OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

(Teleconference)

Board Meeting, Thursday, May 7, 2015
10:00 a.m.

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento CA 95834

OMBC Phone (916) 928-8390

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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

May 7, 2015 at 10:00 a.m.

Meeting Site:
Osteopathic Medical Board
1300 National Dr., Ste. 150
Sacramento CA 95834-1991

Teleconference Site:
Joseph Zammuto, D.O.
2287 Mowry Ave. Suite #C
Fremont CA 94538

Teleconference Site:
Keith Higginbotham, Esq.
255 South Grand Ave., Suite 2109
Los Angeles CA 90012-3045

Teleconference Site:
David Connett, D.O.
Western University of Health Sciences
Vice Deans Office
309 E 2nd Street
Pomona CA 91766

Teleconference Site:
James Lally, D.O.
Chino Valley Medical Center
5451 Walnut Ave.
Chino CA 91710

Teleconference Site:
Jane Xenos, D.O.
1100 Quail Street, Ste. #114
Newport Beach CA 9266

Teleconference Site:
Michael Feinstein, D.O.
1100 Adella Ave., #26
Coronado CA 92118

Teleconference Site:
Alan Howard
Naval Postgraduate School
281 Stone Road
Monterey CA 93943

Teleconference Site:
Claudia Mercado
123 Mission St., Suite 1020
San Francisco CA 94105

Teleconference Site:
Cheryl Williams
1636 50th Street
San Diego CA 92102

AGENDA

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

Open Session

1. Call to Order and Roll Call / Establishment of a Quorum

2. Public Comment for Items Not on the Agenda
   Note: The Board may not discuss or take action on any matter raised during this public comment section except to decide whether to place the matter on the agenda of a future meeting [Government Code Sections 11125, 11125.7(a)]

3. Review and Approval of Minutes – January 22, 2015 Board Meeting

4. Introduction of New Legal Counsel

5. President's Report

   - Federation of State Medical Board (FSMB) Annual Meeting

6. Executive Director's Report – Angie Burton

- Licensing
- Staffing
- Diversion Program
- Budget
- BreEZe Update
- Interstate Licensing Compact
- Enforcement Report / Discipline - Corey Sparks

7. Legislation

- **AB 85** – Open Meetings
- **AB 159** – Investigational drugs, biological products, and devices
- **AB 333** – Healing Arts: Continuing Education
- **AB 483** – Healing Arts: Initial License fees: Proration
- **AB 611** – Controlled Substances: Prescriptions: Reporting
- **AB 750** – Business and Professions: Retired Category: License
- **AB 1060** – Professions and Vocations: Licensure
- **SB 277** – Public Health: Vaccinations
- **SB 538** – Naturopathic Doctors

8. Discussion and possible action on promulgating regulations pertaining to the renewal of licenses.

9. Guidelines for Prescribing Controlled Substances for Pain – Discussion and Possible action

10. Controlled Substance Utilization Review and Evaluation System (CURES) – Discussion and Possible action regarding outreach

11. DO Student Protection Against Discrimination – Discussion and Possible Action

12. <u>Closed Session</u>

- Deliberate on Disciplinary Matters Pursuant to Government Code Section 11126(c)(3).
- Performance evaluation of the Executive Director pursuant to Government Code Section 11126(a)(1).
- Adjourn Closed Session

<u>Return to Open Session</u>

13. Agenda Items for Next Meeting

14. Future Meeting Dates

15. 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

In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board, including the teleconference sites, are open to the public. Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Board prior to the Board taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before the Board, but the Board President, at his or her discretion, may apportion available time among those who wish to speak. Individuals may appear before the Board to discuss items not on the agenda; however, the Board can neither discuss nor take official action on these items at the time of the same meeting. (Government Code sections 11125, 11125.7(a).)

The meeting sites 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

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, January 22, 2015

BOARD MEMBERS PRESENT:	Joseph Zammuto, D.O., President Keith Higginbotham, Esq., Vice President James Lally, D.O., Board Member Claudia Mercado, Board Member David Connett, D.O., Board Member Cheryl Williams, Board Member Jane Xenos, D.O., Board Member
STAFF PRESENT:	Angelina Burton, Executive Director Michael Santiago, Esq., Legal Counsel, DCA Machiko Chong, Executive Analyst Francine Davies, Assistant Executive Director Corey Sparks, Lead Enforcement Analyst Donald J. Krpan, D.O., Medical Consultant
BOARD MEMBERS ABSENT:	Alan Howard, Board Member Michael Feinstein, D.O. Secretary Treasurer

The Board meeting of the Osteopathic Medical Board of California (OMBC) was called to order by President, Joseph Zammuto, D.O. at 10:05 a.m. at the Department of Consumer Affairs, 1747 North Market Blvd. (HQ2), Hearing Room, Sacramento, CA 95834.

1. Roll Call:

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

2. Election of Officers:

- Dr. Zammuto asked if there were any motions/nominations for election of Board President.
- Joseph Zammuto, D.O. was nominated as (President)
  M – J. Lally, **S** – D. Connett.
- Dr. Zammuto opened the floor to additional nominations, none were given.
- Roll Call Vote was taken **Aye** – Dr. Connett, Mr. Higginbotham, Dr. Lally, Ms. Mercado, Dr. Xenos, Dr. Zammuto, Mrs. Williams; **Nay** – None; **Abstention** – None.
- Dr. Zammuto was unanimously elected.

- Dr. Zammuto asked if there were any motions/nominations for election of Vice – President.
- Keith Higginbotham, Esq. was nominated as (Vice-President)
  M – J. Zammuto, **S** – D. Connett.
- Dr. Zammuto opened the floor to any additional nominations, none were given.
- Roll Call Vote was taken **Aye** – Dr. Connett, Mr. Higginbotham, Dr. Lally, Ms. Mercado, Dr. Xenos, Dr. Zammuto, Mrs. Williams; **Nay** – None; **Abstention** – None.
- Mr. Higginbotham was unanimously elected.

- Dr. Zammuto asked if there were any motions/nominations for election of Secretary/ Treasurer
- David Connett, D.O. was nominated as (Secretary/Treasurer)
  M – K. Higginbotham, **S** – J. Zammuto.
- Dr. Zammuto opened the floor to any additional nominations, none were given.
- Roll Call Vote was taken **Aye** – Dr. Connett, Mr. Higginbotham, Dr. Lally, Ms. Mercado, Dr. Xenos, Dr. Zammuto, Mrs. Williams; **Nay** – None; **Abstention** – None.
- Dr. Connett was unanimously elected.

3. Approval of Minutes – August 7, 2014 Board Meeting:

Dr. Zammuto called for approval of the Board Meeting minutes of August 7, 2014. Kathleen Creason, Director of Osteopathic Physician and Surgeons of California (OPSC), proposed that further clarification be made to the Public Comment Section noting that the legislation being introduced by OPSC relates to osteopathic medical students, not physicians. Also, there were 3 rotation sites that prohibited osteopathic medical students from applying for rotation slots.

- **M** – K. Higginbotham, **S** – D. Connett for approval of the minutes.
- **M** – D. Connett, **S** – K. Higginbotham for approval of the minutes as amended.
- Roll Call Vote was taken **Aye** – Dr. Connett, Mr. Higginbotham, Dr. Lally, Ms. Mercado, Dr. Xenos, Dr. Zammuto, Mrs. Williams; **Nay** – None; **Abstention** – None.

Motion carried to approve minutes as amended.

4. DCA Update:

Sean O'Conner, Chief, Division of Program and Policy Review presented a BreEZe update to the board on behalf of DCA Executive Director, Awet Kidane who was unable to attend the meeting. He notified the board that DCA had completed negotiations with the current solution vendor Accenture, and that those negotiations have allowed DCA and the control agency CalTech the ability to increase their maintenance capacity. He explained that the increase would be a great benefit to those boards involved in Release 1 as it allowed them the ability; to complete updates to the system, implement new legislation and/or any changes, and upload online application transactions (i.e. changing business rules in the system). By increasing the maintenance capacity of the system DCA's ability in facilitating these changes for the boards increased 10 fold. DCA

is also accelerating a knowledge transfer between Accenture and DCA which means that rather than having to wait for the solutions vendor to put fixes into system and use maintenance hours, they are accelerating the ability for the knowledge transfer to be transferred to DCA. This change has always been a desired outcome of the BreEZe system as it would give DCA the ability to maintain the system without needing a contractor on board. Another component of the negotiations which is significant but not impactful to Release 1 boards is that Release 2 which is underway to go-live through the current vendor will remain, however Release 3 has been severed from the contract. The reason for the severance was to give DCA the ability re-plan and complete a cost benefit analysis based on Release 1 and 2 boards, and determine the best contractual vehicle and IT solution to meet the needs of the Release 3 boards.

Negotiations are currently being ratified in a contractual artifact labeled Special Contract Report 3.1(SPR 3.1) which was expected to have already been approved, however it is still under discussion and should hopefully receive approving signatures from CalTech in the near future. In the past, SPR modifications have impacted project costs and will more than likely result in an increase to the current database figures; however DCA will not be able to provide individual cost breakdowns of the database for each board until the contract is approved. Director Kidane has advised that DCA will work with each board to ensure that any adverse impacts to fund conditions if any will be handled with the boards in collaboration with the department. To date ten (10) boards are currently using the BreEZe database, over 400,000 applications have been approved through the system, and over $100 million in total revenue has been collected through the database via both VR (Versa Regulation) in the back office and VO (Versa Online) online.

Ms. Mercado asked what steps were being taking to mitigate risks in case of vendor failure down the road, and was advised by Mr. O'Conner that the implementation process for Release 2 boards has been completely redesigned as the team will be focusing more on creating a design baseline, something that was not initially done with Release 1 boards. As a result of the lack of baseline use during Release 1 the project team encountered a longer user acceptance testing timeframe of over 1 year which is not the norm. With Release 2 there will be a more rigorous process during implementation to ensure that upfront, staff better understands how the system works and are capable of providing better feedback on how they feel it should be set up. By keeping this baseline there should be a decrease in the amount of requested fixes by each board during the testing process and also a decrease in the amount of client text updates requested. While it may be a challenge for DCA to maintain the baseline as it requires them to correctly state how the system needs to function, it would however be a way to hold the vendor accountable as any deviation from the baseline are contractual defects. If the defects are so severe that it prevents business processes or result in legal liability then the vendor would be held from go-live with Release 2.

Dr. Zammuto asked who would be handling the training for Release 2 and 3 boards and was notified that it would be a combination of DCA, Accenture, and Organizational Change Management groups to focus with the boards on the IT component and business processes to support going onto the new system. Ms. Mercado inquired who the software developer was on the project and wanted to know if DCA intended on

putting the source code in escrow in case there was vendor failure, so that there would be access to all implemented updates. She was advised that the current integrator is Accenture who functions as the primary, and that the subcontractor who owns the solution is Iron Data Services who supply the core technology solution being used (Versa Regulation and Versa Online). Mr. O'Conner informed her that the product being used is a Commercial off the Shelf (COTS) Product and that the main position of the department is to try and stay on the core model that is available to ensure that all of the updates and bug fixes that come through are in behavior of the system. By staying on the core COTS model it would ensure that the department receives data patch updates that are more technical and source code related. In terms of maintenance it would address the configurable elements of the system so that it could be designed to meet the business requirements in implementation of new changes to legislation and/or business processes. Mr. Higginbotham asked whether the reporting stats of the program were being handled as the board had previously received data that was not totally accurate and was advised that they had been getting better.

Brian Clifford, Manager, Division of Legislative & Policy Review presented the board with an update regarding CURES which is currently in phase 3 of production and is scheduled to go-live on June 30, 2015. The project will soon be entering into the user acceptance phase which will take place sometime between late April and early May, and will begin holding biweekly conference calls beginning in February which will allow the project team to hear feedback from the programs regarding any issue that they may have and also allow the team to provide the boards with any new updates from DOJ. Dr. Zammuto inquired whether the current system was still functioning and also asked if the user information in the current system would suffice as registration for the new program at time of conversion. He was notified by Mr. Clifford that the current system was in fact still active and would remain so until the conversion took place in June, and that physicians currently active within the CURES system would have their information transferred over into the new system, however because the program would now be web based they would still need to enter additional information into the system at the time of go-live in order to identify themselves for all future use. Mr. Higginbotham inquired who had access to the CURES database and was notified that only physicians, law enforcement personnel, and regulatory boards are allowed access to the database.

5. Executive Director's Report:

Angie Burton updated the board on licensing stats, staffing, budget activity, and diversion program statistics. She notified the board that Francine Davies, Staff Supervisor for the board had contact DCA – SOLID to assist in the creation of Licensing Desk Procedure Manuals which should help the board define work processes and timelines and also assist in the creation of a work metric which will facilitate the boards' participation in Performance Based Budgeting.

Budget – The board was informed that there was currently 18.5 months of funds in reserve. Mrs. Burton stated that the FY 14/15 budget is extremely tight due to the increase in staff and that the board is only expected to receive a 2% surplus, however the board will begin meeting with the budgets office monthly to ensure that we are working within our budget. It was found that the tight budget is due to the staffing

increase of 3 positions and lack of increase to the personnel services line within the budget to accommodate the additions. Because of this, the board anticipates submitting a Budget Change Proposal (BCP) in Spring of this year to request additional funding for the personnel services line for FY 16/17.

Ms. Mercado inquired what the roles of the 3 new staff members were in the office and how they were helping with the workload. She was advised that 2 of the 3 positions established had previously been Part-Time Permanent Intermittent (PI) Positions that were converted into Full-Time positions. One of the positions added was a Receptionist to handle office duties such as license verifications, preparation of certified correspondences (i.e. wall certificates), and answering of the phones. The other was a Program Technician II position added to handle all of the incoming initial applications for the department. Previously, the Board's Executive Analyst was tasked with the responsibility of processing the initial applications along with completing the Administrative duties; however the workloads needed to be separated and a dedicated person assigned to the task of handling the initial applications solely. A cashier was also brought in to handle the boards cashiering workload to alleviate the timeframe it was taking to send the funds over to DCA's main cashiering unit for processing of the boards workload.

Mr. Higginbotham asked about the current office lease and how the board was planning on moving forward. He was advised by Mrs. Burton that the board has been in discussion with the Facilities Unit and that review of the space planning is currently underway to ensure that the square footage needed to facilitate the board's needs is arranged and also that the mandatory state requirements are met as well. The move is set to take place sometime prior to August 2016 as the current lease expires in September 2016.

Enforcement/ Discipline - The boards Lead Enforcement Analyst Corey Sparks presented the enforcement report to the board.

Ms. Mercado questioned whether additional staffing was needed in the Enforcement Unit to assist in closing the cases faster. Mr. Sparks informed her that additional staff was not needed to assist and explained that data entry into the system was slightly more complex than it had been previously but that they are beginning to understand the system a little more and are also making changes to better fit the board as they go along.

6. Osteopathic Medical Board Strategic Plan – Dennis Zanchi (DCA-SOLID):

Mr. Zanchi, Manager, DCA Strategic Planning Unit gave a brief introduction and began explaining the strategic plan creation process. He advised that the Planning Process would take between 12 - 16 weeks (roughly 1 quarter) to be completed depending on the processing timeframe, during which time the board will go through an Environmental Scan, Planning Session, Creation and Finalization of the plan, and Action Planning Process. During the Environmental Scanning Phase facilitators will conduct focus groups with board staff and gain further insight from board selected stakeholders (i.e. licensees, consumer groups, colleges, etc.). The Planning Unit will also interview both

the EO and all managers of the program in addition to holding separate interviews with all board members to discuss the strengths and weaknesses of the program to compile a report/ subject matter which will be discussed during the Planning Session with Board members. During the Planning session facilitation plans will be provided to the board members who will establish goals and objectives over a two (2) day period for the board to accomplish over the next 3-5 years. Once the plan is finalized the documents will be brought back to the board for adoption and approval to post to the website. Mr. Higginbotham asked if there were any board members still present on the board that participated in the Strategic Planning Process for 2010-2015 and was advised by Mrs. Burton that Alan Howard had previously participated. Dr. Zammuto noted that it would be more beneficial if the entire board participated in the creation process of the strategic plan rather than creation of a subcommittee.

7. Interstate Licensing Compact – Lisa Robin, MLA, Chief Advocacy Officer (FSMB):

Ms. Robin gave an in depth PowerPoint presentation on the proposed Interstate Licensing Compact that the Federation of State Medical Boards introduced for national use by Healing Arts Boards to expedite the initial licensing process from state to state.

Dr. Zammuto thanked Ms. Robins for her presentation and asked if she could provide additional information to the board regarding a topic that was introduced and discussed at a previous meeting regarding the compact. He noted that the compact would require statute acceptance by state legislators and was concerned of how to protect or avoid the Medical Practice Act from being disrupted. Ms. Robin informed him that because the compact is a separate piece of legislation, States would have some leeway with regards to changing the format or particular language to better meet their legislative requirements. However, the essential elements of the compact and its language would not be eligible for amendments. Since the compact is its own piece of legislation the Medical Practice Act should not be affected due to the separation.

Dr. Xenos asked about the push for National Licensure and how long it had been occurring. Ms. Robin stated that in 2012 the first piece of legislation was drafted but was subsequently never introduced because many states sent opposition letters to their delegations as they felt it was a bad idea. However, since then there has been a huge lobby from Health IT Coalitions like Verizon and other major Tech Companies; Alliance for Connected Health formed of companies like Walgreens, Verizon, and United Health Care; and the American Telehealth Association that are really pushing for some relief and the implementation of H.R. 3077 as an alternative.

Mrs. Creason questioned whether or not amendments would be allowed to the proposed legislation as she had heard somewhat conflicting information in a similar presentation given by another representative of the Federation whom stated that there could be no alteration of the language. Ms. Robin advised that both were correct and that although the essential information included in the legislation could not be changed, amendments to certain language, numbering, or things that would affect the implementation of state requirements could be made.

8. D.O. Student Protection Against Discrimination – Jennifer Snyder (OPSC):

Dr. Connett began the presentation by recusing himself from participation in any actions that may be taken by the board due to his presidential position held with OPSC's board. He made note that although he could not participate, he would make himself available for any questions that arouse or offer any historical information regarding the proposed legislation.

Ms. Snyder introduced a bill proposal to the board regarding the discrimination of Osteopathic Medical Students by Residency Programs held at both University Systems and Private Training Programs. It was found that the programs have been denying osteopathic residents the ability to apply or obtain equal accessibility to the application process at these programs. OPSC felt that it was necessary to put into writing some protective measures in state law to ensure that osteopathic residents did not suffer from inequality, but also wanted to ensure that the language created did not infringe upon the medical training facilities ability to make a decision on an individual basis based on an applicant's criteria and qualifications. An OPSC representative presented the bill to Assemblywoman Susan Bonilla who showed a willingness to author the bill, and has already sent the proposed language to legislative council for review.

Dr. Xenos inquired about the push for uniformed graduate medical education residency sites and wondered if expansion to uniformed accreditation systems would allow for more sites as med students are coming out, as she is unsure of the need for combined professions. Dr. Connett explained that with the increase of osteopathic graduates nationwide the profession is finding that there are now fewer positions available for graduates to apply for and be accepted into. Research has found that there are roughly 25,000 graduate students between the Osteopathic and Allopathic professions that are competing for 33,000 residency slots leaving a surplus of about 7,500 positions for either foreign medical grads or osteopathic physicians. In addition there are roughly 95,000 foreign and Caribbean allopathic graduates that are also looking to match into stateside programs as well. With 60% of Osteopathic Physicians matching into ACGME programs and the remaining 40% either going into Military or AOA accredited programs, OPSC felt that it was extremely important that there was some type of comradery between both professions to ensure that there is also continued AOA heritage and culture that is present in the training that is given and the ACGME sites that are attended by osteopathic residents.

Mrs. Creason requested if the OMBC would support the issue brought forth and advised that parity between both osteopathic and allopathic graduates was important to the future of the osteopathic profession and to the access and availability of positions in the State of California. Although the bill is still in its early stages OPSC is asking that the board take action in supporting the concept of proposed legislation to prevent further discrimination of osteopathic residents.

- **M** – J. Lally, **S** – J. Xenos for support of the proposed legislation and concept brought forth by OPSC.
- Roll Call Vote was taken **Aye** – Dr. Lally, Ms. Mercado, Dr. Xenos, Dr. Zammuto, Mrs. Williams; **Nay** – None; **Abstention** – Mr. Higginbotham; **Recuse** – Dr. Connett.

9. Agenda Items for Next Board Meeting:

- D.O. Student Protection Legislation - Discussion
- Interstate Licensing Compact – Discussion

10. Future Meeting Dates:

- Thursday, May 7, 2015 @ 10:00 am – Pomona
- Thursday, September 17, 2015 @ 10:00 am – Tentative

11. Public Comments

There were no public comments.

12. Adjournment

There being no further business, the Meeting was adjourned at 11:59 a.m.

- **M** – K. Higginbotham, **S** – D. Connett to adjourn board meeting.
- Roll Call Vote was taken **Aye** – Dr. Connett, Mr. Higginbotham, Dr. Lally, Ms. Mercado, Dr. Xenos, Dr. Zammuto, Mrs. Williams; **Nay** – None; **Abstention** – None.

TAB 3

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TAB 4

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TAB 5

AB-85

Open Meetings

California LEGISLATIVE INFORMATION

AB-85 Open meetings. (2015-2016)

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL **No. 85**

Introduced by Assembly Member Wilk

January 06, 2015

An act to amend Section 11121 of the Government Code, relating to state government, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 85, as introduced, Wilk. Open meetings.

The Bagley-Keene Open Meeting Act requires that all meetings of a state body, as defined, be open and public and that all persons be permitted to attend and participate in a meeting of a state body, subject to certain conditions and exceptions.

This bill would specify that the definition of "state body" includes an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body that consists of 3 or more individuals, as prescribed, except a board, commission, committee, or similar multimember body on which a member of a body serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

This bill would make legislative findings and declarations, including, but not limited to, a statement of the Legislature's intent that this bill is declaratory of existing law.

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

Vote: 2/3 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 unpublished decision of the Third District Court of Appeals in Funeral Security Plans v. State Board of Funeral Directors (1994) 28 Cal. App.4th 1470 is an accurate reflection of legislative intent with respect to the applicability of 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) to a two-member standing advisory committee of a state body.

(b) A two-member committee of a state body, even if operating solely in an advisory capacity, already is a "state body," as defined in subdivision (d) of Section 11121 of the Government Code, if a member of the state body sits on the committee and the committee receives funds from the state body.

(c) It is the intent of the Legislature that this bill is declaratory of existing law.

SEC. 2. Section 11121 of the Government Code is amended to read:

11121. As used in this article, "state body" means each of the following:

(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more ~~persons.~~ *persons, except as in subdivision (d).*

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

SEC. 3. 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 avoid unnecessary litigation and ensure the people's right to access the meetings of public bodies pursuant to Section 3 of Article 1 of the California Constitution, it is necessary that act take effect immediately

AB-159

Investigational Drugs, Biological Products, and Devices

California LEGISLATIVE INFORMATION

AB-159 Investigational drugs, biological products, and devices. (2015-2016)

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL **No. 159**

Introduced by Assembly Member Calderon

January 21, 2015

An act to add Article 4.5 (commencing with Section 111548) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 159, as introduced, Calderon. Investigational drugs, biological products, and devices.

Existing law, the federal Food, Drug, and Cosmetic Act, prohibits a person from introducing into interstate commerce any new drug unless the drug has been approved by the federal Food and Drug Administration (FDA). Existing law requires the sponsor of a new drug to submit to the FDA an investigational new drug application and to then conduct a series of clinical trials to establish the safety and efficacy of the drug in human populations and submit the results to the FDA in a new drug application.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. A violation of that law is a crime. The Sherman Food, Drug, and Cosmetic Law prohibits, among other things, the sale, delivery, or giving away of a new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and Cosmetic Act.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California and requires the board to take action against a licensee who is charged with unprofessional conduct. The Osteopathic Act provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California and requires the board to enforce the Medical Practice Act with respect to its licensees.

This bill would permit a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with terminal illnesses, as specified. The bill would authorize, but not require, a health benefit plan, as defined, to provide coverage for any investigational drug, biological product, or device made available pursuant to these provisions. The bill would prohibit the Medical Board of California and the Osteopathic Medical Board of California from taking any disciplinary action against the license of a physician based solely on the physician's recommendation to an eligible patient regarding, or prescription for or treatment with, an investigational drug, biological product, or device, provided that the recommendation or prescription is

consistent with medical standards of care. The bill would prohibit a state agency from altering any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that a patient have access to an investigational drug, biological product, or device. The bill would prohibit an official, employee, or agent of the state from blocking an eligible patient's access to the investigational drug, biological product, or device pursuant to the bill's provisions.

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

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

SECTION 1. Article 4.5 (commencing with Section 111548) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 4.5. Right to Try Act

111548. This article shall be known and may be cited as the Right to Try Act.

111548.1. In this article, unless the context otherwise requires, the following definitions shall apply:

(a) "Eligible patient" means a person who meets all of the following conditions:

(1) Has a terminal illness.

(2) Has considered all other treatment options currently approved by the United States Food and Drug Administration.

(3) Has been unable to participate in a clinical trial for the terminal illness identified in paragraph (1) within 100 miles of his or her home or has not been accepted to that clinical trial within one week of completion of the clinical trial application process.

(4) Has received a recommendation from his or her physician for an investigational drug, biological product, or device.

(5) Has given written informed consent for the use of the investigational drug, biological product, or device, or if he or she lacks the capacity to consent, his or her legally authorized representative has given written informed consent on his or her behalf.

(6) Has documentation from his or her physician attesting that the patient has met the requirements of this subdivision.

(b) "Health benefit plan" means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of this code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.

(c) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(d) "Physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act.

(e) "State regulatory board" means the California Medical Board or the Osteopathic Medical Board of California.

(f) "Terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

(g) "Written, informed consent" means a written document that is signed by an eligible patient, or his or her legally authorized representative where the patient lacks the capacity to consent, and attested to by the patient's physician and a witness that, at a minimum, does all of the following:

(1) Explains the currently approved products and treatments for the terminal illness from which the patient suffers.

