taking opioids, and addiction is unlikely if your risk for addiction is low: those at greatest risk have a history of addiction with alcohol or other drugs.

4. Opioids can help but they do have risks — these can be managed by working cooperatively with your doctor.

- ▶ Take the medication as your doctor prescribed it.
- ▶ Don't drive while your dose is being gradually increased or if the medication is making you sleepy or feel confused.
- ▶ Only one doctor should be prescribing opioid medication for you — don't obtain this medication from another doctor unless both are aware that you have two prescriptions for opioids.
- ▶ Don't take opioids from someone else or share your medication with others.
- ▶ You may be asked for a urine sample — this will help to show all the drugs you are taking and ensure a combination is not placing you at risk.
- ▶ Your doctor will give you a prescription for the amount of medication that will last until your next appointment — keep your prescription safe and use the medications as instructed — if you run out too soon or lose your prescription your doctor will not likely provide another
- ▶ If you cannot follow these precautions it may not be safe for your doctor to prescribe opioid medication for you.

…continued page 2

...*Page 2 of 2*

5. If you stop taking your medication abruptly, you will experience a withdrawal reaction.

- ▶ Withdrawal symptoms do not mean you are addicted — just that you stopped the drug too quickly — your doctor will direct you on how to slowly stop this medication so you won't have this experience.
- ▶ Opioid withdrawal symptoms are flu-like, e.g., nausea, diarrhea, and chills.
- ▶ Withdrawal is not dangerous but it can be very uncomfortable.
- ▶ If you interrupt your medication schedule for three days or more for any reason, do not resume taking it without consulting a doctor.

6. Overdose from opioids is uncommon, but you and your family should be aware of the signs.

- ▶ Opioids are safe over the long term, BUT can be dangerous when starting or increasing a dose.
- ▶ Overdose means thinking and breathing slows down — this could result in brain damage, trauma, and death.
- ▶ Mixing opioids with alcohol or sedating drugs such as pills to help anxiety or sleeping, greatly increases the risk of overdose.
- ▶ You and your family should be aware of signs of overdose — contact a doctor if you notice: slurred or drawling speech, becoming upset or crying easily, poor balance or, "nodding off" during conversation or activity.

7. The medication the doctor prescribes for you can be very dangerous to others.

- ▶ Your body will get used to the dose your doctor sets for you but this same dose can be very dangerous to others.
- ▶ You have reached your proper dose slowly, but someone who is not used to the medication could have a serious reaction, including death — don't give your medication to anyone else – it is illegal and could harm them.
- ▶ Keep you medication securely stored at home — the bathroom medicine cabinet is *not* a safe place; research has shown that others, particularly teenagers might help themselves to these drugs from friends or relatives.

Appendix B-5: Sample Opioid Medication Treatment Agreement

I understand that I am receiving opioid medication from Dr. _____ to treat my pain condition. I agree to the following:

1. I will not seek opioid medications from another physician. Only Dr. _____ will prescribe opioids for me.
2. I will not take opioid medications in larger amounts or more frequently than is prescribed by Dr. _____.
3. I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else.
4. I will not use over-the-counter opioid medications such as 222's and Tylenol® No. 1.
5. I understand that if my prescription runs out early for any reason (for example, if I lose the medication, or take more than prescribed), Dr. _____ will not prescribe extra medications for me; I will have to wait until the next prescription is due.
6. I will fill my prescriptions at one pharmacy of my choice; pharmacy name: _____
7. I will store my medication in a secured location.

I understand that if I break these conditions, Dr. _____ may choose to cease writing opioid prescriptions for me.

Source: Modified from Kahan 2006.

Appendix B-6: Benzodiazepine Tapering

1. Benefits of Benzodiazepine Tapering

- Lower the risk of future adverse drug-related risks such as falls.
- Increased alertness and energy.

2. Approach to Tapering

- Taper slowly: slow tapers are more likely to be successful than fast tapers.
- Use scheduled rather than p.r.n. doses.
- Halt or reverse taper if severe anxiety or depression occurs.
- Schedule follow-up visits q. 1–4 weeks depending on the patient's response to taper.
- At each visit, ask patient about the benefits of tapering (e.g., increased energy, increased alertness).

3. Protocol for Outpatient Benzodiazepine Tapering

3.1 Initiation

- May taper with a longer-acting agent such as diazepam or clonazepam, or taper with the agent that the patient is taking. (Diazepam can cause prolonged sedation in the elderly and those with liver impairment.)
- There is insufficient evidence to strongly support the use of one particular benzodiazepine for tapering.
- Convert to equivalent dose in divided doses (see equivalence table below, Table B Appendix 6.1).
- Adjust initial dose according to symptoms (equivalence table is approximate).

3.2 Decreasing the Dose

- Taper by no more than 5 mg diazepam equivalent per week.
- Adjust rate of taper according to symptoms.
- Slow the pace of the taper once dose is below 20 mg of diazepam equivalent (e.g., 1–2 mg/week).
- Instruct the pharmacist to dispense daily, twice weekly, or weekly depending on dose and patient reliability.

3.3 Another Approach

Taper according to the proportional dose remaining: Taper by 10% of the dose every 1–2 weeks until the dose is at 20% of the original dose; then taper by 5% every 2–4 weeks.

Source: Adapted from Kahan 2002.

4. Benzodiazepine Equivalent Table

Table B Appendix 6.1 Benzodiazepine Equivalent Table

Benzodiazepine	Equivalent to 5 mg diazepam (mg) *
Alprazolam (Xanax®)**	0.5
Bromazepam (Lectopam®)	3–6
Chlordiazepoxide (Librium®)	10–25
Clonazepam (Rivotril®)	0.5–1
Clorazepate (Tranxene®)	7.5
Flurazepam (Dalmane®)	15
Lorazepam (Ativan®)	0.5–1
Nitrazepam (Mogadon®)	5–10
Oxazepam (Serax®)	15
Temazepam (Restoril®)	10–15
Triazolam (Halcion®)**	0.25

* Equivalences are approximate. Careful monitoring is required to avoid oversedation, particularly in older adults and those with impaired hepatic metabolism.

**Equivalency uncertain.

Source: Adapted from Kalvik 1995, Canadian Pharmacists Association 1999.

Appendix B-7: Example of Documenting Opioid Therapy

Opioid Therapy Record Example

Date:	Jan 13 2008	Mar 23 2008	May 23 2008	
Opioid type	Oxycodone	Oxycodone		
Opioid dose	20 tid	30 tid		
MEQ dose	90 mg	135		
Pain worst	8 →	6		
Pain least	3	3		
Pain average	6	5		
Pain right now	6 →	4		
BPI functional improvement	Sleep improved	Back to work		
Adverse effects	Nausea	Nausea continues		
Medical complications	nil	nil		
Compliance	UDS clear	No concerns		
Action	Increase to 30 tid	Keep this dose		
Other Comments				

Appendix B-8: Opioid Conversion and Brand Availability in Canada

Appendix B-8.1 Oral Opioid Analgesic Conversion Table

- The table is based on oral dosing for chronic non-cancer pain.
- The figures are based on the Compendium of Pharmaceutical & Specialties (Canadian Pharmacists Association 2008) and a systematic review by Pereira (2001). Wide ranges have been reported in the literature.
- These equivalences refer to analgesic strength of oral opioids, and not psychoactive effects or effectiveness in relieving withdrawal symptoms.

1. Equivalence to oral morphine 30 mg:

Table B Appendix 8.1 Oral Opioid Analgesic Conversion Table

	Equivalence to oral morphine 30 mg:	To convert to oral morphine equivalent multiply by:	To convert from oral morphine multiply by:
Morphine	30 mg	1	1
Codeine	200 mg	0.15	6.67
Oxycodone	20 mg	1.5	0.667
Hydromorphone	6 mg	5	0.2
Meperidine	300 mg	0.1	10
Methadone and tramadol	Morphine dose equivalence not reliably established.		

2. Equivalence between oral morphine and transdermal fentanyl:

Transdermal fentanyl*	60–134 mg morphine = 25mcg/h 135–179 mg = 37 mcg/h 180–224 mg = 50 mcg/h 225–269 mg = 62 mcg/h 270–314 mg = 75 mcg/h 315–359 mg = 87 mcg/h 360–404 mg = 100 mcg/h

*Formulations include 12, 25, 50, 75 and 100 ucg/hour patches, but the 12 ucg/hour patch is generally used for dose adjustment rather than initiation of fentanyl treatment.

Appendix B-8.2 Opioids: Generic and Brand Names Available in Canada

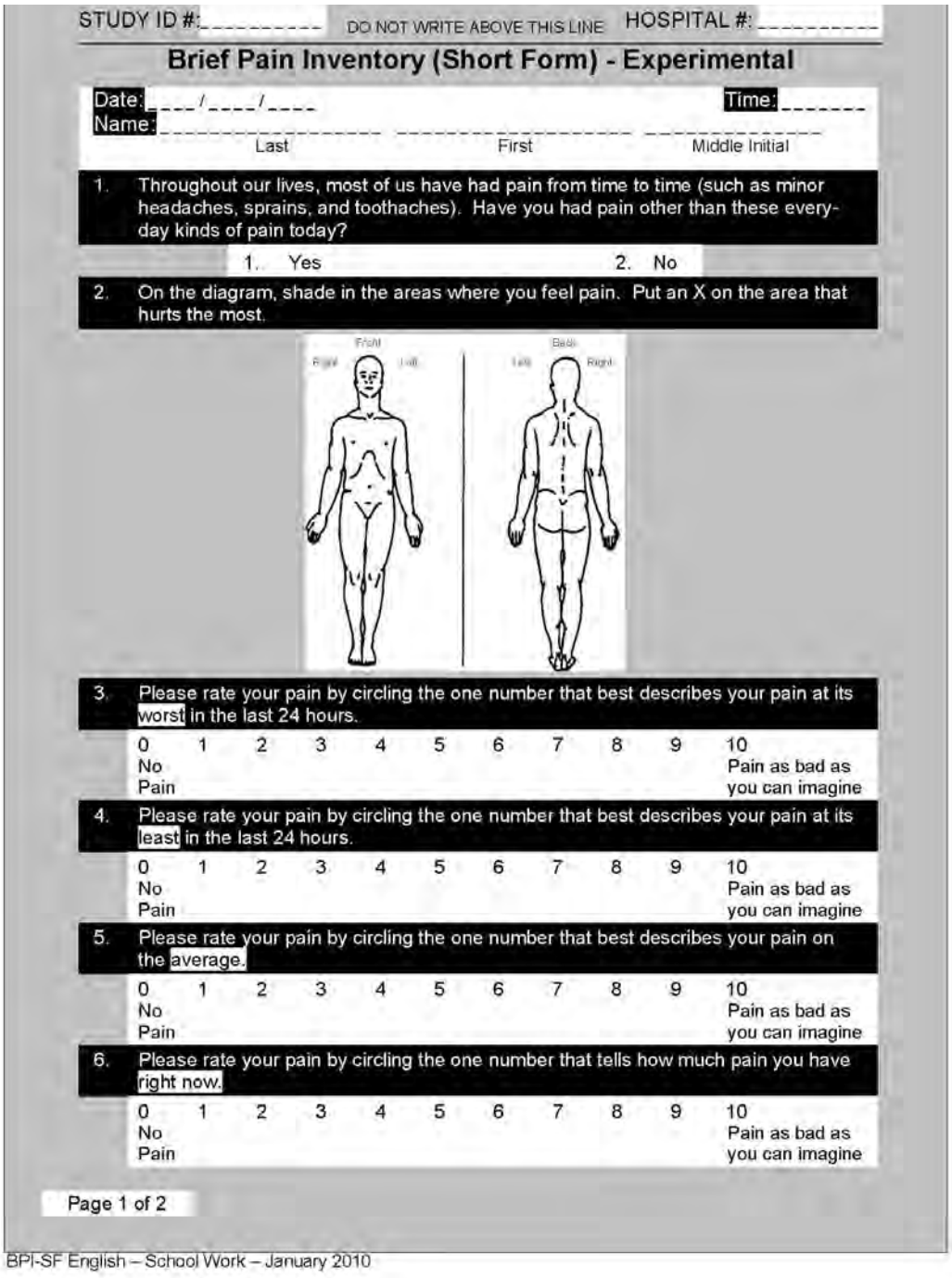
(Canadian Pharmacists Association 2008)

Drug (generic name)	Brand names
STRONG OPIOIDS	
Fentanyl (transdermal)	Duragesic®
Hydromorphone HCL	Dilaudid®, Hydromorph Contin®, Hydromorphone HCL, Hydromorphone HP® (10, 20, 50, Forte), Jurnista®, PMS-Hydromorphone®
Methadone HCL	Metadol®
Morphine sulfate	Statex®, Kadian®, M-Eslon®, M.O.S.-Sulfate®, Morphine HP, Morphine sulphate, MS Contin®, MS-IR®, PMS-Morphine®, Morphine Sulfate SR®, ratio-Morphine SR®
Oxycodone HCL	OxyContin®, Oxy-IR®, Supeudol®
Oxycodone HCL with acetaminophen	Endocet®, Percocet®, Percocet-Demi®, ratio-Oxycocet®, PMS- Oxycodone- Acetaminophen®
Oxycodone HCL/ ASA	Endodan®, Percodan®, Percodan-Demi®, ratio-Oxycodan®
WEAK OPIOIDS	
Codeine monohydrate/ sulphate trihydrate	Codeine, Codeine Contin®
Codeine phosphate/ acetaminophen/ caffeine	Tylenol® (No. 1, 2, 3); Atasol® (No. 8, 15, 30); Lenoltec®
Codeine phosphate/ Acetaminophen without caffeine	Empracet®
Propoxyphene Napsylate	Darvon-N®
Pentazocine HCL	*Talwin®
Pethidine HCL (meperidine)	Demerol®
**Tramadol	Ralivia™, Zytram XL®, Tridural™
**Tramadol/ Acetaminophen	Tramacet®
CANNABINOIDS	
Nabilone	Cesamet®
Dronabinol	Marinol®
	***Sativex®

* Opioid agonist/antagonist
** Tramadol is a weak opioid and serotonin/norepinephrine reuptake inhibitor
*** Orobuccal spray containing extracts of natural cannabis

Note: Reference throughout this document to specific pharmaceutical products as examples does not imply endorsement of any of these products.

Appendix B-9: Brief Pain Inventory©



STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #:_____

Brief Pain Inventory (Short Form) - Experimental

Date: ____/____/____ Time: _____

Name: _____ _____ _____

Last First Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Pain as bad as you can imagine

Page 1 of 2

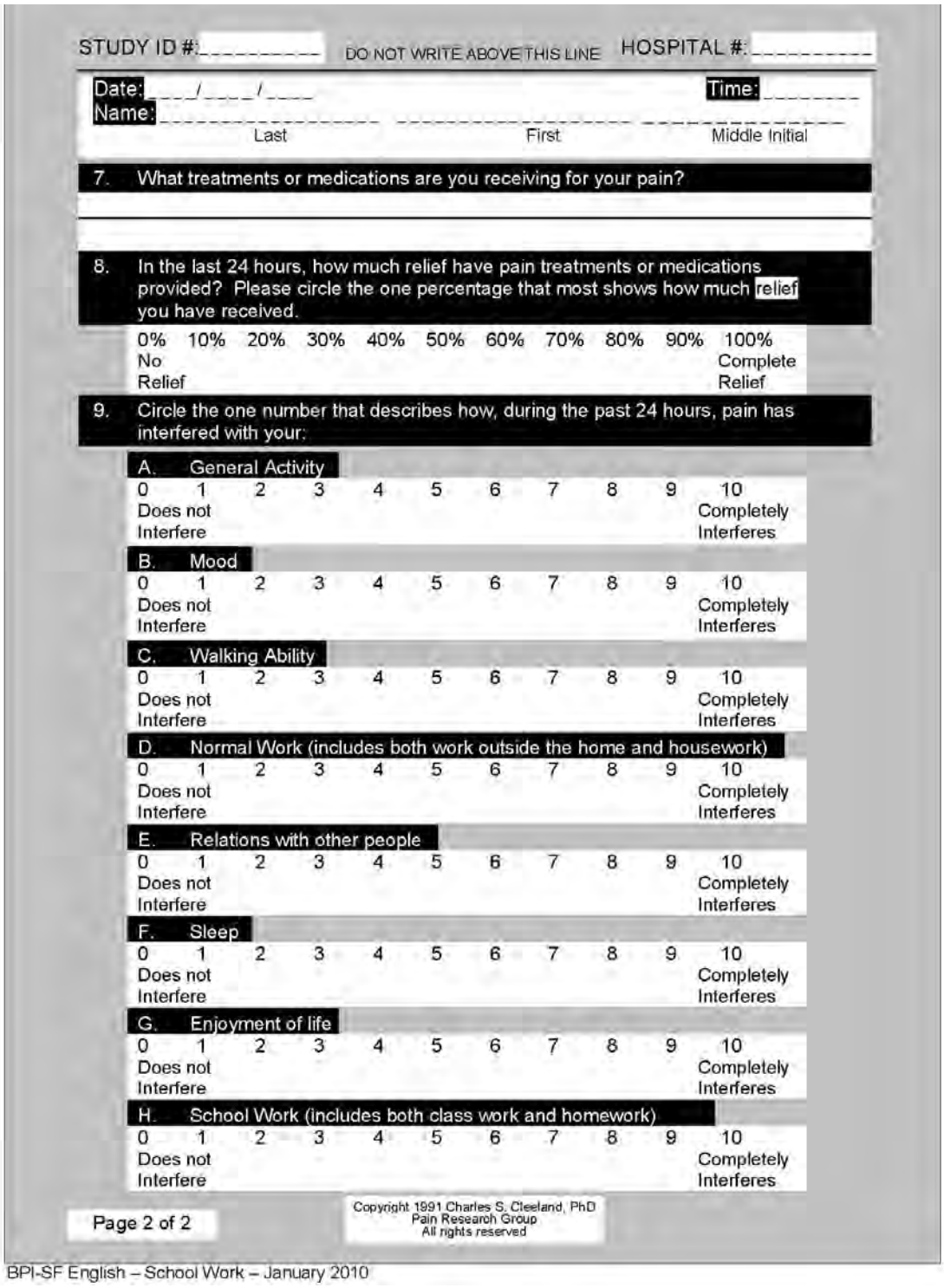
BPI-SF English – School Work – January 2010

Brief Pain Inventory©: Cleeland CS. Measurement of pain by subjective report. In: Chapman CR, Loeser JD, editors. Issues in Pain Measurement. New York: Raven Press; pp. 391-403, 1989. Advances in Pain Research and Therapy; Vol. 12.

