Methods for Evaluating the Opioid Analgesic Risk Evaluation and Mitigation Strategy

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CONTENTS

OVERVIEW 1
BACKGROUND 2
History of the Opioid Analgesic REMS 2
OVERVIEW OF ISSUES 5
Development and Evaluation of Continuing Education 5
Applying Lessons Learned From the ER/LA REMS Assessment to the Development of the OA REMS Assessment 6
Proposed Study To Evaluate the Effect of OA REMS-Compliant CE on Prescriber Behavior and Patient Outcomes 9
SCIENTIFIC WORKSHOP DISCUSSION TOPICS 11
APPENDICES 13

Methods for Evaluating the Opioid Analgesic Risk Evaluation and Mitigation Strategy

OVERVIEW

The Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS), required by the Food and Drug Administration (FDA) and implemented by the manufacturers of opioid analgesics intended for use in an outpatient setting, is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths caused by prescription opioid analgesics. The primary component of this risk evaluation and mitigation strategy (REMS) is a voluntary education program for prescribers, nurses, pharmacists, and other health care providers involved in the treatment or monitoring of patients with pain. A consortium of manufacturers, known as the REMS Program Companies (RPC), conducts annual assessments of the OA REMS and provides summaries of data that are used to determine whether the REMS is meeting its risk mitigation goals.

In January 2019, FDA issued a draft guidance for industry *REMS Assessment: Planning and Reporting*, which describes how to develop a REMS assessment plan and the selection of metrics and data sources that will be used to assess whether the program is meeting its risk mitigation goals.[1] The REMS assessment plan for the OA REMS includes a mixed methods approach as recommended in the draft guidance.

FDA is holding a scientific workshop to publicly discuss methods to evaluate the OA REMS. The workshop has three main topics for discussion:

1. Specific, measurable outcomes that might demonstrate that voluntary training, based on the *Opioid Analgesics REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients With Pain* (FDA Blueprint), is effective in educating prescribers and other health care providers (including pharmacists and nurses) involved in the treatment and monitoring of patients in pain about recommended pain management practices and the appropriate use of opioid analgesics
2. The feasibility of conducting a study to specifically evaluate the effect of OA REMS-compliant continuing education (CE) on prescriber behavior and patient outcomes amidst the numerous concomitant strategies to combat the opioid crisis at the Federal, State, and local levels
3. Whether there might be suitable alternative study approaches to better understand the influence of CE, more broadly, on pain management practice and patient outcomes if a study to *directly* measure the impact of REMS-compliant CE is thought to be infeasible

[1] When final this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

BACKGROUND

HISTORY OF THE OPIOID ANALGESIC REMS

The Extended-Release and Long-Acting Opioid Analgesic REMS

In 2010, FDA determined that a REMS would be required for the extended-release and long-acting (ER/LA) opioid analgesic products, and on July 9, 2012, the ER/LA Opioid Analgesics REMS,[2] hereafter referred to as the ER/LA REMS, was approved. The goal of the ER/LA REMS was to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of interest included addiction, unintentional overdose, and death.

The ER/LA REMS required manufacturers of these products to provide training on the safe use of these products to prescribers of ER/LA opioid analgesics,[3] which was accomplished through unrestricted grants to CE Providers of Accredited CE. Completion of the CE by individual prescribers was voluntary. The ER/LA REMS also included a product-specific Medication Guide for patients; distribution of letters to prescribers, professional organizations, and licensing boards to notify them of the ER/LA REMS; and a Patient Counseling Document. The ER/LA REMS outlined specific performance goals for the number of prescribers trained at 2, 3, and 4 years from the time of the availability of the first REMS-compliant training.

Assessments of the ER/LA REMS were required at 6 months, 1 year, and annually thereafter from the date of approval of the REMS. The assessments included:

- The number of ER/LA prescribers completing the REMS training
- An audit of the quality of the content of the educational materials
- Prescriber and patient knowledge surveys of the risks of ER/LA opioid analgesics
- Surveillance and monitoring for events of interest
- An evaluation of drug utilization patterns
- An evaluation of changes in prescribing behavior (prescriptions to opioid tolerant patients, excessive prescriptions for early refills)
- Monitoring of patterns of prescribing to identify changes in access to ER/LA opioid analgesics

On May 3 and 4, 2016, FDA held a joint meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and the Anesthetic and Analgesic Drug

[2] A more detailed history of the ER/LA REMS may be found in the FDA background document for the May 3 and 4, 2016, joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee, available at https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM497290.pdf, accessed July 30, 2020.

[3] For the purposes of the ER/LA REMS, an ER/LA prescriber was defined as clinicians who are registered with the Drug Enforcement Agency to prescribe Schedule II and/or III controlled substances and have written at least one ER/LA opioid analgesic prescription in the past year.