(2) Attests to the fact that the patient, or where the patient lacks the capacity to consent, his or her legally authorized representative, concurs with the patient's physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(3) Clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

(4) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device and describes the most likely outcome. This description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(5) Clearly states that the patient's health benefit plan, if any, and health care provider are not obligated to pay for the investigational drug, biological product, or device or any care or treatments consequent to use of the investigational drug, biological product, or device.

(6) Clearly states that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(7) Clearly states that in-home health care may be denied if treatment begins.

(8) States that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate, except as otherwise provided in the patient's health benefit plan or a contract between the patient and the manufacturer of the drug, biological product, or device.

111548.2. (a) Notwithstanding Section 110280, 111520, or 111550, a manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient pursuant to this article. This article does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do both of the following:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(2) Require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

(c) (1) This article does not expand or otherwise affect the coverage provided under Sections 1370.4 and 1370.6 of this code, Sections 10145.3 and 10145.4 of the Insurance Code, or Sections 14087.11 and 14132.98 of the Welfare and Institutions Code.

(2) This article does not require a health benefit plan to provide coverage for the cost of any investigational drug, biological product, or device, or the costs of services related to the use of an investigational drug, biological product, or device under this article. A health benefit plan may provide coverage for an investigational drug, biological product, or device made available pursuant to this section.

(d) If an eligible patient dies while being treated by an investigational drug, biological product, or device made available pursuant to this article, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance for the treatment.

111548.3. (a) Notwithstanding any other law, a state regulatory board shall not revoke, fail to renew, or take any other disciplinary action against a physician's license based solely on the physician's recommendation to an eligible patient regarding, or prescription for or treatment with, an investigational drug, biological product, or device, provided that the recommendation or prescription is consistent with medical standards of care.

(b) A state agency shall not alter any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that a patient have access to an investigational drug, biological product, or device.

(c) An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to

an investigational drug, biological product, or device pursuant to this article. Counseling, advice, or a recommendation consistent with medical standards of care from an individual licensed under Division 2 (commencing with Section 500) of the Business and Professions Code shall not be considered a violation of this section.

(d) A violation of this section shall not be subject to Chapter 8 (commencing with Section 111825).

111548.5. This article does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this article, unless there was a failure to exercise reasonable care.

AB-333

Healing Arts: Continuing Education

California LEGISLATIVE INFORMATION

AB-333 Healing arts: continuing education. (2015-2016)

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL **No. 333**

Introduced by Assembly Member Melendez

February 13, 2015

~~An act to amend Section 49417 of the Education Code, relating to pupil health.~~ *An act to add Section 856 to the Business and Professions Code, relating to healing arts.*

LEGISLATIVE COUNSEL'S DIGEST

AB 333, as amended, Melendez. ~~Pupil health: automated external defibrillators.~~ *Healing arts: continuing education.*

Existing law provides for the licensure and regulation of various healing arts licensees by various boards, as defined, within the Department of Consumer Affairs and imposes various continuing education requirements for license renewal.

This bill would allow specified healing arts licensees to apply one unit, as defined, of continuing education credit towards any required continuing education units for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (`AED), and would allow specified healing arts licensees to apply up to 2 units of continuing education credit towards any required continuing education units for conducting CPR or AED training sessions for employees of school districts and community college districts in the state.

~~Existing law authorizes a public school to solicit and receive nonstate funds to acquire and maintain an automated external defibrillator (AED). Existing law provides that the employees of the school district are not liable for civil damages resulting from certain uses, attempted uses, or nonuses of an AED, except as provided. Existing law provides that a public school or school district that complies with certain requirements related to an AED is not liable for any civil damages resulting from any act or omission in the rendering of the emergency care or treatment, except as provided.~~

~~This bill would make a nonsubstantive change to these provisions.~~

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

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

SECTION 1. *Section 856 is added to the Business and Professions Code, to read:*

856. (a) A person licensed pursuant to this division who is required to complete continuing education units as a condition of renewing his or her license may apply one unit of continuing education credit towards that requirement for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (AED).

(b) A person licensed pursuant to this division who is required to complete continuing education units as a condition of renewing his or her license may apply up to two units of continuing education credit towards that requirement for conducting CPR or AED training sessions for employees of school districts and community college districts in the state.

(c) For purposes of this section, "unit" means any measurement for continuing education, such as hours or course credits.

SECTION 1.Section 49417 of the Education Code is amended to read:

49417.(a)A public school may solicit and receive nonstate funds to acquire and maintain an automated external defibrillator (AED). These funds shall only be used to acquire and maintain an AED and to provide training to school employees regarding the use of an AED.

(b)Except as provided in subdivision (d), if an employee of a school district complies with Section 1714.21 of the Civil Code in rendering emergency care or treatment through the use, attempted use, or nonuse of an AED at the scene of an emergency, the employee shall not be liable for any civil damages resulting from any act or omission in the rendering of the emergency care or treatment.

(c)Except as provided in subdivision (d), if a public school or school district complies with the requirements of Section 1797.196 of the Health and Safety Code, the public school or school district shall be covered by Section 1714.21 of the Civil Code and shall not be liable for any civil damages resulting from any act or omission in the rendering of the emergency care or treatment.

(d)Subdivisions (b) and (c) do not apply in the case of personal injury or wrongful death that results from gross negligence or willful or wanton misconduct on the part of the person who uses, attempts to use, or maliciously fails to use an AED to render emergency care or treatment.

(e)This section does not alter the requirements of Section 1797.196 of the Health and Safety Code.

AB-483

Healing Arts: Initial License Fees: Proration

California LEGISLATIVE INFORMATION

AB-483 Healing arts: initial license fees: proration. (2015-2016)

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL **No. 483**

Introduced by Assembly Member Patterson
(Principal coauthor: Assembly Member Gordon)
(Coauthors: Assembly Members Chang, Chávez, Grove, Obernolte, Waldron, and Wilk)
(Coauthor: Senator Anderson)

February 23, 2015

An act to amend Sections 1724, 1944, 2435, 2538.57, 2570.16, 2688, 2987, 4842.5, 4905, 4970, and 5604 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 483, as introduced, Patterson. Healing arts: initial license fees: proration.

Existing law provides for the regulation and licensure of various professions and vocations. Existing law establishes fees for initial licenses, initial temporary and permanent licenses, and original licenses for those various professions and vocations. Existing law requires that licenses issued to certain licensees, including, among others, architects, acupuncturists, dental hygienists, dentists, occupational therapists, physical therapists, physicians and surgeons, psychologists, and veterinarians, expire at 12 a.m. on either the last day of the birth month of the licensee or at 12 a.m. of the legal birth date of the licensee during the 2nd year of a 2-year term, if not renewed.

This bill would require that the fees imposed by these provisions for an initial license, an initial temporary or permanent license, or an original license be prorated on a monthly basis.

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

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

SECTION 1. Section 1724 of the Business and Professions Code is amended to read:

1724. The amount of charges and fees for dentists licensed pursuant to this chapter shall be established by the board as is necessary for the purpose of carrying out the responsibilities required by this chapter as it relates to dentists, subject to the following limitations:

(a) The fee for application for examination shall not exceed five hundred dollars ($500).

(b) The fee for application for reexamination shall not exceed one hundred dollars ($100).

(c) The fee for examination and for reexamination shall not exceed eight hundred dollars ($800). Applicants who are found to be ineligible to take the examination shall be entitled to a refund in an amount fixed by the board.

(d) The fee for an initial license and for the renewal of a license is five hundred twenty-five dollars ($525). *The fee for an initial license fee shall be prorated on a monthly basis.*

(e) The fee for a special permit shall not exceed three hundred dollars ($300), and the renewal fee for a special permit shall not exceed one hundred dollars ($100).

(f) The delinquency fee shall be the amount prescribed by Section 163.5.

(g) The penalty for late registration of change of place of practice shall not exceed seventy-five dollars ($75).

(h) The application fee for permission to conduct an additional place of practice shall not exceed two hundred dollars ($200).

(i) The renewal fee for an additional place of practice shall not exceed one hundred dollars ($100).

(j) The fee for issuance of a substitute certificate shall not exceed one hundred twenty-five dollars ($125).

(k) The fee for a provider of continuing education shall not exceed two hundred fifty dollars ($250) per year.

(l) The fee for application for a referral service permit and for renewal of that permit shall not exceed twenty-five dollars ($25).

(m) The fee for application for an extramural facility permit and for the renewal of a permit shall not exceed twenty-five dollars ($25).

The board shall report to the appropriate fiscal committees of each house of the Legislature whenever the board increases any fee pursuant to this section and shall specify the rationale and justification for that increase.

SEC. 2. Section 1944 of the Business and Professions Code is amended to read:

1944. (a) The committee shall establish by resolution the amount of the fees that relate to the licensing of a registered dental hygienist, a registered dental hygienist in alternative practice, and a registered dental hygienist in extended functions. The fees established by board resolution in effect on June 30, 2009, as they relate to the licensure of registered dental hygienists, registered dental hygienists in alternative practice, and registered dental hygienists in extended functions, shall remain in effect until modified by the committee. The fees are subject to the following limitations:

(1) The application fee for an original license and the fee for *the* issuance of an original license shall not exceed two hundred fifty dollars ($250). *The fee for the issuance of an original license shall be prorated on a monthly basis.*

(2) The fee for examination for licensure as a registered dental hygienist shall not exceed the actual cost of the examination.

(3) For third- and fourth-year dental students, the fee for examination for licensure as a registered dental hygienist shall not exceed the actual cost of the examination.

(4) The fee for examination for licensure as a registered dental hygienist in extended functions shall not exceed the actual cost of the examination.

(5) The fee for examination for licensure as a registered dental hygienist in alternative practice shall not exceed the actual cost of administering the examination.

(6) The biennial renewal fee shall not exceed one hundred sixty dollars ($160).

(7) The delinquency fee shall not exceed one-half of the renewal fee. Any delinquent license may be restored only upon payment of all fees, including the delinquency fee, and compliance with all other applicable requirements of this article.

(8) The fee for issuance of a duplicate license to replace one that is lost or destroyed, or in the event of a name change, shall not exceed twenty-five dollars ($25) or one-half of the renewal fee, whichever is greater.

(9) The fee for certification of licensure shall not exceed one-half of the renewal fee.

(10) The fee for each curriculum review and site evaluation for educational programs for dental hygienists who are not accredited by a committee-approved agency shall not exceed two thousand one hundred dollars ($2,100).

(11) The fee for each review or approval of course requirements for licensure or procedures that require additional training shall not exceed seven hundred fifty dollars ($750).

(12) The initial application and biennial fee for a provider of continuing education shall not exceed five hundred dollars ($500).

(13) The amount of fees payable in connection with permits issued under Section 1962 is as follows:

(A) The initial permit fee is an amount equal to the renewal fee for the applicant's license to practice dental hygiene in effect on the last regular renewal date before the date on which the permit is issued.

(B) If the permit will expire less than one year after its issuance, then the initial permit fee is an amount equal to 50 percent of the renewal fee in effect on the last regular renewal date before the date on which the permit is issued.

(b) The renewal and delinquency fees shall be fixed by the committee by resolution at not more than the current amount of the renewal fee for a license to practice under this article nor less than five dollars ($5).

(c) Fees fixed by the committee by resolution pursuant to this section shall not be subject to the approval of the Office of Administrative Law.

(d) Fees collected pursuant to this section shall be collected by the committee and deposited into the State Dental Hygiene Fund, which is hereby created. All money in this fund shall, upon appropriation by the Legislature in the annual Budget Act, be used to implement ~~the provisions of~~ this article.

(e) No fees or charges other than those listed in this section shall be levied by the committee in connection with the licensure of registered dental hygienists, registered dental hygienists in alternative practice, or registered dental hygienists in extended functions.

(f) The fee for registration of an extramural dental facility shall not exceed two hundred fifty dollars ($250).

(g) The fee for registration of a mobile dental hygiene unit shall not exceed one hundred fifty dollars ($150).

(h) The biennial renewal fee for a mobile dental hygiene unit shall not exceed two hundred fifty dollars ($250).

(i) The fee for an additional office permit shall not exceed two hundred fifty dollars ($250).

(j) The biennial renewal fee for an additional office as described in Section 1926.4 shall not exceed two hundred fifty dollars ($250).

(k) The initial application and biennial special permit fee is an amount equal to the biennial renewal fee specified in paragraph (6) of subdivision (a).

(l) The fees in this section shall not exceed an amount sufficient to cover the reasonable regulatory cost of carrying out ~~the provisions of~~ this article.

SEC. 3. Section 2435 of the Business and Professions Code is amended to read:

2435. The following fees apply to the licensure of physicians and surgeons:

(a) Each applicant for a certificate based upon a national board diplomate certificate, each applicant for a certificate based on reciprocity, and each applicant for a certificate based upon written examination, shall pay a nonrefundable application and processing fee, as set forth in subdivision (b), at the time the application is filed.

(b) The application and processing fee shall be fixed by the board by May 1 of each year, to become effective on July 1 of that year. The fee shall be fixed at an amount necessary to recover the actual costs of the licensing program as projected for the fiscal year commencing on the date the fees become effective.

(c) Each applicant who qualifies for a certificate, as a condition precedent to its issuance, in addition to other fees required herein, shall pay an initial license fee, if any, in an amount fixed by the board consistent with this section. The initial license fee shall not exceed seven hundred ninety dollars ($790). *The initial license fee shall be prorated on a monthly basis.* An applicant enrolled in an approved postgraduate training program shall be

required to pay only 50 percent of the initial license fee.

(d) The biennial renewal fee shall be fixed by the board consistent with this section and shall not exceed seven hundred ninety dollars ($790).

(e) Notwithstanding subdivisions (c) and (d), and to ensure that subdivision (k) of Section 125.3 is revenue neutral with regard to the board, the board may, by regulation, increase the amount of the initial license fee and the biennial renewal fee by an amount required to recover both of the following:

(1) The average amount received by the board during the three fiscal years immediately preceding July 1, 2006, as reimbursement for the reasonable costs of investigation and enforcement proceedings pursuant to Section 125.3.

(2) Any increase in the amount of investigation and enforcement costs incurred by the board after January 1, 2006, that exceeds the average costs expended for investigation and enforcement costs during the three fiscal years immediately preceding July 1, 2006. When calculating the amount of costs for services for which the board paid an hourly rate, the board shall use the average number of hours for which the board paid for those costs over these prior three fiscal years, multiplied by the hourly rate paid by the board for those costs as of July 1, 2005. Beginning January 1, 2009, the board shall instead use the average number of hours for which it paid for those costs over the three-year period of fiscal years 2005-06, 2006-07, and 2007-08, multiplied by the hourly rate paid by the board for those costs as of July 1, 2005. In calculating the increase in the amount of investigation and enforcement costs, the board shall include only those costs for which it was eligible to obtain reimbursement under Section 125.3 and shall not include probation monitoring costs and disciplinary costs, including those associated with the citation and fine process and those required to implement subdivision ~~(b)~~ *(d)* of Section 12529 of the Government Code.

(f) Notwithstanding Section 163.5, the delinquency fee shall be 10 percent of the biennial renewal fee.

(g) The duplicate certificate and endorsement fees shall each be fifty dollars ($50), and the certification and letter of good standing fees shall each be ten dollars ($10).

(h) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Contingent Fund of the Medical Board of California in an amount not less than two nor more than four months' operating expenditures.

(i) Not later than January 1, 2012, the Office of State Audits and Evaluations within the Department of Finance shall commence a preliminary review of the board's financial status, including, but not limited to, its projections related to expenses, revenues, and reserves, and the impact of the loan from the Contingent Fund of the Medical Board of California to the General Fund made pursuant to the Budget Act of 2008. The office shall make the results of this review available upon request by June 1, 2012. This review shall be funded from the existing resources of the office during the 2011-12 fiscal year.

SEC. 4. Section 2538.57 of the Business and Professions Code is amended to read:

2538.57. The amount of fees and penalties prescribed by this article shall be those set forth in this section unless a lower fee is fixed by the board:

(a) The fee for applicants applying for the first time for a license is seventy-five dollars ($75), which shall not be refunded, except to applicants who are found to be ineligible to take an examination for a license. Those applicants are entitled to a refund of fifty dollars ($50).

(b) The fees for taking or retaking the written and practical examinations shall be amounts fixed by the board, which shall be equal to the actual cost of preparing, grading, analyzing, and administering the examinations.

(c) The initial temporary license fee is one hundred dollars ($100). The fee for *an initial temporary license shall be prorated on a monthly basis. The fee for* renewal of a temporary license is one hundred dollars ($100) for each renewal.

(d) The initial permanent license fee is two hundred eighty dollars ($280). The fee for *an initial permanent license shall be prorated on a monthly basis. The fee for* renewal of a permanent license is not more than two hundred eighty dollars ($280) for each renewal.

(e) The initial branch office license fee is twenty-five dollars ($25). The fee for renewal of a branch office license is twenty-five dollars ($25) for each renewal.

(f) The delinquency fee is twenty-five dollars ($25).

(g) The fee for issuance of a replacement license is twenty-five dollars ($25).

(h) The continuing education course approval application fee is fifty dollars ($50).

(i) The fee for official certification of licensure is fifteen dollars ($15).

SEC. 5. Section 2570.16 of the Business and Professions Code is amended to read:

2570.16. Initial license and renewal fees shall be established by the board in an amount that does not exceed a ceiling of one hundred fifty dollars ($150) per year. The *initial license fee shall be prorated on a monthly basis. The* board shall establish the following additional fees:

(a) An application fee not to exceed fifty dollars ($50).

(b) A late renewal fee as provided for in Section 2570.10.

(c) A limited permit fee.

(d) A fee to collect fingerprints for criminal history record checks.

SEC. 6. Section 2688 of the Business and Professions Code is amended to read:

2688. The amount of fees assessed in connection with licenses issued under this chapter is as follows:

(a) (1) The fee for an application for licensure as a physical therapist submitted to the board prior to March 1, 2009, shall be seventy-five dollars ($75). The fee for an application submitted under Section 2653 to the board prior to March 1, 2009, shall be one hundred twenty-five dollars ($125).

(2) The fee for an application for licensure as a physical therapist submitted to the board on or after March 1, 2009, shall be one hundred twenty-five dollars ($125). The fee for an application submitted under Section 2653 to the board on or after March 1, 2009, shall be two hundred dollars ($200).

(3) Notwithstanding paragraphs (1) and (2), the board may decrease or increase the amount of an application fee under this subdivision to an amount that does not exceed the cost of administering the application process, but in no event shall the application fee amount exceed three hundred dollars ($300).

(b) The examination and reexamination fees for the physical therapist examination, physical therapist assistant examination, and the examination to demonstrate knowledge of the California rules and regulations related to the practice of physical therapy shall be the actual cost to the board of the development and writing of, or purchase of the examination, and grading of each written examination, plus the actual cost of administering each examination. The board, at its discretion, may require the licensure applicant to pay the fee for the examinations required by Section 2636 directly to the organization conducting the examination.

(c) (1) The fee for a physical therapist license issued prior to March 1, 2009, shall be seventy-five dollars ($75).

(2) The fee for a physical therapist license issued on or after March 1, 2009, shall be one hundred dollars ($100).

(3) Notwithstanding paragraphs (1) and (2), the board may decrease or increase the amount of the fee under this subdivision to an amount that does not exceed the cost of administering the process to issue the license, but in no event shall the fee to issue the license exceed one hundred fifty dollars ($150).

(4) The fee assessed pursuant to this subdivision for an initial physical therapist license issued on or after January 1, 2016, shall be prorated on a monthly basis.

(d) (1) The fee to renew a physical therapist license that expires prior to April 1, 2009, shall be one hundred fifty dollars ($150).

(2) The fee to renew a physical therapist license that expires on or after April 1, 2009, shall be two hundred dollars ($200).

(3) Notwithstanding paragraphs (1) and (2), the board may decrease or increase the amount of the renewal fee under this subdivision to an amount that does not exceed the cost of the renewal process, but in no event shall the renewal fee amount exceed three hundred dollars ($300).

(e) (1) The fee for application and for issuance of a physical therapist assistant license shall be seventy-five dollars ($75) for an application submitted to the board prior to March 1, 2009.

(2) The fee for application and for issuance of a physical therapist assistant license shall be one hundred twenty-five dollars ($125) for an application submitted to the board on or after March 1, 2009. The fee for an application submitted under Section 2653 to the board on or after March 1, 2009, shall be two hundred dollars ($200).

(3) Notwithstanding paragraphs (1) and (2), the board may decrease or increase the amount of the fee under this subdivision to an amount that does not exceed the cost of administering the application process, but in no event shall the application fee amount exceed three hundred dollars ($300).

(f) (1) The fee to renew a physical therapist assistant license that expires prior to April 1, 2009, shall be one hundred fifty dollars ($150).

(2) The fee to renew a physical therapist assistant license that expires on or after April 1, 2009, shall be two hundred dollars ($200).

(3) Notwithstanding paragraphs (1) and (2), the board may decrease or increase the amount of the renewal fee under this subdivision to an amount that does not exceed the cost of the renewal process, but in no event shall the renewal fee amount exceed three hundred dollars ($300).

(g) Notwithstanding Section 163.5, the delinquency fee shall be 50 percent of the renewal fee in effect.

(h) (1) The duplicate wall certificate fee shall be fifty dollars ($50). The duplicate renewal receipt fee amount shall be fifty dollars ($50).

(2) Notwithstanding paragraph (1), the board may decrease or increase the amount of the fee under this subdivision to an amount that does not exceed the cost of issuing duplicates, but in no event shall that fee exceed one hundred dollars ($100).

(i) (1) The endorsement or letter of good standing fee shall be sixty dollars ($60).

(2) Notwithstanding paragraph (1), the board may decrease or increase the amount of the fee under this subdivision to an amount that does not exceed the cost of issuing an endorsement or letter, but in no event shall the fee amount exceed one hundred dollars ($100).

SEC. 7. Section 2987 of the Business and Professions Code is amended to read:

2987. The amount of the fees prescribed by this chapter shall be determined by the board, and shall be as follows:

(a) The application fee for a psychologist shall not be more than fifty dollars ($50).

(b) The examination and reexamination fees for the examinations shall be the actual cost to the board of developing, purchasing, and grading of each examination, plus the actual cost to the board of administering each examination.

(c) The initial license fee is an amount equal to the renewal fee in effect on the last regular renewal date before the date on which the license is issued. *The initial license fee shall be prorated on a monthly basis.*

(d) The biennial renewal fee for a psychologist shall be four hundred dollars ($400). The board may increase the renewal fee to an amount not to exceed five hundred dollars ($500).

(e) The application fee for registration and supervision of a psychological assistant by a supervisor under Section 2913, which is payable by that supervisor, shall not be more than seventy-five dollars ($75).

(f) The annual renewal fee for registration of a psychological assistant shall not be more than seventy-five dollars ($75).

(g) The duplicate license or registration fee is five dollars ($5).

(h) The delinquency fee is twenty-five dollars ($25).

(i) The endorsement fee is five dollars ($5).

Notwithstanding any other provision of law, the board may reduce any fee prescribed by this section, when, in

its discretion, the board deems it administratively appropriate.

SEC. 8. Section 4842.5 of the Business and Professions Code is amended to read:

4842.5. The amount of fees prescribed by this article is that fixed by the following schedule:

(a) The fee for filing an application for examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purposes of this chapter, not to exceed three hundred fifty dollars ($350).

(b) The fee for the California registered veterinary technician examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purposes of this chapter, not to exceed three hundred dollars ($300).

(c) The initial registration fee shall be set by the board at not more than three hundred fifty dollars ~~($350), except that, if the license is issued less than one year before the date on which it will expire, then the fee~~ *($350) and* shall be ~~set by the board at not more than one hundred seventy-five dollars ($175).~~ *prorated on a monthly basis.* The board may adopt regulations to provide for the waiver or refund of the initial registration fee ~~where~~ *when* the registration is issued less than 45 days before the date on which it will expire.

(d) The biennial renewal fee shall be set by the board at not more than three hundred fifty dollars ($350).

(e) The delinquency fee shall be set by the board at not more than fifty dollars ($50).

(f) Any charge made for duplication or other services shall be set at the cost of rendering the services.

(g) The fee for filing an application for approval of a school or institution offering a curriculum for training registered veterinary technicians pursuant to Section 4843 shall be set by the board at an amount not to exceed three hundred dollars ($300). The school or institution shall also pay for the actual costs of an onsite inspection conducted by the board pursuant to Section 2065.6 of Title 16 of the California Code of Regulations, including, but not limited to, the travel, food, and lodging expenses incurred by an inspection team sent by the board.

(h) The fee for failure to report a change in the mailing address is twenty-five dollars ($25).

SEC. 9. Section 4905 of the Business and Professions Code is amended to read:

4905. The following fees shall be collected by the board and shall be credited to the Veterinary Medical Board Contingent Fund:

(a) The fee for filing an application for examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars ($350).

(b) The fee for the California state board examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars ($350).

(c) The fee for the Veterinary Medicine Practice Act examination shall be set by the board in an amount it determines reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed one hundred dollars ($100).

(d) The initial license fee shall be set by the board not to exceed five hundred dollars ($500) ~~except that, if the license is issued less than one year before the date on which it will expire, then the fee~~ *and* shall be ~~set by the board at not to exceed two hundred fifty dollars ($250).~~ *prorated on a monthly basis.* The board may, by appropriate regulation, provide for the waiver or refund of the initial license fee ~~where~~ *when* the license is issued less than 45 days before the date on which it will expire.

(e) The renewal fee shall be set by the board for each biennial renewal period in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed five hundred dollars ($500).

(f) The temporary license fee shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed two hundred fifty dollars ($250).

(g) The delinquency fee shall be set by the board, not to exceed fifty dollars ($50).

(h) The fee for issuance of a duplicate license is twenty-five dollars ($25).

(i) Any charge made for duplication or other services shall be set at the cost of rendering the service, except as specified in subdivision (h).

(j) The fee for failure to report a change in the mailing address is twenty-five dollars ($25).

(k) The initial and annual renewal fees for registration of veterinary premises shall be set by the board in an amount not to exceed four hundred dollars ($400) annually.