For further information and to obtain copies for clinical use: www.mdanderson.org/BPI

... continued

Brief Pain Inventory©, page 2 of 2



STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #:_____

Date: ____/____/____ Time: _____

Name: _____ _____ _____

Last First Middle Initial

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

B. Mood

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

C. Walking Ability

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

E. Relations with other people

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

F. Sleep

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

G. Enjoyment of life

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

H. School Work (includes both class work and homework)

0 Does not Interfere 1 2 3 4 5 6 7 8 9 10 Completely Interferes

Page 2 of 2

BPI-SF English – School Work – January 2010

Appendix B-10: Aberrant Drug-Related Behaviours Resources

Table B Appendix 10.1 Aberrant Drug-Related Behaviours Indicative of Opioid Misuse

(Modified from Passik 2004)

Note: * = behaviours more indicative of addiction than the others

Indicator	Examples
*Altering the route of delivery	• Injecting, biting or crushing oral formulations
*Accessing opioids from other sources	• Taking the drug from friends or relatives • Purchasing the drug from the "street" • Double-doctoring
Unsanctioned use	• Multiple unauthorized dose escalations • Binge rather than scheduled use
Drug seeking	• Recurrent prescription losses • Aggressive complaining about the need for higher doses • Harassing staff for faxed scripts or fit-in appointments • Nothing else "works"
Repeated withdrawal symptoms	• Marked dysphoria, myalgias, GI symptoms, craving
Accompanying conditions	• Currently addicted to alcohol, cocaine, cannabis or other drugs • Underlying mood or anxiety disorders not responsive to treatment
Social features	• Deteriorating or poor social function • Concern expressed by family members
Views on the opioid medication	• Sometimes acknowledges being addicted • Strong resistance to tapering or switching opioids • May admit to mood-leveling effect • May acknowledge distressing withdrawal symptoms

Supporting Information:

1. Aberrant drug-related behaviours are common in patients with chronic pain.

A systematic review (Fishbain 2008) estimated that the prevalence of aberrant drug-related behaviours among chronic pain patients was 11.5% (range 0–44%). Urine drug screening with illicit drugs present was 14.5%, while a non-prescribed opioid or no opioid present was 20.4%.

2. There is evidence that some aberrant drug-related behaviours are more predictive of opioid addiction than others.

One study compared a sample of HIV patients with a history of substance abuse, to cancer patients without a history of substance abuse (Passik 2006a). Both groups were on opioids for chronic pain. Aberrant behaviours were significantly more common in the group with a history of substance abuse, and pain control was worse. Behaviours strongly predictive of opioid **addiction** (illegal activity, altering the route of delivery) were much more common in the group with a history of substance abuse than the group with no history of substance abuse. Aberrant behaviours in the group with a history of substance abuse were seen as frequently in patients who reported good pain control as in patients who reported poor pain control, suggesting that aberrant behaviours usually indicate something other than inadequately treated pain.

…continued

Appendix B-10: Aberrant Drug-Related Behaviours Resources…continued

Tools used to assist in identifying aberrant drug-related behaviours.

- *Addiction Behaviors Checklist* (ABC): In 2006, Wu, Compton et al. also developed and tested the ABC, a 20-item instrument designed to identify problematic drug-use in chronic pain patients treated with opioids (Wu 2006).
- *Current Opioid Misuse Measure* (COMM®): In 2007, Butler et al. developed and demonstrated the potential for a brief and easy-to-administer 17-item questionnaire, the COMM®, to identify aberrant drug-related behaviours (Butler 2007).
- *Patient Assessment and Documentation Tool* (PADT): developed by Passik et al. 2004, Clin Ther. This instrument focuses on key outcomes and provides a consistent way to document progress in pain management therapy over time. Items assess four domains: pain relief, patient functioning, adverse events, and drug-related behaviors.
- *Prescription Drug Use Questionnaire* (PDUQ): In 1998, Compton et al. developed and piloted the *PDUQ* for screening for addiction in chronic pain patients receiving opioids (Compton 1998). This is a 42-item interview to assess abuse/misuse for pain patients.
- *Prescription Opioid Therapy Questionnaire* (POTQ): In 2004, Michna et al. developed and tested the POTQ, an 11-item scale where the provider answers "yes" or "no" to questions indicative of misuse of opioids (Michna 2004).
- *Screener and Opioid Assessment for Patients with Pain* (SOAPP®-R). In 2004, Butler et al. developed the SOAPP® instrument (Butler 2004). In 2008 they published the revised SOAPP®-R, a 24-item self-report questionnaire that may also be useful for identifying risk of aberrant behaviours (Butler 2008).

Appendix B-11: SOAPP®-R and COMM®

1. SOAPP®-R

Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R)

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

For further information and to obtain copies for clinical use:
http://www.painedu.org/registration.asp?target=terms

…continued page 2

Appendix B-11…continued

SOAPP®-R, page 2

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

Appendix B-11…continued

2. COMM®

Current Opioid Misuse Measure (COMM)®

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

PainEDU

For further information and to obtain copies for clinical use:
http://www.painedu.org/registration.asp?target=terms

…continued page 2

Appendix B-11…continued

2. COMM®… page 2

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

Appendix B-12: Opioid Tapering

1. Precautions for Outpatient Opioid Tapering

1) **Pregnancy**: Severe, acute opioid withdrawal has been associated with premature labour and spontaneous abortion.
2) **Unstable medical and psychiatric conditions that can be worsened by anxiety**: While opioid withdrawal does not have serious medical consequences, it can cause significant anxiety and insomnia.
3) **Addiction to opioids obtained from multiple doctors or "the street:"** Outpatient tapering is unlikely to be successful if the patient regularly accesses opioids from other sources; such patients are usually best managed in an opioid agonist treatment program (methadone or buprenorphine).
4) **Concurrent medications**: Avoid sedative-hypnotic drugs, especially benzodiazepines, during the taper.

2. Opioid Tapering Protocol

2.1 Before Initiation

1) Emphasize that the goal of tapering is to make the patient feel better: to reduce pain intensity and to improve~~,~~ mood and function.
2) Have a detailed treatment agreement.
3) Be prepared to provide frequent follow-up visits and supportive counselling.

2.2 Type of Opioid, Schedule, Dispensing Interval

1) Use controlled-release morphine if feasible (see 2.3 below).
2) Prescribe scheduled doses (not p.r.n.).
3) Prescribe at frequent dispensing intervals (daily, alternate days, weekly, depending on patient's degree of control over opioid use). Do not refill if patient runs out.
4) Keep daily schedule the same for as long as possible (e.g., t.i.d.).

2.3. Rate of the Taper

1) The rate of the taper can vary from 10% of the total daily dose every day, to 10% of the total daily dose every 1–2 weeks.
2) Slower tapers are recommended for patients who are anxious about tapering, may be psychologically dependent on opioids, have co-morbid cardio-respiratory conditions, or express a preference for a slow taper.
3) Once one-third of the original dose is reached, slow the taper to one-half or less of the previous rate.
4) Hold the dose when appropriate: The dose should be held or increased if the patient experiences severe withdrawal symptoms, a significant worsening of pain or mood, or reduced function during the taper.

2.4 Switching to Morphine

1) Consider switching patients to morphine if the patient might be dependent on oxycodone or hydromorphone.
2) Calculate equivalent dose of morphine (see Appendix B-8: Oral Opioid Analgesic Conversion Table).
3) Start patient on one-half this dose (tolerance to one opioid is not fully transferred to another opioid).
4) Adjust dose up or down as necessary to relieve withdrawal symptoms without inducing sedation.

…Appendix B-12 continued next page

Appendix B-12: "Opioid Tapering"…continued

2.5 Monitoring during the Taper

1) Schedule frequent visits during the taper (e.g. weekly).
2) At each visit, ask about pain status, withdrawal symptoms and possible benefits of the taper: reduced pain and improved mood, energy level and alertness.
3) Use urine drug screening to assess compliance.

2.6 Completing the Taper

1) Tapers can usually be completed between 2–3 weeks and 3–4 months.
2) Patients who are unable to complete the taper may be maintained at a lower dose if their mood and functioning improve and they follow the treatment agreement.