Products (AADP) Advisory Committee (meeting of the DSaRM and AADP Advisory Committees or joint advisory committee meeting) to discuss whether the ER/LA REMS was meeting its goals and assuring safe use of ER/LA opioid analgesics; whether it was not unduly burdensome to patient access to the drugs; and to the extent practicable, whether it minimized the burden to the health care delivery system. Findings and conclusions from REMS assessments were presented, and committee members agreed that it could not be determined that the REMS was meeting its goal of reducing serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics. Some of the challenges of determining whether the goals were met included issues with representativeness of patient and prescriber surveys, which limited the evaluation of patient and prescriber understanding of risks and safe prescribing and use practices for these products. Observed trends in the utilization of ER/LA opioid analgesics and adverse events of interest also complicated the evaluation of the ER/LA REMS, because these trends predated the implementation of the REMS. In addition, multiple concurrent activities directed at reducing harm from opioid analgesics also made the evaluation of the ER/LA REMS difficult. The DSaRM and AADP Advisory Committees acknowledged challenges with evaluating the REMS-compliant training; however, they maintained that it was important to rigorously assess the REMS to determine whether it was meeting its goals.

Despite the challenges with assessing the ER/LA REMS and determining whether it was meeting its goals, the DSaRM and AADP Advisory Committees ultimately advised that the ER/LA REMS be modified to:

- Expand REMS requirements to include immediate-release (IR) opioid analgesics
- Expand the FDA Blueprint to incorporate information on pain management more broadly and to include other health care professionals involved in the management of patients with pain
- Require that education be mandatory, though options other than a REMS should be explored

The Opioid Analgesic REMS

On September 18, 2018, the ER/LA REMS was modified to include the IR opioid analgesics intended for use in the outpatient setting (and not covered by other REMS programs). The OA REMS now covers all branded and generic:

- Oral dosage forms of extended-release and immediate-release opioids containing codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol, and tramadol
- Intranasal, buccal, and transdermal delivery systems containing fentanyl, butorphanol, and buprenorphine
- Methadone tablets and solutions indicated for use as analgesics

Additionally, the FDA Blueprint was expanded to incorporate the fundamentals of pain management. The education was also expanded to nurses, pharmacists, and other health care providers involved in the treatment or monitoring of patients with pain. As was done

under the ER/LA REMS, the RPC is fulfilling its requirement to provide education under the OA REMS through unrestricted grants to CE Providers of Accredited CE.

The OA REMS covers approximately 360 individual products that are listed on the FDA REMS website, available at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17.

The goal of the OA REMS is to educate prescribers and other health care providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. The education provided through the REMS is based on the FDA Blueprint (Appendix 1). Through better education, the health care team will have an improved understanding of how to manage pain and the role of opioid analgesics as well as nonpharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies, which is intended to assist health care providers in reducing adverse outcomes of addiction; unintentional overdose; and death resulting from inappropriate prescribing, abuse, and misuse. The REMS aims to accomplish this goal by:

1. Ensuring that training based on the FDA Blueprint is effective in educating prescribers and other health care providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and appropriate use of opioid analgesics.

2. Informing patients about their roles and responsibilities regarding their pain treatment plan, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and Patient Counseling Guide for opioid analgesics.

The OA REMS requires that the REMS be assessed at 6 months, 1 year, and annually thereafter from the date of approval of the REMS. The full assessment plan for the OA REMS can be found in Appendix 2. The assessment includes:

- Evaluations of the distribution of letters to health care providers, professional societies, and licensing boards
- The status of grants and descriptions of CE programs awarded
- The number of CE activity completers
- Audits of activities
- The overall pain/opioid CE landscape
- An evaluation of the effect of REMS CE on prescriber behavior and patient outcomes
- Surveillance and monitoring related to opioid analgesic use, misuse, abuse, overdose, addiction, and death
- An evaluation of drug utilization patterns
- An evaluation of CE completers' knowledge

- An evaluation of patient experiences around pain management and an evaluation of patient knowledge

OVERVIEW OF ISSUES

DEVELOPMENT AND EVALUATION OF CONTINUING EDUCATION

Moore et al. proposed an outcomes framework for planning and assessing Continuing Medical Education (CME) activities identifying seven levels of outcomes to determine learning and assessment strategies in CME.[4] These levels have been presented as a pyramid, with the simplest outcomes of learner participation and satisfaction forming the base of the pyramid, followed by knowledge, competence, performance, and patient health, with community health at the pinnacle. Typically, participants in a CE activity for health care providers (e.g., physicians, nurses, pharmacists) complete a knowledge assessment and answer questions on their intent to change behavior following completion of a CE activity. These evaluations most often provide information on the lower levels of the pyramid. Studies of CME effectiveness have attempted to answer the challenging question of the effect of this education on the higher levels of this pyramid, including prescriber performance and patient health, and a limited number of studies have demonstrated favorable effects of education on physician performance and patient outcomes. The literature describes challenges, however, with the evaluation of a single educational activity and the expectation that completion of a single activity will result in immediate effects in practice change. Accreditors and providers of CE cite previous research, summarized by Wakefield et al.,[5] that describes the complexity of changing clinical practice, and describes "stages" in the change process, concluding that, "[i]t is extremely unlikely that any single educational intervention can address all of these stages and effect a specific change in the clinical practice of the majority of participants." Nevertheless, in their 2015 systematic review of CME effectiveness, Cervero and colleagues[6] concluded:

- CME does improve physician performance and patient health outcomes.
- CME has a more reliably positive impact on physician performance than on patient outcomes.
- CME leads to greater improvement in physician performance and patient outcomes if it is more interactive, uses more methods, involves multiple exposures, is longer, and is focused on outcomes that are considered important by physicians.

[4] Moore Jr. DE, Green JS, Gallis HA, 2009, Achieving Desired Results and Improved Outcomes: Integrating Planning and Assessment Throughout Learning Activities. J Contin Educ Health Prof, 29(1):1-5.

[5] Wakefield JG, 2004, Commitment to Change: Exploring Its Role in Changing Physician Behavior through Continuing Education, J Contin Educ Health Prof, 24:197-204.

[6] Cervero R, Gaines J, 2015, The Impact of CME on Physician Performance and Patient Health Outcomes: An Updated Synthesis of Systematic Reviews, J Contin Educ Health Prof, 35(2):131-138.

The CE community (i.e., CE Accreditors and CE Providers) has encouraged the RPC to fund a variety of educational activity types. The most recently awarded grants for the OA REMS (December 2018) awarded funding to 14 grant applications with a variety of formats, including didactic, case-based, multimedia, interactive, and adaptive learning, and the RPC stated their aim to fund grants for programs with unique and innovative formats that are more conducive to the adult learner.[7]

APPLYING LESSONS LEARNED FROM THE ER/LA REMS ASSESSMENT TO THE DEVELOPMENT OF THE OA REMS ASSESSMENT

The assessment of the ER/LA REMS focused on the number of ER/LA opioid analgesic prescribers completing REMS training, prescriber and patient knowledge of the risks and safe use of ER/LA opioid analgesics, changes in the utilization of ER/LA and IR opioid analgesics following REMS approval, and changes in safety outcomes of interest (i.e., serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse). Over the years that the ER/LA REMS and now the OA REMS have been in place, evaluation of the effect of the voluntary CE programs on prescribing practices and patient outcomes has proven to be challenging. A more complete discussion of these challenges can be found in the meeting materials for the May 3 and 4, 2016, joint meeting of the DSaRM and AADP Advisory Committees.[2] Some examples of the challenges discussed were:

- Though a large number of ER/LA opioid prescribers (as well as other health care providers) completed REMS training, these numbers did not reach the prespecified targets outlined in the REMS and represented a minority of ER/LA opioid prescribers.
- Surveys of knowledge of both patients and prescribers showed overall a good understanding of the risks and safe use of ER/LA opioid analgesics; however, methodological flaws limited the representativeness of the surveyed populations to the overall population of ER/LA prescribers and patients treated with ER/LA opioid analgesics, which did not allow a robust assessment of the impact of training on prescriber and patient knowledge.
- Some measures of adverse outcomes of interest (e.g., poison center calls involving misuse or abuse of ER/LA opioid analgesics) did decrease following the approval of the ER/LA REMS; however, these decreases began before approval of the REMS, and decreases were also seen for drug classes not covered by the REMS. Therefore, it was not clear whether the implementation of the REMS contributed to the decline, particularly given the evolving landscape of the opioid crisis and the many other concurrent efforts to reduce inappropriate prescribing and opioid overdoses.
- Given that a minority of prescribers had completed REMS-compliant training and changes in prescribing or patient outcomes could not be linked to completion of CE, it was unclear whether any changes in prescribing patterns or patient

[7] Information on available accredited REMS CE can be found at https://opioidanalgesicrems.com/RpcUI/home.u, accessed August 7, 2020.

> outcomes were even occurring in the subset of prescribers who had completed training.

In the background document[8] for the May 3 and 4, 2016, joint meeting of the DSaRM and AADP Advisory Committees, FDA noted:

> Without being able to link prescriber participation in REMS training to changes in practice or patient outcomes, it is exceedingly difficult to assess the impact of the REMS on any of the surveillance outcomes. Discussion is needed to explore whether it would be worthwhile and feasible to conduct a study that directly examines the association between provider participation in trainings and specific desired changes in prescribing or practice behaviors or patient outcomes. Although it would be challenging, this type of study could augment and complement an evaluation on the impact of REMS training on prescriber knowledge and self-reported behavior change. A discussion of such a study would need to address issues such as study design, sample size, data sources, cohort selection and defining exposure, defining and operationalizing outcome metrics, and controlling for confounding.