(l) If the money transferred from the Veterinary Medical Board Contingent Fund to the General Fund pursuant to the Budget Act of 1991 is redeposited into the Veterinary Medical Board Contingent Fund, the fees assessed by the board shall be reduced correspondingly. However, the reduction shall not be so great as to cause the Veterinary Medical Board Contingent Fund to have a reserve of less than three months of annual authorized board expenditures. The fees set by the board shall not result in a Veterinary Medical Board Contingent Fund reserve of more than 10 months of annual authorized board expenditures.

SEC. 10. Section 4970 of the Business and Professions Code is amended to read:

4970. The amount of fees prescribed for licensed acupuncturists shall be those set forth in this section unless a lower fee is fixed by the board in accordance with Section 4972:

(a) The application fee shall be seventy-five dollars ($75).

(b) The examination and reexamination fees shall be the actual cost to the Acupuncture Board for the development and writing of, grading, and administering of each examination.

(c) The initial license fee shall be three hundred twenty-five dollars ~~($325), except that if the license will expire less than one year after its issuance, then the initial license fee shall be an amount equal to 50 percent of the initial license fee.~~ *($325) and shall be prorated on a monthly basis.*

(d) The renewal fee shall be three hundred twenty-five dollars ($325) and in the event a lower fee is fixed by the board, shall be an amount sufficient to support the functions of the board in the administration of this chapter. The renewal fee shall be assessed on an annual basis until January 1, 1996, and on and after that date the board shall assess the renewal fee biennially.

(e) The delinquency fee shall be set in accordance with Section 163.5.

(f) The application fee for the approval of a school or college under Section 4939 shall be three thousand dollars ($3,000). This subdivision shall become inoperative on January 1, 2017.

(g) The duplicate wall license fee is an amount equal to the cost to the board for the issuance of the duplicate license.

(h) The duplicate renewal receipt fee is ten dollars ($10).

(i) The endorsement fee is ten dollars ($10).

(j) The fee for a duplicate license for an additional office location as required under Section 4961 shall be fifteen dollars ($15).

SEC. 11. Section 5604 of the Business and Professions Code is amended to read:

5604. The fees prescribed by this chapter for architect applicants or architect licenseholders shall be fixed by the board as follows:

(a) The application fee for reviewing a candidate's eligibility to take any section of the examination ~~may~~ *shall* not exceed one hundred dollars ($100).

(b) The fee for any section of the examination administered by the board ~~may~~ *shall* not exceed one hundred dollars ($100).

(c) The fee for an original license at an amount equal to the renewal fee in effect at the time the license is ~~issued, except that, if the~~ *issued. The fee for an original* license ~~is issued less than one year before the date on which it will expire, then the fee~~ shall be ~~fixed at an amount equal to 50 percent of the renewal fee in effect at the time the license is issued.~~ *prorated on a monthly basis.* The board may, by appropriate regulation, provide

for the waiver or refund of the fee for an original license if the license is issued less than 45 days before the date on which it will expire.

(d) The fee for an application for reciprocity ~~may~~ *shall* not exceed one hundred dollars ($100).

(e) The fee for a duplicate license ~~may~~ *shall* not exceed twenty-five dollars ($25).

(f) The renewal fee ~~may~~ *shall* not exceed four hundred dollars ($400).

(g) The delinquency fee ~~may~~ *shall* not exceed 50 percent of the renewal fee.

(h) The fee for a retired license ~~may~~ *shall* not exceed the fee prescribed in subdivision (c).

AB-611

Controlled Substances: Prescriptions: Reporting

California LEGISLATIVE INFORMATION

AB-611 Controlled substances: prescriptions: reporting. (2015-2016)

AMENDED IN ASSEMBLY MARCH 24, 2015

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL **No. 611**

Introduced by Assembly Member Dahle

February 24, 2015

An act to amend Section 11165.1 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 611, as amended, Dahle. Controlled substances: prescriptions: reporting.

Existing law requires certain health care practitioners and pharmacists to apply to the Department of Justice to obtain approval to access information contained in the Controlled Substance Utilization Review and Evaluation System (CURES) Prescription Drug Monitoring Program (PDMP) regarding the controlled substance history of a patient under his or her care. Existing law requires the Department of Justice, upon approval of an application, to provide the approved health care practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care. *Existing law authorizes an application to be denied, or a subscriber to be suspended, for specified reasons, including, among others, a subscriber accessing information for any reason other than caring for his or her patients.*

This bill would also authorize an individual designated to investigate a holder of a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled substance history of an applicant or a licensee for the purpose of investigating the alleged substance abuse of a licensee. The bill would, upon approval of an application, require the department to provide to the approved individual the history of controlled substances dispensed to the licensee. *The bill would clarify that only a subscriber who is a health care practitioner or a pharmacist may have an application denied or be suspended for accessing subscriber information for any reason other than caring for his or her patients. The bill would also specify that an application may be denied, or a subscriber may be suspended, if a subscriber who has been designated to investigate the holder of a professional license accesses information for any reason other than investigating the holder of a professional license.*

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

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

SECTION 1. 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.

(iii) An individual designated by a board, bureau, or program within the Department of Consumer Affairs to investigate a holder of a professional license may, for the purpose of investigating the alleged substance abuse of a licensee, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a licensee that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that individual the electronic history of controlled substances dispensed to the licensee based on data contained in the CURES PDMP. The application shall contain facts demonstrating the probable cause to believe the licensee has violated a law governing controlled substances.

(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 *described in clause (i) or (ii) of subparagraph (A)* accessing information for any other reason than caring for his or her patients.

(vi) Any subscriber described in clause (iii) of subparagraph (A) accessing information for any other reason than investigating the holder of a professional license.

(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 an authorized subscriber 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 an authorized subscriber

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.

AB-750

Business and Professions: Retired

Category: Licenses

California LEGISLATIVE INFORMATION

AB-750 Business and professions: retired category: licenses. (2015-2016)

AMENDED IN ASSEMBLY APRIL 06, 2015

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL No. 750

Introduced by Assembly Member Low

February 25, 2015

An act to ~~amend~~ *add* Section ~~462 of~~ *463 to* the Business and Professions Code, relating to business and professions.

LEGISLATIVE COUNSEL'S DIGEST

AB 750, as amended, Low. Business and professions: *retired category:* licenses.

Existing law provides for numerous boards, bureaus, commissions, or programs within the Department of Consumer ~~Affairs,~~ *Affairs* that administer the licensing and regulation of various businesses and professions. Existing law authorizes any of the boards, bureaus, commissions, or programs within the department, except as specified, to establish by regulation a system for an inactive category of license for persons who are not actively engaged in the practice of their profession or vocation. Under existing law, the holder of an inactive license is prohibited from engaging in any activity for which a license is required. *Existing law defines "board" for these purposes to include, unless expressly provided otherwise, a bureau, commission, committee, department, division, examining committee, program, and agency.*

This bill would additionally authorize any of the boards, bureaus, commissions, or programs within the ~~department, except as specified,~~ *department* to establish by regulation a system for a retired category of license for persons who are not actively engaged in the practice of their profession or vocation, and would prohibit the holder of a retired license from engaging in any activity for which a license is ~~required.~~ *required, unless regulation specifies the criteria for a retired licensee to practice his or her profession. The bill would authorize a board upon its own determination, and would require a board upon receipt of a complaint from any person, to investigate the actions of any licensee, including, among others, a person with a license that is retired or inactive.*

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

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

SECTION 1. *Section 463 is added to the Business and Professions Code, to read:*

463. (a) Any of the boards, bureaus, commissions, or programs within the department may establish, by

regulation, a system for a retired category of licensure for persons who are not actively engaged in the practice of their profession or vocation.

(b) The regulation shall contain the following:

(1) The holder of a retired license issued pursuant to this section shall not engage in any activity for which a license is required, unless the board, by regulation, specifies the criteria for a retired licensee to practice his or her profession or vocation.

(2) The holder of a retired license shall not be required to renew that license.

(3) In order for the holder of a retired license issued pursuant to this section to restore his or her license to an active status, the holder of that license shall meet all the following:

(A) Pay a fee established by regulation.

(B) Not have committed an act or crime constituting grounds for denial of licensure.

(C) Comply with the fingerprint submission requirements established by regulation.

(D) If the board requires completion of continuing education for renewal of an active license, complete continuing education equivalent to that required for renewal of an active license, unless a different requirement is specified by the board.

(E) Complete any other requirements as specified by the board by regulation.

(c) A board may upon its own determination, and shall upon receipt of a complaint from any person, investigate the actions of any licensee, including a person with a license that either restricts or prohibits the practice of that person in his or her profession or vocation, including, but not limited to, a license that is retired, inactive, canceled, revoked, or suspended.

~~SECTION 1.Section 462 of the Business and Professions Code is amended to read:~~

~~462.(a)Any of the boards, bureaus, commissions, or programs within the department may establish, by regulation, a system for an inactive and a retired category of licensure for persons who are not actively engaged in the practice of their profession or vocation.~~

~~(b)The regulation shall contain the following provisions:~~

~~(1)The holder of an inactive or retired license issued pursuant to this section shall not engage in any activity for which a license is required.~~

~~(2)An inactive license issued pursuant to this section shall be renewed during the same time period in which an active license is renewed. The holder of an inactive license need not comply with any continuing education requirement for renewal of an active license.~~

~~(3)The renewal fee for a license in an active status shall apply also for a renewal of a license in an inactive status, unless a lesser renewal fee is specified by the board.~~

~~(4)In order for the holder of an inactive license issued pursuant to this section to restore his or her license to an active status, the holder of an inactive license shall comply with all the following:~~

~~(A)Pay the renewal fee.~~

~~(B)If the board requires completion of continuing education for renewal of an active license, complete continuing education equivalent to that required for renewal of an active license, unless a different requirement is specified by the board.~~

~~(c)This section shall not apply to any healing arts board as specified in Section 701.~~

AB-1060

Professions and Vocations: Licensure

California LEGISLATIVE INFORMATION

AB-1060 Professions and vocations: licensure. (2015-2016)

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL **No. 1060**

Introduced by Assembly Member Bonilla

February 26, 2015

An act to amend Section 491 of the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1060, as amended, Bonilla. Professions and vocations: licensure.

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 board to suspend or revoke a license on the ground that the licensee has been convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires the board, upon suspension or revocation of a license, to provide the ex-licensee with certain information pertaining to rehabilitation, reinstatement, or reduction of penalty, as specified.

This bill would ~~authorize~~ *require* the board to provide that information through first-class mail and by ~~electronic means.~~ *email if the board has an email address on file for the ex-licensee.*

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

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

SECTION 1. Section 491 of the Business and Professions Code is amended to read:

491. (a) Upon suspension or revocation of a license by a board on one or more of the grounds specified in Section 490, the board shall:

(1) Send a copy of the provisions of Section 11522 of the Government Code to the ex-licensee.

(2) Send a copy of the criteria relating to rehabilitation formulated under Section 482 to the ex-licensee.

(b) Subdivision (a) ~~may~~ *shall* be satisfied through first-class mail and by ~~electronic means.~~ *email if the board has an email address on file for the ex-licensee.*

SB-277

Public Health: Vaccinations

California LEGISLATIVE INFORMATION

SB-277 Public health: vaccinations. (2015-2016)

AMENDED IN SENATE APRIL 09, 2015

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

SENATE BILL **No. 277**

Introduced by Senators Pan and Allen
(Principal coauthor: Assembly Member Gonzalez)
(Coauthors: Senators Beall, Block, De León, Hall, Hertzberg, Hill, Jackson, Leno, McGuire, Mitchell, Stone, Wieckowski, and Wolk)
(Coauthors: Assembly Members Baker, Chiu, Cooper, Low, McCarty, Nazarian, Rendon, Mark Stone, and Wood)

February 19, 2015

An act to add Section 48980.5 to the Education Code, and to amend ~~Section 120325~~ *Sections 120325, 120335, and 120370* of, and to repeal ~~and add~~ Section 120365 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 277, as amended, Pan. Public health: vaccinations.

(1) Existing law prohibits the governing authority of a school or other institution from unconditionally admitting any person as a pupil of any public or private elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless prior to his or her admission to that institution he or she has been fully immunized against various diseases, including measles, mumps, and pertussis, subject to any specific age criteria. Existing law authorizes an exemption from those provisions for medical reasons or because of personal beliefs, if specified forms are submitted to the governing authority. *Existing law requires the governing authority of a school or other institution to require documentary proof of each entrant's immunization status. Existing law authorizes the governing authority of a school or other institution to temporarily exclude a child from the school or institution if the authority has good cause to believe that the child has been exposed to one of those diseases, as specified.*

This bill would eliminate the exemption from immunization based upon personal beliefs. *This bill would except a home-based private school from the prohibition described above of all of the school's pupils are residents of the household or are members of a single family. The bill would narrow the authorization for temporary exclusion to make it applicable only to a child whose documentary proof of immunization status does not show proof of immunization against one of the diseases described above.* The bill would make conforming changes to related provisions.

(2) Existing law requires the governing board of a school district, at the beginning of the first semester or

quarter of the regular school term, to make certain notifications to parents or guardians of minor pupils including, among others, specified rights and responsibilities of a parent or guardian and specified school district policies and procedures.

This bill would require the governing board of a school district to also include in the notifications provided to parents or guardians of minor pupils at the beginning of the regular school term the immunization rates for the school in which a pupil is enrolled for each required immunization. By requiring school districts to notify parents or guardians of school immunization rates, the bill would impose a state-mandated local program.

(3) 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, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

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

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

SECTION 1. Section 48980.5 is added to the Education Code, to read:

48980.5. The notification required pursuant to Section 48980 shall also include the immunization rates for the school in which a pupil is enrolled for each of the immunizations required pursuant to Section 120335 of the Health and Safety Code.

SEC. 2. Section 120325 of the Health and Safety Code is amended to read:

120325. In enacting this chapter, but excluding Section 120380, and in enacting Sections 120400, 120405, 120410, and 120415, it is the intent of the Legislature to provide:

(a) A means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:

(1) Diphtheria.

(2) Hepatitis B.

(3) Haemophilus influenzae type b.

(4) Measles.

(5) Mumps.

(6) Pertussis (whooping cough).

(7) Poliomyelitis.

(8) Rubella.

(9) Tetanus.

(10) Varicella (chickenpox).

(11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

(b) That the persons required to be immunized be allowed to obtain immunizations from whatever medical source they so desire, subject only to the condition that the immunization be performed in accordance with the regulations of the department and that a record of the immunization is made in accordance with the regulations.

(c) Exemptions from immunization for medical reasons.

(d) For the keeping of adequate records of immunization so that health departments, schools, and other institutions, parents or guardians, and the persons immunized will be able to ascertain that a child is fully or only partially immunized, and so that appropriate public agencies will be able to ascertain the immunization

needs of groups of children in schools or other institutions.

(e) Incentives to public health authorities to design innovative and creative programs that will promote and achieve full and timely immunization of children.

SEC. 3. *Section 120335 of the Health and Safety Code is amended to read:*

120335. (a) As used in this chapter, "governing authority" means the governing board of each school district or the authority of each other private or public institution responsible for the operation and control of the institution or the principal or administrator of each school or institution.

(b) The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless, prior to his or her first admission to that institution, he or she has been fully immunized. *This subdivision does not apply to a home-based private school if all of the pupils are residents of the household or are members of a single family.* The following are the diseases for which immunizations shall be documented:

(1) Diphtheria.

(2) Haemophilus influenzae type b.

(3) Measles.

(4) Mumps.

(5) Pertussis (whooping cough).

(6) Poliomyelitis.

(7) Rubella.

(8) Tetanus.

(9) Hepatitis B.

(10) Varicella (chickenpox).

(11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

(c) Notwithstanding subdivision (b), full immunization against hepatitis B shall not be a condition by which the governing authority shall admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school.

(d) The governing authority shall not unconditionally admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school unless the pupil has been fully immunized against pertussis, including all pertussis boosters appropriate for the pupil's age.

(e) The department may specify the immunizing agents that may be utilized and the manner in which immunizations are administered.

(f) This section shall become operative on July 1, 2012.

~~SEC. 3.~~ ***SEC. 4.*** Section 120365 of the Health and Safety Code is repealed.

~~SEC. 4.Section 120365 is added to the Health and Safety Code, to read:~~

~~120365.(a)Immunization of a person shall not be required for admission to a school or other institution listed in Section 120335 if the parent or guardian or adult who has assumed responsibility for his or her care and custody in the case of a minor, or the person seeking admission if an emancipated minor, files with the governing authority a letter or affidavit that documents which immunizations required by Section 120355 have been given and which immunizations have not been given pursuant to an exemption from immunization for medical reasons.~~

~~(b)When there is good cause to believe that the person has been exposed to one of the communicable diseases~~

~~listed in subdivision (a) of Section 120325, that person may be temporarily excluded from the school or institution until the local health officer is satisfied that the person is no longer at risk of developing the disease.~~

SEC. 5. *Section 120370 of the Health and Safety Code is amended to read:*

120370. *(a)* If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances that contraindicate immunization, that ~~person~~ *child* shall be exempt from the requirements of Chapter 1 (commencing with Section 120325, but excluding Section 120380) and Sections 120400, 120405, 120410, and 120415 to the extent indicated by the physician's statement.

(b) When there is good cause to believe that a child whose documentary proof of immunization status does not show proof of immunization against a communicable disease listed in subdivision (b) of Section 120335 has been exposed to one of those diseases, that child may be temporarily excluded from the school or institution until the local health officer is satisfied that the child is no longer at risk of developing or transmitting the disease.

~~SEC. 5.~~ ***SEC. 6.*** If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

SB-538

Naturopathic Doctors

California LEGISLATIVE INFORMATION

SB-538 Naturopathic doctors. (2015-2016)

AMENDED IN SENATE APRIL 06, 2015

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

SENATE BILL **No. 538**

Introduced by Senator Block

February 26, 2015

An act to amend Sections 3640 and 3640.5 of the Business and Professions Code, relating to naturopathic doctors.

LEGISLATIVE COUNSEL'S DIGEST

SB 538, as amended, Block. Naturopathic doctors.

(1) Existing law, the Naturopathic Doctors Act, provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee in the Osteopathic Medical Board of California. Existing law authorizes a naturopathic doctor to perform certain tasks, including physical and laboratory examinations for diagnostic purposes, and to order diagnostic imaging studies, as specified.

This bill would revise and recast those provisions and would expressly authorize a naturopathic doctor to order, perform, review, and interpret the results of diagnostic procedures commonly used by physicians and surgeons in general practice and to dispense, administer, order, prescribe, provide, furnish, or perform parenteral therapy and minor procedures, among other duties. The bill would include cervical routes of administration among the authorized routes of administration. The bill would define terms for those purposes.

(2) Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitation generally placed on controlled substances classified in Schedule V.

Existing law states that nothing in the Naturopathic Doctors Act or any other law shall be construed to prohibit a naturopathic doctor from furnishing or ordering drugs when, among other requirements, the naturopathic doctor is functioning pursuant to standardized procedure, as defined, or protocol developed and approved, as specified, and the Naturopathic Medicine Committee has certified that the naturopathic doctor has satisfactorily completed adequate coursework in pharmacology covering the drugs to be furnished or ordered. Existing law requires that the furnishing or ordering of drugs by a naturopathic doctor occur under the supervision of a physician and surgeon. Existing law also authorizes a naturopathic doctor to furnish or order controlled substances classified in Schedule III, IV, or V of the California Uniform Controlled Substances Act, but limits this authorization to those drugs agreed upon by the naturopathic doctor and physician and surgeon as specified in the standardized procedure. Existing law further requires that drugs classified in Schedule III be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician.

This bill would instead provide that, *except as specified,* nothing in the provisions governing naturopathic doctors or any other law shall be construed to prohibit a naturopathic doctor from furnishing, prescribing, administering, or ordering drugs and would make a conforming change to the scope of the certification duties of the Naturopathic Medicine Committee. The bill would delete ~~the other~~ *certain* provisions described above restricting the authority of naturopathic doctors to furnish or order drugs, including the requirements that the naturopathic doctor function pursuant to a standardized procedure, or furnish or order drugs under the supervision of a physician and surgeon.

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

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

SECTION 1. Section 3640 of the Business and Professions Code is amended to read:

3640. (a) A naturopathic doctor may order, perform, review, and interpret the results of diagnostic procedures commonly used by physicians and surgeons in general practice, including:

(1) Venipuncture.

(2) Physical and orificial examinations.

(3) Electrocardiograms.

(4) Diagnostic imaging technique consistent with the practice of naturopathic medicine.

(5) Phlebotomy.

(6) Clinical laboratory test and examinations, as described in subdivision (e).

(7) Obtaining samples of human tissue, consistent with the practice of naturopathic medicine.

(b) A naturopathic doctor may dispense, administer, order, prescribe, provide, furnish, or perform the following:

(1) Food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act, consistent with the routes of administration identified in subdivision (d).

(2) Hot or cold hydrotherapy; naturopathic physical medicine inclusive of the manual use of massage, stretching, resistance, or joint play examination but exclusive of small amplitude movement at or beyond the end range of normal joint motion; electromagnetic energy; colon hydrotherapy; and therapeutic exercise.

(3) Devices, including, but not limited to, therapeutic devices, barrier contraception, and durable medical equipment consistent with naturopathic training as determined by the committee.

(4) Health education and health counseling.

(5) Parenteral therapy.

(6) Minor procedures.

(c) A naturopathic doctor may utilize routes of administration that include oral, nasal, auricular, ocular, cervical, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular.

(d) The committee may establish regulations regarding ocular or intravenous routes of administration that are consistent with the education and training of a naturopathic doctor.

(e) Nothing in this section shall exempt a naturopathic doctor from meeting applicable licensure requirements for the performance of clinical laboratory tests, including the requirements imposed under Chapter 3 (commencing with Section 1200).

(f) For purposes of this section:

(1) "Minor procedures" means care and operative procedures relative to superficial laceration, lesions, and abrasions, and the removal of foreign bodies located in superficial structures and aspiration of joints, and the topical and parenteral use of substances consistent with the practice of naturopathic medicine, in accordance

with rules established by the Naturopathic Medicine Committee.

(2) "Parenteral therapy" means the administration of substances by means other than through the gastrointestinal tract, including intravenous, ~~subcutaneous and~~ *subcutaneous,* intramuscular, ~~intravenous~~ and other areas of the body excluding the ventral and dorsal body cavities.

SEC. 2. Section 3640.5 of the Business and Professions Code is amended to read:

3640.5. (a) ~~Nothing~~ *Except as set forth in this section, nothing* in this chapter or any other law shall be construed to prohibit a naturopathic doctor from furnishing, prescribing, administering, or ordering drugs.

(b) Drugs furnished or ordered by a naturopathic doctor may include Schedule III through Schedule V controlled substances under the California Uniform Controlled Substances ~~ActDivision~~ *Act (Division* 10 (commencing with Section 11000) of the Health and Safety ~~Code.~~ *Code), and any drug approved by the federal Food and Drug Administration that is not classified and labeled "for prescription only" or words of similar import.*

(c) The committee shall certify that the naturopathic doctor has satisfactorily completed adequate coursework in pharmacology covering the drugs to be furnished, prescribed, administered, or ordered under this section. The committee shall establish the requirements for satisfactory completion of this subdivision.

(d) Use of the term "furnishing" in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include ordering and furnishing a drug.

(e) For purposes of this section, "drug order" or "order" means an order for medication which is dispensed to or for an ultimate user, issued by a naturopathic doctor as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations.

(f) Notwithstanding any other provision of law, both of the following shall apply:

(1) All references to prescription in this code and the Health and Safety Code shall include drug orders issued by naturopathic doctors.

(2) The signature of a naturopathic doctor on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

TAB 6

Article 4. Physician and Surgeon Applications

§1610. Applications and Refund of Fee.

(a) All applications ~~(Application~~ for Osteopathic Physician's and Surgeon's Certificates ~~OMB-1 Rev.01/92) for a Physician and Surgeon Certificate~~ shall be accompanied by the appropriate fees set forth in Section 1690.

(b) An application shall be denied without prejudice and the applicant shall be refunded whatever fee is due as set forth by Section 1690 when an applicant's credentials are insufficient or the examination is not taken.

(c) Applications shall be valid for one (1) year.

(d) The processing times for original Physicians and Surgeons applications are set forth in Section 1691.

(e) When an application is deemed complete and approved, the applicant's initial license fee and renewal shall be determined based on the applicant's birth month, as follows:

(1) The initial licensing fee shall be prorated based on the number of months of licensure, for no less than three months and no more than twenty-four months:

(2) Applicants with even-numbered birth months shall be billed for a license expiring in an even year,)applicants whose birth months are in February, April, June, August, October, December, shall renew every even-numbered year);

(3) Applicants with odd-numbered birth months shall be billed for a license expiring in an odd year, (applicants whose birth months are in January, March, May, July, September, November, shall renew every odd-numbered year);

(4) A prorated license fee shall be no less than $25 and no more than $400. The fee shall be prorated monthly based on a biennial fee of $400 for a two year license, renewable every other year in their birth month.

NOTE: Authority cited: Osteopathic Act (Initiative Measure, Stats. 1923, p. xciii), Section 1; and Section 3600-1, Business and Professions Code. Reference: Sections 2099.5, ~~2154 and~~ 2455, and 2456.1. Business and Professions Code.

HISTORY

1. Repealer of chapter 16 (sections 1600-1697, not consecutive) and new chapter 16 (sections 1600-1697, not consecutive and Appendix) filed 12-10-87; operative 1-9-88 (Register 87, No. 52). For prior history, see Registers 81, No. 50; 81, No. 36; 81, No. 9; 80, No. 40; 78, No. 15; 77, No. 21; and 63, No. 25.

2. Amendment of subsections (b) and (d) filed 9-28-90; operative 10-28-90 (Register 90, No. 45).

3. Amendment of subsections (a), (b), and (f) filed 1-26-95; operative 1-26-95 pursuant to Government Code section 11343.4(d) (Register 95, No. 4).

