

**BOARD OF REGISTERED NURSING**  
**Nursing Practice Committee**  
**Agenda Item Summary**

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**AGENDA ITEM: 10.1**  
**DATE: June 16, 2016**

**ACTION REQUESTED:**       **Vote on Whether to Recommend Initiating Formal Rulemaking Process for Draft Regulatory Language for Article 8 Standards for Nurse Practitioner with the Office of Administrative Law.**

**REQUESTED BY:**           Trande Phillips RN Chair  
Nursing Practice Committee

**BACKGROUND:**

The proposed language for regulatory revisions to Article 8 Nurse Practitioners §1480-1485 and to add section 1483.1 Requirements for Nurse Practitioner Education Programs in California, 1483.2 Requirements for Reporting Nurse Practitioner Education Programs, 1486 Requirements for Clinical Practice Experience for Nurse Practitioner Students Enrolled in Out of State Nurse Practitioner Education Program. If approved by the Practice Committee and Board the language as attached will enter into the regulatory revision process as required by the Office of Administrative Law.

The following organizations have provided comment on the proposed language for Article 8 Standards for Nurse Practitioner Practice: California Action Coalition, California Association of Nurse Practitioners, California Hospital Association, Association of California Nurse Leaders, Western University of Health, American Nurses Association/California, California Nursing Association, SEIU 121 Nursing and letters from practicing nurse practitioners (see attachment for each Practice Committee and Board meeting at “meetings” on the BRN website)

Many of the organizations and individuals representing nurse practitioners are requesting the proposed regulations include national certification in a specialty/category. At the April 14, 2016 Board meeting DCA legal presented Business and Professions Section 350 and 350.1 that contains the prohibition of adding such a national certification requirement in regulation that is not established in law.  
(see attachment)

The following interested party letters were received and are attached:

The Dean and Interim Director of the University of California (UC) Schools/Programs of Nursing- Heather M Young, PhD, RN, FAAN, E. Alison Holman, PhD, FNP, RN, FAAN  
Linda Sarna, PhD, RN, FAAN, David Vlahov, PhD, RN, FAAN  
Barbara J. Ritter, Ed.D, FNP  
Chad R. Barylski, NP-C, DC, DACBSP  
Emily J. Baker, RN, FNP-C

Previous letter received for the Board's Practice Committee:  
Samuel Merritt University Faculty, Sacramento Campus  
Samuel Merritt University Scot D. Foster CRNA, PhD, FAAN Academic Vice President/Provost  
Nancy Trego, DNP,GNP-C ,CANP and member Health Policy Practice & Practice Committee

The Practice Committee and Board have provided the following meetings for interested parties to provide review and comment on proposed language for Article 8 Standards for Nurse Practitioner Practice as a preliminary activity before the formal rulemaking process.

- August 6, 2015 Practice Committee
- September 3, 2015 Board Meeting
- October 8, 2015 Practice Committee
- November 5, 2015 Board Meeting
- January 14, 2016 Practice Committee
- February 11, 2016 Board Meeting

The Board's Nursing Education Consultants developed a comprehensive review of nurse practitioner practice, education, and regulation from a variety of state and national sources to produce changes to California Code of Regulation §1480-1484.

Place on Board agenda.

**NEXT STEPS:**

**FISCAL IMPACT, IF ANY:**

**None**

**PERSON(S) TO CONTACT:**

Janette Wackerly, MBA, BSN, RN  
Supervising Nursing Education Consultant  
[Janette.Wackerly@dca.ca.gov](mailto:Janette.Wackerly@dca.ca.gov)  
(916) 574-7686

#### 1480. Definitions.

- (a) “Nurse practitioner” means an advanced practice registered nurse who meets board education and certification requirements and possesses additional advanced practice educational preparation and skills in physical diagnosis, psycho-social assessment, and management of health-illness needs in primary health care, and/or acute care, who has been prepared in a program conforms to board standards as specified in Section 1484.
- (b) “Primary health care” is that which occurs when a consumer makes contact with a health care provider who assumes responsibility and accountability for the continuity of health care regardless of the presence or absence of disease. “Primary care” means comprehensive and continuous care provided to patients, families, and the community. Primary care focuses on basic preventative care, health promotion, disease prevention, health maintenance, patient education and the diagnoses and treatment of acute and chronic illnesses in a variety of practice settings.
- (c) “Clinically competent” means that one the individual possesses and exercises the degree of learning, skill, care and experience ordinarily possessed and exercised by a member of the appropriate discipline in clinical practice certified nurse practitioner providing healthcare in the same nurse practitioner category.
- (d) “Holding oneself out” means to use the title of nurse practitioner. “Acute care” means restorative care provided by the nurse practitioner to patients with rapidly changing, unstable, chronic, complex acute and critical conditions in a variety of clinical practice settings.
- (e) “Category” means the population focused area of practice in which the certified nurse practitioner provides patient care.
- (f) “Advanced health assessment” means the knowledge of advanced processes of collecting and interpreting information regarding a patient’s health care status. Advanced health assessment provides the basis for differential diagnoses and treatment plans.
- (g) “Advanced pathophysiology” means the advanced knowledge and management of physiological disruptions that accompany a wide range of alterations in health.
- (h) “Advanced pharmacology” means the integration of the advanced knowledge of pharmacology, pharmacokinetics, and pharmacodynamics content across the lifespan and prepares the certified nurse practitioner to initiate appropriate pharmacotherapeutics safely and effectively in the management of acute and chronic health conditions.
- (i) “Nurse practitioner curriculum” means a curriculum that consists of the graduate core; advanced practice registered nursing core, and nurse practitioner role and population-focused courses.
- (j) “Graduate core” means the foundational curriculum content deemed essential for all students pursuing a graduate degree in nursing.
- (k) “Advanced practice registered nursing core” means the essential broad-based curriculum required for all nurse practitioner students in the areas of advanced health assessment, advanced pathophysiology, and advanced pharmacology.
- (l) “California based nurse practitioner education program” means a board approved academic program, physically located in California that offers a graduate degree or

graduate level certificate to qualified students and is accredited by a nursing organization recognized by the United States Department of Education or the Council of Higher Education Accreditation.

- (m) “Clinical practice experience” means supervised direct patient care in the clinical setting that provides for the acquisition and application of advanced practice nursing knowledge, skills, and competencies.
- (n) “Direct supervision of students” means a clinical preceptor or a faculty member is physically present at the practice site. The clinical preceptor or faculty member retains the responsibility for patient care while overseeing the student.
- (o) “Lead nurse practitioner educator faculty” means the nurse practitioner faculty member of the nurse practitioner education program who has administrative responsibility for developing and implementing the curriculum in the nurse practitioner category.
- (p) “Major curriculum change” means a substantive change in a nurse practitioner education program curriculum, structure, content, method of delivery, or clinical hours.
- (q) “National Certification” means the certified nurse practitioner has passed an examination provided by a national certification organization accredited by the National Commission for Certifying Agencies or the American Board of Nursing Specialties, as approved by the board.
- (r) “Nurse practitioner education program director” means the individual responsible for administration, implementation, and evaluation of the nurse practitioner education program and the achievement of the program outcomes in collaboration with program faculty.
- (s) “Non-California based nurse practitioner education programs” means an academic program accredited by a nursing organization recognized by the United States Department of Education or the Council of Higher Education Accreditation that offers a graduate degree or graduate level certificate to qualified students and does not have a physical location in California.

Authority cited: Sections 2715, 2725(c), 2725.5, 2835.5, 2836, 2836.1, Business and Professions Code. References: Section 2834 and 2836.1, Business and Professions Code.