Appendix B-13: Meta-analysis Evidence Table

Characteristics of the 62 randomized controlled trials included in this updated systematic review.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
1. Placebo-controlled (Neuropathic pain)				
Harati 1998 **USA** **Parallel** Quality: 4	Diabetic neuropathy 131 (49)	Tramadol 50 – 400 mg/d for 6 wk	**Primary:** Pain intensity* (5-point Likert scale). **Secondary:** Pain relief, quality of life (Medical Outcomes Study): physical functioning*, social functioning, current health perception, psychological distress, overall role functioning, and the two overall sleep problem indexes and sleep subscales.	Tramadol, at an average dose of 210 mg/d was significantly more effective than placebo. Patients on tramadol scored significantly better in physical and social functioning.
Sindrup 1999 **Germany** **Crossover** Quality:4	Polyneuropathy 45 (11)	Tramadol 200 – 400 mg/d for 4 wk	**Primary:** Pain ratings* (0-10 NRS), paraesthesia and touch-evoked pain. **Secondary:** Dynamic allodynia, rescue medication, patient's preference.	Pain, paraesthesia, touch-evoked pain and allodynia were lower on tramadol than on placebo. NNT to obtain one patient with ≥50% pain relief was 4.3 (95% CI 2.4 to 20).
Boureau 2003 **France** **Parallel** Quality:5	Postherpetic neuralgia 127 (19)	Tramadol 100 – 400 mg/d for 6 wk	**Primary:** Pain intensity (100-mm VAS* and 5-point NRS). **Secondary:** Global improvement, quality of life (Nottingham scale) and rescue medication (paracetamol).	Mean pain intensity was significantly lower with tramadol in both per protocol and intention-to-treat population. No significant difference was found between groups in pain intensity on a 5-point verbal scale or in quality of life measurement.
Norrbrink 2009 **Sweden** **Parallel** Quality:3	Spinal Cord Injury with neuropathic pain at or below level > 6 months. 35 (13)	Tramadol 50 mg TID – 400 mg/day. For 4 weeks.	**Primary:** present, general and worst pain. MPI subscale pain severity. Patient Global Impression of Change. **Secondary:** anxiety, global life satisfaction, and sleep quality.	Significant differences in present pain, general pain, and worst pain as well as MPI favouring tramadol. Seven patients on active drug (30%) rated an improvement, but only 4 (17%) rated their pain to be much improved. One patient in the placebo group reported minimal improvement (8%). No patients in either group reported their pain to be very much improved.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Watson and Babul 1998 Canada Crossover Quality:3	Postherpetic neuralgia 50 (12)	CR Oxycodone 20 – 60 (mean 45) mg/d for 4 wk	**Primary:** Pain intensity (100-mm VAS* and 5-point categorical scale). **Secondary:** Pain relief, steady pain, brief pain, skin pain, disability* (using a categorical scale: 0= no disability, 3= severe disability), BDI, POMS.	Oxycodone was significantly better in pain relief, reductions in steady pain, allodynia, paroxysmal spontaneous pain, global effectiveness, disability and masked preference.
Watson 2003 Canada Crossover Quality:4	Diabetic neuropathy 45 (3)	CR Oxycodone 20 – 80 (mean 40) mg/d for 4 wk	**Primary:** Pain intensity (100-mm VAS* and 5-point categorical scale). **Secondary:** Pain relief, steady pain, brief pain, skin pain, PDI*, SF-36 health survey, pain and sleep questionnaires.	Oxycodone was significantly better on daily pain, steady pain, brief pain, skin pain,total pain and disability. NNT to obtain one patient with at least 50% pain relief was 2.6
Gimbel 2003 USA Parallel Quality:5	Diabetic neuropathy 159 (44)	CR Oxycodone 20 – 120 (mean 37) mg/d for 6 wk	**Primary:** Pain intensity* (0-10 numeric scale). **Secondary:** Current and worse pain, satisfaction, BPI* (physical function score), SF-36 health survey.	Oxycodone provided more analgesia than placebo in the intent-to-treat cohort.
Huse 2001 Germany Crossover Quality:1	Phantom limb pain 12 (3)	SR morphine 70 – 300 (mean 120) mg/d for 4 wk	**Primary:** Pain intensity* (2-cm VAS) **Secondary:** PES, SDS, PRSS, WHYMPI, BSS.	Based on pain diary data, 42% of patients on morphine showed a pain reduction of more than 50% compared to only one patient in the placebo group.
Harke 2001 Germany Parallel Quality:4	Peripheral neuropathy 38 (3)	SR morphine 90 mg/d for 1 wk	Pain intensity* (0-10 numeric analogue scale), and reactivation of their spinal cord stimulator.	The differences between morphine and placebo were not significant.
Wu 2008 USA Crossover Quality:4	Postamputation pain 60 (25)	SR Morphine 15 - 180 mg day x 6 weeks.	**Primary:** Average change in overall pain intensity from the baseline to the last week of maintenance therapy using 0-10. **Secondary:** Pain relief (0-100%) and the interference and general activity subscales from the MPI. Side effects.	Morphine provided lower pain scores compared with placebo. The mean percent pain relief during treatment with placebo and morphine was 19 53%, respectively. NNT to obtain 50% and 33% decreases in pain intensity with morphine were 5.6 and 4.5, respectively.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Raja 2002(a) **USA** **Crossover** Quality:4	Postherpetic neuralgia 76 (32)	CR morphine 15-240 (mean 91) mg/d for 6 wk or methadone 15mg/d.	**Primary:** Pain intensity* (0-10 NRS). **Secondary:** Pain relief, cognitive function, MPI* (physical functioning subscale), sleep, mood, global preference.	Morphine reduced pain (1.9) more than placebo (0.2). Pain relief was greater with morphine (38%) compared with placebo (11%).
Gilron 2005 **Canada** **Crossover** Quality:4	35 diabetic neuropathy and 22 postherpetic neuralgia. 57 (16)	A) SR morphine maximum tolerated for 5 wk. B) SR morphine maximum tolerated combined with gabapentin for 5 wk C) Gabapentin maximum tolerated for 5 wk	**Primary:** Pain intensity* (0-10 NRS) **Secondary:** SF-MPQ, Maximal tolerated doses, Mood (BDI), SF-36 (physical function*), Mental Status (Mini-Mental), and global pain relief.	Mean pain intensity at the maximal tolerated dose was 4.49 with placebo, 4.15 with gabapentin, 3.7 with morphine and 3.06 with gabapentin-morphine combination. Total scores in SF-36 were lower with gabapentin-morphine combination than placebo or each drug alone.
Khoromi 2007 **USA** **Crossover** Quality:1	Chronic lumbar radiculopathy (sciatica) 55 (27)	A) SR morphine 15-90 mg/d B) Nortriptyline 25-100 mg/d C) Combination Each phase: 5 + 2 + 2 wk	**Primary:** Average leg pain during the two weeks*. **Secondary:** Global pain relief, ODI*, BDI and SF-36.	None of the treatments produced significant reductions in average leg pain or other leg or back pain scores.
Simpson 2007 **USA** **Crossover (Enrichment)** Quality:4	Acute on chronic pain 79 (4)	Fentanyl buccal tablet 100-800 mcg. (This formulation is not available in Canada) Duration: 9 episodes or 21 days	**Primary:** Sum of pain intensity differences (0-10 NRS) in the first 60 minutes (SPID-60). **Secondary:** Proportion of breakthrough episodes with 33% and 50% improvement; time to significant pain relief, pain intensity differences, proportion of episodes with meaningful pain relief, and proportion of episodes that required supplemental medication.	SPID-60 was significantly greater for breakthrough pain episodes treated with fentanyl buccal tablets compared with those in which placebo was administered.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
2. Placebo-controlled (Nociceptive pain)				
Roth 1998 **USA** **Parallel** **(Enrichment)** Quality:3	Osteoarthritis (not specified) 42 (8)	Tramadol 200 – 400 mg/d for 2 wk	**Primary:** Time to exit from the study due to therapeutic failure. **Secondary:** Severity of pain*(0-3 numeric scale), Ability to perform activities.	Time to exit from the study because of insufficient pain relief was longer in the tramadol group. Pain at rest and severity of pain on motion were less in the tramadol group. No differences were noted in general severity of current pain and on disability to perform ADLs.
Silverfield 2002 **USA** **Parallel** Quality:5	Osteoarthritis (not specified) 308 (68)	Tramadol 37.5 – 70 mg/d + acetaminophen 325 – 650 mg/d for 1.5 wk	**Primary:** Pain intensity*(0-3 numeric scale), Pain relief. **Secondary:** SPID, WOMAC* (physical function subscale).	The addition of tramadol/acetaminophen to NSAID or COX-2 selective inhibitor therapy was effective in the treatment of OA flare pain.
Emkey 2004 **USA** **Parallel** Quality:3	Osteoarthritis (not specified) 307 (80)	Tramadol 37.5 – 300 mg/d + acetaminophen 325 – 2600 mg/d for 13 wk	**Primary:** Pain intensity* (100-mm VAS) **Secondary:** Pain relief, WOMAC* (physical function subscale), SF-36 survey.	Mean final VAS scores, mean final pain relief rating scores, WOMAC physical function and SF-36 role-physical measures were all significantly better with tramadol/acetaminophen than with placebo.
Fleischmann 2001, USA **Parallel** Quality:4	Osteoarthritis knee 129 (93)	Tramadol 50-400 mg/d for 12 wk	**Primary:** Pain intensity* (0-4 Likert scale). **Secondary:** Pain relief, WOMAC* (overall), global assessment, time to failure	Mean final pain intensity score, and all secondary outcomes were significantly better in the tramadol group than in the placebo group.
Babul 2004 **USA** **Parallel** Quality:4	Osteoarthritis knee 246 (122)	CR Tramadol 100 – 400 mg/d for 11 wk	**Primary:** Pain intensity* (100-mm VAS). **Secondary:** WOMAC* (physical function subscale), CSPI.	Tramadol resulted in significant improvements in pain, stiffness, physical function, global status and sleep.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Ruoff 1999 **USA** **Parallel** Quality:5	Chronic joint pain 465 (113)	A) Tramadol starting at 200mg/d B) Tramadol starting at 50mg/d and reaching 200 mg/d on day 4 C) Tramadol starting at 50mg/d and reaching 200 mg/d on day 10 Duration of treatment: 2 wk	**Primary:** Discontinuation due to adverse effect or ineffectiveness.	40 patients (30.8% of group taking 200 mg/d from day 1) reached the primary end point; 31 patients (24.0% from day 4); 20 patients (15.2% from day 10); and 3 (4.4% of placebo group).
Schnitzer 1999 **USA** **Parallel (Enrichment)** Quality:3	Osteoarthritis knee 240 (4)	Tramadol 200 mg/d + Naproxen 750 mg/d reduced by 250 mg/d every 2 wk. Duration total: 8 wk	**Primary:** Minimum effective naproxen dose.	The addition of tramadol allowed a significant reduction in the dosage of naproxen without compromising pain relief.
Schnitzer 2000 **USA** **Parallel (Enrichment)** Quality:5	Low-back pain 254 (22)	Tramadol 200 – 400 (mean 242) mg/d for 4 wk	**Primary:** Time to exit the double-blind trial. **Secondary:** Pain intensity* (10-cm VAS), Pain relief, SF-MPQ, RDQ*	Discontinuation rate due to therapeutic failure was 20.7% in the tramadol group and 51.3% in the placebo group. Pain scores, MPQ and RDQ were significantly better in the tramadol group.
Ruoff 2003 **USA** **Parallel** Quality:3	Low-back pain. 322 (157)	Tramadol 37.5 – 300 (mean 157.5) mg/d + acetaminophen 325 – 2600 mg/d for 13 wk	**Primary:** Pain intensity* (100-mm VAS) **Secondary:** PRRS, SF-MPQ, RDQ*, SF-36.	Pain intensity, final PRRS scores, RDQ scores and many subscales of SF-MPQ and SF-36 were significantly better with tramadol than with placebo.
Peloso 2004 **Canada** **Parallel** Quality:3	Low-back pain 338 (191)	Tramadol 37.5 – 300 (mean 158) mg/d + acetaminophen 325 – 2600 mg/d for 91 days	**Primary:** Pain intensity* (100-mm VAS) **Secondary:** PRRS, SF-MPQ, SF-36, RDQ*, overall medication assessment.	VAS, pain relief scores, RDQ, physical-related subcategories of MPQ and Sf-36 were significantly better for tramadol/acetaminophen than for placebo. More patients rated tramadol/acetaminophen as “very good” or “good” than placebo.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Vorsanger 2008 USA and CANADA Parallel (Enrichment) Quality:4	Chronic Low Back Pain 386 (145)	A) CR Tramadol 300 mg/d* for 12 wk B) CR Tramadol 200 mg/d for 12 wk	**Primary:** pain intensity VAS since the previous visit. **Secondary:** current pain intensity VAS*, global assessment of study medication, Roland Disability Index*, and overall quality of sleep.	The placebo group had greater mean deterioration for pain intensity since the previous visit (+12.2 mm) compared with patients who continued to receive tramadol 300 mg (+5.2 mm) and patients whose dose was reduced to Tramadol 200 mg (+7.8). There were better response in the tramadol groups versus placebo for the secondary variables.
Burch 2007 Canada Parallel (Enrichment) Quality:5	Osteoarthritis knee 646 (155)	Tramadol (200-300 mg/d) for 12 wk	**Primary**: Pain intensity (11-point NRS)* **Secondary:** Patient and physician global impression of change.	The absolute mean reduction in pain intensity in the tramadol group was 3.0 ± 2.1. There was a statistically significant difference from placebo.
Kosinski 2007 Gana 2006 Schein 2008 USA Parallel Quality:2	Osteoarthritis (knee or hip), ACR Functional Class I-III 1020 (462)	A) Tramadol ER 100 mg/d for 12 wk B) Tramadol ER 200 mg/d for 12 wk C) Tramadol ER 300 mg/d for 12 wk D) Tramadol ER 400 mg/d for 12 wk	**Primary:** Pain intensity (100-mm VAS)* **Secondary:** Chronic pain sleep inventory.	Mean pain reduction at 12 weeks was -0.4 mm and -21.5 mm for tramadol ER and placebo, respectively ($P < 0.001$).
Lee 2006 Korea Parallel Quality:3	Rheumatoid arthritis pain inadequately controlled by NSAIDs and DMARD 277 (10)	Tramadol 37.5 mg/d plus acetaminophen 325 mg/d for 1 wk	**Primary:** mean daily pain relief score on a 6-point scale. **Secondary:** mean daily pain intensity (100-mm VAS)*, pain intensity at day 7, subjects and investigators mean overall assessment, physical function* (Health Assessment Questionnaire).	Pain relief scores and Pain intensity scores were significantly better in the tramadol/acetaminophen group compared with the placebo group Physical function did not differ significantly between tramadol/acetaminophen and placebo.
Thorne 2008 Canada Crossover Quality:3	OA knee or hip 100 (25)	CR Tramadol: 150 – 300 mg x 8 weeks	**Primary:** daily diary pain intensity score* **Secondary:** WOMAC pain and physical function*	Tramadol resulted in significantly lower pain intensity (37.4±23.9) compared with placebo (45.1±24.3). WOMAC index subscale score for pain and physical function were significantly better with tramadol than placebo.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Boureau 1991 **France** **Parallel** Quality:3	Rheumatoid Arthritis 40 (2)	Codeine 90 mg/d + acetaminophen 1500 mg/d for 1 week	**Primary:** Pain intensity (100-mm VAS* and 5-point Likert scale). **Secondary:** Pain relief, activity, sleep, overall efficacy.	Analgesic efficacy was significantly better with codeine/acetaminophen than with placebo for all criteria except the number of awakenings.
Arkinstall 1995 **Canada** **Crossover** Quality:3	Mixed nociceptive 46 (16)	CR Codeine 200 – 400 mg/d for 1 week	**Primary:** Pain intensity (100-mm VAS* and 5-point categorical scale). **Secondary:** Rescue acetaminophen + codeine consumption, PDI*, and patients' and investigators' treatment preferences.	The codeine group was significantly better on overall pain intensity (35±18) than placebo (49±16), on categorical pain intensity and on pain scores by day and time of day. Daily rescue analgesic consumption was lower in the codeine group. Disability was lower in the codeine group compared with placebo.
Peloso 2000 **Canada** **Parallel** Quality:3	Osteoarthritis hip or knee 103 (37)	CR Codeine 100 – 400 mg/d for 4 wk	**Primary:** WOMAC – Pain intensity* (0-500 VAS). **Secondary:** WOMAC* (stiffness and physical function), sleep, global assessment.	All variables in the efficacy analysis indicated superiority of codeine over placebo. The WOMAC improved 44.8% over baseline in the codeine group compared with 12.3% in the placebo group.
Roth 2000 **USA** **Parallel** Quality:3	Osteoarthritis 133 (70)	A) CR Oxycodone 20mg/d for 2 wk(*) B) CR Oxycodone 40mg/d for 2 wk	**Primary:** Pain intensity* (4-point numeric scale). **Secondary:** Quality of sleep, BPI, Interference of pain on key functional activities.	Oxycodone was superior to placebo in reducing pain intensity and the interference of pain with mood, sleep and enjoyment of life.
Caldwell 1999 **USA** **Parallel (Enrichment)** Quality:3	Osteoarthritis 107 (36)	A) IR Oxycodone 20 mg/d + acetaminophen 1300 mg/d for 4 wk(*) B) CR Oxycodone 20 mg/d for 4 wk	**Primary:** Pain intensity* (4-point numerical scale). **Secondary:** Global measure of sleep.	Pain intensity and quality of sleep were significantly improved in both active groups compared with the placebo group.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Webster 2006 **USA** **Parallel** Quality:3	Low-back pain 719 (391)	A) Oxycodone 10-80 mg/d once daily* B) Oxycodone 10-80 mg/d + ultra-low dose naltrexone once daily C) Oxycodone 10-80 mg/d + ultra-low dose naltrexone twice daily Duration: 12 wk	**Primary:** 11-point numerical diary pain intensity scale* **Secondary:** SF-12, ODI*, Quality of analgesia, global assessment of study drug.	All active treatment groups were significantly better than placebo on measures of pain reduction, physical component score of the SF-12 and ODI.
Markenson 2005 **USA** **Parallel** Quality:4	Osteoarthritis 109 (73)	Oxycodone CR 10-120 (mean 57) mg/d for 12 wk	**Primary:** BPI average pain intensity*, WOMAC scores at days 30 and 60, the number of patients who discontinued the study due to inadequate pain control. **Secondary:** BPI (pain interference and function), WOMAC, PGI, time to stable dosing, percentage of patients achieving stable dosing within 30 days, average daily dose at completion of initial titration, patient satisfaction, average and current pain intensity from pain diaries.	Oxycodone was significantly superior to placebo in decreasing average pain intensity and in reducing pain induced interference with general activity, walking ability (except at day 30), and normal work, as well as mood, sleep, relations with people (at days 60 and 90), and enjoyment in life. Daily functioning, as measured by WOMAC was also significantly improved in the oxycodone group. In the placebo group, a significantly greater percentage of patients discontinued due to inadequate pain control.
Chindalore 2005 **USA** **Parallel** Quality:3	Osteoarthritis hip and knee 362 (121)	A) Oxycodone 10 mg qid* B) Oxycodone 10 mg plus ultra-low dose naltrexone 0.001 mg qid C) Oxycodone 20 mg plus ultra-low dose naltrexone 0.001 mg bid Duration: 3 wk	**Primary:** Pain intensity measured by 11-point NRS* **Secondary:** quality of analgesia, pain control, global assessment of study drug, SF-12, WOMAC.	Although oxycodone was significantly better than placebo at wk 1, this treatment was not different from placebo at later time points. Oxycodone was significantly better than placebo on the pain subscale, the physical function scale, and the WOMAC total score, but at week 1 only.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Ma 2008 China Parallel Quality:4	Chronic neck pain with acute flare ups 116 (0 on day 7)	A) CR Oxycodone 5 to 10 mg bid for 4 wk	**Primary and secondary:** Frequency of pain episodes, pain intensity* (VAS), quality of life (QOL)*, quality of sleep (QOS), side effects, withdrawal symptoms, SF-36, performance status, patient satisfaction.	Results were extracted for the 7-day measurement. The frequency of pain episodes and VAS were decreased significantly with Oxycodone. Improvements in QOL and QOS were significant on day 3 after treatment with Oxycodone. Most domains of SF-36 were improved in the treated patients at the end of study.
Caldwell 2002 USA Parallel Quality:3	Osteoarthritis hip and/or knee 295 (111)	A) ER Morphine 30 mg/d (morning) for 4 wk* B) ER morphine 30 mg/d (evening) for 4 wk C) CR morphine 15 mg twice a day for 4 wk	**Primary:** WOMAC OA index pain (0-500) and overall arthritis pain intensity* (0-100). **Secondary:** WOMAC stiffness and physical function* (0-1700).	Morphine once daily and morphine twice daily both reduced pain and improved several sleep measures when compared with placebo. Analgesic efficacy was comparable between once daily and twice daily formulations.
Moran 1991 UK Crossover Quality:2	Rheumatoid Arthritis 20 (16)	CR Morphine 20 – 120 mg/d for 2 wk	**Primary:** Pain intensity* (100-mm VAS) **Secondary:** FIHAQ*, RS, GSS.	Although only 4 patients completed the study, results showed a significant improvement in pain in those taking morphine.
Moulin 1996 Canada Crossover Quality:4	Musculoskeletal pain 61 (18)	SR Morphine 30 – 120 (mean 83.5) mg/d for 6 wk	**Primary:** Pain intensity* (10-cm VAS) **Secondary:** Pain relief, MPQ, Drug liking, rescue medication, SCL-90, POMS, SIP, PDI*, HSCS, patient's preferences.	On VAS of pain, the morphine group showed a reduction in pain intensity relative to placebo in period I and this group also fared better in a crossover analysis of the sum of pain intensity differences from baseline. No other significant differences were detected.
Hale 2007 USA Parallel (Enrichment) Quality:2	Low-back pain 143 (76)	Oxymorphone ER 20-260 (mean 87.2, median 60 mg/d)o for 12 wk	**Primary:** change in average pain intensity (VAS) from baseline to final study visit* **Secondary:** 24-h pain intensity, use of medication, patients and physicians overall satisfaction.	Pain intensity increased significantly more for patients randomized to placebo than for patients who continued their stabilized dose of oxymorphone. The increase from baseline to final visit was 31.6 mm for placebo and 8.7 mm with oxymorphone.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Matsumoto 2005 **USA** **Parallel** Quality:4	Osteoarthritis 491 (222)	A) Oxymorphone ER 40 mg bid* B) Oxymorphone ER 20 mg bid C) Oxycodone CR 20 mg bid Duration: 4 wk	**Primary:** Pain intensity (VAS) at week 3 **Secondary:** Pain intensity from pain diary at wk 4*, WOMAC, patient and physician global assessments, drop outs due to lack of analgesia, sleep assessment, quality of life physical* and mental components (SF-36.	The primary end point showed a significant difference in favour of oxymorphone over placebo. Compared to placebo, both Oxymorphone 20 and 40 mg produced greater reductions in the WOMAC subscales at weeks 3 and 4.
Kivitz 2006 **USA** **Parallel** Quality:4	OA hip or knee 370 (172)	A) Oxymorphone ER 10 mg bid for 2 wk B) Oxymorphone ER 20 mg bid for 1 week, then 40 mg bid for 1 wk C) Oxymorphone ER 20 mg bid for 1 wk, then 50 mg bid for 1 wk.*	**Primary:** Arthritis pain intensity from VAS at week 1 and 2*. **Secondary:** WOMAC*, SF-36, chronic pain sleep inventory (CPSI), vital signs, clinical laboratory parameters, and adverse events.	Oxymorphone ER administered twice daily for 2 weeks produced dose-related reductions in arthritis pain intensity and improvements in physical function.
Zautra 2005 **USA** **Parallel** Quality:3	Moderate to severe pain due to OA 107 (71)	A) CR Oxycodone 10 mg bid for 2 wk They reported the results at 2-weeks, but the study lasted for 3 months.	**Primary:** Average 24 hour pain rating* (average of twelve daily reports was used for the 2-weeks posttest score on pain). **Secondary:** Positive and negative Watson's scale for affect. Vanderbilt multidimensional pain coping inventory. Coping efficacy and arthritis helplessness.	Oxycodone administered twice daily for 2 weeks demonstrated a significant reduction not only in 24 hour pain intensity but also in the other variables (coping and affect) favouring the active group. A significant drop out rate was observed (75% and 59% in the placebo and active group respectively)