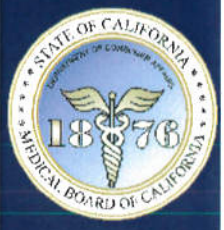
TAB 7

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR PAIN

MEDICAL BOARD OF CALIFORNIA

NOVEMBER 2014

Edmund G. Brown Jr., Governor
David Serrano Sewell, J.D., President, Medical Board of California
Kimberly Kirchmeyer, Executive Director, Medical Board of California



Guidelines for Prescribing Controlled Substances for Pain

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PREAMBLE

Protection of the public is the highest priority for the Medical Board of California (Board) in exercising its licensing, regulatory, and disciplinary functions. The Board recognizes that principles of high-quality medical practice and California law dictate that the people of California have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life for patients who suffer from pain, particularly chronic pain.

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." This was used to provide guidance to physicians prescribing controlled substances. Several legislative changes since 1994 necessitated revising these guidelines; most recently in 2007.

In November 2011, the Centers for Disease Control and Prevention declared prescription drug abuse to be a nationwide epidemic. Drug overdose is now the leading cause of accidental deaths, exceeding deaths due to motor vehicle accidents. A majority of those overdose deaths involved prescription drugs. The diversion of opioid medications to non-medical uses has also contributed to the increased number of deaths, although the problem is not limited to the aberrant, drug-seeking patient. Injuries are occurring among general patient populations, with some groups at high risk, (e.g., those with depression). Consequently, the Board called for revision of the guidelines to provide additional direction to physicians who prescribe controlled substances for pain.

These guidelines are intended to help physicians improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain. Opioid analgesics are widely accepted as appropriate and effective for alleviating moderate-to-severe acute pain, pain associated with cancer, and persistent end-of-life pain. [1] Although some of the recommendations cited in these guidelines might be appropriate for other types of pain, they are not meant for the treatment of patients in hospice or palliative care settings and are not in any way intended to limit treatment where improved function is not anticipated and pain relief is the primary goal. These guidelines underscore the extraordinary complexity in treating pain and how long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up, and close supervision are ensured. Since opioids are only one of many options to mitigate pain, and because prescribing opioids carries a substantial level of risk, these guidelines offer several non-opioid treatment alternatives. These guidelines are not intended to mandate the standard of care. The Board recognizes that deviations from these guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Medicine is practiced one patient at a time and each patient has individual needs and vulnerabilities. Physicians are encouraged to document their rationale for each

[1] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

prescribing decision. Physicians should understand that if one is ever the subject of a quality of care complaint, peer expert review will be sought by the Board. The expert reviewer must consider the totality of circumstances surrounding the physician's prescribing practice (e.g., issues relating to access of care, paucity of referral sources, etc.) Specifically, experts are instructed to "define the standard of care in terms of the level of skill, knowledge, and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question."[2]

In an effort to provide physicians with as many sources of information as possible, these guidelines link to numerous references relating to prescribing. Additionally, numerous appendices are attached. The Board recognizes that some of the links/appendices may not be consistent with either each other or the main text of the guidelines. The intent for including as many sources of information as practicable is so that physicians can consider varying perspectives to arrive at the best patient-appropriate treatment decision. The Board does not endorse one treatment option over another and encourages physicians to undertake independent research on this continuously evolving subject matter.

UNDERSTANDING PAIN

The diagnosis and treatment of pain is integral to the practice of medicine. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives long-term opioid therapy.

The California Medical Association[3] has defined and clarified key concepts relating to pain, excerpted below:

Pain: The definition of pain proposed by the International Association for the Study of Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." It has also been said that "Pain is what the patient says it is." Both definitions acknowledge the subjective nature of pain and are reminders that, with the rare exception of patients who intentionally deceive, a patient's self-report and pain behavior are likely the most reliable indicators of pain and pain severity. As a guide for clinical decision-making, however, both of these definitions are inadequate. In addition, it is important to remember that the subjectivity of pain, particularly when the cause is not apparent, can lead to the stigmatization of those with pain.

[2] Medical Board of California Expert Reviewer Guidelines (rev. January, 2013)
[3] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Acute and Chronic Pain: Traditionally, pain has been classified by its duration. In this perspective, "acute" pain is relatively short-duration, arises from obvious tissue injury, and usually fades with healing. "Chronic" pain, in contrast, has been variously defined as lasting longer than would be anticipated for the usual course of a given condition, or pain that lasts longer than arbitrary cut-off times, such as 3 or 6 months. Temporal pain labels, however, provide no information about the biological nature of the pain itself, which is often of critical importance.

Nociceptive and Neuropathic Pain: A more useful nomenclature classifies pain on the basis of its patho-physiological process. Nociceptive pain is caused by the activation of nociceptors, and is generally, though not always, short-lived and is associated with the presence of an underlying medical condition. It is a "normal" process; a physiological response to an injurious stimulus. Nociceptive pain is a symptom. Neuropathic pain, on the other hand, results either from an injury to the nervous system or from inadequately-treated nociceptive pain. It is an abnormal response to a stimulus; a pathological process. It is a neuro-biological disease. Neuropathic pain is caused by abnormal neuronal firing in the absence of active tissue damage. It may be continuous or episodic and varies widely in how it is perceived. Neuropathic pain is complex and can be difficult to diagnose and to manage because available treatment options are limited.

A key aspect of both nociceptive and neuropathic pain is the phenomenon of sensitization, which is a state of hyper-excitability in either peripheral nociceptors or neurons in the central nervous system. Sensitization may lead to either hyperalgia or allodynia. Sensitization may arise from intense, repeated or prolonged stimulation of nociceptors, or from the influence of compounds released by the body in response to tissue damage or inflammation. Importantly, many patients – particularly those with persistent pain --- present with "compound" pain that has both nociceptive and neuropathic components, a situation which complicates assessment and treatment.

Differentiating between nociceptive and neuropathic pain is critical because the two respond differently to pain treatments. Neuropathic pain, for example, typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory drug (NSAID) agents. Other classes of medications, such as anti-epileptics, antidepressants or local anesthetics, may provide more effective relief for neuropathic pain.

Cancer and Non-Cancer Pain: Pain associated with cancer is sometimes given a separate classification, although it is not distinct from a patho-physiological perspective. Cancer-related pain includes pain caused by the disease itself and/or painful diagnostic or therapeutic procedures [and the sequelae of those processes]. The treatment of cancer-related pain may be influenced by the life expectancy of the patient, by co-morbidities and by the fact that such pain may be of exceptional severity and duration. A focus of recent attention by the public, regulators, legislators, and physicians has been chronic pain that is not associated with cancer. A key feature of such pain, which may be caused by conditions such as musculoskeletal injury, lower back trauma and dysfunctional wound healing, is that the severity of pain may not correspond well to identifiable levels of tissue damage.

Tolerance, Dependence and Addiction: Related to the nomenclature of pain itself is continuing confusion not only among the public, but also in the medical community, about terms used to describe the effects of drugs on the brain and on behavior. To help clarify and standardize understanding, the American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) have recommended the following definitions:

> *Tolerance:* A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drugs' effects over time.
>
> *Physical Dependence:* A state of adaptation that often includes tolerance and is 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.
>
> *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.

Pain as an Illness: Finally, it may be helpful to point out that pain can be regarded as an illness as well as a symptom or a disease. "Illness" defines the impact a disease has on an organism and is characterized by epiphenomena or co-morbidities with bio-psycho-social dimensions. Effective care of any illness, therefore, requires attention to all of these dimensions. Neuropathic pain, end-of-life pain and chronic pain should all be viewed as illnesses.

SPECIAL PATIENT POPULATIONS

All patients may experience pain. Below are treatment considerations for differing patient populations or scenarios. As previously addressed, these guidelines are intended to particularly address the use of opioids in the long-term treatment of chronic, non-cancer pain. However, since many of the recommendations cited in these guidelines might be appropriate for other types of pain, other scenarios are listed below to provide additional guidance in prescribing opioids, when appropriate.

Acute Pain[4]

Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies likely will not provide adequate pain relief. When opioid medications are prescribed for treatment of acute pain, the number dispensed should be for a short duration and no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

[4] Utah Department of Health (Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, 2009).

Long (and intermediate) duration-of-action opioids or extended-release/long-acting opioids (ER/LA) should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely, if ever, indicated for treatment of acute pain. The use of opioids should be re-evaluated carefully, including the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

It is important to emphasize that numerous (but not all) recommendations cited in these guidelines may not be relevant for the physician treating a patient for acute pain. For example, a physician treating a patient who presents to an emergency department or primary care physician with a medical condition manifested by objective signs (e.g., a fractured ulna or kidney stones discernible with imaging studies) would not necessarily need to undertake an opioid trial, perform a psychological assessment, utilize a pain management agreement, confer with the Prescription Drug Monitoring Program database, order a drug toxicology screen, etc.

Emergency Departments

Treating patients in an emergency department (ED) or urgent care clinic presents unique challenges in that, oftentimes, there is limited ability to procure adequate patient history and the primary physician is not available. Drug seeking patients may take advantage of this in order to secure controlled substances.

The American College of Emergency Physicians (ACEP) Clinical Policy - Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department (Appendix 1) - identifies acute low back pain as a common presenting complaint in the ED. Opioids are frequently prescribed, expected or requested for such presentations. Consequently, ACEP clinical policy recommends:

(1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether non-opioid analgesics and non-pharmacologic therapies will be adequate for initial pain management.
(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or non-opioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.
(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (e.g.,<1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

For patients presenting to the ED with an acute exacerbation of non-cancer chronic pain, ACEP recommends the following:

(1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic non-cancer pain seen in the ED.
(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., < 1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

(3) The physician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs.

ACEP recommends that the use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

End-of-Life Pain[5]

Pain management at the end of life seeks to improve or maintain a patient's overall quality of life in addition to relieving suffering. This focus is important because sometimes a patient may have priorities that compete with, or supersede, the relief of pain. For some patients, mental alertness sufficient to allow lucid interactions with loved ones may be more important than physical comfort. Optimal pain management, in such cases, may mean lower doses of an analgesic and the experience, by the patient, of higher levels of pain.

Fear of inducing severe or even fatal respiratory depression may lead to the clinician[6] under-prescribing and reluctance by patients to take an opioid medication. Despite this fear, studies have revealed no correlation between opioid dose, timing of opioid administration and time of death in patients using opioids in the context of terminal illness. A consult with a specialist in palliative medicine in these situations may be advisable.

Cancer Pain

Pain is one of the most common symptoms of cancer, as well as being one of the most feared cancer symptoms. Opioid pain medications are the mainstay of cancer pain management, and are appropriate to consider for cancer patients with moderate to severe pain, regardless of the known or suspected pain mechanism. However, some cancer survivors with moderate-to-severe pain may additionally or alternatively benefit from the use of non-opioid treatments, and opioids may not be necessary. Other treatments such as surgeries, radiation therapy, and other procedures may provide sufficient pain relief so that opioids are not necessary.

ER/LA opioid formulations may lessen the inconvenience associated with the use of short-acting opioids. Patient-controlled analgesia using an ambulatory infusion device may provide optimal patient control and effective analgesia. The full range of adjuvant medications should be considered for patients with cancer pain, with the caveat that such patients are often on already complicated pharmacological regimens, which raises the risk of adverse reactions associated with polypharmacy.[7]

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[5] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).
[6] The term "clinician" throughout the document means "physician."
[7] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Older Adults
With appropriate precautions opioid therapy for elderly patients can be efficacious. It is important to begin with lower starting doses, slower titration, longer dosing intervals, and more frequent monitoring. Tapering of benzodiazepines is important to reduce the potential for respiratory depression.

For additional information, see Appendix 2.

Pediatric Patients
Extreme caution should be used in prescribing opioids for pediatric patients. A trial of opioid therapy may be considered with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed or are unlikely to be effective for acute pain. Additionally, close monitoring and consultation should be undertaken.

For additional information, see Appendix 3.

Pregnant Women
Clinicians should encourage minimal or no use of opioids during pregnancy unless the potential benefits clearly outweigh risks. 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.

Additional information on the appropriate use of opioids for pregnant patients is available from the American Congress of Obstetricians and Gynecologists (ACOG) committee opinion titled *Opioid Abuse, Dependence, and Addiction in Pregnancy*.

Patients Covered by Workers' Compensation[8]
This population of patients presents its own unique circumstances. Injured workers are generally sent to an occupational medicine facility for treatment. Ideally, the injured worker recovers and returns to work in full capacity. If recovery or healing does not occur as expected, early triage and appropriate, timely treatment is essential to restore function and facilitate a return to work.

The use of opioids in this population of patients can be problematic. Some evidence suggests that early treatment with opioids may actually delay recovery and a return to work. Conflicts of motivation may also exist in patients on workers' compensation, such as when a person may not want to return to an unsatisfying, difficult or hazardous job. Clinicians are advised to apply the same careful methods of assessment, creation of treatment plans and monitoring used for other pain patients but with the added consideration of the psycho-social dynamics inherent in the workers' compensation system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

[8] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

For additional information on treating patients covered by Workers' Compensation please see *State of California Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries*.

Patients with History of Substance Use Disorder[9]

Use of opioids for patients with a history of substance use disorder is challenging because such patients are more vulnerable to drug misuse, abuse and addiction. In patients who are actively using illicit drugs, the potential benefits of opioid therapy are likely to be outweighed by potential risks, and such therapy should not be prescribed outside of highly controlled settings (such as an opioid treatment program with directly observed therapy). In other patients, the potential benefits of opioid therapy may outweigh potential risks. Although evidence is lacking on best methods for managing such patients, potential risks may be minimized by more frequent and intense monitoring compared with lower risk patients, authorization of limited prescription quantities and consultation or co-management with a specialist in addiction medicine. Clinicians should use the [Controlled Substance Utilization Review and Evaluation System (CURES)/Prescription Drug Monitoring Program (PDMP)] CURES/PDMP to identify patients who obtain drugs from multiple sources.

If either the patient's medical history, self-report or scores on screening assessment tools such as the Opioid Risk Tool (Appendix 4) suggest an above-average risk of substance abuse, clinicians should consider the following steps in proceeding with a pain management strategy:

- Exhaust all non-opioid pain management methodologies prior to considering opioid therapy;
- Consult with a specialist in addiction medicine;
- Create a written treatment plan and patient agreement and review carefully with the patient, obtaining their signed informed consent;
- Closely monitor and assess pain, functioning and aberrant behaviors;
- Regularly check with a PDMP for compliance with prescribed amounts of opioids (using cross-state PDMP systems whenever they are available);
- While the patient is on long-term opioid therapy, implement urine drug testing, if possible; or
- If misuse or abuse of opioid analgesics is suspected or confirmed, initiate a non-confrontational in-person meeting, use a non-judgmental approach to asking questions, present options for referral, opioid taper/discontinuation or switching to non-opioid treatments, and avoid "abandoning" the patient or abruptly stopping opioid prescriptions.

Psychiatric Patients

A higher risk for deleterious side effects exists for patients with psychiatric diagnoses who are receiving opioid treatment. Opioids should only be prescribed for well-defined

[9] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

somatic or neuropathic pain conditions. Physicians should titrate slowly, closely monitor the patient and seek consultation from the appropriate specialist.

Patients Prescribed Benzodiazepines
Patients taking benzodiazepines and opioids are at an increased risk for respiratory depression, particularly elderly patients. Physicians should consider a trial of benzodiazepine tapering in patients concomitantly using opioids or other respiratory depressant medications. If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. For additional information, see Benzodiazepines: How They Work and How to Withdraw.

Patients Prescribed Methadone or Buprenorphine for Treatment of a Substance Use Disorder
Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief from acute and/or chronic pain, beyond that provided by their maintenance medication. For more information on pain relief for persons on methadone or buprenorphine, see *Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy*.

PATIENT EVALUATION AND RISK STRATIFICATION

When considering long-term use of opioids for chronic, non-cancer pain, given the potential risks of opioid analgesics, careful and thorough patient assessment is critical. Risk stratification is one of the most important things a physician can do to mitigate potentially adverse consequences of opioid prescribing. The nature and extent of the clinical assessment depends on the type of pain and the context in which it occurs. This includes but is not limited to:

- Completing a medical history and physical examination (Appendix 5).
- Performing a psychological evaluation.
    - Psychological assessment should include risk of addictive disorders. Screening tools that can be considered for use include:
        - CAGE-AID (Appendix 6);
        - PHQ-9 (Appendix 7);
        - Opioid Risk Tool (ORT) (Appendix 4); and
        - SOAPP®-R (Appendix 8).
        - Note: Although the above-listed assessment tools are well-established with proven effectiveness, physicians must be aware that seasoned diverters know the right answers to these tools so they look "normal."
- Establishing a diagnosis and medical necessity (review past medical records, laboratory studies, imaging studies, etc. and order new ones, if necessary or if previous studies are outdated). Screening tools that can be considered for use include:
    - Pain Intensity and Interference (pain scale) (Appendix 9); and
    - Sheehan Disability Scale.
- Exploring non-opioid therapeutic options.

Opioid medications may not be the appropriate first line of treatment for a patient with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. Resources that can be consulted include:
  - Therapeutic Options for Pain Management (Appendix 10); and
  - Non-Opioid Pain Management Tool (Appendix 11).
- Evaluating both potential benefits and potential risks of opioid therapy.
- Being cognizant of aberrant or drug seeking behaviors.
- As a universal precaution, undertaking urine drug testing.
- Reviewing the CURES/PDMP report for the patient. This allows a physician to check to see if a patient is receiving controlled substances from other prescribers in California (assuming the prescription is being filled at a California pharmacy).

CONSULTATION

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, or an addiction or mental health specialist as needed. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available.

Physicians who prescribe long-term opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed.

TREATMENT PLAN AND OBJECTIVES

When considering long-term use of opioids for chronic, non-cancer pain, the physician and the patient should develop treatment goals together. The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Pain relief is important, but it is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. Effective pain relief improves functioning, whereas addiction decreases functionality. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including

medications other than opioids) and non-pharmacologic. It also should specify measurable goals and objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function.

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. The treatment plan should also include an "exit strategy" for discontinuing opioid therapy in the event the tapering or termination of opioid therapy becomes necessary.

PATIENT CONSENT

When considering long-term use of opioids, or in other medically appropriate situations, the physician should discuss the risks and benefits of the treatment plan with the patient, with persons designated by the patient, or with the patient's conservator if the patient is without medical decision-making capacity. If opioids are prescribed, the patient (and possibly family members, if appropriate) should be counseled on safe ways to store and dispose of medications. For convenience, patient consent and a pain management agreement can be combined into one document.

Patient consent typically addresses:

- The potential risks and anticipated benefits of long-term opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as nausea, opioid-induced constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Gegmann et al., 2008) and cognitive impairment.
- The likelihood that some medications will cause tolerance and physical dependence to develop.
- The risk of drug interactions and over-sedation.
- The risk of respiratory depression.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.

PAIN MANAGEMENT AGREEMENT

Use of a pain management agreement is recommended for patients:

- On short-acting opioids at the time of third visit within two months;
- On long-acting opioids; or
- Expected to require more than three months of opioids.

Pain management agreements typically outline the joint responsibilities of the physician and the patient and should include:

- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.

- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication to prevent misuse by other household members).
- The patient's agreement to share information with family members and other close contacts on how to recognize and respond to an opiate overdose, including administering an opioid antagonist, such as naloxone, if necessary.(Appendix 12)
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice and one pharmacy.
- The patient's agreement to periodic drug testing (blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills, if appropriate and in accordance with the patient's pain management agreement.

Samples of pain management agreements:

- Patient Pain Medication Agreement and Consent (Appendix 13)
- Treatment Plan Using Prescription Opioids (Appendix 14)

COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE

Empirical evidence has shown that lay persons can be trained to recognize the signs of an opiate overdose and to safely administer naloxone, an opiate antagonist. Programs that have trained lay persons in naloxone administration have reported more than 10,000 overdose reversals.[10]

It is important to educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

- Snoring heavily and cannot be awakened.
- Periods of ataxic (irregular) or other sleep-disordered breathing.
- Having trouble breathing.
- Exhibiting extreme drowsiness and slow breathing.
- Having slow, shallow breathing with little chest movement or no breathing.
- Having an increased or decreased heartbeat.
- Feeling faint, very dizzy, confused or has heart palpitations.
- Blue skin/lips.
- Non-responsiveness to painful stimulation.

[10] Centers for Disease Control and Prevention. Community-based opioid overdose prevention programs providing naloxone-United States, 2010. Morbidity and mortality weekly report, February 17, 2012 / 61(06);101-105

Effective January 1, 2015, California pharmacists will be able to furnish an opioid overdose reversal drug in accordance with standardized procedures or protocols, naloxone, to family members of patients at risk for overdose, those who might be in contact with an individual at risk for overdose, or anyone who requests the drug without a prescription.

SAMHSA's Opiate Overdose Toolkit and Prescribe to Prevent contain numerous documents relating to overdose prevention and management.

INITIATING OPIOID TRIAL

Safer alternative treatments should be considered before initiating opioid therapy for chronic pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 45 days) and with specific evaluation points. The *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*[11] reveals that "[o]ver half of persons receiving 90 days of continuous opioid therapy remain on opioids years later. Factors most strongly associated with continuation were intermittent prior opioid exposure, daily opioid dose≥120 mg MED, and possible opioid misuse. Since high dose and opioid misuse have been shown to increase the risk of adverse outcomes, special caution is warranted when prescribing more than 90 days of opioid therapy in these patients."

The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety.

According to the California Medical Association:[12]

> Oral administration, especially for the treatment of chronic pain, is generally preferred because it is convenient, flexible and associated with stable drug levels. Intravenous administration provides rapid pain relief and, along with rectal, sublingual and subcutaneous administration, may be useful in patients who cannot take medications by mouth. Continuous infusions produce consistent drug blood levels but are expensive, require frequent professional monitoring and may limit patient mobility.
>
> Transdermal administration is a convenient alternate means of continuous drug delivery that does not involve needles or pumps. Patient-controlled analgesia (PCA) allows patients to self-administer pain medications and may be useful if analgesia is required for 12 hours or more and mobility is not required. Intrathecal delivery of opioids is a viable option for patients with chronic pain who have not responded to other treatment options, or for whom the required doses result in unacceptable side-effects. Patients with intrathecal delivery systems typically require ongoing ambulatory monitoring and supportive care.

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[11] Journal of General Internal Medicine article (December 2011, Volume 26, Issue 12, pp 1450-1457).
[12] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Patients on a steady dose of an opioid medication may experience pain that breaks through the analgesic effects of the steady-state drug. Paper or electronic pain diaries may help patients track these breakthrough episodes and spot correlations between the episodes and variables in their lives. A short-acting opioid is typically prescribed for treatment by patients with breakthrough pain.

Continuation of opioid therapy after an appropriate trial should be based on outcomes such as: making progress toward functional goals; presence and nature of side effects; pain status; and a lack of evidence of medication misuse, abuse, or diversion. Patients with no, or modest, previous opioid exposure should be started at the lowest appropriate initial dosage of a short-acting opioid and titrated upward to decrease the risk of adverse effects. The selection of a starting dose and manner of titration are clinical decisions made on a case-by-case basis because of the many variables involved. Some patients, such as frail older persons or those with co-morbidities, may require an even more cautious therapy initiation. Short-acting opioids are usually safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of overdose from drug accumulation. The general approach is to "start low and go slow."

Since opioids are known in some circumstances to worsen pain (hyperalgesia), instances of ongoing pain may suggest opioid insensitivity (or an inadequate dose). Careful assessment must be undertaken. If hyperalgesia is suspected, a dose reduction, opioid rotation or tapering to cessation could be considered.

Dosing Recommendations For Opioid Naïve Patients
There is a plethora of data available regarding recommended dosages for various analgesics. Because this is continuously evolving, physicians are encouraged to review the Food and Drug Administration's website and other relevant information sources.

Morphine Equivalent Dose (MED)
There are differing opinions among reputable experts and organizations as to what MED should trigger a consultation. The Board recommends that physicians proceed cautiously (yellow flag warning) once the MED reaches 80 mg/day. Referral to an appropriate specialist should be considered when higher doses are contemplated. There is no absolute safe ceiling dose of opioids, however, and caution and monitoring are appropriate for applications of these medications.

The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

ONGOING PATIENT ASSESSMENT

When a trial of an opioid medication is successful and the physician and patient decide to continue opioid therapy, regular review and monitoring should be undertaken for the duration of treatment.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale or other validated assessment tools, may be helpful and time effective.

Consider the 5-As method for chronic pain management assessment:

Analgesia:	the patient is experiencing a reduction in pain.
Activity:	the patient is demonstrating an improvement in level of function.
Adverse:	the patient is not experiencing side effects.
Aberrance:	the patient is complying with the pain management agreement and there are no signs of medication abuse or diversion.
Affect:	the patient's behavior and mood are appropriate.

"Opioid rotation," the switching from one opioid to another in order to better balance analgesia and side effects, may be used if pain relief is inadequate, if side effects are bothersome or unacceptable, or if an alternative route of administration is suggested. Opioid rotation must be done with great care, particularly when converting from an immediate-release formulation to an extended-release/long-acting (ER/LA) product. Equianalgesic charts, conversion tables and calculators must be used cautiously with titration and appropriate monitoring. Patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind, hence physicians may want to use initially lower-than-calculated doses of the switched-to opioid.

COMPLIANCE MONITORING

Physicians who prescribe opioids or other controlled substances for pain should ensure the provisions of a pain management agreement are being heeded. Strategies for monitoring compliance may include:

CURES/PDMP Report
The CURES/PDMP report can be useful in establishing whether or not an individual is receiving controlled substances from multiple prescribers. The CURES/PDMP report should be requested frequently for patients who are being treated for pain as well as addiction.

Drug Testing
A patient's report of medication use is not always reliable; therefore, drug testing can be an important monitoring tool.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately. For example,

when a drug test is ordered, it is important to specify that it include the opioid being prescribed. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist. Urine toxicology tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies and interpreting laboratory data. Laboratories vary in their testing methodologies, thresholds and standards. Results from drug screens may involve diverse drug classes and interpreting them requires clinical understanding well beyond opioids.