#### **1481. Categories of Nurse Practitioners.**

~~A registered nurse who has met the requirements of Section 1482 for holding out as a nurse practitioner, may be known as a nurse practitioner and may place the letters “R.N., N.P.” after his/her name alone or in combination with other letters or words identifying categories of specialization, including but not limited to the following: adult nurse practitioner, pediatric nurse practitioner, obstetrical-gynecological nurse practitioner, and family nurse practitioner.~~

- (a) Categories of nurse practitioners shall include, but are not limited to the following:
  - (1) Family/individual across the lifespan;
  - (2) Adult-gerontology, primary care or acute care;
  - (3) Neonatal;
  - (4) Pediatrics, primary care or acute care;

- (5) Women's health/gender-related;
- (6) Psychiatric-Mental Health across the lifespan.
- (b) A registered nurse who has been certified by the board as a nurse practitioner may use the title, "advanced practice registered nurse," and or "certified nurse practitioner" and may place the letters APRN-CNP after his or her name or in combination with other letters or words that identify the category.

Authority cited: Sections 2715, 2835.5, 2836, Business and Professions Code.  
Reference: Sections 2834 and 2836, 2836.1 and 2837, Business and Professions Code.

### **1482. Requirements for ~~Holding Out As a~~ Certification as a Nurse Practitioner.**

~~The requirements for holding oneself out as a nurse practitioner are:~~

- (a) To obtain certification as a Nurse Practitioner, an applicant must hold a valid and active license as a registered nurse in California and possess a master's degree in nursing, a master's degree in a clinical field related to nursing, or a graduate degree in nursing and one of the following:
  - ~~(a) active licensure as a registered nurse in California; and~~
  - ~~(b) one of the following:~~
    - ~~(1) Successful completion of a nurse practitioner education program approved by the Board; of study which conforms to board standards; or~~
    - ~~(2) National Certification as a nurse practitioner by a national or state organization whose standards are equivalent to those set forth in Section 1484; or in one or more categories from a national certification organization accredited by the National Commission on Certifying Agencies or the American Board of Nursing Specialties, as approved by the Board.~~
  - ~~(3) (b) A nurse who has not completed an academically affiliated nurse practitioner education program of study which meets board standards as specified in Section 1484, or shall be able to provide: evidence of having completed equivalent education and supervised clinical practice, as set forth in this article.~~
    - ~~(A) Documentation of remediation of areas of deficiency in course content and/or clinical experience, and~~
    - ~~(B) Verification by a nurse practitioner and by a physician who meet the requirements for faculty members specified in Section 1484(c), of clinical competence in the delivery of primary health care.~~
  - (c) Graduates who have completed a nurse practitioner education program in a foreign country shall meet the requirements as set forth in this article. The applicant shall submit the required credential evaluation through a board approved evaluation service evidencing education equivalent to a Master's or Doctoral degree in Nursing.

Note: Authority cited: Section 2715, Business and Professions Code. Reference: Sections 2835 and 2836, Business and Professions Code.

### **1483. Evaluation of Credentials.**

An application for evaluation of a registered nurse's qualifications ~~to hold out to be certified~~ as a nurse practitioner shall be filed with the board by submitting forms

Application for Nurse Practitioner Certification (rev 5/2014) and Nurse Practitioner Furnishing Number Application (rev 10/2012) on a form prescribed by the board and shall be accompanied by the fee prescribed in Section 1417 and such evidence, statements or documents as therein required by the board, to conform with Sections 1482 and 1484.

A Nurse Practitioner application shall include submission of the following information:

- (a) Name of the graduate nurse practitioner education program or post-graduate nurse education practitioner program.
- (b) Official sealed transcript with the date of graduation or post-graduate program completion, nurse practitioner category, credential conferred, and the specific courses taken to provide sufficient evidence the applicant has completed the required course work including the required number of supervised direct patient care clinical practice hours.

A student who graduate from a board approved nurse practitioner education program shall be considered a graduate of a nationally accredited program if the program held national nursing accreditation at the time the graduate completed the program. The program graduate is eligible to apply for nurse practitioner certification with the board regardless of the program's national nursing accreditation status at the time of submission of the application to the Board.

The board shall notify the applicant in writing that the application is complete and accepted for filing or that the application is deficient and what specific information is required within 30 days from the receipt of an application. A decision on the evaluation of credentials shall be reached within 60 days from the filing of a completed application. The median, minimum, and maximum times for processing an application, from the receipt of the initial application to the final decision, shall be 42 days, 14 days, and one year, respectively, taking into account Section 1410.4(e) which provides for abandonment of incomplete applications after one year.

Note: Authority cited: Sections 2715 and 2718, Business and Professions Code.  
Reference: Sections 2815 and 2835.5, Business and Professions Code.

### **1483.1 Requirements for Nurse Practitioner Education Programs in California.**

- (a) The nurse practitioner education program shall:
  - (1) Provide evidence to the board that the nurse practitioner program is in an accredited academic institution located in California.
  - (2) Be an academic program approved by the board and accredited by a nursing organization recognized by the United States Department of Education or the Council of Higher Education Accreditation that offers a graduate degree or graduate level certificate to qualified students.
  - (3) Provide the board evidence of ongoing continuing nurse practitioner education program accreditation within 30 days of the program receiving this information from the national nursing accreditation body.

- (4) Notify the board of changes in the program's institutional and national nursing accreditation status within 30 days.
- (b) The board may grant the nurse practitioner education program initial and continuing approval when the board receives the required accreditation evidence from the program.
- (c) The board may change the approval status for a board approved nurse practitioner education program at any time, if the Board determines the program has not provided necessary compliance evidence to meet board regulations notwithstanding institutional and national nursing accreditation status and review schedules.

Authority cited: Section 2715, Business and Professions Code. Reference: Sections 2785, 2786, 2786.5, 2786.6, 2788, 2798, 2815 and 2835.5, Business and Professions Code.

### **1483.2 Requirements for Reporting Nurse Practitioner Education Program Changes.**

- (a) A board approved nurse practitioner education program shall notify the board within thirty (30) days of any of the following changes:
  - (1) A change of legal name or mailing address prior to making such changes. The program shall file its legal name and current mailing address with the board at its principal office and the notice shall provide both the old and the new name and address as applicable.
  - (2) A fiscal condition that adversely affects students enrolled in the nursing program.
  - (3) Substantive changes in the organizational structure affecting the nursing program.
- (b) An approved nursing program shall not make a substantive change without prior board notification. Substantive changes include, but are not limited to the following:
  - (1) Change in location;
  - (2) Change in ownership;
  - (3) Addition of a new campus or location;
  - (4) Major curriculum change.

Authority cited: Section 2715, Business and Professions Code. Reference: Sections 2785, 2786, 2786.5, 2786.6, 2788, 2798, 2815 and 2835.5, Business and Professions Code.

### **1484. Standards of Nurse Practitioner Education.**

- (a) The program of study preparing a nurse practitioner shall meet the following criteria: Be approved by the board and be consistent with the nurse practitioner curriculum core competencies as specified by the National Organization of Nurse Practitioner Faculties.
- (a) (b) Purpose, Philosophy and Objectives
  - (1) have as its primary purpose the preparation of registered nurses who can provide primary health care; The purpose of the nurse practitioner education program shall be to prepare a graduate nurse practitioner to provide competent primary care and/or acute care services in one or more of the categories.