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Portenoy 2007 **USA** **Parallel (Enrichment)** Quality:5	Acute on chronic low-back pain, 77 (3)	Fentanyl buccal tablets, maximum dose 800 mcg per episode. Duration 3 wk	**Primary:** electronic pain diary, 0 to 120 minutes after pain crisis. SPID-60 was the sum of pain intensity differences for the first 60 min. **Secondary:** proportion of breakthrough pain episodes with improvement >33% and 50%, pain relief at each posttreatment time point, proportion of episodes in which meaningful pain relief was obtained, time to meaningful pain relief, and proportion of episodes that required the use of supplemental medication.	SPID-60 was significantly better in the fentanyl group. All secondary measures also favoured fentanyl.
Langford 2006 **Multicenter in Europe** **Parallel** Quality:4	Osteoarthritis of hip and knee. Moderate to severe pain. 416 (217)	Transdermal fentanyl (25-100 mcg) for 6 wk	**Primary:** pain relief* (average area under the curve of the VAS scores over time). **Secondary:** WOMAC* score and its components.	Transdermal fentanyl provided significantly better pain relief than placebo, as demonstrated by the primary area under the curve for VAS scores -20 in the TDF group versus -14.6 in the placebo group. TDF was also associated with significantly better overall WOMAC scores and pain scores.
Landau 2007 **UK and USA** **Parallel (Enrichment)** Quality:4	Non-cancer pain (49% low back) 267 (12)	Buprenorphine transdermal (5-20 mg) for 2 wk	**Primary:** proportion of subjects with ineffective treatment* **Secondary:** time to ineffective treatment, proportion of subjects who reached ineffective treatment or discontinued for any reason, amount of escape medication used.	The proportion with ineffective treatment was lower in the buprenorphine group than in the placebo group (51.2% vs 65%). The odds of ineffective treatment were 1.79 times greater for placebo than buprenorphine.
3. Placebo-controlled (Fibromyalgia pain)				
Russell 2000 **USA** **Parallel (Enrichment)** Quality:5	Fibromyalgia 69 (1)	Tramadol 50 – 400 mg/d for 6 wk	**Primary:** Nº of patients exiting due to inadequate pain relief. **Secondary:** Pain intensity* (10-cm VAS), pain relief, tender-point count, myalgic score, FMIQ* (0-100).	Twenty (57.1%) patients in the tramadol group successfully completed the double-blind phase compared with nine (27%) in the placebo group.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Bennett 2003 **USA** **Parallel** Quality:4	Fibromyalgia 315 (177)	Tramadol 37.5 – 300 mg/d + acetaminophen 325 – 2600 mg/d for 11.5 wk	**Primary:** Cumulative time of discontinuation due to lack of efficacy. **Secondary:** Pain Intensity* (100-mm VAS), pain relief, tender-point count, myalgic score, FMIQ*, SF-36,12-SQ.	Discontinuation was less common in the tramadol group (48%) compared with the placebo group (62%). Tramadol treated patients also had significantly less pain at the end of the study, better pain relief and better FMIQ scores.
4. Placebo-controlled (Mixed pain)				
Maier 2002 **Germany** **Crossover** Quality:5	Neuropathic (67%) Nociceptive (32%) 49 (13)	SR Morphine 10 – 180 mg/d for 1 week (mean 114 mg/d)	**Primary:** Pain intensity* (0-10 NRS). **Secondary:** Tolerability of pain, sleep quality, physical fitness, mental state and mood, PDI*, symptom complain.	At the first wk, 44% under morphine and 0% under placebo had full responsiveness. After 2 wk 40% under morphine and 2% under placebo had full responsivenss.
5.Opioids versus other analgesics				
Gobel 1995 **Germany** **Parallel** Quality:1	Postherpetic neuralgia 35 (14)	Tramadol 200 – 600 mg/d for 6 wk Control: Clomipramine 50 – 100 mg/d with or without Levomepromazine 25–50 mg/d	**Primary:** Pain intensity*(5-point verbal rating scale). **Secondary:** Psychological and physical condition.	In both groups the pain intensity decreased over the 6-wk treatment period. (Reviewers' comments: no significant difference between groups). There were no essential differences in the current psychic/physical conditions during tramadol treatment.
Pavelka 1998 **Czech Republic** **Crossover** Quality:5	Osteoarthritis hip and knee 60 (6)	Tramadol 150 - 300 mg/d for 4 wk Control: Diclofenac 75 - 150 mg/d	**Primary:** WOMAC OA index (pain*, stiffness and physical disability*). **Secondary:** Drug preference.	Both treatments modestly improved median pain intensity, paralleled by an improvement in functional parameters, and there were no statistically significant differences between the groups.
Beaulieu 2008 **Canada** **Parallel** Quality:5	OA knee or hip 129 (32)	CR Tramadol 200 - 400/d for 6 wk Control: SR diclofenac 75mg/d for 6 wk	**Primary:** daily pain intensity by VAS* and WOMAC* pain subscale.	Mean change for WOMAC pain subscale was 73.2 ± 99.9 for tramadol and 80,2 ± 108 for diclofenac. Mean change for overall VAS pain score was 17.3 ± 22.6 for tramadol and 16.4 ± 24.4 for diclofenac.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Parr 1989 **USA** **Parallel** Quality:3	Pain in ≤2 joints. 846 (213)	D&A:dextropropoxyphene 1080 mg/d + acetaminophen 1950 mg/d for 4 wk Control: SR Diclofenac 100 mg/d	**Primary:** Pain intensity* (100-mm VAS) **Secondary:** Nottingham Health Profile. (NHP)*, energy, sleep, social isolation and emotional reactions.	Pain as measured by VAS showed 8% greater pain reduction with diclofenac as compared with D&A. Physical mobility as measured by the NHP improved by 13% more with diclofenac as compared with D&A.
Salzman and Brobyn 1983 (A) **USA** **Parallel** Quality:4	Osteoarthritis 57 (11 at 1 wk) in Salzman's group and 57 (7 at 1 wk) in Brobyn's	Propoxyphene 250 mg/d for 24 wk Control: Suprofen 800 mg/d	**Primary:** Pain intensity* (5-point numerical scale). **Secondary:** Pain relief, global improvement.	Both suprofen and propoxyphene produced a considerable reduction in pain intensity from baseline after only 1 wk treatment. This beneficial effect did not diminish with continued therapy. Further improvement occurred in both groups by 24 wk.
Glowinski 1999 **France** **Parallel** Quality:3	Rheumatoid Arthritis 60 (2)	Codeine 90 mg/d + acetaminophen 1500 mg/d for 1 week. Control: Diclofenac 100 mg/d + placebo.	**Primary:** Global efficacy (5-point verbal scale). **Secondary:** Pain intensity* (100-mm VAS), Impairment of activity (4-point scale), duration of morning stiffness, number of awakenings.	Analgesic efficacy was not significantly different between the two groups on all criteria.
Kjaersgaard-Andersen 1990 **Denmark** **Parallel** Quality:3	Osteoarthritis hip 161 (64)	Codeine 180 mg/d + acetaminophen 3 g/day for 4 wk Control: Acetaminophen 3 g/day. Rescue Medication: Ibuprofen tablets 400 mg	**Primary:** Daily intake of rescue medication. **Secondary:** Daily and weekly hip pain.	At 7 days, the addition of codeine was better than acetaminophen alone. After this, there was no difference.
Jamison 1998 **USA** **Parallel** Quality:2	Back pain 36 (3)	A) Oxycodone + SR Morphine 90 mg/d for 16 wk(*) B) SR Oxycodone 40 mg/d for 16 wk Control: Naproxen 1000 mg/d.	**Primary:** Pain intensity* (0-100 scale). **Secondary:** Mood. Level of activity, Number of hours and amount of study medication.	Both opioid groups had significantly less pain and emotional distress than the naproxen-only group. No differences in activity level or hours of sleep were found.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Vlok 1987 **South Africa** **Crossover** Quality:4	Osteoarthritis 31 (3)	Codeine 20 mg/d + Ibuprofen 400 mg/d + acetaminophen 500 mg/d for 4 wk Control: Ibuprofen 1200 mg/d	**Primary:** Pain intensity (VAS) **Secondary:** PAD, drug choice.	Combination of codeine with ibuprofen with acetaminophen was better than ibuprofen alone.
Raja 2002(b) **USA** **Crossover** Quality:4	Postherpetic neuralgia 76 (32)	CR morphine up to 240 mg/d for 6 wk. Methadone was an alternative opioid. Control: Nortriptyline up to 160 mg/d. Desipramine was an alternative antidepressant	**Primary:** Pain intensity* (0-10 NRS). **Secondary:** Pain relief, cognitive function, MPI* (physical functioning subscale), sleep, mood, global preference.	The trend favouring opioids over tricyclic antidepressants fell short of significance and reduction in pain with opioids did not correlate with that following tricyclics.
Gilron 2005 **Canada** **Crossover** Quality:4	35 diabetic neuropathy and 22 postherpetic neuralgia. 57 (16)	A) SR morphine maximum tolerated for 5 wk. B) SR morphine maximum tolerated combined with gabapentin for 5 wk C) Gabapentin maximum tolerated for 5 wk	**Primary:** Pain intensity (0-10 NRS). **Secondary:** SF-MPQ, Maximal tolerated doses, Mood (BDI), SF-36, Mental Status (Mini-Mental), and global pain relief.	Mean pain intensity at the maximal tolerated dose was 4.49 with placebo, 4.15 with gabapentin, 3.7 with morphine and 3.06 with gabapentin-morphine combination. Total scores in SF-36 were lower with gabapentin-morphine combination than placebo or each drug alone.
Wu 2008 **USA** **Crossover** Quality:4	Postamputation pain 60 (25)	A) SR Morphine 15 - 180 mg day for 6 wk B) Mexiletine: 75 – 1200 mg day for 6 wk	**Primary:** Average change in overall pain intensity from the baseline to the last week of maintenance therapy using 0-10. **Secondary:** Pain relief (0-100%) and the interference and general activity subscales from the MPI.	Morphine treatment provided lower pain scores compared with placebo and mexiletine. The mean percent pain relief during treatment with mexiletine, and morphine was 30 and 53%, respectively.

Study Country Design Quality	Population Number randomized (drop-outs)	Interventions and comparison groups	Outcomes: Primary and Secondary	Results (as reported in the studies)
Khoromi 2007 **USA** **Crossover** Quality:1	Chronic lumbar radiculopathy (sciatica) 55 (27)	A) SR morphine 15-90 mg/d B) Nortriptyline 25-100 mg/d C) Combination Duration: 9 wk	**Primary:** Average leg pain during the two weeks. **Secondary:** Global pain relief, ODI, BDI and SF-36.	In the 28 out of 61 patients who completed the study, none of the treatments produced significant reductions in average leg pain or other leg or back pain scores. Within the limitations of the modest sample size and high dropout rate, these results suggest that nortriptyline, morphine and their combination may have limited effectiveness in the treatment of chronic sciatica.
Frank 2008 **UK** **Crossover** Quality:3	Neuropathic pain 96 (32)	A) Dihydrocodeine maximum 240 mg/d for 14 wk B) Nabilone maximum 2 mg/d for 14 wk	**Primary:** difference in pain (VAS) computed over the last 2 weeks of each treatment period. **Secondary:** change in mood, quality of life, sleep and psychometric function.	The mean score was 6.0 mm longer for nabilone than for dihydrocodeine in the available case analysis and 5.6 mm in the per protocol analysis. Dihydrocodeine provided better pain relief than the synthetic cannabinoid nabilone. Nabilone was significantly superior to dihydrocodeine on the SF-36 (role-physical).
6. N of 1 randomized trial				
Sheather-Reid 1998 **Australia** Quality:3	Regional cervicobrachial pain 8 (3)	A) Codeine 120 mg/d for 4 wk B) Ibuprofen 800 mg/d for 4 wk C) Placebo for 4 wk	**Primary:** Pain intensity (VAS). **Secondary:** Change in pain, uptime, and hours of sleep.	In none of the 5 subjects who completed the 12-week trial was analgesic efficacy of either drug shown.

* Data used for meta-analysis; ADL: Activity of Daily Living, BDI = Beck Depression Inventory, BPI = Brief Pain Inventory©, BSS = Brief Stress Scale, CR = controlled-release, DMARD= Disease-Modifying Anti Rheumatic Drug, MPI = Multidimensional Pain Inventory, NNT: number needed to treat, NRS = numeric rating scale, ODI = Oswestry Disability Index, PES = Pain Experience Scale, POMS = Profile of Mood State, PDI = Pain Disability Index, PRSS = Pain-Related Self statement Scale, SDS = Self-Rating Depression Scale, SF-36 = Short Form 36 Health Survey, SR = sustained release, VAS = visual analog scale, WHYMPI = West Haven–Yale Multidimensional Pain Inventory,

REFERENCE LIST

(1) Adams NJ, Plane MB, Fleming MF, Mundt MP, Saunders LA, Stauffacher EA. Opioids and the treatment of chronic pain in a primary care sample. J Pain Symptom Manage 2001 Sep;22(3):791-6. (GRADE B, ***Supports Recommendation 17***).

(2) Adlaf EM, Paglia-Boak A, Brands B. Use of OxyContin by adolescent students. CMAJ 2006 Apr 25;174(9):1303- (GRADE B, ***Supports Recommendation 18***).

(3) Alattar MA, Scharf SM. Opioid-associated central sleep apnea: A case series. Sleep and Breathing 2009;13(2):201-6. (GRADE B, ***Supports Recommendation 10***).

(4) Amar PJ, Schiff ER. Acetaminophen safety and hepatotoxicity--where do we go from here? Expert Opin Drug Saf 2007 Jul;6(4):341-55.

(5) Arkinstall W, Sandler A, Goughnour B, Babul N, Harsanyi Z, Darke AC. Efficacy of controlled-release codeine in chronic non-malignant pain: a randomized, placebo-controlled clinical trial. Pain 1995 Aug;62(2):169-78. (GRADE A, ***Supports Recommendations 4***, ***10***).

(6) Arnold RM, Han PK, Seltzer D. Opioid contracts in chronic nonmalignant pain management: objectives and uncertainties. American Journal of Medicine 2006 Apr;119(4):292-6.

(7) Arundel C, Lewis JH. Drug-induced liver disease in 2006. Curr Opin Gastroenterol 2007 May;23(3):244-54.

(8) Babul N, Noveck R, Chipman H, Roth SH, Gana T, Albert K. Efficacy and safety of extended-release, once-daily tramadol in chronic pain: a randomized 12-week clinical trial in osteoarthritis of the knee. J Pain Symptom Manage 2004 Jul;28(1):59-71. (GRADE A, ***Supports Recommendations 4***, ***10***).

(9) Baillargeon L, Landreville P, Verreault R, Beauchemin JP, Gregoire JP, Morin CM. Discontinuation of benzodiazepines among older insomniac adults treated with cognitive-behavioural therapy combined with gradual tapering: a randomized trial. CMAJ 2003;169(10):1015-20. (GRADE A, ***Supports Recommendation 6***).

(10) Ballantyne JC, Mao J. Opioid therapy for chronic pain. New England Journal of Medicine 349(20):1943-53, 2003 Nov 13.

(11) Ballantyne JC, LaForge KS. Opioid dependence and addiction during opioid treatment of chronic pain. Pain 2007 Jun;129(3):235-55.

(12) Baron MJ, McDonald PW. Significant pain reduction in chronic pain patients after detoxification from high-dose opioids. Journal of Opioid Management 2006 Sep;2(5):277-82. (GRADE B, ***Supports Recommendation 13***).

(13) Barry DT, Moore BA, Pantalon MV, Chawarski MC, Sullivan LE, O'Connor PG, et al. Patient satisfaction with primary care office-based buprenorphine/naloxone treatment. J Gen Intern Med 2007;22(2):242-5. (GRADE B, ***Supports Recommendation 21***).

(14) Beaulieu AD, Peloso PM, Haraoui B, Bensen W, Thomson G, Wade J, et al. Once-daily, controlled-release tramadol and sustained-release diclofenac relieve chronic pain due to osteoarthritis: a randomized controlled trial. Pain Res Manag 2008 Mar;13(2):103-10. (GRADE A, ***Supports Recommendations 4***, ***10***).

(15) Becker N, Sjogren P, Bech P, Olsen AK, Eriksen J. Treatment outcome of chronic non-malignant pain patients managed in a danish multidisciplinary pain centre compared to general practice: a randomised controlled trial. Pain 2000 Feb;84(2-3):203-11. (GRADE A, ***Supports Recommendations 13***, ***16***).

(16) Becker WC, Fiellin DA. Provider Satisfaction with Office-Based Treatment of Opioid DependenceA Systematic Review. Subst Abus 2006;26(1):15-22. (GRADE B, ***Supports Recommendation 21***).

(17) Becker WC, Sullivan LE, Tetrault JM, Desai RA, Fiellin DA. Non-medical use, abuse and dependence on prescription opioids among U.S. adults: psychiatric, medical and substance use correlates. Drug & Alcohol Dependence 2008 Apr 1;94(1-3):38-47. (GRADE B, ***Supports Recommendations 1***, ***20***).

(18) Bennett RM, Kamin M, Karim R, Rosenthal N. Tramadol and acetaminophen combination tablets in the treatment of fibromyalgia pain: a double-blind, randomized, placebo-controlled study. American Journal of Medicine 2003 May;114(7):537-45. (GRADE A, ***Supports Recommendations 4***, ***10***).

(19) Bhamb B, Brown D, Hariharan J, Anderson J, Balousek S, Fleming MF. Survey of select practice behaviors by primary care physicians on the use of opioids for chronic pain. Current Medical Research & Opinion 2006 Sep;22(9):1859-65.

(20) Bieber CM, Fernandez K, Borsook D, Brennan MJ, Butler SF, Jamison RN, et al. Retrospective accounts of initial subjective effects of opioids in patients treated for pain who do or do not develop opioid addiction: a pilot case-control study. Experimental & Clinical Psychopharmacology 2008 Oct;16(5):429-34. (GRADE B, ***Supports Recommendation 11***).

(21) Bigal ME, Lipton RB. Excessive opioid use and the development of chronic migraine. Pain 2009;142(3):179-82.

(22) Blinick G, Wallach RC, Jerez E, Ackerman BD. Drug addiction in pregnancy and the neonate. Am J Obstet Gynecol 1976;125(2):135-42. (GRADE B, ***Supports Recommendation 19***).

(23) Boulanger A, Clark AJ, Squire P, Cui E, Horbay GL. Chronic pain in Canada: have we improved our management of chronic noncancer pain? Pain Res Manag 2007;12(1):39-47.

(24) Boureau F, Boccard E. Placebo-controlled study of analgesic efficacy of 500mg paracetamol 30mg codeine association combined with a low dose of diclofenac versus high dose of diclofenac in rheumatoid arthritis. Acta Therapeutica 1991;17(2):123-36. (GRADE A, ***Supports Recommendations 4***, ***10***).

(25) Boureau F, Legallicier P, Kabir-Ahmadi M. Tramadol in post-herpetic neuralgia: A randomized, double-blind, placebo-controlled trial. Pain 2003;104(1-2):323-31. (GRADE A, ***Supports Recommendations 4***, ***10***).

(26) Boyd CJ, McCabe SE, Cranford JA, Young A. Adolescents' motivations to abuse prescription medications. Pediatrics 2006 Dec;118(6):2472-80. (GRADE B, ***Supports Recommendation 18***).

(27) Brands B, Brands J. Methadone maintenance: a physicians guide to treatment. Toronto: Addiction Research Foundation; 1998.

(28) Brands B, Blake J, Sproule B, Gourlay D, Busto U. Prescription opioid abuse in patients presenting for methadone maintenance treatment. Drug & Alcohol Dependence 2004 Feb 7;73(2):199-207. (GRADE B, ***Supports Recommendation 11***).

(29) Breckenridge J, Clark JD. Patient characteristics associated with opioid versus nonsteroidal anti-inflammatory drug management of chronic low back pain. J Pain 2003;4(6):344-50. (GRADE B, ***Supports Recommendations 1***, ***20***).

(30) Brown RT, Zuelsdorff M, Fleming M. Adverse effects and cognitive function among primary care patients taking opioids for chronic nonmalignant pain. Journal of Opioid Management 2006 May;2(3):137-46.

(31) Bruera E, MacMillan K, Hanson J, MacDonald RN. The cognitive effects of the administration of narcotic analgesics in patients with cancer pain. Pain 1989;39(1):13-6. (GRADE B, ***Supports Recommendation 7***).

(32) Bruera E, Palmer JL, Bosnjak S, Rico MA, Moyano J, Sweeney C, et al. Methadone versus morphine as a first-line strong opioid for cancer pain: a randomized, double-blind study. Journal of Clinical Oncology 2004 Jan 1;22(1):185-92. (GRADE A, ***Supports Recommendation 7***).