At the joint advisory committee meeting, FDA presented for consideration and discussion a study design evaluating changes in selected outcome measures for prescribers who complete REMS training compared with prescribers who have not. A number of challenges were anticipated with such a design. Prescriber-level data on training completion, prescribing patterns, and patient outcomes would need to be linked. Outcomes, time frames, and appropriate study population and settings would need to be carefully selected, defined, and operationalized. Also, selection bias and other confounding factors would have to be adequately addressed. It was unclear whether such a study would indeed be feasible and likely to yield valuable findings.

The May 3 and 4, 2016, joint advisory committee panel provided thoughts on challenges to such an evaluation, including the likelihood of detecting a change in prescriber behavior from one educational intervention, the difficulty in defining *inappropriate prescribing*, and the feasibility of an observational study that would capture the outcome of appropriate prescribing. One panelist stated that educating prescribers on how to safely use these products empirically makes sense; however, attempting to prove that prescriber behavior and patient outcomes actually improve as a result may not be possible and would likely be unsuccessful.

Following the May 3 and 4, 2016, joint advisory committee meeting, a team was formed in FDA's Center for Drug Evaluation and Research (CDER) to propose a REMS modification that considered the DSaRM and AADP Advisory Committees' advice. The team focused on three proposed modifications to the REMS: (1) including IR opioid analgesics; (2) broadening the educational content to include general pain management principles; and (3) expanding training targets to all health care providers involved in the care of patients with pain. As part of the proposed modifications, the FDA team also

[8] Available at https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM497290.pdf, p. 161.

revised the REMS goals and the assessment plan to include methods and metrics that would more rigorously evaluate the REMS intervention. Similar to the ER/LA REMS assessment plan, the OA REMS assessment plan includes training completion numbers, audits of CE activities for content and quality, stakeholder knowledge surveys, drug use trends and patterns, and surveillance of adverse events of interest as well as the CE Providers' requirement for post-training knowledge assessments for participants to obtain credit. However, the OA REMS assessment plan also includes methods and metrics to more rigorously evaluate the REMS intervention, including:

- The development and validation of a new instrument for use across several different CE formats to evaluate participant knowledge before and after completing an activity to better understand how CE completion affects knowledge about best pain management practices and appropriate opioid prescribing. A patient focus group component would be added to collect information about patient experiences around pain management.
- An evaluation of the overall pain and opioid CE program landscape in the United States, and governmental and nongovernmental policies targeting opioid prescribing would be provided to inform concurrent educational interventions.
- An evaluation of the effect of completing REMS-compliant CE on participants' behavior and patient outcomes, and on any barriers that providers may face in treating patients with pain according to the best practices outlined in the FDA Blueprint, would be provided.

In addition, following the May 3 and 4, 2016, joint advisory committee meeting, FDA directed the RPC to submit concept papers on the evaluation of the impact of the ER/LA REMS on:

- Prescribing practices and patient outcomes
- Prescriber and patient knowledge using alternate study designs
- Patient access

In June 2018, the RPC provided a report of a preliminary assessment of the impact of a single large ER/LA REMS-compliant CE program, the Pri-Med CE program, on opioid prescribing patterns. This report included results of a study that linked the National Prescriber Index (NPI) numbers of prescriber CE completers and non-completers with those providers' opioid analgesic prescriptions dispensed, using the IQVIA Real-World Data Prescription claims file. Comparisons of opioid prescribing characteristics in the year after Pri-Med CE completion were compared to the same measures in those prescribers during the year before the education, as well as to these measures in prescribers who did not complete Pri-Med CE training. Neither of these comparisons demonstrated measurable differences either in overall opioid prescribing volume or in discouraged practices, such as prescribing high-dose opioid analgesics to opioid-naïve patients and concomitant dispensing of ER/LA opioid analgesics with central nervous system depressant medications. It was also noted, however, that the providers included in the study came overwhelmingly from primary care and had very low volume of opioid prescribing, in general. In addition, despite baseline matching of CE completers and non-completers on categories of opioid prescription volume, prescribers who did not complete the Pri-Med CE had subsequent 20 to 25 percent lower opioid prescription volume than

those who did, suggesting that providers with a greater expectation of prescribing opioids may have self-selected to pursue training. Report authors noted that the study design did not account for confounding by secular trends and other interventions to influence opioid prescribing behavior.

To date, the Pri-Med CE program is the only RPC-funded REMS CE provider that has captured participant NPI numbers. Both CE Providers and Accreditors have cautioned FDA against requiring collection of NPI numbers of CE participants based on privacy concerns as well as the likelihood of missing some members of the health care team who do not have NPI numbers. It should also be noted that in the 2018 Request for Applications for grant support for REMS-compliant CE, Pri-Med was not awarded grant funding to provide OA REMS-compliant CE.