~~(2) have a clearly defined philosophy available in written form; Written program materials shall reflect the mission, philosophy, purposes, and outcomes of the program and be available to students.~~

~~(3) have objectives which reflect the philosophy, stated in behavioral terms, describing the theoretical knowledge and clinical competencies of the graduate. Learning outcomes for the nurse practitioner education program shall be measurable and reflect assessment and evaluation of the theoretical knowledge and clinical competencies required of the graduate.~~

~~(b) (c) Administration and organization of the nurse practitioner education program shall:~~

~~(1) Be conducted in conjunction with one of the following:~~

~~(A) (1) An institution of higher education that offers a baccalaureate or higher degree in nursing, medicine, or public health. Be taught in a college or university accredited by a nursing organization that is recognized by the United States Department of Education or the Council of Higher Education Accreditation that offers a graduate degree to qualified students.~~

~~(B) (2) A general acute care hospital licensed pursuant to Chapter 2 (Section 1250) of Division 2 of the Health and Safety Code, which has an organized outpatient department. Prepare graduates for national certification as a certified nurse practitioner in one or more nurse practitioner category by the National Commission on Certifying Agencies or the American Board of Nursing Specialties.~~

~~(2) (3) Have admission requirements and policies for withdrawal, dismissal and readmission that are clearly stated and available to the student in written form.~~

~~(3) (4) Have written policies for clearly informing applicants of the academic accreditation and board approval status of the program.~~

~~(4) (5) Provide the graduate with official evidence indicating that he/she has demonstrated clinical competence in delivering primary health care and has achieved all other objectives of the program. Document the nurse practitioner role and the category of educational preparation on the program's official transcript.~~

~~(5) (6) Maintain systematic, retrievable records of the program including philosophy, objectives, administration, faculty, curriculum, students and graduates. In case of program discontinuance, the board shall be notified of the method provided for record retrieval. Maintain a method for retrieval of records in the event of program closure.~~

~~(6) (7) Provide for program evaluation by faculty and students during and following the program and make results available for public review. Have and implement a written total program evaluation plan.~~

~~(8) Have sufficient resources to achieve the program outcomes.~~

~~(c) (d) Faculty. There shall be an adequate number of qualified faculty to develop and implement the program and to achieve the stated objectives.~~

~~(1) There shall be an adequate number of qualified faculty to develop and implement the program and to achieve the stated outcomes.~~

~~(1) (2) Each faculty person member shall demonstrate current competence in the area in which he/ or she teaches.~~

~~(3) There shall be a lead nurse practitioner faculty educator who meets the faculty qualifications and is nationally certified in the same category track he or she serves as the lead faculty.~~

(4) Faculty who teach in the nurse practitioner education program shall be educationally qualified and clinically competent in the same category as the theory and clinical areas taught. Faculty shall meet the following requirements:

(A) Hold an active, valid California registered nurse license;

(B) Have a Master's degree or higher degree in nursing;

(C) Have at least two years of clinical experience as a nurse practitioner, certified nurse midwife, clinical nurse specialist, or certified registered nurse anesthetist within the last five (5) years of practice and consistent with the teaching responsibilities.

(5) Faculty teaching in clinical courses shall be current in clinical practice.

(6) Each faculty member shall assume responsibility and accountability for instruction, planning, and implementation of the curriculum, and evaluation of students and the program.

(7) Interdisciplinary faculty who teach non-clinical nurse practitioner nursing courses, such as but not limited to, pharmacology, pathophysiology, and physical assessment, shall have a valid and active California license issued by the appropriate licensing agency and an advanced graduate degree in the appropriate content areas.

(e) Director.

(1) The nurse practitioner education program director shall be responsible and accountable for the nurse practitioner education program within an accredited academic institution including the areas of education program, curriculum design, and resource acquisition, and shall meet the following requirements:

(2) The director or co-director of the program shall:

(A) ~~be a~~ Hold an active, valid California registered nurse license;

(B) ~~Have held~~ a Master's or ~~a~~ higher degree in nursing ~~or a related health field from an accredited college or university;~~

(C) ~~H~~have had one academic year of experience, within the last five (5) years, as an instructor in a school of professional nursing, or in a program preparing nurse practitioners.

(D) Be certified by the board as a nurse practitioner and by a national certification organization as a nurse practitioner in one or more nurse practitioner categories.

(2) The director, if he or she meets the requirements for the certified nurse practitioner role, may fulfill the lead nurse practitioner faculty educator role and responsibilities.

(f) Clinical Preceptors.

(1) A clinical preceptor in the nurse practitioner education program shall:

(3) Faculty in the theoretical portion of the program must include instructors who hold a Master's or higher degree in the area in which he or she teaches.

(4) (A) A clinical instructor shall ~~H~~hold an active licensure valid, California license to practice his/ or her respective profession and demonstrate current clinical competence.

(5) (B) A clinical instructor shall ~~P~~participate in teaching, supervising, and evaluating students, and shall be ~~appropriately matched~~ competent with in the content and skills being taught to the students.

(2) A clinical preceptor is a health care provider qualified by education, licensure and clinical competence in a nurse practitioner category and who provides direct supervision of the clinical practice experiences for a nurse practitioner student.

(3) Clinical preceptor functions and responsibilities shall be clearly documented in a written agreement between the agency, the preceptor, and the nurse practitioner education program including the clinical preceptor's role to teach, supervise and evaluate students in the nurse practitioner education program.

(4) A clinical preceptor is oriented to program and curriculum requirements, including responsibilities related to student supervision and evaluation;

(5) A clinical preceptor shall be evaluated by the program faculty at least every two (2) years.

~~(d)~~ (g) Curriculum—Students shall hold an active, valid California registered nurse license to participate in nurse practitioner education program clinical experiences.

(h) Nurse Practitioner Education Program Curriculum.

The nurse practitioner education program curriculum shall include all theoretical and clinical instruction that meet the standards set forth in this section and be consistent with national standards for graduate and nurse practitioner education, including nationally recognized core role and category competencies and be approved by the board.

~~(1) The program shall include all theoretical and clinical instruction necessary to enable the graduate to provide primary health care for persons for whom he/she will provide care.~~

~~(2) The program shall provide evaluation~~ evaluate ~~of previous education and/ or experience in primary health care for the purpose of granting credit for meeting program requirements.~~

~~(3) (2) Training for practice in an area of specialization shall be broad enough, not only to detect and control presenting symptoms, but to minimize the potential for disease progression.~~ The curriculum shall provide broad educational preparation and include a graduate core, advance practice registered nurse core, the nurse practitioner core role competencies, and the competencies specific to the category.

~~(4) (3) Curriculum, course content, and plans for clinical experience shall be developed through collaboration of the total faculty.~~ The program shall prepare the graduate to be eligible to sit for a specific national nurse practitioner category certification examination consistent with educational preparation.

~~(5) (4) Curriculum, course content, methods of instruction and clinical experience shall be consistent with the philosophy and objectives of the program.~~ The curriculum plan shall have appropriate course sequencing and progression, which includes, but is not limited to the following:

(A) The advance practice registered nursing graduate core courses in advanced health assessment, advanced pharmacology, and advanced pathophysiology shall be completed prior to or concurrent with commencing clinical course work.

(B) Instruction and skills practice for diagnostic and treatment procedures shall occur prior to application in the clinical setting.

(C) Concurrent theory and clinical practice courses in the category shall emphasize the management of health-illness needs in primary and/or acute care.

(D) The supervised direct patient care precepted clinical experiences shall be under the supervision of the certified nurse practitioner and or physician.

~~(6) (5) Outlines and descriptions of all learning experiences shall be available, in writing, prior to enrollment of students in the program.~~ The program shall meet the

minimum of 500 clinical hours of supervised direct patient care experiences as specified in current nurse practitioner national education standards. Additional clinical hours required for preparation in more than one category shall be identified and documented in the curriculum plan for each category.

(6) The nurse practitioner education curriculum shall include content related to California Nursing Practice Act, Business & Professions Code, Division 2, Chapter 6, Article 8, Nurse Practitioners and California Code of Regulations Title 16, Division 14, Article 7 Standardized Procedure Guidelines and Article 8 Standards for Nurse Practitioners, including, but not limited to:

(A) Section 2835.7 of Business & Professions Code Authorized standardized procedures;

(B) Section 2836.1 of Business & Professions Code Furnishing or ordering of drugs or devices by nurse practitioners, and other appropriate codes, Pharmacy, Welfare and Institution.