(33) Burch F, Fishman R, Messina N, Corser B, Radulescu F, Sarbu A, et al. A comparison of the analgesic efficacy of Tramadol Contramid OAD versus placebo in patients with pain due to osteoarthritis. J Pain Symptom Manage 2007 Sep;34(3):328-38. (GRADE A, ***Supports Recommendations 4***, ***10***).

(34) Burns JM, Martyres RF, Clode D, Boldero JM. Overdose in young people using heroin: associations with mental health, prescription drug use and personal circumstances. Med J Aust 2004;181(7 Suppl):S25-S28.

(35) Butler SF, Budman SH, Fernandez K, Jamison RN. Validation of a screener and opioid assessment measure for patients with chronic pain. Pain 2004 Nov;112(1-2):65-75.

(36) Butler SF, Benoit C, Budman SH, Fernandez KC, McCormick C, Venuti SW, et al. Development and validation of an Opioid Attractiveness Scale: a novel measure of the attractiveness of opioid products to potential abusers. Harm Reduct J 2006;3:5- (GRADE B, ***Supports Recommendation 7***).

(37) Butler SF, Budman SH, Fernandez KC, Houle B, Benoit C, Katz N, et al. Development and validation of the Current Opioid Misuse Measure. Pain 2007 Jul;130(1-2):144-56.

(38) Butler SF, Fernandez K, Benoit C, Budman SH, Jamison RN. Validation of the Revised Screener and Opioid Assessment for Patients With Pain (SOAPP-R). Journal of Pain 2008;9(4):360-72.

(39) Caldwell JR, Hale ME, Boyd RE, Hague JM, Iwan T, Shi M, et al. Treatment of osteoarthritis pain with controlled release oxycodone or fixed combination oxycodone plus acetaminophen added to nonsteroidal antiinflammatory drugs: a double blind, randomized, multicenter, placebo controlled trial. Journal of Rheumatology 1999 Apr;26(4):862-9. (GRADE A, ***Supports Recommendations 4***, ***10***).

(40) Caldwell JR, Rapoport RJ, Davis JC, Offenberg HL, Marker HW, Roth SH, et al. Efficacy and safety of a once-daily morphine formulation in chronic, moderate-to-severe osteoarthritis pain: results from a randomized, placebo-controlled, double-blind trial and an open-label

extension trial. Journal of Pain & Symptom Management 2002 Apr;23(4):278-91. (GRADE A, ***Supports Recommendations 4***, ***10***).

(41) Canadian Medical Association [Internet]. Determining medical fitness to operate motor vehicles: CMA driver's guide (7th). Available from: http://www.cma.ca/index.cfm/ci_id/18223/la_id/1.htm

(42) Canadian Pharmacists Association [Internet]. Compendium of pharmaceuticals and specialties, online version (e-CPS) 2008. Available from: http://www.pharmacists.ca/content/products/ecps_english.cfm

(43) Caplehorn JR. A comparison of buprenorphine treatment in clinic and primary care settings: a randomised trial. Med J Aust 2003;179(10):557-8. (GRADE A, ***Supports Recommendation 21***).

(44) Carville SF, Arendt-Nielsen S, Bliddal H, Blotman F, Branco JC, Buskila D, et al. EULAR evidence-based recommendations for the management of fibromyalgia syndrome. Annals of the Rheumatic Diseases 2008 Apr;67(4):536-41. (GRADE A, ***Supports Recommendation 4***).

(45) Catchlove RFH, Hoirch AM. Survey of Canadian Pain Centres: a preliminary report. Pain Clinic 1988;2:231-7.

(46) Centre for Addiction and Mental Health [Internet}. Low-risk drinking guidelines 2004. Available from: http://www.camh.net/About_Addiction_Mental_Health/Drug_and_Addiction_Information/low_risk_drinking_guidelines.html

(47) Chelminski PR, Ives TJ, Felix KM, Prakken SD, Miller TM, Perhac JS, et al. A primary care, multi-disciplinary disease management program for opioid-treated patients with chronic non-cancer pain and a high burden of psychiatric comorbidity. BMC Health Services Research 2005 Jan 13;5(1):3. (GRADE B, ***Supports Recommendation 21***).

(48) Chindalore VL, Craven RA, Yu KP, Butera PG, Burns LH, Friedmann N. Adding ultralow-dose naltrexone to oxycodone enhances and prolongs analgesia: a randomized, controlled trial of Oxytrex. J Pain 2005 Jun;6(6):392-9. (GRADE A, ***Supports Recommendations 4***, ***10***).

(49) Chou R, Fanciullo GJ, Fine PG, Miaskowski C, Passik SD, Portenoy RK. Opioids for chronic noncancer pain: prediction and identification of aberrant drug-related behaviors: a review of the evidence for an American Pain Society and American Academy of Pain Medicine clinical practice guideline. Journal of Pain 2009 Feb;10(2):131-46.

(50) Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009 Feb;10(2):113-30.

(51) Chu LF, Clark DJ, Angst MS. Opioid tolerance and hyperalgesia in chronic pain patients after one month of oral morphine therapy: a preliminary prospective study. Journal of Pain 2006 Jan;7(1):43-8. (GRADE B, ***Supports Recommendation 5***).

(52) Cicero TJ, Inciardi JA, Adams EH, Geller A, Senay EC, Woody GE, et al. Rates of abuse of tramadol remain unchanged with the introduction of new branded and generic products: results of an abuse monitoring system, 1994-2004. Pharmacoepidemiology & Drug Safety 2005 Dec;14(12):851-9. (GRADE B, ***Supports Recommendations 7***, ***11***).

(53) Cicero TJ, Dart RC, Inciardi JA, Woody GE, Schnoll S, Munoz A. The development of a comprehensive risk-management program for prescription opioid analgesics: Researched abuse, diversion and addiction-related surveillance (RADARS). Pain Medicine 2007;8(2):157-70. (GRADE B, ***Supports Recommendation 7***).

(54) Cicero TJ, Lynskey M, Todorov A, Inciardi JA, Surratt HL. Co-morbid pain and psychopathology in males and females admitted to treatment for opioid analgesic abuse. Pain 2008 Sep 30;139(1):127-35.

(55) Clark AJ, Ahmedzai SH, Allan LG, Camacho F, Horbay GL, Richarz U, et al. Efficacy and safety of transdermal fentanyl and sustained-release oral morphine in patients with cancer and chronic non-cancer pain. Current Medical Research & Opinion 2004;(9):1419-28.

(56) Cohen J. Statistical power analysis for the behavioral sciences. 1st ed. New York,San Francisco,London: Academic press; 1988.

(57) Cohen SP, Christo PJ, Wang S, Chen L, Stojanovic MP, Shields CH, et al. The effect of opioid dose and treatment duration on the perception of a painful standardized clinical stimulus. Regional Anesthesia & Pain Medicine 2008 May;33(3):199-206. (GRADE B, ***Supports Recommendation 10***).

(58) College of Physicians and Surgeons of Ontario. Evidence-based Recommendations for Medical Management of Chronic Non-malignant Pain. Ontario, Canada; 2000.

(59) Compton P, Darakjian J, Miotto K. Screening for addiction in patients with chronic pain and "problematic" substance use: evaluation of a pilot assessment tool. Journal of Pain & Symptom Management 1998 Dec;16(6):355-63.

(60) Cone EJ, Fant RV, Rohay JM, Caplan YH, Ballina M, Reder RF, et al. Oxycodone involvement in drug abuse deaths: a DAWN-based classification scheme applied to an oxycodone postmortem database containing over 1000 cases. J Anal Toxicol 2003;27(2):57-67.

(61) Cone EJ, Fant RV, Rohay JM, Caplan YH, Ballina M, Reder RF, et al. Oxycodone involvement in drug abuse deaths. II. Evidence for toxic multiple drug-drug interactions. J Anal Toxicol 2004;28(4):217-25. (GRADE B, ***Supports Recommendation 6***).

(62) Cook JM, Biyanova T, Thompson R, Coyne JC. Older primary care patients' willingness to consider discontinuation of chronic benzodiazepines. Gen Hosp Psychiatry 2007;29(5):396-401. (GRADE B, ***Supports Recommendation 6***).

(63) Crisostomo RA, Schmidt JE, Hooten WM, Kerkvliet JL, Townsend CO, Bruce BK. Withdrawal of analgesic medication for chronic low-back pain patients: improvement in outcomes of multidisciplinary rehabilitation regardless of surgical history. Am J Phys Med Rehabil 2008;87(7):527-36. (GRADE B, ***Supports Recommendation 13***).

(64) Currie SR, Hodgins DC, Crabtree A, Jacobi J, Armstrong S. Outcome from integrated pain management treatment for recovering substance abusers. Journal of Pain 2003 Mar;4(2):91-100. (GRADE B, ***Supports Recommendation 21***).

(65) Daniell HW. DHEAS Deficiency During Consumption of Sustained-Action Prescribed Opioids: Evidence for Opioid-Induced Inhibition of Adrenal Androgen Production. Journal of Pain 7(12)()(pp 901-907), 2006 Date of Publication: Dec 2006 2006;(12):901-7. (GRADE B, ***Supports Recommendation 5***).

(66) Dasgupta N, Kramer ED, Zalman MA, Carino S Jr, Smith MY, Haddox JD, et al. Association between non-medical and prescriptive usage of opioids. Drug Alcohol Depend 2006 Apr 28;82(2):135-42. (GRADE B, ***Supports Recommendations 7***, ***11***).

(67) Dhalla IA, Mamdani MM, Sivilotti ML, Kopp A, Qureshi O, Juurlink DN. Prescribing of opioid analgesics and related mortality before and after the introduction of long-acting oxycodone. CMAJ 2009 Dec 8;181(12):891-6.

(68) Eccleston C. Chronic pain and distraction: an experimental investigation into the role of sustained and shifting attention in the processing of chronic persistent pain. Behavioral Research Therapy 1996;33(4):391-405.

(69) Edlund MJ, Sullivan M, Steffick D, Harris KM, Wells KB. Do users of regularly prescribed opioids have higher rates of substance use problems than nonusers? Pain Medicine 2007 Nov;8(8):647-56. (GRADE B, ***Supports Recommendation 1***).

(70) Edlund MJ, Steffick D, Hudson T, Harris KM, Sullivan M. Risk factors for clinically recognized opioid abuse and dependence among veterans using opioids for chronic non-cancer pain. Pain 2007 Jun;129(3):355-62. (GRADE B, ***Supports Recommendations 1***, ***20***).

(71) Eisenberg E, McNicol ED, Carr DB. Efficacy and safety of opioid agonists in the treatment of neuropathic pain of nonmalignant origin: systematic review and meta-analysis of randomized controlled trials. JAMA 2005 Jun 22;293(24):3043-52. (GRADE A, ***Supports Recommendation 4***).

(72) Elliott AM, Smith BH, Penny KI, Smith WC, Chambers WA. The epidemiology of chronic pain in the community. Lancet 1999 Oct 9;354(9186):1248-52.

(73) Emkey R, Rosenthal N, Wu S-C, Jordan D, Kamin M. Efficacy and Safety of Tramadol/Acetaminophen Tablets (Ultracet) as Add-on Therapy for Osteoarthritis Pain in Subjects Receiving a COX-2 Nonsteroidal Antiinflammatory Drug: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial. Journal of Rheumatology 2004;31(1):150-6. (GRADE A, ***Supports Recommendations 4***, ***10***).

(74) Eriksen J, Ekholm O, Sjogren P, Rasmussen NK. Development of and recovery from long-term pain. A 6-year follow-up study of a cross-section of the adult Danish population. Pain 2004 Mar;108(1-2):154-62.

(75) Farney RJ, Walker JM, Cloward TV, Rhondeau S. Sleep-disordered breathing associated with long-term opioid therapy. Chest 2003 Feb;123(2):632-9. (GRADE B, ***Supports Recommendation 5***).

(76) Farrar JT, Young JP, Jr., LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001 Nov;94(2):149-58.

(77) Farre M, Mas A, Torrens M, Moreno V, Cami J. Retention rate and illicit opioid use during methadone maintenance interventions: a meta-analysis. Drug Alcohol Depend 2002;65(3):283-90. (GRADE B, ***Supports Recommendation 21***).

(78) Federal Drug Administration. 2007 Public Health Advisories. Available from: http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm051192.htm

(79) Fiellin DA, Pantalon MV, Pakes JP, O'Connor PG, Chawarski M, Schottenfeld RS. Treatment of heroin dependence with buprenorphine in primary care. Am J Drug Alcohol Abuse 2002;28(2):231-41. (GRADE A, ***Supports Recommendation 21***).

(80) Fischer B, Rehm J, Patra J. Changes in illicit opioid use across Canada. CMAJ 2006;175(11):1385-7. (GRADE B, ***Supports Recommendation 11***).

(81) Fishbain DA, Cutler RB, Cole B, Lewis J, Rosomoff RS, Rosomoff HL. Medico-legal rounds: medico-legal issues and alleged breaches of "standards of medical care" in opioid rotation to methadone: a case report. Pain Medicine 2003 Jun;4(2):195-201.

(82) Fishbain DA, Cutler RB, Cole B, Lewis J, Smets E, Rosomoff HL, et al. Are patients with chronic low back pain or chronic neck pain fatigued? Pain Med 2004;5(2):187-95. (GRADE B, ***Supports Recommendations 1***, ***20***).

(83) Fishbain DA, Cole B, Lewis J, Rosomoff HL, Rosomoff RS. What percentage of chronic nonmalignant pain patients exposed to chronic opioid analgesic therapy develop abuse/addiction and/or aberrant drug-related behaviors? A structured evidence-based review. Pain Medicine 2008 May;9(4):444-59. (GRADE B, ***Supports Recommendation 1*)**.

(84) Fishman SM, Wilsey B, Yang J, Reisfield GM, Bandman TB, Borsook D. Adherence monitoring and drug surveillance in chronic opioid therapy. Journal of Pain & Symptom Management 2000 Oct;20(4):293-307.

(85) Fishman SM, Mahajan G, Jung SW, Wilsey BL. The trilateral opioid contract. Bridging the pain clinic and the primary care physician through the opioid contract. J Pain Symptom Manage 2002 Sep;24(3):335-44. (GRADE B, ***Supports Recommendation 5***).

(86) Fleischmann RM, Caldwell JR, Roth SH, et al. Tramadol for the treatment of join pain associated with osteoarthritis: A randomized, double-blinded, placebo-controlled trial. Current Therapeutic Research 2001;62:113-28. (GRADE A, ***Supports Recommendations 4***, ***10***).

(87) Fodale V, Mafrica F, Santamaria LB, Coleman JJ. Killer fentanyl: Is the fear justified? Expert Opinion on Drug Safety 2008;7(3):213-7. (GRADE B, ***Supports Recommendation 7***).

(88) Foral PA, Ineck JR, Nystrom KK. Oxycodone accumulation in a hemodialysis patient. South Med J 2007;100(2):212-4.

(89) Frank B, Serpell MG, Hughes J, Matthews JN, Kapur D. Comparison of analgesic effects and patient tolerability of nabilone and dihydrocodeine for chronic neuropathic pain: randomised, crossover, double blind study. BMJ 2008 Jan 26;336(7637):199-201. (GRADE A, ***Supports Recommendations 4***, ***10***).

(90) Franklin GM, Stover BD, Turner JA, Fulton-Kehoe D, Wickizer TM, Disability Risk Identification Study Cohort. Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort. Spine 2008 Jan 15;33(2):199-204. (GRADE B, ***Supports Recommendation 10***).

(91) Freye E, Levy JV. Use of opioids in the elderly - Pharmacokinetic and pharmacodynamic considerations. Anasthesiologie Intensivmedizin Notfallmedizin Schmerztherapie 2004;39(9):527-37.

(92) Furlan AD, Sandoval JA, Mailis-Gagnon A, Tunks E. Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects. CMAJ 2006 May 23;174(11):1589-94.

(93) Furlan AD, Pennick V, Bombardier C, van Tulder M. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine 2009 Aug 15;34(18):1929-41.

(94) Furlan AD, Chaparro LE, Irvin E, Mailis-Gagnon A. Opioids for chronic non cancer pain: A meta-analysis comparing enrichment and non-enrichment trial designs. Unpublished. 2010.

(95) Gana TJ, Pascual ML, Fleming RR, Schein JR, Janagap CC, Xiang J, et al. Extended-release tramadol in the treatment of osteoarthritis: a multicenter, randomized, double-blind, placebo-controlled clinical trial. Curr Med Res Opin 2006 Jul;22(7):1391-401.

(96) Gibson AE, Doran CM, Bell JR, Ryan A, Lintzeris N. A comparison of buprenorphine treatment in clinic and primary care settings: a randomised trial. Med J Aust 2003;179(1):38-42. (GRADE A, ***Supports Recommendation 21***).

(97) Gilron I, Bailey JM, Tu D, Holden RR, Weaver DF, Houlden RL. Morphine, gabapentin, or their combination for neuropathic pain. New England Journal of Medicine 2005 Mar 31;352(13):1324-34. (GRADE A, ***Supports Recommendations 4***, ***10***).

(98) Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. Journal of Pain & Symptom Management 2004 Aug;28(2):176-88. (GRADE B, ***Supports Recommendation 11***).

(99) Gimbel JS, Richards P, Portenoy RK. Controlled-release oxycodone for pain in diabetic neuropathy: a randomized controlled trial. Neurology 2003 Mar 25;60(6):927-34. (GRADE A, ***Supports Recommendations 4*** , ***10***).

(100) Glowinski J, Boccard E. Placebo-controlled study of the analgesic efficacy of a paracetamol 500 mg/Codeine 30 mg combination together with low-dose vs high-dose diclofenac in rheumatoid arthritis. Clinical Drug Investigation 1999;18(3):189-97. (GRADE A, ***Supports Recommendations 4***, ***10***).

(101) Gobel H, Stadler TH. Treatment of pain due to postherpetic neuralgia with tramadol. Results of an open, parallel pilot study vs clomipramine with and without levomepromazine. Clinical Drug Investigation 1995;10(4):208-14. (GRADE A, ***Supports Recommendations 4***, ***10***).