Despite these efforts to improve the assessment of the OA REMS, many challenges remain. Foremost among these is the wide variety of CE venues, formats, and targeted health care provider types for the currently funded REMS CE activities, as well as the expectations of effect from a one-time completion of the CE. In addition, multiple concurrent education activities from non-REMS sources may make the effect of REMS-compliant CE more difficult to detect.

PROPOSED STUDY TO EVALUATE THE EFFECT OF OA REMS-COMPLIANT CE ON PRESCRIBER BEHAVIOR AND PATIENT OUTCOMES

In response to FDA's request for a study proposal to evaluate the effect of the new OA REMS-compliant CE on prescriber behavior and patient outcomes (a required element of the assessment plan), the RPC provided a White Paper entitled *Evaluation of the Impact of REMS-Compliant Accredited CE* as part of the 12-month OA REMS assessment report, which was received September 18, 2019 (Appendix 3). The White Paper proposed a retrospective observational study using prescription dispensing claims data (and potentially other administrative claims data). The study employed a conceptual framework incorporating past prescribing behavior, patient and prescriber characteristics, and environmental factors and local secular trends in opioid prescribing and patient management to inform the determinants of opioid prescribing. This framework was proposed to be the basis for statistical modeling of opioid prescription and pain management practices over time. NPI-linked individual-level data on completion of REMS-compliant CE would then be superimposed on this model to assess the marginal effect of REMS-compliant CE on opioid prescribing and pain management practices. The study would use a multivariable repeated measures analysis with prescriber-semesters as the unit of observation, controlling for time-varying predictors of both prescribing behavior and REMS-compliant CE completion. The main endpoints would be based on the Centers for Disease Control and Prevention (CDC) guidelines for population-level assessment of safe opioid prescribing and patient management.[9] This study would require

[9] Centers for Disease Control and Prevention. Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain. 2018. National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention, Atlanta, GA. Available at https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf.

access to NPI numbers for prescribers who have completed REMS-compliant CE and a data resource that can be linked to the NPI, possibly using an irreversible encryption technique to preserve prescriber anonymity while allowing linkage of diverse data streams.

Subsequently, the RPC's *Concurrent Education Interventions Report,* which describes other CE programs related to opioid prescribing and pain management in the United States (Appendix 4), and the RPC's *Legislative and Policy Changes Report,* which describes governmental and nongovernmental policies targeting opioid prescribing (Appendix 4), were completed (both also required as part of the 12-month assessment report, as described above). Following receipt of these reports, the authors of the White Paper submitted an addendum (Appendix 5) stating reasons why the observational population-level assessment study proposed in the White Paper (and described above) would not be feasible. The authors describe how the impact of 273 existing non-REMS CE programs, many of which had content that overlapped that of REMS-compliant CE, and the 526 identified policies directed at opioid prescribing provide insurmountable barriers to evaluate the impact of OA REMS-compliant CE. Given the widespread requirements for opioid-related CE from State medical boards, the authors note that the options for a concurrent comparator group become extremely limited, because the few providers who have not received any training may no longer be good representatives of the counterfactual scenario, i.e., usual care without any effects of recent CE training. In addition, considering the hundreds of recent laws and policies related to opioid prescribing being implemented variably across States and local areas at different times, the authors opined that adjusting for all of these impacts on prescribing trends using statistical modeling is "aspirational at best, and may be foolhardy." The addendum suggested, instead, the ongoing monitoring of prescription patterns at the State level and comparing them to CDC guidelines to assess the net impact of the forces changing opioid prescribing practice in the United States.

Members of the FDA REMS Assessment review team met to discuss the White Paper and the addendum described above and agreed that the proposed claims-based study would likely face some potentially insurmountable hurdles and may yield little useful information on the specific impact of the REMS-compliant CE activities on prescriber behavior and patient outcomes. Some team members noted, however, that the RPC had only proposed one study design—a large retrospective, observational population-based study using prescription claims data—then subsequently determined that it would be infeasible. The RPC did not share any assessments of the feasibility of any additional designs or approaches, for example, smaller, targeted investigations within individual health care systems; prospective studies; or interventional designs (i.e., pragmatic trials). Such approaches, however, would still face similar challenges as the claims-based study proposed by the RPC, including (1) identifying an appropriate study population, (2) identifying and operationalizing meaningful outcome metrics capable of detecting potentially small and highly variable effects of CE, (3) isolating any effects of the REMS-compliant CE from the many other policies and educational activities in this area, and (4) interpreting findings in light of the widely varying formats and participant compositions of funded REMS-compliant CE programs.