(7) The program may be full-time or part-time, and shall be comprised of not less than thirty (30) semester units, (forty-five (45) quarter units), and shall be consistent with national standards for graduate and nurse practitioner education, which shall that include theory and supervised clinical practice.

(8) The course of instruction shall be calculated according to the following formula: The course of instruction program units and contact hours shall be calculated using the following formulas:

(A) One (1) hour of instruction in theory each week throughout a semester or quarter equals one (1) unit. One (1) hour of instruction in theory each week throughout a semester or quarter equals one (1) unit.

(B) Three (3) hours of clinical practice each week throughout a semester or quarter equals one (1) unit. Three (3) hours of clinical practice each week throughout a semester or quarter equals one (1) unit. Academic year means two semesters, where each semester is 15-18 weeks; or three quarters, where each quarter is 10-12 weeks.

(C) One (1) semester equals 16-18 weeks and one (1) quarter equals 10-12 weeks.

(9) Supervised clinical practice shall consist of two phases: at least 12 semester units or 18 quarter units.

(A) Concurrent with theory, there shall be provided for the student, demonstration of and supervised practice of correlated skills in the clinical setting with patients.

(B) Following acquisition of basic theoretical knowledge prescribed by the curriculum the student shall receive supervised experience and instruction in an appropriate clinical setting.

(C) At least 12 semester units or 18 quarter units of the program shall be in clinical practice.

(10) The duration of clinical experience and the setting shall be such that the student will receive intensive experience in performing the diagnostic and treatment procedures essential to the practice for which the student is being prepared shall be sufficient for the student to demonstrate clinical competencies in the nurse practitioner category.

(11) The nurse practitioner education program shall have the responsibility arrange for arranging for clinical instruction and supervision for of the student.

(12) The curriculum shall include, but is not limited to:

- (A) Normal growth and development
- (B) Pathophysiology
- (C) Interviewing and communication skills
- (D) Eliciting, recording and maintaining a developmental health history
- (E) Comprehensive physical examination
- (F) Psycho-social assessment
- (G) Interpretation of laboratory findings
- (H) Evaluation of assessment data to define health and developmental problems
- (I) Pharmacology
- (J) Nutrition
- (K) Disease management
- (L) Principles of health maintenance
- (M) Assessment of community resources
- (N) Initiating and providing emergency treatments
- (O) Nurse practitioner role development
- (P) Legal implications of advanced practice
- (Q) Health care delivery systems
- (13) The course of instruction of a program conducted in a non-academic setting shall be equivalent to that conducted in an academic setting.

Authority cited: Sections 2715, 2835.5, 2835.7, 2836, 2826.1, Business and Professions Code. Reference: Sections 2835, 2835.5, 2835.7, 2836, 2836.1, 2836.2, 2836.3, 2837, Business and Professions Code.

**1486. Requirements for Clinical Practice Experience for Nurse Practitioner Students Enrolled in Out of State Nurse Practitioner Education Programs.**

- (a) The out-of-state Nurse Practitioner education program requesting clinical placements for students in clinical practice settings in California shall:
  - (1) Obtain prior board approval;
  - (2) Ensure students have successfully completed prerequisite courses and are enrolled in the nurse practitioner education program;
  - (3) Secure clinical preceptors who meet board requirements;
  - (4) Ensure the clinical preceptorship experiences in the program meet all board requirements and national education standards and competencies for the nurse practitioner role and population;
  - (5) A clinical preceptor in the nurse practitioner education program shall:
    - (a) Hold a valid and active California license to practice his or her respective profession and demonstrate current clinical competence.
    - (b) Participate in teaching, supervising, and evaluating students, and shall be competent in the content and skills being taught to the students.
    - (c) Be a health care provider qualified by education, licensure and clinical competence in the assigned nurse practitioner category to provide direct supervision of the clinical practice experiences for a nurse practitioner student.
    - (d) Be oriented to program and curriculum requirements, including responsibilities related to student supervision and evaluation;
    - (e) Be evaluated by the program faculty at least every

two (2) years.

Clinical preceptor functions and responsibilities shall be clearly documented in a written agreement between the agency, the preceptor, and the nurse practitioner education program including the clinical preceptor's role to teach, supervise and evaluate students in the nurse practitioner education program.

(b) Students shall hold an active, valid California registered nurse license to participate in nurse practitioner education program clinical experiences.

(c) The nurse practitioner education program shall demonstrate evidence that the curriculum includes content related to legal aspects of California certified nurse practitioner laws and regulations.

(1) The curriculum shall include content related to California Nursing Practice Act, Business & Professions Code, Division 2, Chapter 6, Article 8, Nurse Practitioners and California Code of Regulations Title 16, Division 14, Article 7 Standardized Procedure Guidelines and Article 8 Standards for Nurse Practitioners, including, but not limited to:

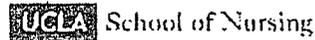
(A) Section 2835.7 of Business & Professions Code Authorized standardized procedures;

(B) Section 2836.1 of Business & Professions Code Furnishing or ordering of drugs or devices by nurse practitioners, and other appropriate codes, Pharmacy, Welfare and Institution.

(d) The nurse practitioner education program shall notify the board of pertinent changes within 30 days.

(e) The board may withdraw authorization for program clinical placements in California, at any time.

Authority cited: Section 2715, Business and Professions Code. Reference: Sections 2729, 2835, 2835.5 and 2836, Business and Professions Code.



May 12, 2016

Members of the Board of Registered Nursing  
C/O Janette Wackerly, MBA, BSN, RN  
Supervising Education Consultant  
Board of Registered Nursing  
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Sacramento, CA 95834

**RE: SUPPORT: Adoption and Revision 1480 -1486 in Article 8 of Title 16 of the California Code of Regulations**

Dear Distinguished Board Members,

The Deans and Interim Director of the University of California (UC) Schools/Program of Nursing strongly recommend and support board approval for initiation of the formal rulemaking process for draft regulatory language pertaining to Article 8 Standards of Nurse Practitioner with the Office of Administrative Law.

UC Nursing, with its primary focus on graduate education, has an important role in preparing the health workforce needed in the state. UC educates new nursing faculty at the doctoral level, and educates advanced practice and baccalaureate-level nurses. Collectively, the four UC nursing programs enroll more than 1,300 students annually.

Each school/program is already accredited by the national Commission on Collegiate Nursing Education (CCNE) – which is an autonomous accrediting agency contributing to the improvement of the public's health by ensuring the quality and integrity of baccalaureate, graduate, and residency programs in nursing. All of these UC programs have exceptional records of success, with virtually no attrition. Of particular relevance to the state, graduates of UC nurse practitioner programs consistently meet high national and state standards in terms of certification and licensure, and also demonstrate high rates of in-state retention and a long-standing commitment to serving medically underserved communities in both rural and urban inner-city locations.

The administration and faculty of our nationally-accredited schools of nursing are well-versed in national standards for graduate nurse practitioner education and practice and serve as exemplars throughout the country. California lags behind the nation in its enactment of advanced practice nursing at the level for which our graduates are prepared. The efforts to achieve a consensus in advanced practice education

set a national standard for practice, made advance practice preparation more transparent to consumers, and facilitated mobility of this workforce across states, an important consideration for disaster response and for employment in multi-state organizations. California remains as only one of three states in the nation who have not adopted the national certification as essential to entry into practice. Our graduates are prepared to successfully complete national certification, and it is time to bring our standards up to the national level, so that they are recognized for their skills and abilities.

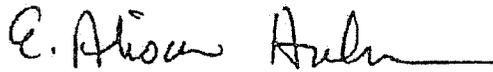
Current rules were enacted decades ago. There is a pressing demand for advanced practice nursing care that is accessible and of high quality and value. The proposed rules directly affect consumers of health care in a positive way. Revision and updating these outdated regulations will not only assist our Schools in maintaining the highest quality nurse practitioner education in the country, but also streamline the approval process for the Board of Registered Nursing. We urge you to move forward with this revision.