(102) Gosselin P, Ladouceur R, Morin CM, Dugas MJ, Baillargeon L. Benzodiazepine discontinuation among adults with GAD: A randomized trial of cognitive-behavioral therapy. J Consult Clin Psychol 2006 Oct;74(5):908-19. (GRADE A, ***Supports Recommendation 6***).

(103) Hadi I, da Silva O, Natale R, Boyd D, Morley-Forster PK. Opioids in the parturient with chronic nonmalignant pain: a retrospective review. Journal of Opioid Management 2006 Jan;21(1):31-4. (GRADE B, ***Supports Recommendation 19***).

(104) Hale ME, Ahdieh H, Ma T, Rauck R. Efficacy and Safety of OPANA ER (Oxymorphone Extended Release) for Relief of Moderate to Severe Chronic Low Back Pain in Opioid-Experienced Patients: A 12-Week, Randomized, Double-blind, Placebo-controlled Study. Journal of Pain 2007 Feb;8(2):175-84. (GRADE A, ***Supports Recommendations 4***, ***10***).

(105) Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, et al. Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities. JAMA 2008;(300):2613-20. (GRADE B, ***Supports Recommendation 11***).

(106) Hanks GW, O'Neill WM, Simpson P, Wesnes K. The cognitive and psychomotor effects of opioid analgesics. II. A randomized controlled trial of single doses of morphine, lorazepam and placebo in healthy subjects. Eur J Clin Pharmacol 1995;48(6):455-60.

(107) Harati Y, Gooch C, Swenson M, Edelman S, Greene D, Raskin P, et al. Double-blind randomized trial of tramadol for the treatment of the pain of diabetic neuropathy. Neurology 1998 Jun;50(6):1842-6. (GRADE A, ***Supports Recommendations 4***, ***10***).

(108) Harke H, Gretenkort P, Ladleif HU, Rahman S, Harke O. The response of neuropathic pain and pain in complex regional pain syndrome I to carbamazepine and sustained-release morphine in patients pretreated with spinal cord stimulation: a double-blinded randomized study. Anesthesia & Analgesia 2001 Feb;92(2):488-95. (GRADE A, ***Supports Recommendations 4***, ***10***).

(109) Hartikainen S, Mantyselka P, Louhivuori-Laako K, Enlund H, Sulkava R. Concomitant use of analgesics and psychotropics in home-dwelling elderly people-Kuopio 75 + study. Br J Clin Pharmacol 2005;60(3):306-10.

(110) Hendler N, Cimini C, Ma T, Long D. A comparison of cognitive impairment due to benzodiazepines and to narcotics. Am J Psychiatry 1980 Jul;137(7):828-30. (GRADE B, ***Supports Recommendation 7***).

(111) Hermos JA, Young MM, Gagnon DR, Fiore LD. Characterizations of long-term oxycodone/acetaminophen prescriptions in veteran patients. Archives of Internal Medicine 2004 Nov 22;164(21):2361-6. (GRADE B, ***Supports Recommendation 6***).

(112) Hooten WM, Townsend CO, Sletten CD, Bruce BK, Rome JD. Treatment outcomes after multidisciplinary pain rehabilitation with analgesic medication withdrawal for patients with fibromyalgia. Pain Med 2007 Jan;8(1):8-16. (GRADE B, ***Supports Recommendation 13***).

(113) Howard LA, Sellers EM, Tyndale RF. The role of pharmacogenetically-variable cytochrome P450 enzymes in drug abuse and dependence. Pharmacogenomics 2002;3(2):185-99. (GRADE C, ***Supports Recommendation 7***).

(114) Huse E, Larbig W, Flor H, Birbaumer N. The effect of opioids on phantom limb pain and cortical reorganization. Pain 2001 Feb 1;90(1-2):47-55. (GRADE A, ***Supports Recommendations 4***, ***10***).

(115) IASP Task Force on Taxonomy. Part III: Pain Terms, A current List with Definitions and Notes on Usage. In: Merskey H, Bogduk N, editors. Classification of Chronic Pain. Second Edition ed. Seattle: IASP Press; 1994. p. 209-14.

(116) Ilgen MA, Trafton JA, Humphreys K. Response to methadone maintenance treatment of opiate dependent patients with and without significant pain. Drug & Alcohol Dependence 2006 May 20;82(3):187-93. (GRADE B, ***Supports Recommendation 21***).

(117) International Narcotics Control Board. Narcotic Drugs: Estimated world requirements for 2007; Statistics for 2005. New York, NY.; 2006.

(118) International Narcotics Control Board. Narcotic Drugs: Estimated World Requirements for 2010; Statistics for 2008. New York, NY: United Nations; 2009.

(119) Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Controlled Clinical Trials 1996 Feb;17(1):1-12.

(120) Jamison RN, Raymond SA, Slawsby EA, Nedeljkovic SS, Katz NP. Opioid therapy for chronic noncancer back pain. A randomized prospective study. Spine 1998 Dec 1;23(23):2591-600. (GRADE A, ***Supports Recommendations 4***, ***10***).

(121) Johnson RE, Fudala PJ, Payne R. Buprenorphine: considerations for pain management. Journal of Pain & Symptom Management 2005 Mar;29(3):297-326. (GRADE B, ***Supports Recommendation 21***).

(122) Kahan M, Wilson L. Managing Alcohol, Tobacco and Other Drug Problems - A Pocket Guide for Physicians and Nurses. Toronto: Centre for Addiction and Mental Health; 2002.

(123) Kahan M, Srivastava A, Wilson L, Mailis-Gagnon A, Midmer D. Opioids for managing chronic non-malignant pain: safe and effective prescribing. Canadian Family Physician 2006 Sep;52(9):1091-6.

(124) Kaltenbach K, Berghella V, Finnegan L. Opioid dependence during pregnancy. Effects and management. Obstet Gynecol Clin North Am 1998;25(1):139-51. (GRADE B, ***Supports Recommendation 19***).

(125) Kalvik A, Isaac P, Janecek E. Benzodiazepines: Treatment of anxiety, insomnia and alcohol withdrawal. Pharmacy Connection 1995;Sept-Oct:20-32.

(126) Kandall SR, Doberczak TM, Jantunen M, Stein J. The methadone-maintained pregnancy. Clin Perinatol 1999;26(1):173-83. (GRADE B, ***Supports Recommendation 19***).

(127) Katz N, Rauck R, Ahdieh H, Ma T, Gerritsen vdH, Kerwin R, et al. A 12-week, randomized, placebo-controlled trial assessing the safety and efficacy of oxymorphone extended release for opioid-naive patients with chronic low back pain. Curr Med Res Opin 2007 Jan;23(1):117-28.

(128) Khoromi S, Cui L, Nackers L, Max MB. Morphine, nortriptyline and their combination vs. placebo in patients with chronic lumbar root pain. Pain 2007 Jul;130(1-2):66-75. (GRADE A, ***Supports Recommendations 4***, ***10***).

(129) Kivitz A, Ma C, Ahdieh H, Galer BS. A 2-week, multicenter, randomized, double-blind, placebo-controlled, dose-ranging, phase III trial comparing the efficacy of oxymorphone extended release and placebo in adults with pain associated with osteoarthritis of the hip or knee. Clin Ther 2006 Mar;28(3):352-64. (GRADE A, ***Supports Recommendations 4***, ***10***).

(130) Kjaersgaard-Andersen P, Nafei A, Skov O, Madsen F, Andersen HM, Kroner K, et al. Codeine plus paracetamol versus paracetamol in longer-term treatment of chronic pain due to osteoarthritis of the hip. A randomised, double-blind, multi-centre study. Pain 1990 Dec;43(3):309-18. (GRADE A, ***Supports Recommendations 4***, ***10***).

(131) Kosinski M, Janagap C, Gajria K, Schein J, Freedman J. Pain relief and pain-related sleep disturbance with extended-release tramadol in patients with osteoarthritis. Curr Med Res Opin 2007 Jul;23(7):1615-26. (GRADE A, ***Supports Recommendations 4***, ***10***).

(132) Krenzelok EP. The FDA Acetaminophen Advisory Committee Meeting - what is the future of acetaminophen in the United States? The perspective of a committee member. Clin Toxicol (Phila) 2009 Sep;47(8):784-9. (GRADE B, ***Supports Recommendation 7***).

(133) Kuehn BM. Opioid prescriptions soar: increase in legitimate use as well as abuse. JAMA 297(3):249-51, 2007 Jan 17.

(134) Lamas X, Farre M, Moreno V, Cami J. Effects of morphine in postaddict humans: a meta-analysis. Drug Alcohol Depend 1994 Oct;36(2):147-52. (GRADE B, ***Supports Recommendation 7***).

(135) Lamb RJ, Preston KL, Schindler CW, Meisch RA, Davis F, Katz JL, et al. The reinforcing and subjective effects of morphine in post-addicts: a dose-response study. J Pharmacol Exp Ther 1991 Dec;259(3):1165-73. (GRADE B, ***Supports Recommendations 7***, ***11***).

(136) Landau CJ, Carr WD, Razzetti AJ, Sessler NE, Munera C, Ripa SR. Buprenorphine transdermal delivery system in adults with persistent noncancer-related pain syndromes who require opioid therapy: a multicenter, 5-week run-in and randomized, double-blind maintenance-of-analgesia study. Clin Ther 2007 Oct;29(10):2179-93. (GRADE A, ***Supports Recommendations 4***, ***10***).

(137) Langford R, McKenna F, Ratcliffe S, Vojtassak J, Richarz U. Transdermal fentanyl for improvement of pain and functioning in osteoarthritis: a randomized, placebo-controlled trial. Arthritis Rheum 2006 Jun;54(6):1829-37. (GRADE A, ***Supports Recommendations 4***, ***10***).

(138) Leber PD, Davis CS. Threats to the validity of clinical trials employing enrichment strategies for sample selection. Control Clin Trials 1998 Apr;19(2):178-87.

(139) Lee EY, Lee EB, Park BJ, Lee CK, Yoo B, Lim MK, et al. Tramadol 37.5-mg/acetaminophen 325-mg combination tablets added to regular therapy for rheumatoid arthritis pain: a 1-week, randomized, double-blind, placebo-controlled trial. Clin Ther 2006 Dec;28(12):2052-60. (GRADE A, ***Supports Recommendations 4***, ***10***).

(140) Levenson JL, McClish DK, Dahman BA, Bovbjerg VE, de AC, Penberthy LT, et al. Depression and anxiety in adults with sickle cell disease: the PiSCES project. Psychosomatic medicine 2008;70(2):192-6 (GRADE B, ***Supports Recommendations 1***, ***20***).

(141) Lintzeris N, Ritter A, Panjari M, Clark N, Kutin J, Bammer G. Implementing buprenorphine treatment in community settings in Australia: experiences from the Buprenorphine Implementation Trial. Am J Addict 2004;13 Suppl 1:S29-S41. (GRADE A, ***Supports Recommendation 21***).

(142) Ma K, Jiang W, Zhou Q, Du DP. The efficacy of oxycodone for management of acute pain episodes in chronic neck pain patients. International journal of clinical practice 2008;62(2):241-7. (GRADE A, ***Supports Recommendations 4***, ***10***).

(143) Madadi P, Shirazi F, Walter FG, Koren G. Establishing causality of CNS depression in breastfed infants following maternal codeine use. Paediatric Drugs 2008;10(6):399-404. (GRADE B, ***Supports Recommendation 19***).

(144) Madadi P, Ross CJ, Hayden MR, Carleton BC, Gaedigk A, Leeder JS, et al. Pharmacogenetics of neonatal opioid toxicity following maternal use of codeine during breastfeeding: a case-control study.[see comment]. Clinical Pharmacology & Therapeutics 2009 Jan;85(1):31-5. (GRADE B, ***Supports Recommendation 19***).

(145) Mahowald ML, Singh JA, Majeski P. Opioid use by patients in an orthopedics spine clinic. Arthritis Rheum 2005;52(1):312-21.

(146) Maier C, Hildebrandt J, Klinger R, Henrich-Eberl C, Lindena G, MONTAS Study Group. Morphine responsiveness, efficacy and tolerability in patients with chronic non-tumor associated pain - results of a double-blind placebo-controlled trial (MONTAS). Pain 2002 Jun;97(3):223-33. (GRADE A, ***Supports Recommendations 4***, ***10***).

(147) Man LH, Best D, Gossop M, Stillwell G, Strang J. Relationship between prescribing and risk of opiate overdose among drug users in and out of maintenance treatment. Eur Addict Res 2004;10(1):35-40.

(148) Manchikanti L, Damron KS, Pampati V, McManus CD, Weaver SE. Prospective evaluation of patients with increasing opiate needs: Prescription opiate abuse and illicit drug use. Pain Physician 2004;7(3):339-44 (Grade B, **Supports Recommendation 3)**.

(149) Manchikanti L, Manchukonda R, Damron KS, Brandon D, McManus CD, Cash K. Does adherence monitoring reduce controlled substance abuse in chronic pain patients? Pain Physician 2006 Jan;9(1):57-60.

(150) Manchikanti L, Manchukonda R, Pampati V, Damron KS, Brandon DE, Cash KA, et al. Does random urine drug testing reduce illicit drug use in chronic pain patients receiving opioids? Pain Physician 2006 Apr;9(2):123-9. (GRADE B, ***Supports Recommendation 21***).

(151) Manchikanti L, Cash KA, Damron KS, Manchukonda R, Pampati V, McManus CD. Controlled substance abuse and illicit drug use in chronic pain patients: An evaluation of multiple variables. Pain Physician 2006 Jul;9(3):215-25.

(152) Manchikanti L, Giordano J, Boswell MV, Fellows B, Manchukonda R, Pampati V. Psychological factors as predictors of opioid abuse and illicit drug use in chronic pain patients. Journal of Opioid Management 2007 Mar;3(2):89-100. (GRADE B, ***Supports Recommendations 1***, ***20***).

(153) Markenson JA, Croft J, Zhang PG, Richards P. Treatment of persistent pain associated with osteoarthritis with controlled-release oxycodone tablets in a randomized controlled clinical trial. Clin J Pain 2005 Nov;21(6):524-35. (GRADE A, ***Supports Recommendations 4***, ***10***).

(154) Martin TL, Woodall KL, McLellan BA. Fentanyl-related deaths in Ontario, Canada: toxicological findings and circumstances of death in 112 cases (2002-2004). J Anal Toxicol 2006 Oct;30(8):603-10. (GRADE B, ***Supports Recommendation 7***).

(155) Matsumoto AK, Babul N, Ahdieh H. Oxymorphone extended-release tablets relieve moderate to severe pain and improve physical function in osteoarthritis: results of a randomized, double-blind, placebo- and active-controlled phase III trial. Pain Med 2005 Sep;6(5):357-66. (GRADE A, ***Supports Recommendations 4***, ***10***).

(156) Mattick RP, Kimber J, Breen C, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews 2008;CD002207(April 16).

(157) Maxwell JC. Trends in the abuse of prescription drugs. Austin: The Centre for Excellence in Drug Epidemiology; 2006.

(158) McCabe SE, West BT, Morales M, Cranford JA, Boyd CJ. Does early onset of non-medical use of prescription drugs predict subsequent prescription drug abuse and dependence? Results from a national study. Addiction (Abingdon , England) 2007;102(12):1920-30. (GRADE B, ***Supports Recommendation 18***).

(159) McLellan AT, Turner B. Prescription Opioids, Overdose Deaths, and Physician Responsibility. JAMA 2008;300:2672-3.

(160) McQuay HJ, Derry S, Moore RA, Poulain P, Legout V. Enriched enrolment with randomised withdrawal (EERW): Time for a new look at clinical trial design in chronic pain. Pain 2008 Apr;135(3):217-20.

(161) Mercadante S, Ferrera P, Villari P, Casuccio A. Rapid switching between transdermal fentanyl and methadone in cancer patients. Journal of Clinical Oncology 2005 Aug 1;23(22):5229-34. (GRADE B, ***Supports Recommendation 7***).

(162) Michna E, Ross EL, Hynes WL, Nedeljkovic SS, Soumekh S, Janfaza D, et al. Predicting aberrant drug behavior in patients treated for chronic pain: importance of abuse history. Journal of Pain & Symptom Management 2004 Sep;28(3):250-8.

(163) Miller NS, Swiney T, Barkin RL. Effects of opioid prescription medication dependence and detoxification on pain perceptions and self-reports. American Journal of Therapeutics 2006 Sep;13(5):436-44. (GRADE B, ***Supports Recommendation 13***).

(164) Minister of Justice. Controlled Drugs and Substance Act. Available from: http://laws.justice.gc.ca/en/C-38.8/

(165) Mintzer IL, Eisenberg M, Terra M, MacVane C, Himmelstein DU, Woolhandler S. Treating opioid addiction with buprenorphine-naloxone in community-based primary care settings. Annals of family medicine 2007;5(2):146-50. (GRADE A, ***Supports Recommendation 21***).

(166) Mirakbari SM, Innes GD, Christenson J, Tilley J, Wong H. Do co-intoxicants increase adverse event rates in the first 24 hours in patients resuscitated from acute opioid overdose? J Toxicol Clin Toxicol 2003;41(7):947-53. (GRADE B, ***Supports Recommendation 6***).

(167) Mogri M, Khan MIA, Grant BJB, Mador MJ. Central sleep apnea induced by acute ingestion of opioids. Chest 2008;133(6):1484-8. (GRADE B, ***Supports Recommendation 5***).

(168) Moore BA, Fiellin DA, Barry DT, Sullivan LE, Chawarski MC, O'Connor PG, et al. Primary care office-based buprenorphine treatment: comparison of heroin and prescription opioid dependent patients. J Gen Intern Med 2007;22(4):527-30. (GRADE B, ***Supports Recommendation 21***).

(169) Moran C. MST continus tablets and pain control in severe rheumatoid arthritis. British Jounal of Clinical Research 1991;2:1-12. (GRADE A, ***Supports Recommendations 4***, ***10***).