"Variability may result from differences between laboratories. Some labs, for example, only report values above a certain preset threshold. So, a patient might have a measureable level of drug, but since it does not exceed the given threshold, it is reported as negative finding. This might lead the physician to suspect that a prescribed drug, which should be present at the time of testing, is absent."[13]

"Limitations to Urine Drug Testing (UDT): There is currently no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug. A recent systematic review of the use of drug treatment agreements and urine drug testing to discourage misuse when opioids are prescribed for chronic non-cancer pain, found weak, heterogeneous evidence that these strategies were associated with less misuse. Limited research did find that UDT was a valuable tool to detect use of non-prescribed drugs and confirm adherence to prescribed medications beyond that identified by patient self-report or impression of the treating physician."[14] "Consequently, additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, may be deemed necessary to monitor and treat patients receiving chronic opioid treatment and is considered part of a medically necessary treatment and monitoring program."[15]

It is important to be aware of cost barriers related to a patient's ability to pay for the testing. There are numerous Clinical Laboratory Improvement Amendments waived office drug testing kits which are inexpensive and which physicians may wish to consider for use for initial drug testing. However, unexpected results from office-based testing should be confirmed by the more-sensitive laboratory testing before the patient's plan of care is changed.

Pill Counting

Periodic pill counting can be a useful strategy to confirm medication adherence and to minimize diversion (selling, sharing or giving away medications).

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[13] Responsible Opioid Prescribing, A Clinician's Guide, Second Edition, 2012, Scott Fishman, M.D.; Federation of State Medical Boards (FSMB), FSMB Foundation, and University of Nebraska Medical Center.

[14] State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part D: Comparison Of Recommendations From Existing Opioid Guidelines.

[15] State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part B Recommendations.

The physician must decide whether or not to revise or augment a pain management agreement and/or treatment plan if the patient's progress is unsatisfactory.
If it is suspected that a patient may be abusing or diverting prescribed medications, or using "street" drugs, a careful re-assessment of the treatment plan must be undertaken. A patient's failure to adhere to a pain management agreement is not necessarily proof of abuse or diversion. Failure to comply may be the consequence of inadequate pain relief, confusion regarding the prescription, a language barrier or economic concerns. A physician should arrange for an in-person meeting in order to have a non-judgmental conversation to clarify his or her concerns. If abuse is confirmed, minimally, consultation with an addiction medicine specialist or mental health specialist trained in substance abuse disorders and/or referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) should be immediately facilitated. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firmer, immediate response. The degree to which the patient has breached the pain agreement and/or the presence of criminal activity should govern the physician's response. Although an immediate face-to-face meeting with the patient to re-evaluate the treatment plan may be appropriate, in some instances it may be necessary to taper opioid therapy and/or terminate the physician patient relationship. In situations where the patient has engaged in prescription forgery, prescription theft or assaultive behaviors directed towards physician or staff, the physician is strongly encouraged to contact the police/Drug Enforcement Agency (DEA). For other criminal behaviors, the physician is encouraged to contact legal counsel to determine whether it is appropriate to report to law enforcement. Failing to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death.

DISCONTINUING OPIOID THERAPY

Discontinuing or tapering of opioid therapy may be required for many reasons and ideally, an "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment. Reasons may include:

- Resolution or healing of the painful condition;
- Intolerable side effects;
- Failure to achieve anticipated pain relief or functional improvement (although ensure that this failure is not the result of inadequate treatment);
- Evidence of non-medical or inappropriate use;
- Failure to comply with monitoring, such as urine drug screening (although ensure that this failure is not the result of a cost issue);
- Failure to comply with pain management agreement;

- Exhibition of drug-seeking behaviors (although ensure this behavior is not the result of inadequate treatment) or diversion, such as:
    - Selling prescription drugs;
    - Forging prescriptions;
    - Stealing or borrowing drugs;
    - Aggressive demand for opioids;
    - Injecting oral/topical opioids;
    - Unsanctioned use of opioids;
    - Unsanctioned dose escalation;
    - Concurrent use of illicit drugs;
    - Getting opioids from multiple prescribers and/or multiple pharmacies; or
    - Recurring emergency department visits for chronic pain management.

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely-structured tapering regimen. Opioid withdrawal symptoms are uncomfortable, but are generally not life threatening. Opioids can be stopped abruptly when the risks outweigh the benefits. This is not true for benzodiazepine withdrawals, which can be life threatening. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist. "Approaches to weaning range from a slow 10% reduction per week to a more aggressive 25 to 50% reduction every few days. In general, a slower taper will produce fewer unpleasant symptoms of withdrawal."[16] For strategies on tapering and weaning, see Appendix 15. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate.

If complete termination of care is necessary (as opposed to termination of a specific treatment modality), physicians should treat the patient until the patient has had a reasonable time to find an alternative source of care, and ensure that the patient has adequate medications, if appropriate, to avoid unnecessary risk from withdrawal symptoms. Physicians can be held accountable for patient abandonment if medical care is discontinued without adequate provision for subsequent care. If a patient is known to be abusing a medication, initiating a detoxification protocol may be appropriate. Consultation with an attorney and/or one's malpractice insurance carrier may be prudent in such cases. Physicians may want to also consult health plan contracts to ensure compliance. The Board also provides guidance on how to terminate/sever the patient relationship.

If a patient is dismissed for not honoring treatment agreements, consider referral to addiction resources. This can also include a 12-step program.

[16] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

MEDICAL RECORDS

Every physician must maintain adequate and accurate medical records. The content of a patient's medical record may vary considerably, depending on numerous factors. For a physician treating a patient with opioids for chronic, non-cancer pain, an adequate medical record includes, but is not limited to, the documentation of:

- the patient's medical history;
- results of the physical examination and all laboratory tests ordered by the physician;
- patient consent;
- pain management agreement;
- results of the risk assessment, including results of any screening instruments used;
- description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity);
- instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement;
- notes on evaluations by, and consultations with, specialists;
- any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors (these may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers);
- authorization for release of information to other treatment providers as appropriate and/or legally required; and
- results of CURES/PDMP data searches.

The medical record should include all prescription orders for opioid analgesics and other controlled substances, whether written, telephoned or electronic. In addition, written instructions for the use of all medications should be given to the patient and documented in the record. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed, if the pharmacy that the patient will use is known. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review.

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient.

SUPERVISING ALLIED HEALTH PROFESSIONALS

Physicians who supervise physician assistants or nurse practitioners who prescribe opioids should be aware of the specific regulations and requirements governing them and those whom they supervise.

COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS

California laws:

- California laws regarding controlled substances
- Guide to the Laws Governing the Practice of Medicine

Federal laws:

- Title 21 United States Code (USC) Controlled Substances Act

Other information:

- Pharmacist corresponding responsibilities

Appendix 1 - Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

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ABSTRACT

This clinical policy deals with critical issues in prescribing of opioids for adult patients treated in the emergency department (ED). This guideline is the result of the efforts of the American College of Emergency Physicians, in consultation with the Centers for Disease Control and Prevention, and the Food and Drug Administration. The critical questions addressed in this clinical policy are: (1) In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse? (2) In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications? (3) In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids? (4) In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

INTRODUCTION

Pain is a major symptom of many patients presenting to the emergency department (ED), with up to 42% of ED visits being related to painful conditions.[1] Pain management has received increased emphasis in the past decade, including The Joint Commission's focus on patient analgesia[2] and increasing institutional emphasis placed on patient satisfaction surveys covering pain management. Much literature, including the most recent Institute of Medicine report on this topic, has stressed that health care providers have not done as well as possible in the area of pain management.[3] A possible unintended consequence of these efforts is the increase in prescription drug abuse, especially opioid abuse, the fastest-growing drug abuse problem in the United States.[4]

As part of this issue, there has been a startling increase in unintentional drug overdoses and related deaths since the late 1990s.[5,6] Reported overdose deaths involving opioid analgesics increased from 4,030 in 1999 to 14,800 in 2008.[7,8] Data from 2008 reveal that drug overdoses were the second leading cause of injury death in the United States, after motor vehicle crashes.[9] Currently, deaths from opioid analgesics are significantly greater in number than those from cocaine and heroin combined.[8]

The efforts of clinicians to improve their treatment of pain, along with pharmaceutical industry marketing, have been factors in contributing to a significant increase in the sale and distribution of opioids in the United States. For example, the sales of opioid analgesics to hospitals, pharmacies, and practitioners quadrupled between 1999 and 2010.[8] Drug sales and distribution data of opioids show an increase from 180 mg morphine equivalents per person in the United States in 1997 to 710 mg per person in 2010.[8,10] This is the equivalent of 7.1 kg of opioid medication per 10,000 population, or enough to supply every American adult with 5 mg of hydrocodone every 4 hours for a month.[8]

The dilemma of treating pain appropriately while avoiding adverse events is further complicated by insufficient data supporting the long-term use of opioids in the treatment of chronic noncancer pain. Although selective use of opioids in the treatment of acute pain is traditionally accepted, the treatment of chronic noncancer pain is more complex. Many authors have begun to question the routine long-term use of opioids for the treatment of chronic noncancer pain.[11-13] Multiple practice guidelines have been developed to address this issue.[14-19] However, most recommendations in this area are of a consensus nature, being based on experiential or low-quality evidence.

Data from 2009 show that there were more than 201.9 million opioid prescriptions dispensed in the United States during that year.[20] It is difficult to obtain reliable data concerning the degree to which this is an emergency medicine issue, but during 2009, in the 10- to 19-year-old and 20- to 29-year-old patient groups, emergency medicine ranked third among all specialties in terms of number of opioid prescriptions, writing approximately 12% of the total prescriptions in each age group. In the 30- to 39-year-old group, emergency medicine ranked fourth.[20] Although these data do not deal with total doses dispensed by specialty, it is commonly postulated that the population served in EDs as a whole is at high risk for opioid abuse.[21]

The significant increase in opioid-related deaths has raised the concern of many.[5,6,8] This problem has also been observed in the pediatric population.[22-24] Action at the national level includes the recent proposal from the Food and Drug Administration for the establishment of physician education programs for the prescribing of long-acting and extended-release opioids as part of their national opioid risk evaluation and mitigation strategy (the REMS program).[25] State efforts to address this issue have included the development of statewide opioid prescribing guidelines, such as those developed by the Utah Department of Health[17] and statewide ED opioid prescribing guidelines, such as those developed in Washington State by the Washington chapter of the American College of Emergency Physicians (ACEP) working with other state organizations.[16] Some individual EDs and emergency physician groups have also promulgated opioid prescribing guidelines. Some of these policies also deal with the necessity of patient education about the safe use and proper disposal of opioid medications. Early data indicate that, in some cases, these guidelines may decrease prescription opioid overdose.[26] Anecdotal experience suggests that public policies such as these may change patient perceptions of appropriate prescribing and mitigate complaints arising from more stringent prescribing practices. ACEP has approved related policy statements about optimizing the treatment of pain in patients with acute presentations and the implementation of electronic prescription drug monitoring programs.[27,28]

This clinical policy addresses several issues believed to be important in the prescribing of opioids by emergency physicians for adult patients treated and released from the ED for whom opioids may be an appropriate treatment modality. Although relieving pain and reducing suffering are primary emergency physician responsibilities, there is a concurrent duty to limit the personal and societal harm that can result from prescription drug misuse and abuse. Because long-acting or extended-release opioids are not indicated for the treatment of acute pain, the aim of this clinical policy is to provide evidence-based recommendations for prescribing short-acting opioids for adult ED patients with painful acute or chronic conditions while attempting to address the increasing frequency of adverse events, abuse, and overdose of prescribed opioid analgesics.

METHODOLOGY

This clinical policy was created after careful review and critical analysis of the medical literature. The critical questions were formulated in the PICO (patient, intervention, comparison, outcome)[29] format to strengthen the clarity and scientific rigor of the questions. Searches of MEDLINE, MEDLINE InProcess, and the Cochrane Library were performed. All searches were limited to English-language sources, human studies, adults, and years 2000 to 2011. Specific key words/phrases and years used in the searches are identified under each critical question. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members were included.

This policy is a product of the ACEP clinical policy development process, including expert review, and is based on the literature; when literature was not available, consensus of panel members was used. Expert review comments were received from emergency physicians, toxicologists, pain and addiction medicine specialists, pharmacologists, occupational medicine specialists, and individual members of the American Academy of Clinical Toxicology, American Academy of Family Physicians, American Academy of Pain Medicine, American Chronic Pain Association, American College of Occupational and Environmental Medicine, American College of Osteopathic Emergency Physicians, American College of Physicians, American Pain Society, American Society of Health-System Pharmacists, American Society of Interventional Pain Physicians, Emergency Medicine Resident's Association, and Emergency Nurses Association. Their responses were used to further refine and enhance this policy; however, their responses do not imply endorsement of this clinical policy. Clinical policies are scheduled for revision every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly. The Centers for Disease Control and Prevention was the funding source for this clinical policy.

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members for quality and strength of evidence. The articles were classified into 3 classes of evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic studies, respectively (Appendix A). Articles were then graded on dimensions related to the study's methodological features: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (eg, selection, detection, transfer), external validity (ie, generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula, taking into account the design and study quality (Appendix B). Articles with fatal flaws or that were not relevant to the critical question were given an "X" grade and were not used in formulating recommendations for this policy. Evidence grading was done with respect to the specific data being extracted and the specific critical question being reviewed. Thus, the level of evidence for any one study may have varied according to the question, and it is possible for a single article to receive different levels of grading as different critical questions were answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of this policy. Evidence grading sheets may be viewed at http://www.acep.org/clinicalpolicies/?pg=1.

Clinical findings and strength of recommendations about patient management were then made according to the following criteria:

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (ie, based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (ie, based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

Level C recommendations. Other strategies for patient management that are based on Class III studies, or in the absence of any adequate published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

This policy is not intended to be a complete manual on the evaluation and management of adult ED patients with painful conditions where prescriptions for opioids are being considered, but rather is a focused examination of critical issues that have

particular relevance to the current practice of emergency medicine.

The goal of the ACEP Opioid Guideline Panel is to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain enough quality information to answer a critical question, the members of the ACEP Opioid Guideline Panel believe that it is equally important to alert emergency physicians to this fact.

Recommendations offered in this policy are not intended to represent the only management options that the emergency physician should consider. ACEP clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

Scope of Application. This guideline is intended for physicians working in hospital-based EDs.

Inclusion Criteria. This guideline is intended for adult patients presenting to the ED with acute noncancer pain or an acute exacerbation of chronic noncancer pain.

Exclusion Criteria. This guideline is not intended to address the long-term care of patients with cancer or chronic noncancer pain.

CRITICAL QUESTIONS

1. In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. The use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

Key words/phrases for literature searches: opioid, drug prescriptions, drug monitoring, drug utilization review, substance abuse detection, drug-seeking behavior, drug and narcotic control, substance-related disorders, physician's practice patterns, program evaluation, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Emergency physicians must balance oligoanalgesia (undertreatment or ineffectual treatment of pain) with concerns about drug diversion* and doctor shopping.†[30-33] Therefore, the development of mechanisms to address these issues is justified. The expanded use of prescription drug monitoring programs to curb prescription opioid misuse was recommended in the 2011 Prescription Drug Abuse Prevention Plan released by the White House Office of National Drug Control Policy.[34] Prescription drug monitoring programs are state-based monitoring programs for certain controlled substances that are prescribed by licensed practitioners and dispensed by pharmacies. Although existing in various forms for more than 3 decades, the first effort to standardize prescription drug monitoring practice was the passage in 2005 of the National All Schedules Prescription Electronic Reporting Act (NASPER). Unfortunately, this federal legislative mandate that intended to harmonize prescription drug monitoring programs across the various states has yet to be fully funded.

Prescription drug monitoring programs ideally serve multiple functions, including identifying patients who engage in doctor shopping, and patients, providers, or pharmacies who engage in diversion of controlled substances and providing information about prescribing trends for surveillance and evaluation purposes. Such information may serve to benefit the patients, the health care system, epidemiologists, policymakers, regulatory agencies, and law enforcement.[35] Certain large health care systems, particularly closed prescribing systems such as the Veterans Administration and health maintenance organizations, maintain databases that allow prescribers to view recent prescriptions of enrolled clients or patients. Forty-one states have operational prescription drug monitoring programs of various complexity and capability, with an additional 7 states having prescription drug monitoring program legislation in place but with programs that are not yet operational.[36] Most states allow health care providers and pharmacists to access the programs for patients under their care. Other groups such as law enforcement and regulatory boards may also have access. One program tracks only schedule II drug prescriptions, whereas most track drug prescriptions of schedule II to IV or II to V drugs.

Despite prescription drug monitoring programs providing an intuitive perception of benefit for the medical community, there are limited data to indicate any benefit of these programs for improving patient outcomes or reducing the misuse of prescription drugs.[37] In part, this relates to the limited optimization of and standardization between the programs and the lack of a mechanism to allow interstate communication.[35]

*Drug diversion: The diversion of drugs for nonmedical use through routes that do not involve the direct prescription of the drug by a provider. Diverted drugs might be provided by family or friends, purchased on the street market, or obtained through fraudulent prescription. Epidemiologic data suggest that most opioids used nonmedically are obtained through these means.

†Doctor shopping: The practice of obtaining prescriptions for controlled substances from multiple providers, which is regarded as a possible indication of abuse or diversion. There is no rigorous definition, and various authors have defined it in different ways, from 2 or more prescribers within 30 days, greater than 4 during 1 year, and greater than 5 during 1 year.[30-32] It has also been defined as the amount of drug obtained through doctor shopping compared with the amount intended to be prescribed.[33] The use of "pill mills," in which a prescriber provides ready access to prescriptions or pills, can be considered a form of doctor shopping.

One study has demonstrated that compared with states without a prescription monitoring program, those with such a program had a slower rate of increase in opioid misuse.[38]

In an attempt to quantify the effect of a prescription drug monitoring program, Bachren et al[39] conducted a prospective study (Class III) of 18 providers who cared for a convenience sample of adult patients with pain in a single Ohio ED. After the clinical assessment of a patient, the researchers queried the providers about 3 patient-specific issues: (1) the likelihood of querying the state's prescription drug monitoring program, called Ohio Automated Rx Reporting System; (2) the likelihood of providing an opioid prescription at discharge; and (3) if yes, which opioid and what quantity. They were then provided with a printout of the patient data from the prescription drug monitoring program and asked to reassess the same questions. Of the 179 patients with complete data, information from the Ohio Automated Rx Reporting System altered prescribing practice in 74 of 179 (41%). The majority (61%) of these patients received fewer or no opioids, whereas 39% received more. The change in management was attributed to the number of previous prescriptions, 30 of 74 (41%); number of previous prescribers, 23 of 74 (31%); number of pharmacies used, 19 of 74 (26%); and number of addresses listed, 12 of 74 (16%). A limitation of this study was that 4 prescribers accounted for almost two thirds of the total patient encounters. In this study, knowledge of the information provided by a prescription drug monitoring program had an important impact on the prescription practices for controlled substances in an ED, although the actual effect of prescription drug monitoring program data on patient outcomes in this study is unknown.

Although not specifically evaluating the benefit of prescription drug monitoring programs on identifying high-risk patients, Hall et al,[32] in a Class III study, reviewed characteristics of decedents who died of prescription drugs in West Virginia and reported that opioid analgesics accounted for 93% of deaths. Cross-referencing the medical examiner's detailed analysis of the cause of death with the West Virginia prescription monitoring program, the authors determined the prescription history of the drug associated with each fatality. Patients who had received controlled drugs from 5 or more prescribers in the year before death were defined as engaging in "doctor shopping," whereas those whose death was not associated with a valid prescription were considered to have obtained their drugs through "diversion." Of the 295 deaths that were reviewed, the mean age of patients who died was 39 years, and 92% were between ages 18 and 54 years. Diversion was associated with 186 (63%) of the fatalities, and doctor shopping was associated with 63 (21%) of the fatalities. Of the 295 total decedents, 279 (95%) had at least 1 indicator of substance abuse, and these differed according to whether the drug was obtained through diversion or doctor shopping. Deaths involving diversion were associated with a history of substance abuse (82.3% versus 71.6%; odds ratio [OR] 1.8; 95% confidence interval [CI] 1.0 to 3.4), nonmedical route of pharmaceutical administration (26.3% versus 15.6%; OR 1.9; 95% CI 1.0 to 3.8), and a contributory illicit drug (19.4% versus 10.1%; OR 2.1; 95% CI 1.0 to 4.9). Patients with evidence of doctor shopping were significantly more likely to have had a previous overdose (30.2% versus 13.4%; OR 2.8; 95% CI 1.4 to 5.6) and significantly less likely to have used contributory alcohol (7.9% versus 19.8%; OR 0.3; 95% CI 0.1 to 0.9). Few patients (8.1%) were involved in both doctor shopping and diversion. The study suggests that the information provided by a prescription drug monitoring program, with correct interpretation and action based on that knowledge, might have prevented some inappropriate prescribing and poor outcomes in this patient population.

In another Class III study, Pradel et al[33] monitored prescribing trends for buprenorphine in a select area of France, using a prescription drug database during a multiple-year period. During this time, a prescription drug monitoring program was implemented, allowing a before-after comparison of the buprenorphine prescribing pattern for more than 2,600 patients. The doctor shopping drug quantity, which was defined as the total drug quantity received by the patient minus the quantity prescribed by an individual provider, increased from 631 g in the first 6 months of 2000 to a peak of 1,151 g in the first 6 months of 2004, equivalent to 143,750 days of treatment at 8 mg/day. The doctor shopping ratio, determined as the ratio of the quantity delivered to the quantity prescribed, increased steadily from early 2000 (14.9% of the grams of drug prescribed) to a peak value in the first 6 months of 2004 (21.7%). After implementation of the prescription drug monitoring program in early 2004, this value decreased rapidly, in fewer than 2 years reaching the value observed in 2000. The points of inflection of the doctor shopping curves (quantity and ratio) coincided with the implementation of the prescription drug monitoring program, suggesting an immediate benefit of this program. The prescribed quantity did not change after the implementation, indicating that access to treatment may not have changed. Eighty percent of the total doctor shopping quantity of buprenorphine was obtained by approximately 200 (8%) of the total patients. However, it is difficult to make any inferences about the effect of a decrease in doctor shopping, given the fractional amount of total prescribing accounted for by this practice.[33] The authors suggested that the doubling in the street price of buprenorphine after the prescription drug monitoring program implementation was an indicator of success.

An observational study of opioid-related deaths by Paulozzi et al[37] highlights some important considerations in the assessment of the effectiveness of prescription drug monitoring programs. The authors assessed the mortality rate from 1999 to 2005 from schedule II and III prescription opioids in the United States and compared states that had prescription drug monitoring programs with those that did not. They further divided states with prescription drug monitoring programs into those that proactively informed prescribers, generally by mail, of potential

misuse and those that did not. This study found no difference in the mortality rates over time for states with and without a prescription drug monitoring program, nor did states with proactive prescription drug monitoring programs perform better than those with programs that were not proactive. There was a nonsignificantly lower rate of consumption of schedule II opioids and a significantly higher rate of consumption of hydrocodone (schedule III) in states that had a prescription drug monitoring program. A major limitation of this study is that the variability in the prescription drug monitoring program structure, including the ability of health care providers to access the database, was not considered. Current applicability is somewhat limited by substantial changes in the manner in which prescription drug monitoring programs function since the study was conducted, including the extent of physician access and the definition of patient inclusion criteria. Because of the practical limitation of the delay in informing the prescriber of a patient's potential drug misuse, the proactive notification aspect of these programs would have minimal effect on emergency medical practice in states that cannot provide prescription drug monitoring program data in real time.

In conclusion, there are no studies that directly evaluate the effect of real-time, voluntary access to a prescription drug monitoring program on prescribing practices of emergency physicians. In addition, the broader effect of such access on diversion, abuse, doctor shopping, mortality, and the possibility of pain undertreatment remains undefined. Prescription drug monitoring programs have many limitations in their current format, including complex access issues, limitations on access permission, thresholds for patient listing, timeliness, interstate communication, and whether the data are presented to the physician automatically or require physician effort to retrieve. Furthermore, the recent addition of prescription drug monitoring programs in several states and continuing changes in the structure or function of existing programs limit the direct application of even recently published research. Legislation designed to improve prescription drug monitoring program operation (eg, NASPER) has stalled or remained underfunded, and concerns over patient confidentiality have often trumped public health concerns. Until an interstate, frequently updated, multiple-drug-schedule, easily accessible, widely used prescription drug monitoring system is implemented, the likelihood of success is limited.[35]

2. In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. (1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether nonopioid analgesics and nonpharmacologic therapies will be adequate for initial pain management.

(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or nonopioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.

(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

Key words/phrases for literature searches: acute low back pain, opioid, and variations and combinations of the key words/phrases.

Acute low back pain is a common ED presenting complaint. Opioids are frequently prescribed, expected, or requested for such presentations.[40,41] In a recent study, it was estimated that low back pain–related disorders result in approximately 2.6 million annual ED visits in the United States. Of medications either administered in the ED or prescribed at discharge, the most frequently used classes were opioids (61.7%; 95% CI 59.2% to 64.2%), nonsteroidal anti-inflammatory drugs (NSAIDs) (49.6%; 95% CI 46.7% to 52.3%), and muscle relaxants (42.8%; 95% CI 40.2% to 45.4%).[41] The opioid analgesics most commonly prescribed for low back pain, hydrocodone and oxycodone products, are also those most prevalent in a Government Accountability Office study of frequently abused drugs.[42] Low back pain as a presenting complaint was also observed in a recent study to be associated with patients at higher risk for opioid abuse.[43] Low back pain, although a common acute presentation, is also often persistent and recurrent, with 33% of patients continuing to complain of moderate-intensity pain and 15% of severe pain at 1 year from initial presentation. Symptoms recur in 50% to 80% of people within the first year.[44] In one study, 19% reported opioid use at a 3-month follow-up.[40] Emergency physicians, as a specialty, are among the higher prescribers of opioid pain relievers for patients aged 10 to 40 years.[20] Recent data show simultaneous increases in overall opioid sales rates and prescription opioid–related deaths and addiction rates and suggest that widespread use of opioids has adverse consequences for patients and communities.[8]

There is a paucity of literature that addresses the use of opioids after ED discharge for acute low back pain versus the use of NSAIDs or the combination of NSAIDs and muscle relaxants. Two meta-analyses published in the last 5 years identified relatively few valid studies that address the use of opioids for low back pain.[45,46]

In a Class III 2008 Cochrane review, NSAIDs were compared with opioids and muscle relaxants for the treatment of low back pain.[46] Three studies were reviewed that compared opioids (2 of which are no longer in use) with NSAIDs for treatment of acute low back pain, including 1 study considered by the Cochrane reviewers to be of higher quality.[47] None of

the individual studies found statistically significant differences in pain relief. A Class III review by McIntosh and Hall[45] of clinical evidence for treatment of acute low back pain similarly found no evidence for superiority of opioids over other therapies and no direct information to demonstrate that opioids were better than no active therapy; however, the authors concluded that the opioid-related studies were too small to detect any clinically important differences.