We commend you for your leadership on this issue and would like to thank the Board for the opportunity to participate in the pre-notice public discussions related to the proposed amendments and revisions. If you have questions or require additional information, please do not hesitate to contact our respective Schools of Nursing.

Respectfully Submitted,



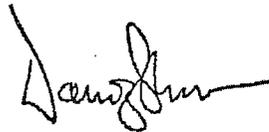
Heather M. Young, PhD, RN, FAAN  
Dean and Professor, UC Davis



E. Alison Holman, PhD, FNP, RN, FAAN  
Interim Director and Associate Professor, UC Irvine



Linda Sarna, PhD, RN, FAAN  
Interim Dean and Professor, UCLA



David Vlahov, PhD, RN, FAAN  
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Barbara J. Ritter  
PO Box 263  
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May 3, 2016

California Board of Registered Nursing  
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Louise R. Bailey, MEd, RN, Executive Officer  
Janette Wackerly, RN, MBA, Nursing Education Consultant  
Ms. Trande Phillips, RN, Board Member and Chair, Nursing Practice Committee

Re: Support Adopted Revisions of Proposed Language for Article 8 Standards of Nurse Practitioner Practice

Dear California Board of Registered Nursing:

As a nurse practitioner practicing in the State of California and as a member of the California Association for Nurse Practitioners (CANP) I appreciate the work of the California Board of Registered Nursing in its review and consideration to adopt revisions to Proposed Language for Article 8, Section 1480-1484, Standards of Nurse Practitioner Practice, from Title 16 of the California Code of Regulations; and applaud your efforts to modernize and update language that reflects current nurse practitioner (NP) practice.

I strongly believe an educated and competent NP workforce, reflected in certifying standards, will ensure that the health care needs of the state's population are safely met. With the addition of millions of newly insured Californians entering the health care system under the Patient Protection and Affordable Care Act (PPACA), NPs play a critical and necessary role in serving the present and future health care needs in this effort.

Over 205, 000 NPs practice nationwide in all fifty states. Many of the revisions as identified outline requirements in licensure, accreditation, certification, and education that have been adopted by several states. Other states are proposing legislation and rules changes to move closer to compliance. This alignment offers benefits to consumers, employers, NP educational programs, legislators, regulators, and present and future NPs. It does so by providing a clear understanding of an NP's role, preparation, training, and scope of practice, and upholds public protection and accountability to the standards for practice.

Article 8 (Standards for Nurse Practitioner Practice) regulations were primarily adopted between 1979-1985. However, the 1979-1985 context and content in Article 8 are no longer relevant in the areas of Definitions, Categories, Holding Out as NP, Evaluation of

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I remain confident that the CA-BRN is interested in updating regulations to reflect current practice. As always, CANP offers its assistance to the Board during this ongoing endeavor. The revisions to sections 1480-1486 in Article 8 of Title 16 of the California Code of Regulations is a forward step in California and will ensure educational standards and competence for the future practice of NPs, providing uniformity in the regulations.

I appreciate your consideration of my comments and thank the Board for its continued work on this important area of our APRN practice.

Respectfully,

A handwritten signature in cursive script, appearing to read "BJRitter".

Barbara J. Ritter, Ed.D, FNP

Chad R. Barylski

500 Doyle Park Dr, Ste G04

Santa Rosa, CA 95405

May 9, 2016

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Chad R. Barylski NP-C, DC, DACBSP

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Emily Baker  
2818 Spring Creek Dr  
Santa Rosa, CA 95405

May 3, 2016

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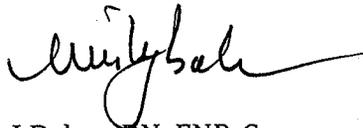
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Respectfully,

A handwritten signature in black ink, appearing to read "Emily Baker", with a long horizontal flourish extending to the right.

Emily J Baker, RN, FNP-C

CALIFORNIA  
BOARD OF REGISTERED NURSING  
MAY 11 2016



# GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

## IMPROVING PRACTICE THROUGH RECOMMENDATIONS

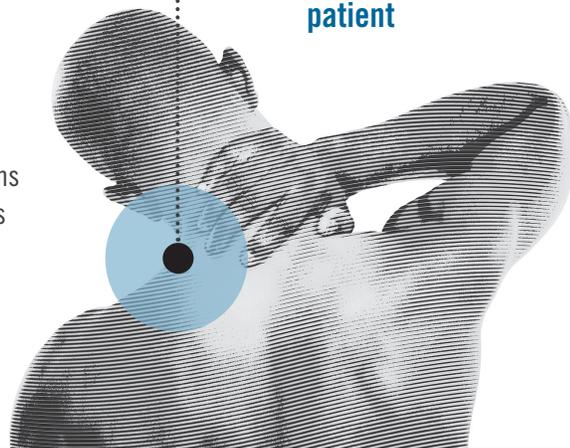
CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

## DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

- 1** Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- 2** Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- 3** Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

### CLINICAL REMINDERS

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient



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# OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

## CLINICAL REMINDERS

- **Use immediate-release opioids when starting**
- **Start low and go slow**
- **When opioids are needed for acute pain, prescribe no more than needed**
- **Do not prescribe ER/LA opioids for acute pain**
- **Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed**

4

When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to  $\geq 50$  morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day.

6

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.



## ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages ( $\geq 50$  MME/day), or concurrent benzodiazepine use, are present.

9

Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10

When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11

Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12

Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

## CLINICAL REMINDERS

- **Evaluate risk factors for opioid-related harms**
- **Check PDMP for high dosages and prescriptions from other providers**
- **Use urine drug testing to identify prescribed substances and undisclosed use**
- **Avoid concurrent benzodiazepine and opioid prescribing**
- **Arrange treatment for opioid use disorder if needed**



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Control and Prevention

LEARN MORE | [www.cdc.gov/drugoverdose/prescribing/guideline.html](http://www.cdc.gov/drugoverdose/prescribing/guideline.html)

# Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain  $\geq 3$  months, excluding cancer, palliative, and end-of-life care

## CHECKLIST

### When **CONSIDERING** long-term opioid therapy

- Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- Check that non-opioid therapies tried and optimized.
- Discuss benefits and risks (eg, addiction, overdose) with patient.
- Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- Set criteria for stopping or continuing opioids.
- Assess baseline pain and function (eg, PEG scale).
- Schedule initial reassessment within 1–4 weeks.
- Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

### If **RENEWING** without patient visit

- Check that return visit is scheduled  $\leq 3$  months from last visit.

### When **REASSESSING** at return visit

**Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.**

- Assess pain and function (eg, PEG); compare results to baseline.
- Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- Check that non-opioid therapies optimized.
- Determine whether to continue, adjust, taper, or stop opioids.
- Calculate opioid dosage morphine milligram equivalent (MME).
  - If  $\geq 50$  MME/day total ( $\geq 50$  mg hydrocodone;  $\geq 33$  mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid  $\geq 90$  MME/day total ( $\geq 90$  mg hydrocodone;  $\geq 60$  mg oxycodone), or carefully justify; consider specialist referral.
- Schedule reassessment at regular intervals ( $\leq 3$  months).

## REFERENCE

### EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

### NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

### EVALUATING RISK OF HARM OR MISUSE

**Known risk factors** include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

**Urine drug testing:** Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

### Prescription drug monitoring program (PDMP):

Check for opioids or benzodiazepines from other sources.