Specifically, regarding meaningful outcome metrics, it is important to note that the FDA Blueprint largely consists of statements such as "[health care providers] should be knowledgeable about…." rather than specific practices that should occur, such as "pain contracts must be completed for all patients receiving opioid analgesics." Considering that the FDA Blueprint addresses pain management practices more broadly rather than just opioid analgesic prescribing, determining which are key practice measures to evaluate in a given prescriber population and determining how to collect information on whether those practices have changed or differ across groups is scientifically challenging. Also, given the plethora of CE activities available, it is unclear how well the results of a study of one or a subset of CE activities might be generalizable to the wide variety of REMS-compliant CE activities. In addition, the inclusion of other, non-prescriber members of the health care delivery team as targets for REMS-complaint CE acknowledges their contribution to facilitating best practices in pain management. It is unclear, however, how studies focused on evaluating prescriber behavior and the outcomes of patients linked to those prescribers would incorporate the contributions of other health care professionals in achieving safer prescribing practices and optimizing outcomes for patients with pain.

Given these many challenges, FDA REMS Assessment review team considered whether a pilot study or studies may be of value to further assess the feasibility of different approaches to studying the effect of REMS-compliant CE on prescriber behavior and patient outcomes. The team also considered whether alternative approaches should be explored if it is ultimately determined that a rigorous evaluation of the effect of REMS-compliant CE on practice and patient outcomes is infeasible. For example, our understanding of the role of CE might be enhanced by a mixed-methods investigation of the major drivers of pain management practice and opioid prescribing in the U.S. health care system, including the barriers to change and reactions to the many recent efforts to reduce opioid analgesic prescribing.

SCIENTIFIC WORKSHOP DISCUSSION TOPICS

The main objective of the workshop is to discuss three major topics. This objective will be achieved through FDA and guest speaker presentations and facilitated discussion with the panel of experts. The three major topics are as follows:

1. Specific, measurable outcomes that might demonstrate that the REMS training based on the FDA Blueprint is effective in educating prescribers and other health care providers (including pharmacists and nurses) involved in the treatment and monitoring of patients in pain about recommended pain management practices and the appropriate use of opioid analgesics.

2. The feasibility of conducting a study to specifically evaluate the effect of OA REMS-compliant CE on prescriber behavior and patient outcomes amidst the numerous concomitant strategies to combat the opioid crisis at the Federal, State, and local levels. This discussion will include, for example, what effect size might be reasonable to expect to result from a one-time completion of a CE program and whether there are methods (e.g., study design, data sources, metrics) that could isolate

and identify the effect that REMS-compliant CE has on prescriber behavior and patient outcomes. Participants may also be asked to discuss:

- Whether a pilot study would be informative and, if so, what features of the pilot study would be key
- Which types of stakeholders might be well-positioned to conduct such a study
- How a study might evaluate the varying formats of CE activity
- Reasonable timing for outcome evaluation relative to completion of a CE activity

3. Whether there might be suitable alternative study approaches to better understand the influence of CE, more broadly, on pain management practice and patient outcomes, if a study to *directly* measure the impact of REMS-compliant CE is thought to be infeasible.

APPENDICES

APPENDIX 1: FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain

APPENDIX 2: Opioid Analgesic REMS Assessment Plan July 2020

APPENDIX 3: White Paper

APPENDIX 4: Concurrent Educational Interventions Report and Legislative and Policy Changes Report

APPENDIX 5: Addendum to White Paper

Introduction
FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain

Background

In July 2012, FDA approved the Extended-Release and Long-Acting (ER/LA) Opioid Analgesic Risk Evaluation and Mitigation Strategy (ER/LA REMS) to ensure that the benefits of ER and LA opioid analgesics used in the outpatient setting outweigh the risks. That REMS was modified and the new *Opioid Analgesic REMS* includes, in addition to ER/LA opioid analgesics, all immediate-release (IR) opioids used in the outpatient setting that are not already covered by another REMS program. The *Opioid Analgesic REMS* is intended to support other national efforts underway to address the misuse and abuse of prescription opioid analgesics.

As part of the Opioid Analgesic REMS, all opioid analgesic companies must provide the following:

- Education for health care providers (HCPs) who participate in the treatment and monitoring of pain. For the purpose of the Opioid Analgesic REMS, HCPs will include not only prescribers, but also HCPs who participate in the treatment and monitoring of patients who receive opioid analgesics, including pharmacists and nurses.
    - Education will be offered through accredited continuing education (CE) activities. These activities will be supported by unrestricted educational grants from opioid analgesic companies.
- Information for HCPs to use when counseling patients about the risks of ER, LA, and IR opioid analgesic use.

To facilitate the development of CE educational materials and activities as part of the Opioid Analgesic REMS, FDA has also revised the education blueprint — originally designed to facilitate development of CE educational materials under the ER/LA REMS. FDA has completed the revisions to the *FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain* (FDA Blueprint), following publication of a draft version and consideration of received public comments.

The FDA Blueprint contains a high-level outline of the core educational messages that will be included in the educational programs developed under the Opioid Analgesic REMS. The FDA Blueprint focuses on the fundamentals of acute and chronic pain management and provides a contextual framework for the safe prescribing of opioid analgesics. The core messages are directed to prescribers, pharmacists, and nurses, but are also relevant for other HCPs who participate in the management of pain. The course work is not intended to be exhaustive nor a substitute for a more comprehensive pain management course.