A Class III Cochrane review of NSAID treatment for acute low back pain evaluated 65 studies (including more than 11,000 patients) of mixed methodological quality that compared various NSAIDs with placebo, other drugs, other therapies, and other NSAIDs.[46] The review authors concluded that NSAIDs are slightly effective for short-term symptomatic relief in patients with acute and chronic low back pain without sciatica (pain and tingling radiating down the leg). In patients with acute sciatica, no difference in effect between NSAIDs and placebo was found but moderate efficacy was found for opioids. The systematic review also reported that NSAIDs are no more effective than other drugs (acetaminophen, opioids, and muscle relaxants). Placebo and acetaminophen had fewer adverse effects than NSAIDs, and NSAIDS had fewer adverse effects than muscle relaxants or opioids.

A 2003 Cochrane review of muscle relaxants for low back pain (Class X because it did not address the role of opioids) found that muscle relaxants were effective for short-term symptomatic relief in patients with acute and chronic low back pain.[48] However, muscle relaxants were associated with a high incidence of adverse effects. This study cited strong evidence in 4 trials involving a total of 294 people that oral nonbenzodiazepine muscle relaxants are more effective than placebo in patients with acute low back pain for short-term pain relief, global efficacy, and improvement of physical outcomes.

Although no superiority has been demonstrated for opioids over other therapies for treatment of acute low back pain, groups have recommended against use of opioids as first-line therapy for treatment of this problem.[49,50] A guideline for diagnosis and treatment of low back pain endorsed by the American College of Physicians and the American Pain Society recommends opioids only for severe, disabling pain that is not controlled or not likely to be controlled with acetaminophen or NSAIDs.[49] In their 2007 guidelines, the American College of Occupational and Environmental Medicine stated that routine use of opioids for acute, subacute, or chronic low back pain is not recommended.[50]

Several observational non-ED studies also suggest caution with regard to opioid prescribing for back pain. Franklin et al,[51] in a retrospective study (Class X because of the non-ED patient population), found that workers with acute low back injury and worker's compensation claims who were treated with prescription opioids within 6 weeks of acute injury for more than 7 days had a significantly higher risk for long-term disability. In a subsequent Class III population-based prospective study of opioid use among injured Washington State workers with low back pain, Franklin et al[52] observed a strong association between the amount of prescribed opioids received early after injury and long-term use of prescription opioids. A retrospective study of 98 workers with acute low back pain and subsequent disability claims by Mahmud et al[53] found that patients whose treatment of new work-related low back pain involved opioid use for 7 days or more were more likely to have long-term disability (relative risk 2.58; 95% CI 1.22 to 5.47); however, the direct applicability of this study (Class X) was limited because most patients were not seen in the ED. In another study that addressed associations of long-term outcome with opioid therapy for nonspecific low back pain, Volinn et al[54] found that the odds of chronic work loss were 11 to 14 times greater for claimants treated with schedule II ("strong") opioids compared with those not treated with opioids at all. They further observed that the strong associations between schedule II use and long-term disability suggest that for most workers, opioid therapy did not arrest the cycle of work loss and pain. Although this study was also graded as Class X because of the population selected and failure to directly address acute or immediate benefit, the results highlight potential problems of treating acute low back pain with opioids.[54] Unfortunately, causation cannot be directly inferred from these studies because of possible confounding.

In summary, although opioids currently offer the most potent form of pain relief, there is essentially no published evidence that the prescription of opioid analgesics for acute low back pain provides benefit over other available medications or vice versa. Several observational studies suggest associations of both prescription of "strong" opioids or longer prescription duration (greater than 7 days) and early opioid prescribing with worsened functional outcomes. Additionally, as noted, the overall increased rate of opioid sales has been strongly associated with adverse effects in the community (overdose, addiction, aberrant use, and death).[8] Therefore, it can be recommended that opioids not be routinely prescribed for acute low back pain but reserved for select ED patients with more severe pain (eg, sciatica) or pain refractory to other drug and treatment modalities. Prescriptions for opioids should always be provided for limited amounts and for a limited period. Extra caution (such as use of prescription drug monitoring programs and seeking of collateral patient information such as patient visit history) may be indicated for patients identified as possibly having an increased risk for substance dependence or abuse.

3. In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids?

Recommendations

Level A recommendations. None specified.

Level B recommendations. For the short-term relief of acute musculoskeletal pain, emergency physicians may prescribe short-acting opioids such as oxycodone or hydrocodone

products while considering the benefits and risks for the individual patient.

Level C recommendations. Research evidence to support superior pain relief for short-acting schedule II over schedule III opioids is inadequate.

Key words/phrases for literature searches: opioids, schedule II narcotics, schedule III narcotics, acute pain, acute disease, emergency service, and variations and combinations of the key words/phrases.

Schedules II and III are classifications established by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and determined by the Drug Enforcement Administration. Among other criteria, classification decisions for specific drugs are based on judgments about the potential for their abuse. Schedule II opioids include morphine (eg, MS Contin), oxymorphone (eg, Opana), oxycodone (eg, Roxicodone) and oxycodone combination products (eg, Percocet, Percodan), as well as hydromorphone (eg, Dilaudid) and fentanyl (eg, Duragesic patch, Actiq). Schedule III opioids include combination products, such as hydrocodone (15 mg or less) combined with acetaminophen (eg, Vicodin, Lortab) or ibuprofen (eg, Vicoprofen), as well as some of the codeine combination products.[55] Schedule classifications for opioids may change over time in response to a number of factors, including their perceived risk of abuse. Calls to reclassify hydrocodone combination products (eg, Vicodin, Lortab) from schedule III to schedule II have increased in recent years in response to increasing levels of abuse of these substances.

These recommendations address only new-onset acute pain. Long-acting or extended-released schedule II products such as oxycodone ER (OxyContin), methadone, fentanyl patches, or morphine extended-release (MS Contin) are indicated for chronic pain and should not be used for acute pain.[56] Long-acting and extended-release opioids are for use in opioid-tolerant patients only and are not intended for use as an "as-needed" analgesic. In addition, the immediate-release oral transmucosal formulations of fentanyl are indicated only for breakthrough pain relief in cancer patients who are already taking sustained-release medications and are opioid tolerant. These formulations should not be used for acute new-onset pain.

As part of the decision to prescribe opioids for new onset of acute pain, the care provider can select between short-acting schedule II or III agents (Table). In general, equianalgesic doses of opioids are equally efficacious in relieving pain. Therefore, *a priori*, there is no reason to consider an equianalgesic dose of a short-acting schedule II opioid more effective in providing pain relief than a short-acting schedule III opioid. However, some studies have compared schedule II and III opioids combined with nonopioid analgesics with one another. Two prospective randomized controlled trials have compared the efficacy of short-acting oxycodone, a schedule II drug, with hydrocodone combination products (schedule III) and found them to be equal.[57,58] In 2005, Marco et al[57] compared single doses of oxycodone 5 mg with hydrocodone 5 mg (both combined with 325 mg acetaminophen). In this single-site Class II study of 67 adolescent and adult subjects with acute fractures, no differences in analgesic efficacy were observed at 30 or 60 minutes. Constipation rates were higher for hydrocodone. In a 2002 Class I study, Palangio et al[58] compared oxycodone 5 mg combined with acetaminophen 325 mg (schedule II) with hydrocodone 7.5 mg combined with ibuprofen 200 mg (schedule III) in a prospective, multicenter, multidose, randomized controlled trial of 147 adults with acute or recurrent low back pain. During an 8-day study period, no differences were found in pain relief, doses taken, global evaluations of efficacy, health status, or pain interference with work. As noted above, equianalgesic doses of opioids have similar efficacy in the treatment of acute pain, no matter their Drug Enforcement Administration classification. Given this understanding, it was not unexpected that 2 randomized controlled trials comparing schedule II with III agents found no differences in analgesic efficacy.

Table. Short-acting oral opioid formulations. Dose and interval are recommended starting dosing ranges.

Medication	Initial Dose/Interval	Schedule
Codeine/APAP	30-60 mg* PO Q4-6h PRN	III
Codeine	30-60 mg PO Q4-6h PRN	II
Hydrocodone/APAP	5-15 mg* PO Q4-6h PRN	III
Hydromorphone	2-4 mg PO Q4-6h PRN	II
Morphine	15-30 mg PO Q4-6h PRN	II
Oxycodone/APAP	5-15 mg* PO Q4-6h PRN	II
Oxycodone	5-15 mg PO Q4-6h PRN	II
Oxymorphone	10-20 mg PO Q4-6h PRN	II

APAP, acetaminophen; *h*, hour; *mg*, milligram; *PO*, by mouth; *PRN*, as needed; *Q*, every.
*Listed dose is of the opioid component. Note that the acetaminophen component is now limited to 325 mg or less per pill.

4. In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. (1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic noncancer pain seen in the ED.

(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

(3) The clinician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and

consider past prescription patterns from information sources such as prescription drug monitoring programs.

Key words/phrases for literature searches: opioid, patient discharge, pain, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Patients with chronic noncancer pain, either already taking opioids or not, commonly present to the ED for treatment of acute exacerbation of their pain. There have been no studies that evaluate the efficacy or potential harms of prescribing opioids specifically for these patients on discharge from the ED. Thus, given the paucity of evidence, this critical question cannot be definitively answered. Despite the biological plausibility that treating any acute exacerbation of pain with parenteral or oral opioids should decrease pain intensity, no studies were found to support this hypothesis.

Only 2 randomized controlled trials were identified that addressed the use of short-acting opioids for the treatment of breakthrough pain in patients taking opioids for chronic noncancer pain; transmucosal fentanyl was the intervention for both trials.[59,60] Because of methodological problems, valid estimates for efficacy of the intervention could not be determined, but adverse event rates among both treated populations were common and similar (range 63% to 65%) (Class III).

A systematic review of nonrandomized studies by Devulder et al[61] examined the effect of rescue medications on overall analgesic efficacy and adverse events. They examined 48 studies of patients treated with long-acting opioids for chronic noncancer pain and compared the analgesic efficacy and adverse events among those that allowed short-acting opioid rescue medications for breakthrough pain with those that did not allow such rescue medications. Although graded Class X because of lack of randomized studies and the limitation of harms studied to adverse effects only, no significant difference in the analgesic efficacy between the rescue and nonrescue studies was found. There was also no difference between these 2 groups in the incidence of nausea, constipation, or somnolence. Kalso et al,[62] in a Class III systematic review, found that 80% of patients receiving opioids for chronic noncancer pain had at least 1 adverse event, including nausea (32%), constipation (41%), and somnolence (29%).

Studies of the use of opioids for chronic pain indicate that adverse effects of these drugs are common. Several studies assessed the adverse effects with the use of tramadol with acetaminophen in the treatment of patients with chronic low back pain.[63-65] All of the studies had high dropout rates and reported adverse event rates of nausea, dizziness, and somnolence between 8% and 17%. Allan et al,[66] in a nonblinded Class III study comparing transdermal fentanyl versus oral morphine, found a constipation rate of 48% in the morphine-treated patients compared with a rate of 31% in the fentanyl-treated patients. Constipation was also the major adverse effect in a Class III study by Hale et al[67] comparing oxymorphone extended release, oxycodone controlled release, and placebo. Furlan et al,[68] in a Class II meta-analysis of 41 randomized studies of opioid use in the treatment of chronic noncancer pain, found that constipation and nausea were the only significant adverse effects. Holmes et al,[69] however, in a Class III study, assessed an opioid screening instrument, the Pain Medication Questionnaire, in chronic noncancer pain patients and found that those patients with a higher score were more likely to have a substance abuse problem or request early refills of their opioid prescription. In a retrospective Class III cohort study, Jensen et al[70] conducted a 10-year follow-up on patients discharged from a pain clinic and found that chronic opioid treatment may put patients at risk for chronic depression. Unfortunately, near-universal shortcomings of these studies include the exclusion of patients with a history of substance abuse, other significant medical problems, or psychiatric disease, and lack of follow-up to detect long-term effects such as aberrant drug-related behaviors, addiction, or overdose. Therefore, studies such as these can be confounded, making the ability to draw conclusions about causality difficult.

Questions of opioid effectiveness involve the assessment of reduction in pain and improvement in function for the patient, potential patient adverse effects, and the potential harm to the community (eg, opioid diversion and abuse) from the drugs prescribed. Hall et al,[32] in a Class III retrospective analysis of 295 unintentional prescription overdose deaths, found that 93% were due to opioids, 63% represented pharmaceutical drug diversion, 21% of the patients had engaged in doctor shopping, and 95% of the patients had a history of substance abuse. Although no studies have addressed the effects related to dose and duration of prescribed opioids in this specific patient population, 2 general studies have shown a correlation between high daily opioid dose and overdose death.[71,72]

Patient assessment tools such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), Opioid Risk Tool (ORT), Diagnosis, Intractability, Risk, and Efficacy (DIRE), and others to assess the risk of prescription opioid misuse and abuse have yet to be fully validated in the ED in terms of sensitivity, specificity, and utility.[73] Many, however, believe that use of these tools, as imperfect as they are, represents a beginning in the ability to better quantify potential risks related to opioid prescribing for outpatients.

Many patients undergoing treatment for chronic noncancer pain have pain contracts/treatment agreements with their primary care providers. These should be honored if possible in treating any acute exacerbation of their pain.[74,75] As discussed in critical question 1, use of prescription drug monitoring programs may also assist the emergency physician in making appropriate clinical decisions about the use of outpatient opioid prescriptions for these patients.

FUTURE RESEARCH

Provider pain management practices related to opioids are highly variable. In part, this variability reflects the lack of evidence to guide many of these therapeutic decisions.[76]

Although there is high-quality research assessing the treatment of acute pain with opioid analgesics during the ED encounter, there is a paucity of studies assessing the benefits of prescribing opioids for discharged ED patients with acute pain and chronic noncancer pain, especially in comparison to other analgesic drugs and pain treatment modalities. Therefore, clinical decisions and practice recommendations must rely on practice experience and consensus rather than research evidence.

ED populations typically include patients with unmet substance abuse treatment needs and psychiatric comorbidities, and many of these patients present with acute pain.[77] In almost all pain studies, these patients are excluded, leaving clinicians with little evidence-based guidance for their pain management. There are also significant research gaps in clearly understanding the long-term harms of opioids, including drug abuse and addiction, aberrant drug-related behaviors, and diversion. As mentioned above, further research and validation is needed on ED patient abuse and addiction-related assessment tools. Additional studies to characterize individual patient-related risks for opioid abuse are also greatly needed.

Although there has been recent widespread adoption of prescription monitoring programs, there remains a dearth of evidence about the effectiveness of these programs in altering physician prescribing patterns or diminishing the adverse effects of opioids in the community. For research in this area to advance, further refinement of prescribing metrics (quantity, duration, and frequency) and public health measures is required. Comparison of the functionality and effectiveness of the various state prescription drug monitoring program models may provide additional insight into developing best practices that could be adopted nationally, including the sharing of data between states. Important distinctions among the states, such as immediate online prescriber access to the prescription monitoring program, should be examined for their relative contributions. However, this type of analysis must consider baseline variability among states for prescription opioid misuse (versus heroin or methadone, for example) and other state-specific issues (such as prescription-writing regulations).

With respect to the treatment of acute low back pain in the ED, there is a need for quality studies comparing the effectiveness of the more commonly prescribed opioids (hydrocodone and oxycodone congeners and other semisynthetic opioids) and nonopioid therapies, with attention to confounding variables such as depression or other psychopathology. Further study is needed to validate or refute the reported associations of early or potent opioid prescribing with increased rates of disability.[51] Given the frequency of acute low back pain as an ED presentation and its association with perceived drug-seeking behavior,[78] and with apparent higher risk for misuse,[43] more attention needs to be paid to discriminatory historical or physical factors that may be predictive of drug-seeking or abuse to allow better matching of treatment modality for individual patients.

Future studies should include additional multiple-dose analgesic protocols to better understand the postdischarge experience of patients with acute pain and what would constitute optimum patient follow-up provisions. Investigators should include clinically relevant study periods (days to weeks), which vary by diagnosis; thus, trials should be stratified by specific presenting complaints, pain site, discharge diagnosis, and classification of pain type, ie, nociceptive, neuropathic, and visceral pain. In addition to measuring pain and adverse effects, functional outcomes, such as return to work or pain-related quality-of-life measures, should be included.[79] Straightforward observational studies are needed to determine the relative duration of different acute pain presentations, thus informing decisions to prescribe an appropriate number of opioid doses per prescription. Current prescribing practice often involves a "one size fits all" pattern that is encouraged by electronic prescribing software. Prescribing practices that ignore variable durations of acute pain syndromes will predictably result in undertreatment for some patients and overtreatment for others. The latter increases the likelihood that unused opioids will be diverted into nonmedical use in communities at risk.

Additional research should include evaluation of the appropriateness of patient satisfaction as a quality metric as related to patient expectations of opioids and the prevalence of providers reporting pressure through low patient satisfaction scores or administrative complaints to provide opioids when the providers believe these drugs are not medically indicated. This issue may gain increased importance with the institution of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which may tie some reimbursement to patient satisfaction scores. Additional work is needed to investigate what constitutes an appropriate educational curriculum in both medical school and residency for physician education concerning safe, appropriate, and judicious use of opioids.

Research addressing the treatment of chronic noncancer pain would be enhanced by the use of accepted case definitions, standardized definitions of adverse events, and validated pain measurements. Case definitions should use a similar definition of chronic, nociceptive (musculoskeletal or visceral) versus neuropathic pain, or pain by disease type (headache, low back pain, etc). Research reporting also requires more refined descriptions of opioid potency and routes of administration.

Although opioids represent a treatment modality that has long been used in patient care, it is clear by the paucity of definitive answers to the questions posed in this document and the significant number of future research issues that much work remains to be done to clarify the best use of opioids in the care of patients.

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American Chronic Pain Association and has previously been a consultant to the pharmaceutical industry.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical questions.

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Evidentiary Table.

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hall et al[32]	2008	Retrospective, population based, observational study	Comparison of West Virginia medical examiner data with patient data from the state prescription monitoring program and opioid abuse treatment program records	Behaviors of those who died of a pharmaceutical overdose; diversion; doctor shopping; substance abuse history; type of drug	295 deaths; 67% male; 92% aged 18-54 y; 63% pharmaceutical diversion; 21% doctor shopping; 95% substance abuse history; 93% opioids	Actual source of opioids involved in death not known; single state; not validated definitions; retrospective	III
Pradel et al[33]	2009	Database	Review of prescription drug database (not prescription monitoring program) to identify amount of buprenorphine delivered, prescribed, and obtained by doctor shopping; extension of 2004 study, used multiple time period comparisons; evaluation of trends in doctor shopping over time	Determined prescribed quantity of buprenorphine, delivered quantity, and the doctor shopping quantity	Although there was some variation over time, the trend for prescribing stayed constant overall and doctor shopping decreased after 2004, associated with the change in the mechanism by which prescriptions are monitored	Reasons for multiple providers or overlapping or interrupted prescriptions unclear; did not examine risk factors for abuse	III
Baehren et al[39]	2010	Prospective, uncontrolled	Physicians prescribing analgesics for nonacute pain were asked details about the patient's prescription and then again after being informed of the prescription monitoring program search result for that patient	Change in prescription for the specific patient	179 enrolled; management changed in 41%; 61% received fewer opioids, 39% received more	Convenience sample; majority of data from 4 prescribers	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
McIntosh and Hall[45]	2011	Review of randomized controlled trials, systematic reviews, and observational studies found searching MEDLINE 1966-12/2009, EMBASE 1980 to 12/2009, and Cochrane database up to 12/2009; 49 studies met inclusion criteria	Multiple treatment modalities for acute low back pain, including oral drugs, local injections, and nondrug treatment	Clinical improvement of low back pain	NSAIDs shown to effectively improve symptoms compared with placebo, but use associated with gastrointestinal adverse effects; muscle relaxants may reduce pain and improve clinical assessment but are associated with adverse effects including drowsiness, dizziness, nausea	The studies examining the effects of analgesics such as acetaminophen or opioids were generally too small to detect any clinically important differences	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Roelofs et al[46]	2008	Cochrane review: search of MEDLINE, EMBASE, and Cochrane central registry of controlled trials up to 7/2007; 65 trials qualified for review	NSAIDs and COX-2 inhibitors administered to treat low back pain	Clinical improvement of low back pain	Review authors found NSAIDs are not more effective than other drugs (acetaminophen, opioids, and muscle relaxants); placebo and acetaminophen had fewer adverse effects than NSAIDs, although the latter had fewer adverse effects than muscle relaxants and opioids; the new COX-2 NSAIDs do not seem to be more effective than traditional NSAIDs but are associated with fewer adverse effects, particularly stomach ulcers, although other literature has shown that some COX-2 NSAIDs are associated with increased cardiovascular risk	7 studies reported on acute low back pain, 5 of which, including 1 higher-quality study, did not find any statistical differences between NSAIDs and opioids or muscle relaxants; there is moderate evidence that NSAIDs are not more effective than other drugs for acute low back pain	III
Videman et al[47]	1984	Double-blind parallel study	70 patients; comparative trial of meptazinol vs diflunisal for up to 3 wk	Patients examined at 1-wk intervals for task capability, range of motion, and subjective pain self-assessment	Both regimens produced marked improvement in most parameters, similar adverse effect profiles	No mention of patient randomization	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Peloso et al[63]	2004	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; 3-mo trial	336 patients randomized; improved mean final pain scores (47 vs 63; $P<.001$), adverse effects: nausea 12%, dizziness 11%, constipation 10%, somnolence 9%	35%-40% dropout rate; pharmaceutical-sponsored research	II
Ruoff et al[64]	2003	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; Roland Disability Questionnaire	318 patients randomized; tramadol improved pain VAS ($P=.15$) and final Pain Relief Rating Scale ($P<.001$); adverse effects: nausea 13%, somnolence 12%, constipation 11%, dizziness 8%	153 of 318 dropped out; pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Schnitzer et al[65]	2000	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Time to discontinuation because of inadequate pain relief; Short Form Magill Pain Questionnaire; Roland Disability Questionnaire	380 patients in open-label phase; 254 entered into blinded phase; time to therapeutic failure was greater in the placebo group ($P<.0001$); other parameters showed improvement; adverse effects: nausea 17%, dizziness 15%, somnolence 14%, headache 12%	The dropout rate was the primary outcome; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Allan et al[66]	2005	Nonblinded, randomized comparison of 2 treatments in patients with chronic low back pain	Transdermal fentanyl vs sustained-release oral morphine; 680 total patients; dose titrated to effect; followed for 13 mo; outpatient setting; not applicable to ED	Pain relief (VAS scale); bowel function (validated questionnaire); quality of life (SF-36); disease, progression (3-point scale), days not working, adverse events all during 13 mo	Comparable pain relief, noninferior, VAS score for fentanyl (56) vs morphine (55); fentanyl had lower constipation rate: fentanyl (31%) vs morphine (48%)	Both groups had half of the participants drop out; vague definition of chronic low back pain; not blinded	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hale et al[67]	2005	Randomized trial, blinded	Comparison of oxymorphone extended-release vs oxycodone controlled release vs placebo in patients with chronic low back pain who were taking a stable dose of opioids	VAS of pain score 4 h after morning dose; use of breakthrough pain medications; categorical pain intensity, pain intensity, global assessment, adverse events	Opioids were superior to placebo at reducing VAS for pain compared with placebo, oxymorphone (-27), oxycodone (-36); oxymorphone was comparable to oxycodone in pain efficacy and adverse effects; sedation and constipation were more common with opioids (35% vs 29% vs 11%)	Only 22 of 75 patients in the placebo group completed the study; included only patients receiving stable opioids and then randomized to opioids or placebo; baseline characteristics between groups not specified; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Franklin et al[52]	2009	Prospective cohort; Washington State workers with back injury; n=1,883	Prospective cohort of workers with back injuries interviewed at 18 days (medial) and 1 y after injury; pharmacy data obtained from computerized records; analyzed for demographic and covariates	Injury severity, pain, function, and quantities of opioids used	For long-term users total number of medications increased significantly (P=.01) from the first to the fourth quarter; after adjustment for baseline pain, function, and injury severity, the strongest predictor of longer-term opioid prescriptions was total number of medications in the first quarter; receipt of ≥10 mg/day medicine in first quarter more than tripled the odds of receiving opioids long term, and receipt of ≥40 mg/day medicine in first quarter had 6-fold odds of receiving long-term opioids; amount of prescribed opioid received early after injury predicts long-term use	Addressed progression to long-term use according to initial treatment and continuation of same	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Marco et al[57]	2005	Single site; prospective; double blind; randomized controlled trial; concealment method described; ED patients with fractures	Single dose of oxycodone 5 mg/acetaminophen 325 mg schedule II vs hydrocodone 5 mg/acetaminophen 325 mg schedule III	Primary outcomes were numeric pain scores (0-10) at 30 and 60 min	88 subjects evaluated, 73 enrolled, 67 completed ED study period, 35 to oxycodone, 32 to hydrocodone; no baseline differences, no differences in outcomes at 30 min: -0.6 (95% CI -1.8 to 0.5); 60 min -0.5 (95% CI -2.0 to 1.0); adverse effects higher for constipation with hydrocodone (21% vs 0%; (95% CI 3% to 39%)	Small sample size powered to address acute pain during the first 30 to 60 min in the ED; study also assessed adverse effects during a longer period of time; excluded history of alcohol or opioid or other substance abuse; limited time period	II
Palangio et al[58]	2002	Prospective multicenter (18 sites), randomized controlled trial, sequential assignment by computer-generated randomization schedule	Hydrocodone 7.5 mg/ibuprofen 200 mg (schedule III) vs oxycodone 5 mg/acetaminophen 325 mg (schedule II)	Primary outcome was mean daily pain relief score at endpoint (day 8 or day of discontinuation), study period up to 8 days, intention-to-treat analysis	147 subjects enrolled (75 hydrocodone/ibuprofen, 72 oxycodone/acetaminophen), adults with acute or recurrent low back pain requiring opioids, 85% completed study in both groups, mean days to endpoint 6.5 vs 6.9 days, no baseline differences, no differences in pain relief, number of pills, global evaluations, SF-36, pain interference with work, adverse events	Excluded drug or alcohol abuse, concealment methods described	I

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Portenoy et al[59]	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic low back pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain in chronic low back pain; adverse effects in 65%; 34% during double-blind phase	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Simpson et al[60]	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain; adverse effects in 63%; 22% dropout	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Kalso et al[62]	2004	Systematic review	Randomized trials in chronic noncancer pain comparing potent opioids with placebo	Pain intensity outcomes	15 randomized trials were included; 11 studies compared oral opioids for 4 wk; pain intensity decrease was 30% compared with placebo; only 44% were taking opioids by mo 7 to 24; 80% of patients experienced at least 1 adverse event: constipation (41%), nausea (32%), somnolence (29%)	4-wk duration on average; differing causes of pain; open label in many of the studies; limited power calculations; concealment not maintained in some studies	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/ Comments	Class
Furlan et al[68]	2006	Meta-analysis	Study included randomized trials of any opioid for chronic noncancer pain (defined as pain for longer than 6 mo) vs placebo or some other nonopioid treatment	41 randomized studies with 6,019 patients evaluated for effectiveness and adverse effects; most (80%) had nociceptive pain	81% of the studies were believed to be of high quality; dropout rates were 33% in the opioid group and 38% in the placebo group; opioids improved pain and functional outcomes compared with placebo in nociceptive and neuropathic pain; strong opioids were superior to naproxen and nortriptyline for pain relief; weak opioids were not superior; constipation and nausea were the only significant adverse effects observed	Average duration of the study was 5 wk (range 1-16 wk); adequate random patient assignment in only 17 of 41 trials; 90% of trials were pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Holmes et al[69]	2006	Prospective cohort	Convenience sample of patients who were new at a pain clinic; Pain Medication Questionnaire was administered; patients were treated with interdisciplinary treatment and/or medications alone, depending on the results of an initial evaluation	Beck Depression Inventory; Confidential Pain questionnaire; SF-36; Million VAS; Oswestry Disability Questionnaire; Physician Risk Assessment; VAS	271 patients, divided into low-, medium-, and high-score pain medication questionnaire; high-score group was more likely to have a known substance use problem (OR 2.6), request early refills (OR 3.2), or drop out of treatment (OR 2.3)	Only 26% of patients completed the full treatment program; heterogeneous types of pain diagnosis; differing treatment plans	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Jensen et al[70]	2006	Retrospective review of cohort	Patients who were treated and discharged from a pain clinic 10 y ago; medical records were abstracted and questionnaires were sent to willing participants	Demographics, health care utilization, SF-36; Hospital Anxiety and Depression Scale; Coping Strategy Questionnaire; CAGE* test	160 patients; 60% of patients were still taking long-acting opioids; dose escalation was unusual; chronic users had lower health-related quality of life and higher occurrence of depression	160 of 279 possible patients participated; no control group	III

COX-2, cyclooxygenase-2; *ED*, emergency department; *h*, hour; *mg*, milligram; *min*, minute; *mo*, month; *NSAID*, nonsteroidal anti-inflammatory drug; *OR*, odds ratio; *SF-36*, Short-Form Health Survey; *VAS*, visual analog scale; *vs*, versus; *wk*, week; *y*, year.
*CAGE (Cutting down, Annoyed, Guilty, Eye-opener) test is a method of screening for alcoholism.