### ASSESSING PAIN & FUNCTION USING PEG SCALE

**PEG score** = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

**Q1:** *What number from 0–10 best describes your **pain** in the past week?*

0 = “no pain”, 10 = “worst you can imagine”

**Q2:** *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*

0 = “not at all”, 10 = “complete interference”

**Q3:** *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*

0 = “not at all”, 10 = “complete interference”



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### TO LEARN MORE

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# NONOPIOID TREATMENTS FOR CHRONIC PAIN

## PRINCIPLES OF CHRONIC PAIN TREATMENT

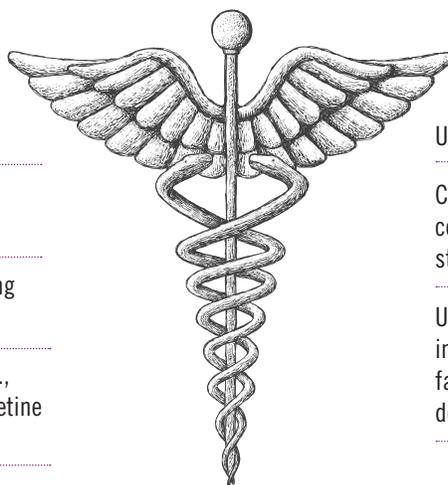
Patients with pain should receive treatment that provides the greatest benefit. Opioids are not the first-line therapy for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Evidence suggests that nonopioid treatments, including nonopioid medications and nonpharmacological therapies can provide relief to those suffering from chronic pain, and are safer. Effective approaches to chronic pain should:

Use nonopioid therapies to the extent possible

Identify and address co-existing mental health conditions (e.g., depression, anxiety, PTSD)

Focus on functional goals and improvement, engaging patients actively in their pain management

Use disease-specific treatments when available (e.g., triptans for migraines, gabapentin/pregabalin/duloxetine for neuropathic pain)



Use first-line medication options preferentially

Consider interventional therapies (e.g., corticosteroid injections) in patients who fail standard non-invasive therapies

Use multimodal approaches, including interdisciplinary rehabilitation for patients who have failed standard treatments, have severe functional deficits, or psychosocial risk factors

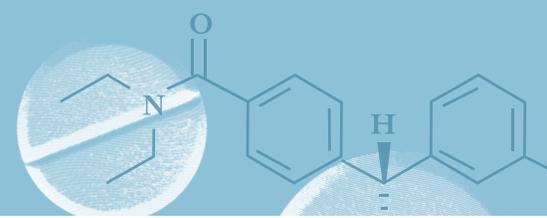
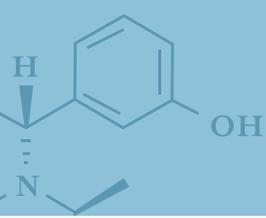
## NONOPIOID MEDICATIONS

Medication	Magnitude of benefits	Harms	Comments
Acetaminophen	Small	Hepatotoxic, particularly at higher doses	First-line analgesic, probably less effective than NSAIDs
NSAIDs	Small-moderate	Cardiac, GI, renal	First-line analgesic, COX-2 selective NSAIDs less GI toxicity
Gabapentin/pregabalin	Small-moderate	Sedation, dizziness, ataxia	First-line agent for neuropathic pain; pregabalin approved for fibromyalgia
Tricyclic antidepressants and serotonin/norepinephrine reuptake inhibitors	Small-moderate	TCAs have anticholinergic and cardiac toxicities; SNRIs safer and better tolerated	First-line for neuropathic pain; TCAs and SNRIs for fibromyalgia, TCAs for headaches
Topical agents (lidocaine, capsaicin, NSAIDs)	Small-moderate	Capsaicin initial flare/burning, irritation of mucus membranes	Consider as alternative first-line, thought to be safer than systemic medications. Lidocaine for neuropathic pain, topical NSAIDs for localized osteoarthritis, topical capsaicin for musculoskeletal and neuropathic pain



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# RECOMMENDED TREATMENTS FOR COMMON CHRONIC PAIN CONDITIONS

## Low back pain

**Self-care and education in all patients;** advise patients to remain active and limit bedrest

**Nonpharmacological treatments:** Exercise, cognitive behavioral therapy, interdisciplinary rehabilitation

### Medications

- First line: acetaminophen, non-steroidal anti inflammatory drugs (NSAIDs)
- Second line: Serotonin and norepinephrine reuptake inhibitors (SNRIs)/tricyclic antidepressants (TCAs)

## Migraine

### Preventive treatments

- Beta-blockers
- TCAs
- Antiseizure medications
- Calcium channel blockers
- Non-pharmacological treatments (Cognitive behavioral therapy, relaxation, biofeedback, exercise therapy)
- Avoid migraine triggers

### Acute treatments

- Aspirin, acetaminophen, NSAIDs (may be combined with caffeine)
- Antinausea medication
- Triptans-migraine-specific

## Neuropathic pain

**Medications:** TCAs, SNRIs, gabapentin/pregabalin, topical lidocaine

## Osteoarthritis

**Nonpharmacological treatments:** Exercise, weight loss, patient education

### Medications

- First line: Acetaminophen, oral NSAIDs, topical NSAIDs
- Second line: Intra-articular hyaluronic acid, capsaicin (limited number of intra-articular glucocorticoid injections if acetaminophen and NSAIDs insufficient)

## Fibromyalgia

**Patient education:** Address diagnosis, treatment, and the patient's role in treatment

**Nonpharmacological treatments:** Low-impact aerobic exercise (i.e. brisk walking, swimming, water aerobics, or bicycling), cognitive behavioral therapy, biofeedback, interdisciplinary rehabilitation

### Medications

- FDA-approved: Pregabalin, duloxetine, milnacipran
- Other options: TCAs, gabapentin



# ASSESSING BENEFITS AND HARMS OF OPIOID THERAPY

## THE EPIDEMIC

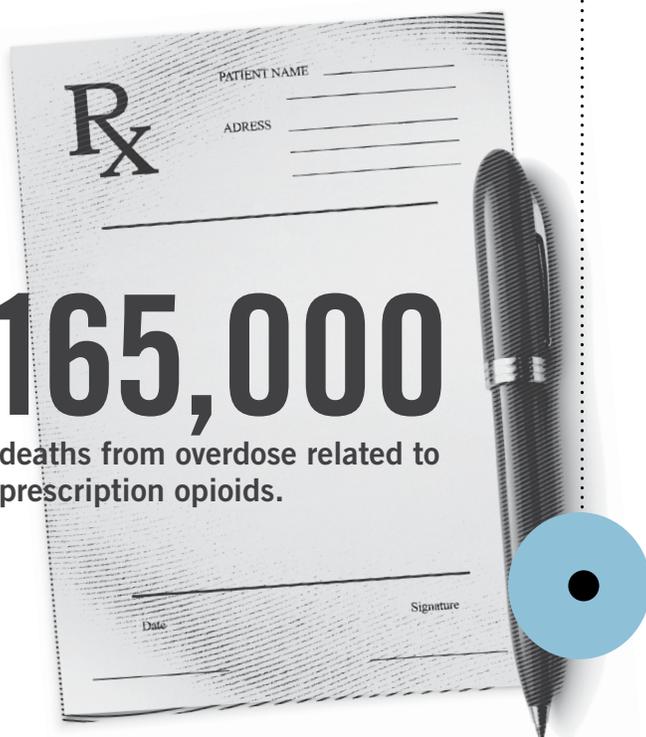
The United States is in the midst of an epidemic of prescription opioid overdose deaths, which killed more than 14,000 people in 2014 alone.

Since 1999, sales of prescription opioids—and related overdose deaths—have quadrupled.

Since 1999, there have been more than

**165,000**

deaths from overdose related to prescription opioids.



## GUIDANCE FOR OPIOID PRESCRIBING

The *CDC Guideline for Prescribing Opioids for Chronic Pain*<sup>1</sup> provides up-to-date guidance on prescribing and weighing the risks and benefits of opioids.

- Before starting and periodically during opioid therapy, discuss the known risks and realistic benefits of opioids.
- Also discuss provider and patient responsibilities for managing therapy.
- Within 1-4 weeks of starting opioid therapy, and at least every 3 months, evaluate benefits and harms with the patient.