(170) Morin CM, Bastien C, Guay B, Radouco-Thomas M, Leblanc J, Vallieres A. Randomized clinical trial of supervised tapering and cognitive behavior therapy to facilitate benzodiazepine discontinuation in older adults with chronic insomnia. Am J Psychiatry 2004;161(2):332-42. (GRADE A, ***Supports Recommendation 6***).

(171) Morley-Forster PK, Clark AJ, Speechley M, Moulin DE. Attitudes toward opioid use for chronic pain: a Canadian physician survey.[see comment]. Pain Research & Management 2003;8(4):189-94. (GRADE B, ***Supports Recommendation 17***).

(172) Moroz G, Rosenbaum JF. Efficacy, safety, and gradual discontinuation of clonazepam in panic disorder: a placebo-controlled, multicenter study using optimized dosages. J Clin Psychiatry 1999 Sep;60(9):604-12. (GRADE A, ***Supports Recommendation 6***).

(173) Moulin DE, Iezzi A, Amireh R, Sharpe WK, Boyd D, Merskey H. Randomised trial of oral morphine for chronic non-cancer pain. Lancet 1996 Jan 20;347(8995):143-7. (GRADE A, ***Supports Recommendations 4***, ***10***).

(174) Moulin DE, Clark AJ, Speechley M, Morley-Forster PK. Chronic pain in Canada--prevalence, treatment, impact and the role of opioid analgesia. Pain Res Manag 2002;7(4):179-84. (GRADE B, ***Supports Recommendation 17***).

(175) Moulin DE, Clark AJ, Gilron I, Ware MA, Watson CP, Sessle BJ, et al. Pharmacological management of chronic neuropathic pain - consensus statement and guidelines from the Canadian Pain Society. Pain Res Manag 2007;12(1):13-21.

(176) Myers DP, Augustyniak M, Molea J. Buprenorphine for pain management physicians: A dilemma or a therapeutic alternative? Techniques in Regional Anesthesia and Pain Management 2005;9(4):216-20. (GRADE B, ***Supports Recommendation 21***).

(177) National Opioid Use Guideline Group. Canadian guideline for safe and effective use of opioids for chronic non-cancer pain. Available from: http://nationalpaincentre.mcmaster.ca/opioid/ 2010.

(178) Noble M, Treadwell JR, Tregear SJ, Coates VH, Wiffen PJ, Akafomo C, et al. Long-term opioid management for chronic noncancer pain. Cochrane Database Syst Rev 2010;(1):CD006605.

(179) Norrbrink C, Lundeberg T. Tramadol in neuropathic pain after spinal cord injury: a randomized, double-blind, placebo-controlled trial. Clin J Pain 2009 Mar;25(3):177-84. (GRADE A, ***Supports Recommendations 4***, ***10***).

(180) Nuesch E, Rutjes AW, Husni E, Welch V, Juni P. Oral or transdermal opioids for osteoarthritis of the knee or hip. Cochrane Database Syst Rev 2009;(4):CD003115. (GRADE A, ***Supports Recommendation 4***).

(181) O'Connor PG, Oliveto AH, Shi JM, Triffleman EG, Carroll KM, Kosten TR, et al. A randomized trial of buprenorphine maintenance for heroin dependence in a primary care clinic for substance users versus a methadone clinic. Am J Med 1998;105(2):100-5. (GRADE A, ***Supports Recommendation 21***).

(182) Parr G, Darekar B, Fletcher A, Bulpitt CJ. Joint pain and quality of life; results of a randomised trial. British Journal of Clinical Pharmacology 1989 Feb;27(2):235-42. (GRADE A, ***Supports Recommendations 4***, ***10***).

(183) Pascual ML, Fleming RR, Gana TJ, Vorsanger GJ. Open-label study of the safety and effectiveness of long-term therapy with extended-release tramadol in the management of chronic nonmalignant pain. Current Medical Research & Opinion 2007 Oct;23(10):2531-42. (GRADE B, ***Supports Recommendation 10***).

(184) Passik SD, Kirsh KL. Assessing aberrant drug-taking behaviors in the patient with chronic pain. Current Pain & Headache Reports 2004 Aug;8(4):289-94. (GRADE B, ***Supports Recommendation 11***).

(185) Passik SD, Kirsh KL, Whitcomb L, Portenoy RK, Katz NP, Kleinman L, et al. A new tool to assess and document pain outcomes in chronic pain patients receiving opioid therapy. Clinical Therapeutics 2004 Apr;26(4):552-61.

(186) Passik SD, Hays L, Eisner N, Kirsh KL. Psychiatric and pain characteristics of prescription drug abusers entering drug rehabilitation. Journal of Pain & Palliative Care Pharmacotherapy 2006;20(2):5-13 (Passik 2006a).

(187) Passik SD, Kirsh KL, Donaghy KB, Portenoy RK. Pain and aberrant drug-related behaviors in medically ill patients with and without histories of substance abuse. Clin J Pain 2006 Feb;22(2):173-81 (Passik 2006b).

(188) Paulozzi LJ. Opioid analgesic involvement in drug abuse deaths in American metropolitan areas. Am J Public Health 2006;96(10):1755-7. (GRADE B, ***Supports Recommendation 11***).

(189) Pavelka K, Peliskova Z, Stehlikova H, Ratcliffe S, Repas C. Intraindividual differences in pain relief and functional improvement in osteoarthritis with diclofenac or tramadol. Clinical Drug Investigation 1998;16(6):421-9. (GRADE A, ***Supports Recommendations 4***, ***10***).

(190) Peloso PM, Bellamy N, Bensen W, Thomson GT, Harsanyi Z, Babul N, et al. Double blind randomized placebo control trial of controlled release codeine in the treatment of osteoarthritis of the hip or knee. Journal of Rheumatology 2000 Mar;27(3):764-71. (GRADE A, ***Supports Recommendations 4***, ***10***).

(191) Peloso PM, Fortin L, Beaulieu A, Kamin M, Rosenthal N. Analgesic efficacy and safety of tramadol/ acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double blind, placebo controlled trial. J Rheumatol 2004 Dec;31(12):2454-63. (GRADE A, ***Supports Recommendations 4***, ***10***).

(192) Peng P, Choiniere M, Dion D, Intrater H, Lefort S, Lynch M, et al. Challenges in accessing multidisciplinary pain treatment facilities in Canada. Canadian Journal of Anaesthesia 2007 Dec;54(12):977-84.

(193) Pereira J, Lawlor P, Vigano A, Dorgan M, Bruera E. Equianalgesic dose ratios for opioids. a critical review and proposals for long-term dosing. Journal of Pain & Symptom Management 2001 Aug;22(2):672-87.

(194) Pergolizzi J, Boger RH, Budd K, Dahan A, Erdine S, Hans G, et al. Opioids and the management of chronic severe pain in the elderly: consensus statement of an International Expert Panel with focus on the six clinically most often used World Health Organization Step III opioids (buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone). Pain Practice 2008 Jul;8(4):287-313. (GRADE B, ***Supports Recommendation 17***).

(195) Peterson GM, Randall CT, Paterson J. Plasma levels of morphine and morphine glucuronides in the treatment of cancer pain: relationship to renal function and route of administration. Eur J Clin Pharmacol 1990;38(2):121-4. (GRADE B, ***Supports Recommendation 7***).

(196) Portenoy RK, Messina J, Xie F, Peppin J. Fentanyl buccal tablet (FBT) for relief of breakthrough pain in opioid-treated patients with chronic low back pain: a randomized, placebo-controlled study. Current Medical Research & Opinion 2007 Jan;23(1):223-33. (GRADE A, ***Supports Recommendations 4***, ***10***).

(197) Preston KL, Jasinski DR, Testa M. Abuse potential and pharmacological comparison of tramadol and morphine. Drug Alcohol Depend 1991;27(1):7-17. (GRADE B, ***Supports Recommendation 7***).

(198) Quigley C. Opioid switching to improve pain relief and drug tolerability. Cochrane Database of Systematic Reviews 2004;(3):CD004847. (GRADE B, ***Supports Recommendation 13***).

(199) Raja SN, Haythornthwaite JA, Pappagallo M, Clark MR, Travison TG, Sabeen S, et al. Opioids versus antidepressants in postherpetic neuralgia: a randomized, placebo-controlled trial. Neurology 2002 Oct 8;59(7):1015-21. (GRADE A, ***Supports Recommendations 4***, ***10***).

(200) Rajagopal A, Bruera ED. Improvement in sexual function after reduction of chronic high-dose opioid medication in a cancer survivor. Pain Med 2003 Dec;4(4):379-83. (GRADE B, ***Supports Recommendation 10***).

(201) Rajagopal A, Vassilopoulou-Sellin R, Palmer JL, Kaur G, Bruera E. Hypogonadism and sexual dysfunction in male cancer survivors receiving chronic opioid therapy. J Pain Symptom Manage 2003 Nov;26(5):1055-61. (GRADE B, ***Supports Recommendation 10***).

(202) Ralphs JA, Williams AC, Richardson PH, Pither CE, Nicholas MK. Opiate reduction in chronic pain patients: a comparison of patient-controlled reduction and staff controlled cocktail methods. Pain 1994 Mar;56(3):279-88. (GRADE B, ***Supports Recommendation 13***).

(203) Ramage-Morin PL. Medication use among senior Canadians. Health Rep 2009 Mar;20(1):37-44.

(204) Reid MC, Engles-Horton LL, Weber MB, Kerns RD, Rogers EL, O'Connor PG. Use of opioid medications for chronic noncancer pain syndromes in primary care. Journal of General Internal Medicine 2002 Mar;17(3):173-9.

(205) Repchinsky C. Table 2: Opioid Analgesics. Approximate analgesic equivalences. Compendium of Pharmaceutical Specialties. Ottawa: Canadian Pharmacists Association; 2004. p. 457.

(206) Reynolds KK, Ramey-Hartung B, Jortani SA. The value of CYP2D6 and OPRM1 pharmacogenetic testing for opioid therapy. Clinics in Laboratory Medicine 2008 Dec;28(4):581-98. (GRADE B, ***Supports Recommendation 10***).

(207) Ricci JA, Stewart WF, Chee E, Leotta C, Foley K, Hochberg MC. Back pain exacerbations and lost productive time costs in United States workers. Spine 2006 Dec 15;31(26):3052-60.

(208) Riley JL, III, Hastie BA. Individual differences in opioid efficacy for chronic noncancer pain. Clin J Pain 2008;24(6):509-20.

(209) Robinson CL. Relieving pain in the elderly. Health Prog 2007 Jan;88(1):48-53, 70.

(210) Roeloffs CA, Wells KB, Ziedonis D, Tang L, Unutzer J. Problem substance use among depressed patients in managed primary care. Psychosomatics 2002;43(5):405-12.

(211) Romach MK, Otton SV, Somer G, Tyndale RF, Sellers EM. Cytochrome P450 2D6 and treatment of codeine dependence. J Clin Psychopharmacol 2000;20(1):43-5. (GRADE B, ***Supports Recommendation 7***).

(212) Rome JD, Townsend CO, Bruce BK, Sletten CD, Luedtke CA, Hodgson JE. Chronic noncancer pain rehabilitation with opioid withdrawal: comparison of treatment outcomes based on opioid use status at admission. Mayo Clinic Proceedings 2004 Jun;79(6):759-68. (GRADE B, ***Supports Recommendations 10***, ***13***).

(213) Rosenblum A, Parrino M, Schnoll SH, Fong C, Maxwell C, Cleland CM, et al. Prescription opioid abuse among enrollees into methadone maintenance treatment. Drug & Alcohol Dependence 2007 Sep 6;90(1):64-71. (GRADE B, ***Supports Recommendation 11***).

(214) Roth SH. Efficacy and safety of tramadol HCl in breakthrough musculoskeletal pain attributed to osteoarthritis. Journal of Rheumatology 1998 Jul;25(7):1358-63. (GRADE A, ***Supports Recommendations 4***, ***10***).

(215) Roth SH, Fleischmann RM, Burch FX, Dietz F, Bockow B, Rapoport RJ, et al. Around-the-clock, controlled-release oxycodone therapy for osteoarthritis-related pain: placebo-controlled trial and long-term evaluation. Archives of Internal Medicine 2000 Mar 27;160(6):853-60. (GRADE A, ***Supports Recommendations 4***, ***10***).

(216) Rowbotham MC, Lindsey CD. How effective is long-term opioid therapy for chronic noncancer pain? Clinical Journal of Pain 2007;23(4):300-2. (GRADE B, ***Supports Recommendation 10***).

(217) Ruoff GE. Slowing the initial titration rate of tramadol improves tolerability. Pharmacotherapy 1999 Jan;19(1):88-93. (GRADE A, ***Supports Recommendations 4***, ***10***).

(218) Ruoff GE, Rosenthal N, Jordan D, Karim R, Kamin M, Protocol CAPS. Tramadol/acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study. Clinical Therapeutics 2003 Apr;25(4):1123-41. (GRADE A, ***Supports Recommendations 4***, ***10***).

(219) Russell J, Kamin M, Bennett RM, Schnitzer TJ, Green JA, Katz WA. Efficacy of tramadol in treatment of pain in fibromyalgia. Journal of Clinical Rheumatology 2000;6(5):250-7. (GRADE A, ***Supports Recommendations 4***, ***10***).

(220) Salzman RT, Brobyn RD. Long-term comparison of suprofen and propoxyphene in patients with osteoarthritis. Pharmacology 1983;27 Suppl 1:55-64. (GRADE A, ***Supports Recommendations 4***, ***10***).

(221) Sandoval JA, Furlan AD, Mailis-Gagnon A. Oral methadone for chronic noncancer pain: a systematic literature review of reasons for administration, prescription patterns, effectiveness, and side effects. Clinical Journal of Pain 2005 Nov;21(6):503-12 (GRADE B, ***Supports Recommendation 7***).

(222) Schein JR, Kosinski MR, Janagap-Benson C, Gajria K, Lin P, Freedman JD. Functionality and health-status benefits associated with reduction of osteoarthritis pain. Curr Med Res Opin 2008 May;24(5):1255-65.

(223) Schepis TS, Krishnan-Sarin S. Characterizing adolescent prescription misusers: a population-based study. J Am Acad Child Adolesc Psychiatry 2008;47(7):745-54. (GRADE B, ***Supports Recommendation 18***).

(224) Schmidt LE, Dalhoff K, Poulsen HE. Acute versus chronic alcohol consumption in acetaminophen - induced hepatotoxicity. Hepatology 2002;35(4):876-82. (GRADE B, ***Supports Recommendation 7***).

(225) Schneider U, Bevilacqua C, Jacobs R, Karst M, Dietrich DE, Becker H, et al. Effects of fentanyl and low doses of alcohol on neuropsychological performance in healthy subjects. Neuropsychobiology 1999;39(1):38-43. (GRADE A, ***Supports Recommendation 7***).

(226) Schnitzer TJ, Kamin M, Olson WH. Tramadol allows reduction of naproxen dose among patients with naproxen-responsive osteoarthritis pain: a randomized, double-blind, placebo-controlled study. Arthritis & Rheumatism 1999 Jul;42(7):1370-7. (GRADE A, ***Supports Recommendations 4***, ***10***).

(227) Schnitzer TJ, Gray WL, Paster RZ, Kamin M. Efficacy of tramadol in treatment of chronic low back pain. Journal of Rheumatology 2000 Mar;27(3):772-8. (GRADE A, ***Supports Recommendations 4***, ***10***).

(228) Schreiber S, Peles E, Adelson M. Association between improvement in depression, reduced benzodiazepine (BDZ) abuse, and increased psychotropic medication use in methadone maintenance treatment (MMT) patients. Drug Alcohol Depend 2008;92(1-3):79-85.

(229) Seifert CF, Kennedy S. Meperidine is alive and well in the new millennium: evaluation of meperidine usage patterns and frequency of adverse drug reactions. Pharmacotherapy 2004 Jun;24(6):776-83. (GRADE B, ***Supports Recommendation 7***).

(230) Seminowicz DA, Davis KD. A re-examination of pain-cognition interactions: implications for neuroimaging. Pain 2007 Jul;130(1-2):8-13.

(231) Sheather-Reid RB, Cohen M. Efficacy of analgesics in chronic pain: a series of N-of-1 studies. Journal of Pain & Symptom Management 1998 Apr;15(4):244-52. (GRADE A, ***Supports Recommendations 4***, ***10***).

(232) Shields LB, Hunsaker Iii JC, Corey TS, Ward MK, Stewart D. Methadone toxicity fatalities: a review of medical examiner cases in a large metropolitan area. J Forensic Sci 2007 Nov;52(6):1389-95. (GRADE B, ***Supports Recommendation 7)***.

(233) Silverfield JC, Kamin M, Wu SC, Rosenthal N, Study Group. Tramadol/acetaminophen combination tablets for the treatment of osteoarthritis flare pain: a multicenter, outpatient, randomized, double-blind, placebo-controlled, parallel-group, add-on study. Clinical Therapeutics 2002 Feb;24(2):282-97. (GRADE A, ***Supports Recommendations 4***, ***10***).

(234) Silversides A. Regulatory colleges to set painkiller guidelines. CMAJ 2009 Oct 13;181(8):464-5.

(235) Simoens S, Matheson C, Bond C, Inkster K, Ludbrook A. The effectiveness of community maintenance with methadone or buprenorphine for treating opiate dependence. Br J Gen Pract 2005;55(511):139-46. (GRADE B, ***Supports Recommendation 21***).

(236) Simpson DM, Messina J, Xie F, Hale M. Fentanyl buccal tablet for the relief of breakthrough pain in opioid-tolerant adult patients with chronic neuropathic pain: a multicenter, randomized, double-blind, placebo-controlled study. Clin Ther 2007 Apr;29(4):588-601. (GRADE A, ***Supports Recommendations 4***, ***10***).

(237) Sims SA, Snow LA, Porucznik CA. Surveillance of methadone-related adverse drug events using multiple public health data sources. Journal of biomedical informatics 2007;40(4):382-9. (GRADE B, ***Supports Recommendation 7***).

(238) Sindrup SH, Andersen G, Madsen C, Smith T, Brosen K, Jensen TS. Tramadol relieves pain and allodynia in polyneuropathy: a randomised, double-blind, controlled trial. Pain 1999 Oct;83(1):85-90. (GRADE A, ***Supports Recommendations 4***, ***10***).