Accrediting bodies and CE providers will ensure that the CE activities developed comply with the standards for CE of the Accreditation Council for Continuing Medical Education, [1,2] or another CE accrediting body, depending on the target audience's medical specialty or health care profession.

FDA is making the FDA Blueprint, approved as part of the Opioid Analgesic REMS, available on the REMS@FDA Website (www.fda.gov/REMS), where it will remain posted for use by CE providers as they develop the CE materials and activities. A list of the REMS-compliant CE activities supported by unrestricted educational grants from the opioid analgesic companies to accredited CE providers will be posted at www.opioidanalgesicREMS.com as that information becomes available.

Reasons Why HCP Education Is So Important

Adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioids have emerged as major public health problems. It is critical that HCPs are knowledgeable about the risks associated with opioid analgesics as they pertain to their patients as well as from a public health perspective. The data continue to show problems associated with prescription opioid analgesics.

- In 2015, over 52,404 Americans died from drug poisonings, and of these, 24% or approximately 12,570 deaths involved opioid analgesics.[3]

- Based on the 2016 National Survey on Drug Use and Health (NSDUH), an estimated 11.5 million Americans aged 12 or older misused a prescription pain reliever in the past year — with hydrocodone, oxycodone, and codeine products being the most commonly reported.[4]

- The most common source of pain relievers in the 2016 NSDUH was "a friend or relative" (53%). "A physician's prescription" was the second most common source, reported by approximately 35% of respondents.[5]

The nation is facing competing public health problems: the need to adequately treat a large number of Americans with acute and chronic pain and an epidemic of prescription opioid abuse.

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[1] Accreditation Council for Continuing Medical Education. 2016. Accreditation Requirements. Criteria for CME Providers-Accreditation Criteria. Accessed July 2018.

[2] Accreditation Council for Continuing Medical Education. 2016. Accreditation Requirements. Criteria for CME Providers-Standards for Commercial Support. Accessed July 2018.

[3] See https://www.cdc.gov/nchs/data/factsheets/factsheet_drug_poisoning.pdf. Accessed July 2018.

[4] Substance Abuse and Mental Health Services Administration. (2017). *Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health* (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.

[5] Ibid.

Described in the 2011 report by the National Academies of Science, Engineering, and Medicine (NASEM), *Relieving PAIN in America, A Blueprint for Transforming Prevention, Care, Education, and Research*,[6] 100 million Americans suffer from common chronic pain conditions; fewer than half of Americans undergoing surgery report adequate pain relief; and 60% of Americans visiting the emergency department with acute painful conditions receive analgesics.

The increasing availability of prescription opioids since the 1990's has been accompanied by an epidemic of opioid addiction. The Substance Abuse and Mental Health Services Administration's *National Survey of Drug Use and Health* has shown that most people who use prescription analgesics "nonmedically" obtain them from friends or family, who it is believed obtained the drugs from a doctor's prescription.[7]

Some of the immediate consequences of untreated or undertreated pain include reduced quality of life, impaired physical function, and high economic costs. Chronic pain is associated with physical disability, fear, anger, depression, anxiety, and reduced ability to carry out the roles of family member, friend, and employee. It is critically important that HCPs have all the information they need to properly treat their patients and safely manage their pain. It is also critical for HCPs to understand when opioid analgesics are the appropriate treatment and how to implement best practices to ensure their patients' safety. A 2017 report by NASEM, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use,* describes the challenges of providing adequate pain management and calls for the establishment of "comprehensive pain education materials and curricula" for HCPs.[8]

Having broad knowledge about how to manage patients with pain can create the opportunity for HCPs to consider ***all*** options for pain management, including nonpharmacologic and non-opioid pharmacologic options, and to reserve opioids for when non-opioid options are inadequate and when the benefits of the opioids are expected to outweigh the risks. This information can also aid HCPs in identifying and intervening when encountering obstacles that may reduce access to nonpharmacological and non-opioid medication options. Fully informed HCPs can help contribute to national efforts to address opioid addiction and reduce opioid misuse and abuse.

[6] http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx. Accessed July 2018.

[7] https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf, Table 6.53A. Accessed July 2018.

[8] http://nationalacademies.org/hmd/Reports/2017/pain-management-and-the-opioid-epidemic.aspx. Accessed July 2018.

FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain

Purpose of the Opioid Analgesic REMS HCP Educational Effort

Following completion of educational activities under the Opioid Analgesic REMS, HCPs should be knowledgeable about the following.

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain, identifying risk factors for abuse and addiction
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient
- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with opioid use disorder

In addition, HCPs will gain an understanding of current information about safe opioid practices and about current Federal[9] and State regulations, national guidelines,[10] and professional organization[11] and medical specialty guidelines on treating pain and prescribing opioids. HCPs will also become familiar with the use of naloxone and with the importance of its availability for use by patients and caregivers both in the community and in the home.