Appendix A. Literature classification schema.*

Design/Class	Therapy†	Diagnosis‡	Prognosis§
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)

*Some designs (eg, surveys) will not fit this schema and should be assessed individually.
†Objective is to measure therapeutic efficacy comparing interventions.
‡Objective is to determine the sensitivity and specificity of diagnostic tests.
§Objective is to predict outcome, including mortality and morbidity.

Appendix B. Approach to downgrading strength of evidence.

	Design/Class		
Downgrading	**1**	**2**	**3**
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

Appendix 2 - Older Adults

Older Adults[17]

The prevalence of pain among older adults has been estimated between 25% and 50%. The prevalence of pain in nursing homes is even higher. Unfortunately, managing pain in older adults is challenging due to: underreporting of symptoms; presence of multiple medical conditions; polypharmacy; declines in liver and kidney function; problems with communication, mobility and safety; and cognitive and functional decline in general.

Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding, renal toxicities, and cognitive side-effects that have been observed with NSAIDs in older adults (although acetaminophen may pose a risk of liver damage). Opioids must be used with particular caution and clinicians should "start low, go slow" with initial doses and subsequent titration. Clinicians should consult the American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults for further information on the many medications that may not be recommended.

The various challenges of pain management in older adults, only sketched here, suggest that early referral and/or consultation with geriatric specialists or pain specialists may be advisable.

[17] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Appendix 3 - Pediatric Patients

Pediatric Patients[18]

Children of all ages deserve compassionate and effective pain treatment. In fact, due to their more robust inflammatory response and immature central inhibitory influences, infants and young children actually may experience greater pain sensations and pain-related distress than adults. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that opioids have a place in the treatment armamentarium. Developmental differences, however, can make opioid dosing challenging, especially in the first several months of life. In the first week of a newborn's life, for example, the elimination half-life of morphine is more than twice as long as that in older children and adults, as a result of delayed clearance. For older children, dosing must be adjusted for body weight.

Although a thorough discussion of this topic is not possible in this document, the following are summary recommendations for pain management in children and teens from the American Pain Society and the American Academy of Pediatrics:

- Provide a calm environment for procedures that reduce distress-producing stimulation;
- Use age-appropriate pain assessment tools and techniques;
- Anticipate predictable painful experiences, intervene and monitor accordingly;
- Use a multimodal approach (pharmacologic, cognitive, behavioral and physical) to pain management and use a multidisciplinary approach when possible;
- Involve families and tailor interventions to the individual child; and
- Advocate for the effective use of pain medication for children to ensure compassionate and competent management of their pain.

[18] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Appendix 4 - Opioid Risk Tool (ORT)

Date _____

Patient Name _____

OPIOID RISK TOOL

		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 Bipolar Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
TOTAL		[ ]		

Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk ≥ 8

Appendix 5 - Patient Evaluation and Risk Stratification

Patient Evaluation and Risk Stratification[19]

The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning.

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing?.

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R] or the Opioid Risk Tool [ORT]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

[19] Federation of State Medical Boards - Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers.

If possible, the patient evaluation should include information from family members and/or significant others. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community.

Appendix 6 - CAGE-AID

CAGE-AID Questionnaire

CAGE-AID Questionnaire

Patient Name _____ Date of Visit _____

When thinking about drug use, include illegal drug use and the use of prescription drug other than prescribed.

Questions:	YES	NO
1. Have you ever felt that you ought to cut down on your drinking or drug use?	☐	☐
2. Have people annoyed you by criticizing your drinking or drug use?	☐	☐
3. Have you ever felt bad or guilty about your drinking or drug use?	☐	☐
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?	☐	☐

Scoring
Regard one or more positive responses to the CAGE-AID as a positive screen.

Psychometric Properties

The CAGE-AID exhibited:	Sensitivity	Specificity
One or more Yes responses	0.79	0.77
Two or more Yes responses	0.70	0.85

(Brown 1995)

Appendix 7 - PHQ-9 Nine Symptom Checklist

PHQ-9 — Nine Symptom Checklist

Patient Name _____ **Date** _____

1. Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.

   a. Little interest or pleasure in doing things
   Not at all **Several days** **More than half the days** **Nearly every day**

   b. Feeling down, depressed, or hopeless
   Not at all **Several days** **More than half the days** **Nearly every day**

   c. Trouble falling asleep, staying asleep, or sleeping too much
   Not at all **Several days** **More than half the days** **Nearly every day**

   d. Feeling tired or having little energy
   Not at all **Several days** **More than half the days** **Nearly every day**

   e. Poor appetite or overeating
   Not at all **Several days** **More than half the days** **Nearly every day**

   f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down
   Not at all **Several days** **More than half the days** **Nearly every day**

   g. Trouble concentrating on things such as reading the newspaper or watching television
   Not at all **Several days** **More than half the days** **Nearly every day**

   h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual
   Not at all **Several days** **More than half the days** **Nearly every day**

   i. Thinking that you would be better off dead or that you want to hurt yourself in some way
   Not at all **Several days** **More than half the days** **Nearly every day**

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

   Not Difficult at All **Somewhat Difficult** **Very Difficult** **Extremely Difficult**

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PHQ-9 — Scoring Tally Sheet

Patient Name _____ **Date** _____

1. **Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.**

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c. Trouble falling asleep, staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down				
g. Trouble concentrating on things such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual				
i. Thinking that you would be better off dead or that you want to hurt yourself in some way				
Totals				

2. **If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**

Not Difficult At All	Somewhat Difficult	Very Difficult	Extremely Difficult
0	1	2	3

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How to Score PHQ-9

Scoring Method For Diagnosis

Major Depressive Syndrome is suggested if:

- Of the 9 items, 5 or more are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Minor Depressive Syndrome is suggested if:

- Of the 9 items, b, c, or d are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Scoring Method For Planning And Monitoring Treatment

Question One

- To score the first question, tally each response by the number value of each response:

  Not at all = 0

  Several days = 1

  More than half the days = 2

  Nearly every day = 3
- Add the numbers together to total the score.
- Interpret the score by using the guide listed below:

Score	Action
≤4	The score suggests the patient may not need depression treatment.
> 5-14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment.
≥15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment

Question Two

In question two the patient responses can be one of four: not difficult at all, somewhat difficult, very difficult, extremely difficult. The last two responses suggest that the patient's functionality is impaired. After treatment begins, the functional status is again measured to see if the patient is improving.

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Appendix 8 - SOAPP®-R

Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is NOT intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

SAMPLE

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PainEDU.org

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?	○	○	○	○	○

SAMPLE

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	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.

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Scoring Instructions for the SOAPP®-R

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is 2.5 times (2.53 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	2.53	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

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How does the SOAPP-R help determine appropriate treatment?
The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater*)

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician' care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21*)

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP-R score < 9*)

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

SAMPLE

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Appendix 9 - Pain Intensity and Interference (pain scale)

Pain Intensity and Interference (pain scale)[20]

Pain intensity and interference

In the last month, on average, how would you rate your pain? Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"? [*That is, your usual pain at times you were in pain.*]

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10

In the last month, how much has pain interfered with your daily activities? Use a scale from 0 to 10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

Interpretation of the Two Item Graded Chronic Pain Scale – This two item version of the Graded Chronic Pain Scale is intended for brief and simple assessment of pain severity in primary care settings. Based on prior research, the interpretation of scores on these items is as follows:

Pain Rating Item	Mild	Moderate	Severe
Average/Usual Pain Intensity	1–4	5–6	7–10
Pain-related interference with activities	1–3	4–6	7–10

Although pain intensity and pain-related interference with activities are highly correlated and tend to change together, it is recommended that change over time be tracked for pain intensity and pain-related interference with activities separately when using these two items.

For an individual patient, a reduction in pain intensity and improvement in pain-related interference with activities of two points is considered moderate but clinically significant improvement.

Similar pain ratings have been widely used in the Brief Pain Inventory, the Multidimensional Pain Inventory, and the Pain Severity Scale of the SF-12.

There is extensive research on the reliability, validity and responsiveness to change of these pain severity ratings, which is summarized in the following reference:

Von Korff M. Chronic Pain Assessment in Epidemiologic and Health Services Research: Empirical Bases and New Directions. Handbook of Pain Assessment: Third Edition. Dennis C. Turk and Ronald Melzack, Editors. Guilford Press, New York., In press

[20] Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy (Washington State Agency Medical Directors' Group)

Appendix 10 - Therapeutic Options for Pain Management

Therapeutic Options for Pain Management[21]

In treating pain, clinicians can avail themselves of five basic modalities of pain-management tools:

1. Cognitive-behavioral approaches
2. Rehabilitative approaches
3. Complementary and alternative therapies
4. Interventional approaches
5. Pharmacotherapy

Not all of these options are necessary or appropriate for every patient, but clinical guidelines suggest that all options should be considered every time a health care provider decides to treat a patient with chronic pain. These options can be used alone or in combinations to maximize pain control and functional gains. Only one of these options involves medications and opioids are only one of many types of medications with potential analgesic utility. Which options are used in a given patient depends on factors such as the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses, patient life expectancy, cost and the local availability of the treatment option.

Cognitive-behavioral Approaches

The brain plays a vitally important role in pain perception and in recovery from injury, illness or other conditions involving pain. Psychological therapies of all kinds, therefore, may be a key element in pain management. At the most basic level, such therapy involves patient education about disease states, treatment options or interventions, and methods of assessing and managing pain. Cognitive therapy techniques may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain. For example, some patients engage in an exaggeration of their condition called "catastrophizing" or they may have an overly passive attitude toward their recovery which leads them to inappropriately expect a physician to "fix" their pain with little or no work or responsibility on their part. Another way to frame this is to assess whether a patient has an internal or external "locus of control" relative to their pain. Someone with an external locus of control attributes the cause/relief of pain to external causes and they expect that the relief comes from someone else. Someone with an internal locus of control believes that they are responsible for their own well being; they own the experience of pain and recognize they have the ability and obligation to undertake remediation, with the help of others.

Some chronic pain patients have a strong external locus of control, and successful management of their pain hinges, in part, on the use of cognitive or other types of

[21] California Medical Association (Prescribing Opioids: Care amid Controversy March 2014)

therapy to shift the locus from external to internal. Individual, group or family psychotherapy may be extremely helpful for addressing this and other psychological issues, depending on the specific needs of a patient.

In general, psychological interventions may be best suited for patients who express interest in such approaches, who feel anxious or fearful about their condition, or whose personal relationships are suffering as a result of chronic or recurrent pain. Unfortunately, the use of psychological approaches to pain management can be hampered by such barriers as provider time constraints, unsupportive provider reimbursement policies, lack of access to skilled and trained providers, or a lack of awareness on the part of patients and/or physicians about the utility of such approaches for improving pain relief and overall function.

Rehabilitative Approaches

In addition to relieving pain, a range of rehabilitative therapies can improve physical function, alter physiological responses to pain and help reduce fear and anxiety. Treatments used in physical rehabilitation include exercises to improve strength, endurance, and flexibility; gait and posture training; stretching; and education about ergonomics and body mechanics. Exercise programs that incorporate Tai Chi, swimming, yoga or core-training may also be useful. Other noninvasive physical treatments for pain include thermotherapy (application of heat), cryotherapy (application of cold), counter-irritation and electroanalgesia (e.g., transcutaneous electrical stimulation). Other types of rehabilitative therapies, such as occupational and social therapies, may be valuable for selected patients.

Complementary and Alternative Therapies

Complementary and alternative therapies (CAT) of various types are used by many patients in pain, both at home and in comprehensive pain clinics, hospitals or other facilities.27 These therapies seek to reduce pain, induce relaxation and enhance a sense of control over the pain or the underlying disease. Meditation, acupuncture, relaxation, imagery, biofeedback and hypnosis are some of the therapies shown to be potentially helpful to some patients. CAT therapies can be combined with other pain treatment modalities and generally have few, if any, risks or attendant adverse effects. Such therapies can be an important and effective component of an integrated program of pain management.

Interventional Approaches

Although beyond the scope of this paper, a wide range of surgical and other interventional approaches to pain management exist, including trigger point injections, epidural injections, facet blocks, spinal cord stimulators, laminectomy, spinal fusion, deep brain implants and neuro-augmentative or neuroablative surgeries. Many of these approaches involve some significant risks, which must be weighed carefully against the potential benefits of the therapy.

Pharmacotherapy

Many types of medications can be used to alleviate pain, some that act directly on pain signals or receptors, and others that contribute indirectly to either reduce pain or improve function. For patients with persistent pain, medications may be used concurrently in an effort to target various aspects of the pain experience.

NSAIDs and Acetaminophen

Non-steroidal anti-inflammatory drugs (NSAIDs), which include aspirin and other salicylic acid derivatives, and acetaminophen, are categorized as non-opioid pain relievers. They are used in the management of both acute and chronic pain such as that arising from injury, arthritis, dental procedures, swelling or surgical procedures. Although they are weaker analgesics than opioids, acetaminophen and NSAIDs do not produce tolerance, physical dependence or addiction. Acetaminophen and NSAIDs are also frequently added to an opioid regimen for their opioid-sparing effect. Since non-opioids and opioids relieve pain via different mechanisms, combination therapy can provide improved relief with fewer side effects.

These agents are not without risk, however. Adverse effects of NSAIDs as a class include gastrointestinal problems (e.g., stomach upset, ulcers, perforation, bleeding, liver dysfunction), bleeding (i.e., antiplatelet effects), kidney dysfunction, hypersensitivity reactions and cardiovascular concerns, particularly in the elderly. The threshold dose for acetaminophen liver toxicity has not been established, although the FDA recommends that the total adult daily dose should not exceed 4,000 mg in patients without liver disease (although the ceiling may be lower for older adults).

In 2009, the FDA required manufacturers of products containing acetaminophen to revise their product labeling to include warnings of the risk of severe liver damage associated with its use. In 2014, new FDA rules went into effect that set a maximum limit of 325 mg of acetaminophen in prescription combination products (e.g. Vicodin and Percocet) in an attempt to limit liver damage and other ill effects from the use of these products. Of note, aspirin (> 325 mg/d), ibuprofen, ketoprofen, naproxen and other non-cyclooxygenase-selective NSAIDs, are listed as "potentially inappropriate medications" for use in older adults in the American Geriatrics Society 2012 Beers Criteria because of the range of adverse effects they can have at higher doses.

Nonetheless, with careful monitoring, and in selected patients, NSAIDs and acetaminophen can be safe and effective for long-term management of persistent pain.

Opioids

Opioids can be effective pain relievers because, at a molecular level, they resemble compounds, such as endorphins, which are produced naturally in the human central nervous system. Opioid analgesics work by binding to one or more of the three major types of opioid receptors in the brain and body: mu, kappa and delta receptors. The

most common opioid pain medications are called "mu agonists" because they bind to and activate mu opioid receptors. The binding of mu agonist opioids to receptors in various body regions results in both therapeutic effects (such as pain relief) and side effects (such as constipation).

Physical tolerance develops for some effects of opioids, but not others. For example, tolerance develops to respiratory suppressant effects within 5-7 days of continuous use, whereas tolerance to constipating effects is unlikely to occur. Tolerance to analgesia may develop early, requiring an escalation of dose, but tolerance may lessen once an effective dose is identified and administered regularly, as long as the associated pathology or condition remains stable.

Opioids, as a class, comprise many specific agents available in a wide range of formulations and routes of administration. Short-acting, orally-administered opioids typically have rapid onset of action (10-60 minutes) and a relatively short duration of action (2-4 hours). They are typically used for acute or intermittent pain, or breakthrough pain that occurs against a background of persistent low-level pain. Extended-release/long-acting (ER/LA) opioids have a relatively slow onset of action (typically between 30 and 90 minutes) and a relatively long duration of action (4 to 72 hours). The FDA states that such drugs are "indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

These agents achieve their extended activity in various ways. Some have intrinsic pharmacokinetic properties that make their effects more enduring than short-acting opioids, while others are modified to slow their absorption or to slow the release of the active ingredient. A given patient might be appropriate for ER/LA therapy only, short-acting only or a combination of an ER/LA opioid with a short-acting opioid. Note that patients may respond in very different ways to any given medication or combination of medications. One size does not fit all, and treatment is best optimized by titrating a given regimen on an individual basis. Combination products that join an opioid with a non-opioid analgesic entail the risk of increasing adverse effects from the non-opioid co-analgesic as doses are escalated, even if an increase of the opioid dose is appropriate.

In response to concerns about opioid misuse and abuse, abuse-deterrent and tamper-resistant opioid formulations have been developed. One class of deterrent formulation incorporates an opioid antagonist into a separate compartment within a capsule; crushing the capsule releases the antagonist and neutralizes the opioid effect. Another strategy is to modify the physical structure of
tablets or incorporate compounds that make it difficult or impossible to liquefy, concentrate, or otherwise transform the tablets. Although abuse-deterrent opioid formulations do not prevent users from simply consuming too much of a medication, they may help reduce the public health burden of prescription opioid abuse.

Patients who receive opioids on a long-term basis to treat pain are considered to be receiving long-term opioid analgesic therapy, which is differentiated from opioid use by

patients who have an established opioid use disorder who use an opioid (e.g. methadone) as part of their treatment program.

Potential Adverse Effects of Opioids

Although opioid analgesics (of all formulations) may provide effective relief from moderate-to-severe pain, they also entail the following significant risks:

- Overdose
- Misuse and diversion
- Addiction
- Physical dependence and tolerance
- Potentially grave interactions with other medications or substances
- Death

At the heart of much of the current controversy over the use of opioid analgesics for chronic pain are beliefs about the degree to which these pain medications are potentially addicting. Unfortunately, it is difficult to quantify the degree of addictive risk associated with opioid analgesics, either for an individual patient or the population of pain patients in general.

In this context, it is critical to differentiate addiction from tolerance and physical dependence which are common physiological responses to a wide range of medications and even to widely-consumed non-prescription drugs (e.g. caffeine). Physical dependence and tolerance alone are not synonymous with addiction. Addiction is a complex disease state that severely impairs health and overall functioning. Opioid analgesics may, indeed, be addicting, but they share this potential with a wide range of other drugs such as sedatives, alcohol, tobacco, stimulants and anti-anxiety medications.

Rigorous, long-term studies of both the potential effectiveness and potential addictive risks of opioid analgesics for patients who do not have co-existing substance-use disorders have not been conducted. The few surveys conducted in community practice settings estimate rates of prescription opioid abuse of between 4% to 26%. A 2011 study of a random sample of 705 patients undergoing long-term opioid therapy for non-cancer pain found a lifetime prevalence rate of opioid-use disorder of 35%.41 The variability in results reflect differences in opioid treatment duration, the short-term nature of most studies and disparate study populations and measures used to assess abuse or addiction. Although precise quantification of the risks of abuse and addiction among patients prescribed opioids is not currently possible, the risks are large enough to underscore the importance of stratifying patients by risk and providing proper monitoring and screening when using opioid analgesic therapy.

Particular caution should be exercised when prescribing opioids to patients with conditions that may be complicated by adverse effects from opioids, including chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current

or past alcohol or substance misuse, mental illness, advanced age or patients with a history of kidney or liver dysfunction.

In addition, opioids generally should not be combined with other respiratory depressants, such as alcohol or sedative-hypnotics (benzodiazepines or barbiturates) unless these agents have been demonstrated to provide important clinical benefits, since unexpected opioid fatalities can occur in these combination situations at relatively low opioid doses.

In addition to the potential risks just described, opioids may induce a wide range of side effects including respiratory depression, sedation, mental clouding or confusion, hypogonadism, nausea, vomiting, constipation, itching and urinary retention. With the exception of constipation and hypogonadism, many of these side effects tend to diminish with time. Constipation requires prophylaxis that is prescribed at the time of treatment initiation and modified as needed in response to frequent monitoring. With the exception of constipation, uncomfortable or unpleasant side effects may potentially be reduced by switching to another opioid or route of administration (such side effects may also be alleviated with adjunctive medications). Although constipation is rarely a limiting side effect, other side effects may be intolerable. Because it is impossible to predict which side effects a patient may experience, it is appropriate to inquire about them on a regular basis.

Patients should be fully informed about the risk of respiratory depression with opioids, signs of respiratory depression and about steps to take in an emergency. Patients and their caregivers should be counseled to immediately call 911 or an emergency service if they observe any of these warning signs.

As of January 2014, a California physician 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. A physician may also issue a standing order for the administration of an opioid antagonist to a person at risk of an opioid-related overdose to a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose.

The potential of adverse effects and the lack of data about the addictive risks posed by opioids do not mean these medications should not be used. Common clinical experience and extensive literature document that some patients benefit from the use of opioids on a short or long term basis. Existing guidelines from many sources, including physician specialty societies (American Academy of Pain Medicine, The American Pain Society), various states (Washington, Colorado, Utah), other countries (Canada) and federal agencies (Department of Defense, Veterans Administration), reflect this potential clinical utility.

Recommendations from authoritative consensus documents have been summarized in concise, user-friendly formats such as: Responsible Opiate Prescribing: A Clinician's

Guide for the Federation of State Medical Boards; the 2013 Washington State Labor and Industries Guideline for Prescribing Opioids to Treat Pain in Injured Workers; and the Agency Medical Directors' Group 2010 Opioid Dosing Guideline for Chronic Non-Cancer Pain.

Methadone

Particular care must be taken when prescribing methadone. Although known primarily as a drug used to help patients recovering from heroin addiction, methadone can be an effective opioid treatment for some pain conditions. Methadone is a focus of current debate because it is frequently involved in unintentional overdose deaths. These deaths have escalated as methadone has increasingly been used to treat chronic pain.

Methadone must be prescribed even more cautiously than other opioids and with full knowledge of its highly variable pharmacokinetics and pharmacodynamics. Of critical importance is the fact that methadone's analgesic half-life is much shorter than its elimination half-life. This can lead to an accumulation of the drug in the body. In addition, methadone is metabolized by a different group of liver enzymes than most other opioids, which can lead to unexpected drug interactions.

When rotating from another opioid to methadone, extreme caution must be used when referring to equianalgesic conversion tables. Consensus recommendations suggest a 75 to 90% decrement in the equianalgesic dose from conventional conversion tables when a switch is made from another opioid to methadone.

Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of mixing unauthorized substances, especially alcohol and other sedatives, with their medication. This should be explicitly stated in any controlled substance agreement that the patient receives, reads and signs before the initiation of treatment [...].

Although uncommon, potentially lethal cardiac arrhythmias can be induced by methadone. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to a history of heart disease or arrhythmias. An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease or cardiac risk factors or is taking agents that may interact with methadone. In addition, it is important that an ECG be repeated periodically, because QT interval prolongation has been demonstrated to be a function of methadone blood levels and/or in response to a variety of other medications.