(239) Solomon DH, Avorn J, Wang PS, Vaillant G, Cabral D, Mogun H, et al. Prescription opioid use among older adults with arthritis or low back pain. Arthritis & Rheumatism 2006 Feb 15;55(1):35-41. (GRADE B, ***Supports Recommendation 17***).

(240) Sproule B, Brands B, Li S, Catz-Biro L. Changing patterns in opioid addiction: characterizing users of oxycodone and other opioids. Canadian Family Physician 2009 Jan;55(1):68-9.

(241) Staud R, Price DD. Long-term trials of pregabalin and duloxetine for fibromyalgia symptoms: how study designs can affect placebo factors. Pain 2008 Jun;136(3):232-4.

(242) Stein MD, Cioe P, Friedmann PD. Buprenorphine retention in primary care. J Gen Intern Med 2005;20(11):1038-41.

(243) Strang J, McCambridge J, Best D, Beswick T, Bearn J, Rees S, et al. Loss of tolerance and overdose mortality after inpatient opiate detoxification: follow up study. BMJ 2003;326(7396):959-60. (GRADE B, ***Supports Recommendation 21***).

(244) Sullivan MD, Edlund MJ, Steffick D, Unutzer J. Regular use of prescribed opioids: association with common psychiatric disorders. Pain 2005 Dec 15;119(1-3):95-103 (GRADE B, ***Supports Recommendations 1***, ***6***, ***20***).

(245) Sullivan MD, Edlund MJ, Zhang L, Unutzer J, Wells KB. Association between mental health disorders, problem drug use, and regular prescription opioid use. Archives of Internal Medicine 2006 Oct 23;166(19):2087-93.

(246) Tegeder I, Geisslinger G, Lotsch J. Therapy with opioids in liver or renal failure. Schmerz 1999;13(3):183-95.

(247) Thorne C, Beaulieu AD, Callaghan DJ, O'Mahony WF, Bartlett JM, Knight R, et al. A randomized, double-blind, crossover comparison of the efficacy and safety of oral controlled-release tramadol and placebo in patients with painful osteoarthritis. Pain Res Manag 2008 Mar;13(2):93-102. (GRADE A, ***Supports Recommendations 4***, ***10***).

(248) Torrance N, Smith BH, Bennett MI, Lee AJ. The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. Journal of Pain 2006 Apr;7(4):281-9.

(249) Townsend CO, Kerkvliet JL, Bruce BK, Rome JD, Hooten WM, Luedtke CA, et al. A longitudinal study of the efficacy of a comprehensive pain rehabilitation program with opioid withdrawal: comparison of treatment outcomes based on opioid use status at admission. Pain 2008;140(1):177-89. (GRADE B, ***Supports Recommendation 20***).

(250) Trescot AM, Boswell MV, Atluri SL, Hansen HC, Deer TR, Abdi S, et al. Opioid guidelines in the management of chronic non-cancer pain. Pain Physician 2006 Jan;9(1):1-39.

(251) Trescot AM, Helm S, Hansen H, Benyamin R, Glaser SE, Adlaka R, et al. Opioids in the management of chronic non-cancer pain: an update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines. Pain Physician 2008 Mar;11(2 Suppl):S5-S62.

(252) Trescot AM, Glaser SE, Hansen H, Benyamin R, Patel S, Manchikanti L. Effectiveness of opioids in the treatment of chronic non-cancer pain. Pain Physician 2008 Mar;11(2 Suppl):S181-S200.

(253) Turk DC, Swanson KS, Gatchel RJ. Predicting opioid misuse by chronic pain patients: a systematic review and literature synthesis. Clinical Journal of Pain 2008 Jul;24(6):497-508.

(254) Tyndale RF, Droll KP, Sellers EM. Genetically deficient CYP2D6 metabolism provides protection against oral opiate dependence. Pharmacogenetics 1997;7(5):375-9. (GRADE B, ***Supports Recommendation 7***).

(255) Utah Department of Health. Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain. 2009. Available from: http://www.useonlyasdirected.org/uploads/UDOH%20Opioid%20Guidelines%20Summary%282%29.pdf

(256) Vicens C, Fiol F, Llobera J, Campoamor F, Mateu C, Alegret S, et al. Withdrawal from long-term benzodiazepine use: randomised trial in family practice. Br J Gen Pract 2006;56(533):958-63. (GRADE B, ***Supports Recommendation 6***).

(257) Vlok GJ, van Vuren JP. Comparison of a standard ibuprofen treatment regimen with a new ibuprofen/paracetamol/codeine combination in chronic osteo-arthritis. South African Medical Journal 1987 Oct 17;1(Suppl 1-6):- (GRADE A, ***Supports Recommendations 4***, ***10***).

(258) Voaklander DC, Rowe BH, Dryden DM, Pahal J, Saar P, Kelly KD. Medical illness, medication use and suicide in seniors: a population-based case-control study. Journal of epidemiology and community health 2008;62(2):138-46. (GRADE B, ***Supports Recommendation 20***).

(259) Vondrackova D, Leyendecker P, Meissner W, Hopp M, Szombati I, Hermanns K, et al. Analgesic efficacy and safety of oxycodone in combination with naloxone as prolonged release tablets in patients with moderate to severe chronic pain. J Pain 2008 Dec;9(12):1144-54.

(260) Vorsanger GJ, Xiang J, Gana TJ, Pascual ML, Fleming RR. Extended-release tramadol (tramadol ER) in the treatment of chronic low back pain. J Opioid Manag 2008 Mar;4(2):87-97. (GRADE A, ***Supports Recommendations 4***, ***10***).

(261) Walker JM, Farney RJ, Rhondeau SM, Boyle KM, Valentine K, Cloward TV, et al. Chronic opioid use is a risk factor for the development of central sleep apnea and ataxic breathing. Journal of Clinical Sleep Medicine 2007 Aug 15;3(5):455-61. (GRADE B, ***Supports Recommendation 10***).

(262) Walsh SL, Nuzzo PA, Lofwall MR, Holtman JR, Jr. The relative abuse liability of oral oxycodone, hydrocodone and hydromorphone assessed in prescription opioid abusers. Drug Alcohol Depend 2008;98(3):191-202. (GRADE B, ***Supports Recommendation 7***).

(263) Wang EC. Methadone treatment during pregnancy. J Obstet Gynecol Neonatal Nurs 1999;28(6):615-22. (GRADE B, ***Supports Recommendation 19***).

(264) Wasan AD, Davar G, Jamison R. The association between negative affect and opioid analgesia in patients with discogenic low back pain. Pain 2005 Oct;117(3):450-61. (GRADE B, ***Supports Recommendations 1***, ***20***).

(265) Watson CP, Babul N. Efficacy of oxycodone in neuropathic pain: a randomized trial in postherpetic neuralgia. Neurology 1998 Jun;50(6):1837-41. (GRADE A, ***Supports Recommendations 4***, ***10***).

(266) Watson CP, Moulin D, Watt-Watson J, Gordon A, Eisenhoffer J. Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy. Pain 2003 Sep;105(1-2):71-8. (GRADE A, ***Supports Recommendations 4***, ***10***).

(267) Weaver M, Schnoll S. Addiction Issues in Prescribing Opioids for Chronic Nonmalignant Pain. J Addict Med 2007;1:2-10.

(268) Webster BS, Verma SK, Gatchel RJ. Relationship between early opioid prescribing for acute occupational low back pain and disability duration, medical costs, subsequent surgery and late opioid use. Spine 2007 Sep 1;32(19):2127-32. (GRADE B, ***Supports Recommendation 10***).

(269) Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. Pain Medicine 2005 Nov;6(6):432-42. (GRADE B, ***Supports Recommendation 2***).

(270) Webster LR, Butera PG, Moran LV, Wu N, Burns LH, Friedmann N. Oxytrex Minimizes Physical Dependence While Providing Effective Analgesia: A Randomized Controlled Trial in Low Back Pain. Journal of Pain 2006 Dec;7(12):937-46. (GRADE A, ***Supports Recommendations 4***, ***10***).

(271) Webster LR, Choi Y, Desai H, Webster L, Grant BJ. Sleep-disordered breathing and chronic opioid therapy. Pain Medicine 2008 May;9(4):425-32. (GRADE B, ***Supports Recommendation 10***).

(272) Wenghofer E, Wilson L, Kahan M, Srivastava A. A survey of Ontario primary care physicians' experiences with opioid prescribing. 2009.

(273) West SL, O'Neal KK, Graham CW. A meta-analysis comparing the effectiveness of buprenorphine and methadone. J Subst Abuse 2000;12(4):405-14.

(274) White JM, Irvine RJ. Mechanisms of fatal opioid overdose. Addiction (Abingdon , England) 1999;94(7):961-72.

(275) Wiedemer NL, Harden PS, Arndt IO, Gallagher RM. The opioid renewal clinic: a primary care, managed approach to opioid therapy in chronic pain patients at risk for substance abuse. Pain Medicine 2007 Oct;8(7):573-84. (GRADE B, ***Supports Recommendation 21***).

(276) Wilder-Smith OHG. Opioid use in the elderly. European Journal of Pain 2005;9(2 SPEC. ISS.):137-40.

(277) Wilsey BL, Fishman SM, Tsodikov A, Ogden C, Symreng I, Ernst A. Psychological comorbidities predicting prescription opioid abuse among patients in chronic pain presenting to the emergency department. Pain Medicine 2008 Nov;9(8):1107-17. (GRADE B, ***Supports Recommendations 1***, ***20)***.

(278) Woolf SH, Battista RN, Anderson GM, Logan AG, Wang E. Assessing the clinical effectiveness of preventive maneuvers: analytic principles and systematic methods in reviewing evidence and developing clinical practice recommendations. A report by the Canadian Task Force on the Periodic Health Examination. J Clin Epidemiol 1990;43(9):891-905.

(279) Wu CL, Agarwal S, Tella PK, Klick B, Clark MR, Haythornthwaite JA, et al. Morphine versus mexiletine for treatment of postamputation pain: a randomized, placebo-controlled, crossover trial. Anesthesiology 2008 Aug;109(2):289-96. (GRADE A, ***Supports Recommendations 4***, ***10***).

(280) Wu SM, Compton P, Bolus R, Schieffer B, Pham Q, Baria A, et al. The addiction behaviors checklist: validation of a new clinician-based measure of inappropriate opioid use in chronic pain. Journal of Pain & Symptom Management 2006 Oct;32(4):342-51.

(281) Ytterberg SR, Mahowald ML, Woods SR. Codeine and oxycodone use in patients with chronic rheumatic disease pain. Arthritis & Rheumatism 1998 Sep;41(9):1603-12.

(282) Zacny JP, Lichtor JL, Zaragoza JG, de Wit H. Subjective and behavioral responses to intravenous fentanyl in healthy volunteers. Psychopharmacology (Berl) 1992;107(2-3):319-26. (GRADE A, ***Supports Recommendation 7***).

(283) Zacny JP, Gutierrez S. Characterizing the subjective, psychomotor, and physiological effects of oral oxycodone in non-drug-abusing volunteers. Psychopharmacology (Berl) 2003 Nov;170(3):242-54. (GRADE A, ***Supports Recommendations 8***, ***11***).

(284) Zacny JP, Gutierrez S, Bolbolan SA. Profiling the subjective, psychomotor, and physiological effects of a hydrocodone/acetaminophen product in recreational drug users. Drug Alcohol Depend 2005 Jun 1;78(3):243-52. (GRADE A, ***Supports Recommendation 8***).

(285) Zacny JP, Lichtor SA. Within-subject comparison of the psychopharmacological profiles of oral oxycodone and oral morphine in non-drug-abusing volunteers. Psychopharmacology (Berl) 2007;196(1):105-16. (GRADE B, ***Supports Recommendation 8***).

(286) Zautra AJ, Smith BW. Impact of controlled-release oxycodone on efficacy beliefs and coping efforts among osteoarthritis patients with moderate to severe pain. Clin J Pain 2005 Nov;21(6):471-7. (GRADE A, ***Supports Recommendations 4***, ***10***).

(287) Zgierska A, Brown RT, Zuelsdorff M, Brown D, Zhang Z, Fleming MF. Sleep and daytime sleepiness problems among patients with chronic noncancerous pain receiving long-term opioid therapy: a cross-sectional study. Journal of Opioid Management 2007 Nov;3(6):317-27. (GRADE B, ***Supports Recommendation 5***).

GLOSSARY

References:	
Utah Department of Health:	"Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain", Utah Department of Health, 2009.
APS/ACPM:	"Opioid Treatment Guidelines – Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," for The American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel, 2009.
IASP:	"Part III: Pain Terms, A Current List with Definitions and Notes on Usage" (pp 209-214). Classification of Chronic Pain, Second Edition, IASP Task Force on Taxonomy, edited by H. Merskey and N. Bogduk. IASP Press: Seattle, © 1994.

Terms

Aberrant drug-related behaviours	Behaviours that may cause suspicion about addiction in opioid-treated pain patients. (Passik 2006b)
Abuse, drug	Any use of an illegal drug, or the intentional self-administration of a medication for a non-medical purpose such as altering one's state of consciousness, e.g., "getting high." (APS/ACPM 2009)
Addiction	A primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. (Utah Department of Health 2009)
Dependence, Physical	A state of adaptation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. (APS/ACPM 2009) (Utah Department of Health 2009)
Diversion	The intentional transfer of a controlled substance from legitimate distribution and dispensing channels. (APS/ACPM 2009)
Dose, optimal	The optimal dose is reached with a BALANCE of three factors: 1) **effectiveness**: improved function or at least 30% reduction in pain intensity 2) **plateauing**: effectiveness plateaus—increasing the dose yields negligible benefit, and 3) **adverse effects/complications**: adverse effects or complications are manageable.
Dose, stable	A "pharmacologically stable dose" is one that produces a fairly steady plasma level; it is established when the *total daily dose* is fixed for at least two weeks *and*: 1) frequency is scheduled and spread throughout the day AND/OR 2) at least 70% of the prescribed opioid is controlled release.
Dose, watchful	Watchful dose = morphine or equivalent dose exceeding 200 mg/day.
Double-doctoring	… receiving a prescription for a narcotic, and then seeking and receiving another prescription or narcotic from a different practitioner without disclosing to that practitioner particulars of every prescription or narcotic obtained within the previous 30 days. (Minister of Justice)

Glossary, continued…

Hyperalgesia	An increased response to a stimulus which is normally painful. (APS/ACPM 2009)
Misuse, opioid	Use of an opioid in ways other than those intended by the prescribing physician (sometimes also called problematic opioid use). (Ballantyne 2007).
Narcotic	Narcotic: any drug included in the "Schedule" under the *Controlled Drugs and Substances Act: Narcotic Control Regulations.* (Minister of Justice)
Opioid, controlled release (CR)	CR (Sustained Release) preparations consist of an opioid embedded in a wax matrix, micro-granules or other milieu that slowly releases the opioid into the GI tract or subcutaneous tissues. CR preparations of morphine, codeine, oxycodone and hydromorphone induce analagesia for up to 12 hours (e.g., MS-Contin®, Codeine-Contin®, OxyContin®, Hydromorph-Contin®). These CR preparations can be easily converted to immediate-release by biting or crushing the tablet. The duration of action of Kadian® (*slow-release morphine*) is 24 hours and for the *transdermal fentanyl patch* (e.g., Duragesic®), 72 hours. Tramadol is also available in a CR preparation (e.g., Zytram®, Tridural™, and Ralivia™).
Opioid, immediate release (IR)	IR formulations release the full dose of the opioid into the GI tract as the tablet dissolves. IR tablets generally contain a much smaller opioid dose than CR preparations. Some of the IR formulations also contain acetaminophen and caffeine. Examples of IR formulations include Tylenol® No. 1, 2, 3 and 4 (acetaminophen plus codeine), Percocet® and Oxycocet® (acetaminophen and oxycodone), Dilaudid® (hydromorphone), Statex® (morphine), Supeudol® (oxycodone), Codeine (codeine), and Tramacet® (tramadol 37.5 mg and acetaminophen 325 mg).
Opioids	A family of drugs that act by attaching to endogenous mu, kappa and delta receptors in the brain and share a common set of clinical effects, including analgesia, sedation, constipation, and respiratory depression. **Note**: Reference throughout this document to specific pharmaceutical products as examples does not imply endorsement of any of these products.
Pain, breakthrough	Transient or episodic exacerbation of pain that occurs in patients with pain that is otherwise considered stable but persistent. (APS/ACPM 2009)
Pain, chronic	Pain that persists for more than six months. (College of Physicians and Surgeons of Ontario 2000)
Pain, chronic non-cancer	(CNCP) Chronic pain that is not associated with cancer.
Pain, chronic non-malignant	Not used in this document; see chronic non-cancer pain.
Pain, neuropathic	Pain initiated or caused by a primary lesion or dysfunction in the nervous system. Peripheral neuropathic pain occurs when the lesion or dysfunction affects the peripheral nervous system. Central pain may be retained as the term when the lesion or dysfunction affects the central nervous system. (IASP)
Substance	Any drug with pleasant psychoactive effects and addiction potential, including alcohol, illegal drugs, and prescription drugs.
Substance dependence	See addiction.

Glossary, continued…

Tapering	A gradual decrease in a dose of a drug; could result in a lower daily dose or cessation of the drug.
Therapy, structured opioid	Use of opioids to treat CNCP with specific controls in place, including: patient education, written treatment agreement, agreed-on dispensing intervals, and frequent monitoring**.**
Therapy, chronic opioid	Not used in this document; see therapy, long-term opioid.
Therapy, long-term opioid	(LTOT). Use of opioids to treat chronic non-cancer pain for prolonged duration.
Titration	A technique of adjusting a dose until a stable/optimal dose is reached; usually means gradually increasing the dose to allow the body to develop tolerance and minimize adverse effects.
Tolerance	A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time. (APS/ACPM) (Utah Department of Health)
Withdrawal	Characteristic syndrome produced by abrupt cessation of a drug.