## ASSESS BENEFITS OF OPIOID THERAPY

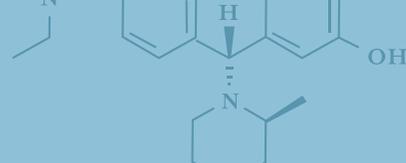
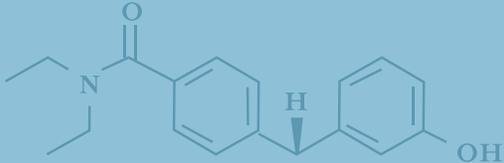
Assess your patient's pain and function regularly. A 30% improvement in pain and function is considered clinically meaningful. Discuss patient-centered goals and improvements in function (such as returning to work and recreational activities) and assess pain using validated instruments such as the 3-item (PEG) Assessment Scale:

1. What number best describes your pain on average in the past week? (from 0=no pain to 10=pain as bad as you can imagine)
2. What number best describes how, during the past week, pain has interfered with your enjoyment of life? (from 0=does not interfere to 10=completely interferes)
3. What number best describes how, during the past week, pain has interfered with your general activity? (from 0=does not interfere to 10=completely interferes)

If your patient does not have a 30% improvement in pain and function, consider reducing dose or tapering and discontinuing opioids. Continue opioids only as a careful decision by you and your patient when improvements in both pain and function outweigh the harms.

<sup>1</sup>Recommendations do not apply to pain management in the context of active cancer treatment, palliative care, and end-of-life care.





## ASSESS HARMS OF OPIOID THERAPY

Long-term opioid therapy can cause harms ranging in severity from constipation and nausea to opioid use disorder and overdose death. Certain factors can increase these risks, and it is important to assess and follow-up regularly to reduce potential harms.

- 1 ASSESS.** Evaluate for factors that could increase your patient's risk for harm from opioid therapy such as:
  - Personal or family history of substance use disorder
  - Anxiety or depression
  - Pregnancy
  - Age 65 or older
  - COPD or other underlying respiratory conditions
  - Renal or hepatic insufficiency

- 2 CHECK.** Consider urine drug testing for other prescription or illicit drugs and check your state's prescription drug monitoring program (PDMP) for:
  - Possible drug interactions (such as benzodiazepines)
  - High opioid dosage ( $\geq 50$  MME/day)
  - Obtaining opioids from multiple providers

- 3 DISCUSS.** Ask your patient about concerns and determine any harms they may be experiencing such as:
  - Nausea or constipation
  - Feeling sedated or confused
  - Breathing interruptions during sleep
  - Taking or craving more opioids than prescribed or difficulty controlling use

- 4 OBSERVE.** Look for early warning signs for overdose risk such as:
  - Confusion
  - Sedation
  - Slurred speech
  - Abnormal gait

If harms outweigh any experienced benefits, work with your patient to reduce dose, or taper and discontinue opioids and optimize nonopioid approaches to pain management.

## TAPERING AND DISCONTINUING OPIOID THERAPY

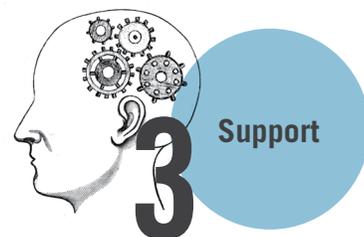
Symptoms of opioid withdrawal may include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, and tremors. Tapering plans should be individualized. However, in general:



To minimize symptoms of opioid withdrawal, decrease 10% of the original dose per week. Some patients who have taken opioids for a long time might find slower tapers easier (e.g., 10% of the original dosage per month).



Work with appropriate specialists as needed—especially for those at risk of harm from withdrawal such as pregnant patients and those with opioid use disorder.



During the taper, ensure patients receive psychosocial support for anxiety. If needed, work with mental health providers and offer or arrange for treatment of opioid use disorder.

Improving the way opioids are prescribed can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs.

# CALCULATING TOTAL DAILY DOSE OF OPIOIDS FOR SAFER DOSAGE

## Higher Dosage, Higher Risk.

Higher dosages of opioids are associated with higher risk of overdose and death—even relatively low dosages (20-50 morphine milligram equivalents (MME) per day) increase risk. Higher dosages haven't been shown to reduce pain over the long term. One randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME).

Dosages at or **above 50 MME/day** increase risks for overdose by at least

**2x**

the risk at  
**<20  
MME/day.**

## WHY IS IT IMPORTANT TO CALCULATE THE TOTAL DAILY DOSAGE OF OPIOIDS?

**Patients prescribed higher opioid dosages are at higher risk of overdose death.**

In a national sample of Veterans Health Administration (VHA) patients with chronic pain receiving opioids from 2004–2009, **patients who died** of opioid overdose were prescribed an average of **98 MME/day**, while **other patients** were prescribed an average of **48 MME/day**.

**Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.**

## HOW MUCH IS 50 OR 90 MME/DAY FOR COMMONLY PRESCRIBED OPIOIDS?

### 50 MME/day:

- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15 mg)
- 12 mg of methadone (<3 tablets of methadone 5 mg)

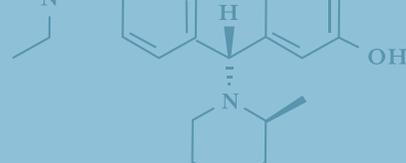
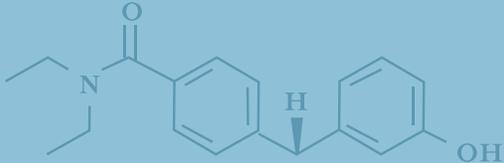
### 90 MME/day:

- 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325)
- 60 mg of oxycodone 12 tablets of hydrocodone/acetaminophen 7.5/300)
- ~20 mg of methadone (4 tablets of methadone 5 mg)



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## HOW SHOULD THE TOTAL DAILY DOSE OF OPIOIDS BE CALCULATED?

1

**DETERMINE** the total daily amount of each opioid the patient takes.

2

**CONVERT** each to MMEs—multiply the dose for each opioid by the conversion factor. (see table)

3

**ADD** them together.



### Calculating morphine milligram equivalents (MME)

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

*These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.*

#### CAUTION:

- Do not use the calculated dose in MMEs to determine dosage for converting one opioid to another—the new opioid should be lower to avoid unintentional overdose caused by incomplete cross-tolerance and individual differences in opioid pharmacokinetics. Consult the medication label.

#### USE EXTRA CAUTION:

- Methadone:** the conversion factor increases at higher doses
- Fentanyl:** dosed in mcg/hr instead of mg/day, and absorption is affected by heat and other factors

## HOW SHOULD PROVIDERS USE THE TOTAL DAILY OPIOID DOSE IN CLINICAL PRACTICE?

- Use caution when prescribing opioids at any dosage and prescribe the lowest effective dose.
- Use extra precautions when increasing to ≥50 MME per day such as:
  - Monitor and assess pain and function more frequently.
  - Discuss reducing dose or tapering and discontinuing opioids if benefits do not outweigh harms.
  - Consider offering naloxone.
- Avoid or carefully justify increasing dosage to ≥90 MME/day.



# PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

## Checking the PDMP: An Important Step to Improving Opioid Prescribing Practices

### WHAT IS A PDMP?

A PDMP is a statewide electronic database that tracks all controlled substance prescriptions. Authorized users can access prescription data such as medications dispensed and doses.

PDMPs improve patient safety by allowing clinicians to:

- Identify patients who are obtaining opioids from multiple providers.
- Calculate the total amount of opioids prescribed per day (in MME/day).
- Identify patients who are being prescribed other substances that may increase risk of opioids—such as benzodiazepines.