Adjuvant Pain Medications

Although opioid medications are powerful pain relievers, in the treatment of neuropathic pain and some other centralized pain disorders such as fibromyalgia, they are of limited effectiveness and are not preferred. Other

classes of medications, however, may provide relief for pain types or conditions that do not respond well to opioids. Some of these adjuvant medications exert a direct analgesic effect mediated by non-opioid receptors centrally or peripherally. Others have no direct analgesic qualities but may provide pain relief indirectly via central or peripheral affects.

Commonly-used non-opioid adjuvant analgesics include antiepileptic drugs (AEDs), tricyclic antidepressants (TCAs) and local anesthetics (LAs). AEDs, such as gabapentin and pregabalin, are used to treat neuropathic pain, especially shooting, stabbing or knife-like pain from peripheral nerve syndromes.TCAs and some newer types of antidepressants may be valuable in treating a variety of types of chronic and neuropathic pain, including post-herpetic neuralgia and diabetic neuropathy. LAs are used to manage both acute and chronic pain. Topical application provides localized analgesia for painful procedures or conditions with minimal systemic absorption or side effects. Topical Las are also used to treat neuropathic pain. Epidural blocks with LAs, with or without opioids, play an important role in managing postoperative and obstetrical pain.

Non-Opiod Pain Management Tool by Jeremy Biggs MD MSPH

Area/Type of Pain	Treatment Options (Strongest Recommendations listed first)	When to Initiate	Population	Duration/Indication of Treatment	Cautions/MISC
Back Pain <4 weeks	Directed Exercise Program 1, 2, 3, 4, 5, 6	Within 7-10 days of injury	All ages	Life long	Consider co morbities
	Controlled Weight Loss 2	Immediately	All ages	Life long	Consider co morbidities
	Ice/Heat 2, 4, 6, 7	During the first 1-4 days	All ages	Most effective in first 1-3 days	Consider co morbidities
	Acetaminophen up to 4 g/day 1, 2, 4, 6, 8, 9	Immediately	Adults	Can be long term	Consider co morbidities
	Physical therapy 4, 6, 10, 11	After 3 weeks of conservative therapy	Adults	1-2 visits	Consider co morbidities
	NSAIDs 2, 4, 6, 9, 12	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers 4, 9, 13	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Back School 14, 15	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain.
	Tramadol/acetaminophen 2	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol 2	After initial acetaminophen trail	Adults	Can be long term	Consider co morbidities
	Manipulation 1, 4, 6, 16, 17, 18, 19	Most effective when used for pain <6 weeks of duration without radiculopathy	Adults	3-4 weeks of treatment has been studied. Up to 8 treatments.	Consider co morbidities, not shown to be better than other therapies. Not to be used with herniated disks
Back Pain >4 weeks	Directed Exercise Program 1, 2, 3, 4, 5, 8, 18, 19	Immediately	Adults	Life Long	Consider co morbidities
	Yoga exercises (viniyoga) 20	Immediately	Adults	Life Long, studies for 12 weekly sessions	Has been shown to be as or more beneficial than exercise in some studies.
	Controlled Weight Loss 2	Immediately	Adults	Life Long	Consider co morbidities
	Acetaminophen up to 4 g/day 1, 2, 4, 8	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs 2, 4, 12	Immediately, recommend acetaminophen trial first. Some evidence that NSAIDs are equal with acetaminophen in chronic low back pain (21) Some	Adults with no CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors

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		evidence that it is superior at pain control. (22)			
	Muscle Relaxers 4, 13	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing, some studies did not show any benefit after 3-4 weeks of injury
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and no CV risk factors.	Adults with no CV risk factors	Short term	Consider co morbidities, no CV risk factors
	Back School 14, 15, 18	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain. Swedish Back School program was studied.
	Tricyclic antidepressants 9, 23	After 3-4 weeks and failing conservative therapy, acetaminophen	Adults	As long as deemed beneficial	Have significant side effects profile, consider co morbidities
	Tramadol/acetaminophen 2	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol 2	After failing acetaminophen trial, co administration with acetaminophen has been shown to have more favorable results	Adults	Can be long term	Consider co morbidities
	Injections, epidural/facet joints 24, 25	After failing conservative treatment	Adults	As long as beneficial, if effective often last 1-4 months in duration, can be used to help diagnosis and evaluate for additional treatment options	Choose population according to guidelines. There are conflicting opinions on efficacy
	Physical Therapy 10, 11	Recommend starting immediately	Adults	1-2 visits	Consider co morbidities
	Message Therapy 26, 27, 28	Recommended in conjunction exercise and education	Adults	As long as beneficial has been shown to effective for up to one year, >5 visits shows better results, most studies showed results in 6-10 treatments	Some disagreement in literature, but done by licensed therapist found to be more effective
	Neuroreflexotherapy 29	Only in Chronic LBP	Adults	Undetermined	Preliminarily this has shown some effect. Requires lengthy training of practitioner to be considered effective
Neck Pain	Directed Exercise Program 1, 2, 3, 6, 30	Within 7-10 days of injury	All ages	Life long	Consider co morbidities, can add mechanical manipulation to an exercise program
	Acetaminophen 4g/day maximum 2, 6, 31	Immediately	Adults	Can be long term	Consider co morbidities

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	NSAIDs 6, 12, 31	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Physical Therapy 6	After 2 weeks of conservative treatment	Adults	1-2 visits for education, counseling of home exercise	Consider co morbidities
	Manipulation 6	Once more conservative measures fail	Adults	Best when combined with exercise	Consider co morbidites, rare instances of CVA
	IV methylprednisolone 31	Within 8 hours of injury for acute whiplash	Adults	One time treatment	Any contraindications to IV steroids.
	IM Lidocaine 31	Chronic neck pain with arm symptoms	Adults	Only a few treatments indicated	Consider co morbidities
	Muscle Relaxers 31	Immediately	Adults	Short term	Consider co morbidities
	Acupuncture 32	After failing exercise and/or acetaminophen/NSAIDs	Adults	Ideally 6 or more treatments, effects have been shown for short-term pain relief	Consider co morbidities
Headache	Directed exercise program 33	Immediately	Adults	When the HA is a result of a mechanical neck disorder	Consider co morbidities
	Acetaminophen 4g/day maximum 34	Immediately	Adults	Long term, has not been shown to be effective in migraines	Consider co morbidities
	NSAIDS 12, 35, 36	Immediately	Adults	Short term, shown to be effective in both migraine and non-migraine HAs	Consider co morbidities, not to be used with CV, renal or GI risk factors
	Triptans 36, 37	Use if unable to control HA with NSAIDs and or acetaminophen	Adults	Beneficial for migraine headaches. IM has been shown to be more effective than oral, but both are superior to placebo. Sumatriptan most studied	Consider co morbidities
	Excedrin 36	Immediately	Adults	Shown to be beneficial in Acute migraines	Consider co morbidities
	Amitriptyline 35	Immediately	Adults	Best for migraine headaches, can be started immediately	Monitor for side effects and complications of medication, can cause drowsiness
	Antidepressants (other TCAs, SNRIs, SSRIs) 38, 39	After failing conservative therapy	Adults	Migraine, tension, and mixed. Studies lasted 4-27 weeks	Independent of depression, SSRI least effective
	Antiemetics 36	With migraine associated nausea	Adults	Has been shown to help with pain and nausea with migraines	Consider co morbidities
	Anticonvulsants 40	After failing other therapies, for prevention	Adults	For prevention of migraine headache	Sodium valproate/divalproex sodium and topiramate are the best studied
	NSAIDS combined with metoclopromide 41	After failing acetaminophen	Adults	Migraine	Consider co morbidities, metoclopromide can cause dystonia. NNT 3.5
	DHE IM/SC/IV 36	After failing more conservative therapies	Adults	Have shown to help migraines, more effective in combination with antiemetics	Consider co morbidities
	Isometheptene 36	After failing more conservative	Adults	Found effective for mild-	Consider co morbidities

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		therapies		moderate migraine	
	Normal barometric oxygen therapy 42	Immediately	Adults	For use in Cluster Headaches	Unknown
	TENS 35	Immediately	Adults	Best for cervical tension headaches, mildly affective in some migraine headaches	Do not use in patients with pacemakers, cardiac conduction abnormalities, or over the carotid body or sinus
	Manipulation 35	Immediately	Adults	Best for tension, post-traumatic headache. Can be helpful in some migraine headaches	Choose population according to literature
	Acupuncture 43	As adjuvant treatment	Adults	Shown to be effective for both tension and migraine	Choose population according to literature, not effective for all
Osteoarthritis	Directed Exercise Program1, 2, 3, 6, 44	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss 2	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 4g/day maximum 2, 8	Immediately first line	Adults	Can be long term	Consider co morbidities
	NSAIDs 2, 12	Immediately	Younger adults, without any CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Non-acetylated salicylates 2	Immediately	Adults	Short term	Consider co morbidities, watch for ototoxicity
	Topical capsaicin 2	Immediately	Adults	Short term	Consider co morbidities
	Intra-articular steroid injection 2, 45	Immediately	Adults	Can be long term, but if too long can consider joint replacement.	This should be considered first-line therapeutic intervention if OA is confined to a single joint.
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Diacerein 46, 47	After failing other therapies	Adults	Studies lasted 2 months to 3 years	Consider co morbidities, shown to have minimal pain relief
Acute Sports Injury	Ice/Heat 2	Immediately for first 1-4 days	All ages	For first 1-4 days	Instruct on timing to not cause tissue damage
	Acetaminophen 4g/day maximum 2	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs 2, 12	Immediately, recommended to try acetaminophen first	Adults	Short term	Consider co morbidities
Neuropathic Pain	Acetaminophen 4g/day maximum 48	Immediately	Adults	Can be long term	Consider co morbidities
	Anticonvulsants 49, 50	After failing acetaminophen	Adults	Can be long term	Have a side effect profile that must be monitored. Carbamezapine and gabapentin found to most effective, some showing crabamezapine to be more

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					effective with lower NNT and higher NNH
	Systemic administration of local anesthetics 51	After failing acetaminophen	Adults	Undetermined	Can be as effective as anticonvulsants. Monitor for side effects
	Antidepressantsv34, 52	After failing acetaminophen.	Adults	Can be long term, TCAs (amitriptyline) and Venlafaxine shown to be most effective. Not shown to be effective in HIV neuropathies	Monitor for side effects, follow black box warnings. Newer SSRIs have less evidence supporting their use in neuropathic pain
Post-Herpetic Pain	Anticonvulsants 49	Immediately	Adults	While symptoms last	Can cause drowsiness
Fibromyalgia	Supervised Aerobic/Strength training exercise 53, 54, 55	Immediately, for at least 20 minutes a day 3 times a week	All ages	Life long, most studies were conducted on average for 12 weeks, 3-24 weeks.	Consider co morbidities
	Cognitive Behavioral Therapy 54, 56	Immediately	Adults	Data showed results from 6-30 months	Works best as a multidisciplinary approach
	Amitriptyline 54, 57, 58	Immediately	Adults	While beneficial	Does have side effect profile, tolerance to effect can occur
	Cyclobenzaprine 54, 57	Typically is after exercise, acetaminophen and amitriptyline	Adults	While beneficial	Significant side effects
	Acupuncture 54, 59, 60	After exercise and amitriptyline	Adults	While beneficial	Mild/weak evidence
	Deep tissue message 54	Immediately	Adults	While beneficial	Mild/weak evidence
	Fluoxetine 54	Typically start with exercise, acetaminophen, and amitriptyline first	Adults	While beneficial	Secondary to amitriptyline, can be used in conjunction with tricyclics
	Dual-reuptake inhibitors (SNRIs): 54	Immediately	Adults	While beneficial	Weaker evidence than previous medications
	Gabapentin 61	Immediately	Audlts	While beneficial, studied over a 12 week period	Consider co morbidities
	Pregabalin 54, 62, 63	Immediately	Adults	While beneficial	Still under investigation, one study showing positive results
Dental Pain	Acetaminophen 64, 65	Immediately	All ages	As needed	Consider co morbidities
	NSAIDs 65	Immediately	Adults	As needed	Consider co morbidities
	Acupuncture 57, 66	Immediately postop	Adults	1-4 sessions	
Pelvic Pain (dysmenorrheal)	Directed exercise program 67	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 68	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	NSAIDs 68, 69	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	Oral contraceptives 70	Immediately	Adults/Adolescents	While beneficial	Consider co morbidities, can be traditional or extended continuous cycle
	Acupuncture 71	Immediately	Adults	10 visits over 3 months	Consider co morbidities
	Chinese herbal medication 72	After other interventions	Adults	While beneficial	Not all interactions known

					with other medications
Pelvic Pain (chronic pelvic pain)	Directed exercise program 73	Immediately	All ages	Life long	Consider co morbidities
	Medroxyprogesterone acetate 73	Immediately	Adults	Not found to be effected after 9 months	Consider co morbidities
	Goserelin 73	After failing more conservative therapies	Adults	As long as beneficial, cannot be taken longer than six months	Consider co morbidities, extensive side effects
Pelvic Pain (Endometriosis)	Danazol 74	After failing conservative therapy	Adults	For up to 6 months	Consider co morbidities, extensive side effects
	OCPs 75	Immediately	Adults	While beneficial	Consider co morbidities
	Goserelin 75	After failing more conservative therapies	Adults	While beneficial, cannot be taken for longer than six months	Consider co morbidities, extensive side effects

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Appendix 12 – Suggested Language on Naloxone for Pain Management Agreement

- I understand that "overdose" is a risk of opioid therapy which can lead to death. I understand and can recognize the signs and symptoms of overdose including respiratory depression.

- I understand that I will be prescribed naloxone because overdose is a risk of opioid therapy. I understand that naloxone is a drug that can reverse opioid overdose. I understand when and how to use naloxone.
  - I understand it is strongly encouraged to share information about naloxone with my family and friends.
  - I understand it is strongly encouraged to teach family and friends how to respond to an overdose.

PATIENT PAIN MEDICATION AGREEMENT AND CONSENT

This agreement is important for you:

- *You will have a safe and controlled pain treatment plan.*
- *Your medicines have a high potential for abuse. They can be dangerous if used in the wrong way. You need to understand the risks that come from use of pain medicines.*

Please read and make sure you understand each statement here. Here are rules about refills and health risks. Here are also reasons for stopping your pain control treatment.

I WILL:

- ☐ I will only get my pain medicine from this clinic during scheduled appointments.
- ☐ I will take my pain medicine the way that my healthcare provider has ordered.
- ☐ I will be honest with all my healthcare providers if I am using street drugs.
- ☐ I will be honest about all the medicine I use. This includes medicine from stores and herbal medicines.
- ☐ I will be honest about my full health history.
- ☐ I will tell my healthcare provider if I go to an emergency room for any reasons.
- ☐ If I get pain medicine from an emergency room, I will tell my healthcare provider.
- ☐ I will call this office if I am prescribed any new medicine.
- ☐ I will call this office if I have a reaction to any medicine.
- ☐ I will tell all other healthcare providers that I have a pain medication agreement.
- ☐ I will tell the emergency room people that I have a pain medication agreement.
- ☐ I will take drug tests and other tests when I am told to do so.
- ☐ I will go to office visits when I am told to do so.
- ☐ I will go to physical therapy when I am told to do so.
- ☐ I will go to counseling when I am told to do so.
- ☐ I will follow directions for all treatment.
- ☐ I will show up on time for all appointments.
- ☐ I will make an appointment for refills before I run out of medicine.
- ☐ I will tell my health provider if I will be out of town so that I can get my refills.
- ☐ I will get past health records from other offices when needed.
- ☐ I will deliver these records by hand if needed. I will do this within one month of being asked. I will pay for these records if needed.
- ☐ I will give permission to this clinic to talk about my treatment with pharmacies, doctors, nurses, and others who are helping me.
- ☐ I will give permission to any healthcare provider to get information from this clinic about my health and my pain treatment.
- ☐ I will take responsibility if I overdose myself accidentally or on purpose.
- ☐ I will tell my healthcare provider if I plan to become pregnant.
- ☐ I will tell my healthcare provider if I am pregnant while I am taking pain medicine.
- ☐ I will only take this medicine the way I was told to take it.

CONTINUED ON NEXT PAGE

I WILL NOT:

- ☐ I will not share or sell, or trade any of my medicine.
- ☐ I will not drink alcohol or take street drugs while I am taking pain medicine.
- ☐ I know that I cannot call the office to have my medicine refilled over the phone.
- ☐ I will not go to the emergency room or other doctors for more pain medicine or other drugs.
- ☐ I know that when I drive a car, I must be fully alert. I know that when I use machines, I must also be fully alert. Pain medicines can make me less alert. When I am taking pain medicines, I need to be sure that I am alert. I need to be sure that it is safe for me to drive a car or use a machine.
- ☐ I will not stand in high places or do anything to hurt others after I have taken pain medicine.
- ☐ I will not leave my medicine where it can be stolen or where others can take it.
- ☐ I will not leave my medicine where children can find it.
- ☐ I will not suddenly stop taking my medicine. I know that if I do this, I can have withdrawals.

WHEN USING A PHARMACY, I WILL:

- ☐ I will use the same pharmacy for all my medicines. This is the pharmacy that I have picked: _____
- ☐ I will not ask for early refills or more pain medicine, even if I lose my medicine.

I KNOW THAT

- ☐ Pain management may include other treatment. Some treatment may not include medicine.
- ☐ Pain medicine will probably not get rid of all of my pain. Pain medicine can reduce my pain so that I can do more and have a better life.
- ☐ Part of my treatment is to reduce my need for pain medicine.
- ☐ If the pain medicines work, I will continue to use them. If the pain medicine does not help me, it will be stopped.
- ☐ My medicines will not be replaced if any of these things happen: Medicine is lost. Medicine gets wet. Medicine is destroyed
- ☐ If my medicine is stolen, I might be able to get more medicine if I get a report from the police about the medicine being stolen.
- ☐ Any of my healthcare providers can find out from the California Prescription Drug Monitoring Program about any other medicines I get from any other pharmacy in California. This is called a CURES report.
- ☐ My healthcare provider may contact the drug enforcement agency, if I try to get other doctors to give me pain medicine.
- ☐ Healthcare providers may contact the drug enforcement agency if I am not honest about how I take pain medicine.
- ☐ My doctor and my clinic will help with any investigation if I am suspected of prescription drug abuse.
- ☐ I may be sent somewhere else for drug abuse or addiction help if I need it.
- ☐ Pain medicine can be addictive. This means that my body may need more and more pain medicine or that it can be hard for me to stop taking this medicine.
- ☐ If I suddenly stop using the medicine, I can get withdrawals.
- ☐ If I use too much pain medicine, I can end up with health problems. I could die.
- ☐ If I mix medicines, I could also end up with health problems. I could die.
- ☐ Here are some things that could go wrong if I use too much medicine or mix medicines:

Overdose	Addiction	Constipation	Vomiting	Sleepiness
Slower reflexes	Nausea	Difficulty with urination	Confusion	Itching
Problems with sex	Dry mouth	Depression	Trouble breathing	Death

CAUSE FOR DISMISSAL FROM THIS CLINIC

- ☐ I know that the pain medicines may be stopped if I break any part of this contract.

My signature below means that I have read this contract. I am signing this to say that I understand all of this contract.

Patient Name _____ Doctor Name _____

Patient Signature _____ Doctor Signature _____

Date: _____

Appendix 14 – Suggested Treatment Plan Using Prescription Opioids

Treatment Plan Using Prescription Opioids

Patient name: _____

Prescriber name: _____

THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.

I (patient) understand the following (initial each):

_____ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: _____

_____ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: _____

_____ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

_____ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

_____ There is a small risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

I agree to the following (initial each):

_____ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

_____ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

_____ I agree not to share, sell, or in any way provide my medication to any other person.

_____ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

_____ I agree not to seek or obtain **ANY** mood-modifying medication, including pain relievers or tranquilizers from **ANY** other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

_____ I agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

_____ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

_____ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.

_____ _____

Patient Signature Date

_____ _____

Prescriber Signature Date

Appendix 15 – Suggested Strategies for Tapering and Weaning

Strategies for Tapering & Weaning

Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation ("You are indifferent to my suffering")
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

TOOLS

TAB 8

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Tools & Resources

Health Information Privacy (HIPAA Guidelines)

FAQ's

PDMP Registration

A streamlined application and approval process for access to the Controlled Substance Utilization Review and Evaluation System (CURES) 2.0 is nearing completion and will become available during Summer 2015. Prescribers and pharmacists are encouraged to register for CURES access as soon as possible in observance of new mandates to enroll before **January 1, 2016.**

California Prescription Drug Monitoring Program (PDMP)

The California Prescription Drug Monitoring Program (PDMP), CURES, is committed to assisting in the reduction of pharmaceutical drug diversion without affecting legitimate medical practice and patient care.

The CURES system is designed to identify and deter drug abuse and diversion through accurate and rapid tracking of Schedule II through IV controlled substances. It is a valuable investigative, preventive and educational tool for law enforcement, regulatory boards, educational researchers, and the healthcare community.

The Department of Justice PDMP system allows pre-registered users including licensed healthcare prescribers, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards to access timely patient prescription history information to better identify and prevent the abuse of prescription drugs. The role of the PDMP entrusts that well informed prescribers and pharmacists can and will use their professional expertise to evaluate their patients care and assist those patients who may be abusing controlled substances.

In order to obtain access to the PDMP System you must submit a registration form electronically. Please be sure to complete the correct form:

- BNE Admin
- BNE Analyst
- DOJ Investigator
- Law Enforcement Agency
- Non-BNE Support
- Pharmacist
- Practitioner
- Regulatory Board

Please note that CURES applicants must complete their registration process by submitting an online registration. Additionally, they must submit a notarized application form (available to print immediately after submitting the online registration), along with the validating documents listed at the top of each application form. Having the following documents available will be helpful to completing the registration application: U.S. Government-issued ID, Drug Enforcement Administration (DEA) Registration, State Professional License (i.e., Physician, Pharmacist, Veterinarian, Physician Assistant, Registered Nurse, etc.) The application must be submitted to the Bureau of Criminal Identification & Investigative Services/PDMP, P.O. Box 160447, Sacramento, CA 95816, or electronically in the form of PDF attachments to pmp@doj.ca.gov .

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PDMP Registration: Practitioner

Application Instructions

To submit this application, complete the following steps:

Step 1: Complete the on-line application form then click the 'Submit' button.

Step 2: Upon successful submission of this form, you will see a confirmation page with additional instructions for completing the registration process.

Important Notes

*Indicates Required Fields

Your E-Mail Address will be used for communicating account information and system notifications. It is therefore very important that this be an E-Mail Address that only you have access to and is not accessible by others. If this condition is not met your registration will be denied.

For assistance, contact the Help Desk at (916) 227-3843 or pmp_registration@doj.ca.gov

Applicant Information:

Last Name *

First Name *

Date of Birth mm/dd/yyyy *

E-Mail Address *

Re-Enter E-mail Address *

Contact Phone *

State Medical License# *

NPI#

Specialty *

-- Select One --

Other Specialty

Degree *

-- Select One --

Other Degree

Address Information

First Address

Business Name * Street Address *

Phone# * City * State * Zip *

Select a State

County *

DEA# *

Please check all options that apply to this location *

☐ Business Location ☐ Home Location ☐ Listed on DEA Certificate

Second Address

Business Name Street Address

Phone# City State Zip

Select a State

County

DEA#

Please check all options that apply to this location

☐ Business Location ☐ Home Location ☐ Listed on DEA Certificate

Account Information

Would you like to receive Notifications/Alerts?: *

○ No ○ Yes

Must create your own individual answers and not answers that are agency sanctioned

Question * Answer *

In what city or town was your first job?

Question * Answer *

In what city or town was your first job?

Question * Answer *

In what city or town was your first job?

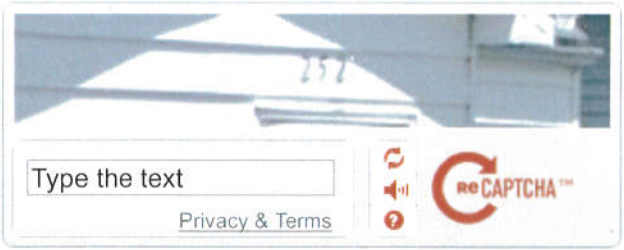
Question * Answer *

In what city or town was your first job?

Question * Answer *

In what city or town was your first job?

Application Validation



The CAPTCHA feature requires that you enter both words exactly as they appear, separated by a space. If you cannot read both words simply click the refresh button, which looks like two arrows in a circle, next to the CAPTCHA words and you will be prompted with two new words.

Application Certification

User Agreements

The California Prescription Drug Monitoring Program's (PDMP) mission is to reduce pharmaceutical drug diversion while promoting legitimate medical practice and patient care. PDMP accumulates Schedule II through IV controlled substance prescription and dispensation information for facilitating

I certify the facts stated above are true to the best of my knowledge.

I accept the terms and conditions of the User Agreements.

☐ **I CERTIFY/AGREE TO THE ABOVE ***

For assistance, contact the Help Desk at (916) 227-3843 or pmp_registration@doj.ca.gov

Submit Reset

TAB 9

Section 2064.2. (Added by Stats. 1989, Ch. 425, Sec. 1.)
Cite as: Cal. Bus. & Prof. Code §2064.2.

No medical school or clinical training program shall deny access to elective clerkships or preceptorships in any medical school or clinical training program in this state solely on the basis that a student is enrolled in an osteopathic medical school.

Any violation of this section or Section 2064.1 may be enjoined in an action brought in the name of the people of the State of California by the district attorney of the county in which the violation occurs, upon receipt of a complaint by an aggrieved student.

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OCLAW.ORG - California Legal Reference

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TAB 10

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TAB 11

Osteopathic Medical Board

Future Agenda Items

Agenda Item	Requestor
Federation State Medical Board (Liaison Attendance)	
Strategic Plan	

TAB 12

Osteopathic Medical Board

Future Meeting Dates

Date	Place	Time
September 17, 2015 (Tentative)	DCA-HQ2 (Hearing Room) 1747 North Market Blvd. Sacramento, CA 95834	10:00 a.m.- 5:00p.m.

**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.*