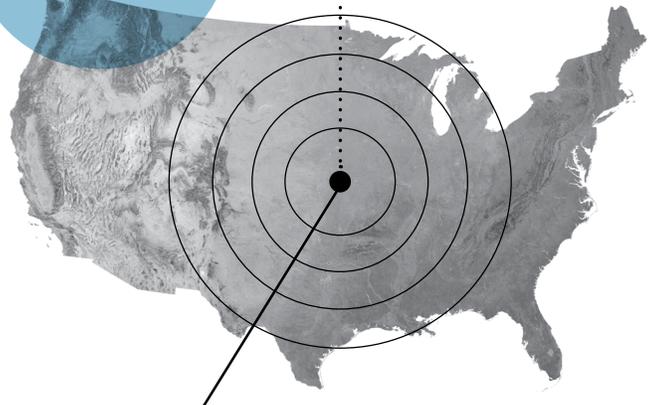
Improving the way opioids are prescribed will ensure patients have access to safer, more effective chronic pain treatment while reducing opioid misuse, abuse, and overdose. Checking your state's PDMP is an important step in safer prescribing of these drugs.



# R<sub>x</sub>

# 249M

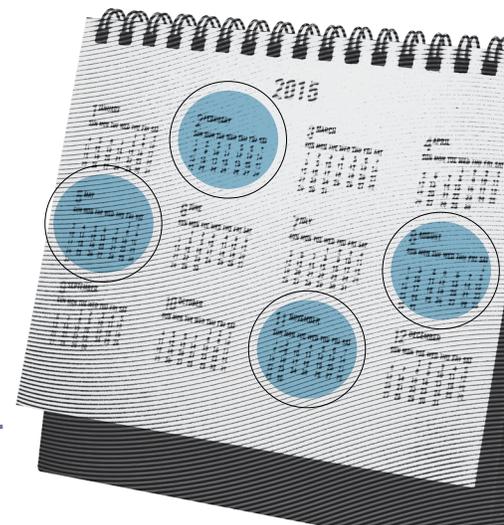
prescriptions for opioids were written by healthcare providers in 2013



enough prescriptions for every American adult to have a bottle of pills

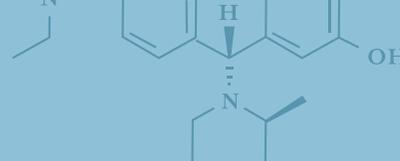
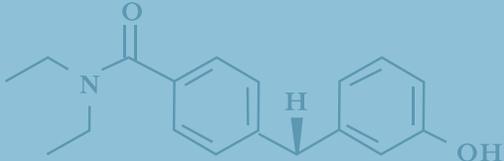
### WHEN SHOULD I CHECK THE PDMP?

State requirements vary, but CDC recommends checking at least once every **3 months** and consider checking **prior to every opioid prescription.**

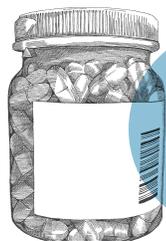


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## WHAT SHOULD I CONSIDER WHEN PRESCRIBING OPIOIDS?



### High Dosage

Talk to your patient about the risks for respiratory depression and overdose. Consider offering to taper opioids as well as prescribing naloxone for patients taking 50 MME/day or more.



### Multiple Providers

Counsel your patient and coordinate care with their other prescribers to improve safety and discuss the need to obtain opioids from a single provider. Check the PDMP regularly and consider tapering or discontinuation of opioids if pattern continues.



### Drug Interactions

Whenever possible, avoid prescribing opioids and benzodiazepines concurrently. Communicate with other prescribers to prioritize patient goals and weigh risks of concurrent opioid and benzodiazepine use.

## WHAT SHOULD I DO IF I FIND INFORMATION ABOUT A PATIENT IN THE PDMP THAT CONCERNS ME?

Patients should not be dismissed from care based on PDMP information. Use the opportunity to provide potentially life-saving information and interventions.

1

### Confirm that the information in the PDMP is correct.

Check for potential data entry errors, use of a nickname or maiden name, or possible identity theft to obtain prescriptions.

2

### Assess for possible misuse or abuse.

Offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients who meet criteria for opioid use disorder. If you suspect diversion, urine drug testing can assist in determining whether opioids can be discontinued without causing withdrawal.

3

### Discuss any areas of concern with your patient and emphasize your interest in their safety.

## HOW CAN I REGISTER AND USE THE PDMP IN MY STATE?

Processes for registering and using PDMPs vary from state to state.

For information on your state's requirements, check The National Alliance for Model State Drug Laws online: ●

[www.namsdl.org/prescription-monitoring-programs.cfm](http://www.namsdl.org/prescription-monitoring-programs.cfm)



# WHY GUIDELINES FOR PRIMARY CARE PROVIDERS?

Primary care providers account for approximately

# 50%

of prescription opioids dispensed



Nearly  
**2 million**

Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014

- An estimated 11% of adults experience daily pain
- Millions of Americans are treated with prescription opioids for chronic pain
- Primary care providers are concerned about patient addiction and report insufficient training in prescribing opioids

## MYTH

## VS

## TRUTH

### 1

Opioids are effective long-term treatments for chronic pain

While evidence supports short-term effectiveness of opioids, there is insufficient evidence that opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

### 2

There is no unsafe dose of opioids as long as opioids are titrated slowly

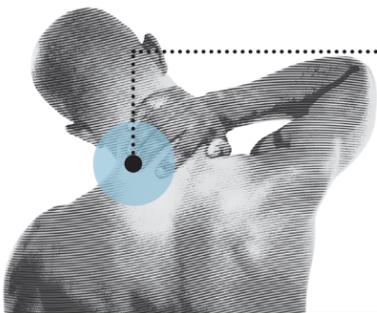
Daily opioid dosages close to or greater than 90 MME/day are associated with significant risks, and lower dosages are safer.

### 3

The risk of addiction is minimal

Up to one quarter of patients receiving prescription opioids long term in a primary care setting struggles with addiction. Certain risk factors increase susceptibility to opioid-associated harms: history of overdose, history of substance use disorder, higher opioid dosages, or concurrent benzodiazepine use.

## WHAT CAN PROVIDERS DO?



First, **do no harm**. Long-term opioid use has uncertain benefits but known, serious risks. CDC's **Guideline for Prescribing Opioids for Chronic Pain** will support informed clinical decision making, improved communication between patients and providers, and appropriate prescribing.

## PRACTICES AND ACTIONS



### USE NONOPIOID TREATMENT

Opioids are not first-line or routine therapy for chronic pain (*Recommendation #1*)

In a systematic review, opioids did not differ from nonopioid medication in pain reduction, and nonopioid medications were better tolerated, with greater improvements in physical function.



### START LOW AND GO SLOW

When opioids are started, prescribe them at the lowest effective dose (*Recommendation #5*)

Studies show that high dosages ( $\geq 100$  MME/day) are associated with 2 to 9 times the risk of overdose compared to  $< 20$  MME/day.



### REVIEW PDMP

Check prescription drug monitoring program data for high dosages and prescriptions from other providers (*Recommendation #9*)

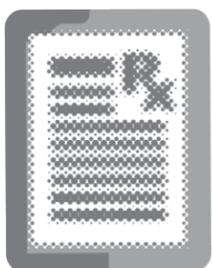
A study showed patients with one or more risk factors (4 or more prescribers, 4 or more pharmacies, or dosage  $> 100$  MME/day) accounted for 55% of all overdose deaths.



### AVOID CONCURRENT PRESCRIBING

Avoid prescribing opioids and benzodiazepines concurrently whenever possible (*Recommendation #11*)

One study found concurrent prescribing to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone.



### OFFER TREATMENT FOR OPIOID USE DISORDER

Offer or arrange evidence-based treatment (e.g. medication-assisted treatment and behavioral therapies) for patients with opioid use disorder (*Recommendation #12*)

A study showed patients prescribed high dosages of opioids long-term ( $> 90$  days) had 122 times the risk of opioid use disorder compared to patients not prescribed opioids.



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