[9] For example, see https://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm and https://www.deadiversion.usdoj.gov/21cfr/21usc/829.htm. Accessed July 2018.

[10] For example, see Dowell D, Haegerich TM, Chou R. 2016. CDC Guideline for Prescribing Opioids for Chronic Pain –United States, 2016. MMWR Recomm Rep 2016; 65 (No.RR-1): 1-49. Accessed July 2018.

[11] For example, see Federation of State Medical Boards' Guidelines for the Chronic Use of Opioid Analgesics. Accessed July 2018.

Section 1: The Basics of Pain Management

I. THE NEED FOR COMPREHENSIVE PAIN EDUCATION

The FDA Blueprint was developed with two, competing, U.S. public health concerns in mind, (1) the large number of Americans with acute and chronic pain and (2) the epidemic of prescription opioid abuse.

1. Providing health care providers (HCPs) with a thorough understanding of the risks associated with opioids can give HCPs the opportunity to consider all pain management options, including nonpharmacologic and pharmacologic options, prescribing opioids only when non-opioid options are inadequate and when the benefits of using an opioid are expected to outweigh the risks.

2. When HCPs have information about the risks of opioid misuse and abuse, they will be better able to create opportunities for patient counseling and other strategies to reduce these risks.

II. DEFINITIONS AND MECHANISMS OF PAIN

Pain can be categorized according to its duration, underlying pathophysiology of the original insult, and whether a central sensitization component has developed. An understanding of these different categorizations can help direct therapeutic decisions.

When defining, and classifying pain, the following should be taken into consideration:

1. Biological significance of pain (survival value)
2. Relationship between acute and chronic pain
3. Distinction between nociceptive and neuropathic pain

III. ASSESSING PATIENTS IN PAIN

HCPs should be knowledgeable about how to assess each patient when initiating a pain management program. When appropriate, evidence-based, standardized scales and tools can be used to document pain characteristics and guide management decisions throughout treatment, noting the strengths and weaknesses regarding specificity and sensitivity of these scales.

Important elements of an initial assessment should include the following:

1. Patient history

2. Screening tools to evaluate the known risk factors for development of chronic pain after an acute injury or disease

3. Screening tools to evaluate the known risk factors for opioid use disorder (OUD) or abuse

4. Queries of state prescription drug monitoring programs (PDMPs)

5. Pain assessment scales/tools

6. Functional assessment scales

7. Physical examination

8. Family planning, including information about use of contraceptives, pregnancy intent/status and plans to breastfeed

9. Psychological and social evaluation

10. Diagnostic studies when indicated

Section 2: Creating the Pain Treatment Plan

A comprehensive pain treatment plan should be developed and customized to the needs of the individual patient. The treatment plan should include the types of therapies planned, the goals of treatment, and an explanation of the patient and prescriber roles and responsibilities. The goals of treatment should be based on (1) expected outcomes of pain reduction; (2) improvement in functional outcomes impaired by pain (e.g., activities of daily living); and (3) quality of life.

If HCPs encounter potential barriers to managing patients with pharmacologic and/or nonpharmacologic treatment options, such as lack of insurance coverage or inadequate availability of certain HCPs who treat patients with pain, attempts should be made to address these barriers. The overall treatment approach and plan should be well documented in the patient record, including written agreements and informed consent/patient provider agreements (PPAs) that reinforce patient-provider responsibilities and avoid punitive tones.

I. COMPONENTS OF AN EFFECTIVE TREATMENT PLAN

1. The goals of treatment, including the degree of improvement in pain and function when function has been impaired by pain

2. Possible constituents of the treatment plan, including nonpharmacologic approaches and pharmacologic therapies

3. Patient/prescriber/health care team interactions, including

- Patient responsibilities/compliance with the plan
- Responsibilities of the prescriber and health care team, including patient monitoring
- Plans for reviewing functional goals
- Use of supplemental medication for intermittent increases in pain
- Use of PPAs

II. GENERAL PRINCIPLES OF NONPHARMACOLOGIC APPROACHES

Pain can arise from a wide variety of causes. There are a number of nonpharmacologic and self-management treatment options that have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain. Examples include, but are not limited to, psychological, physical rehabilitative, and surgical approaches, complementary therapies,[12] and use of approved/cleared medical devices for pain management. HCPs should be knowledgeable about the range of treatment options available, the types of pain that may be responsive to those options, and when they should be used as part of a multidisciplinary approach to pain management. HCPs should also be aware that not all nonpharmacologic options have the same strength of evidence to support their utility in the management of pain, and some may be more applicable for some conditions than others.

III. GENERAL PRINCIPLES OF PHARMACOLOGIC ANALGESIC THERAPY

A variety of analgesics, including non-opioid and opioid medications, are available for use to manage pain symptoms. HCPs should be well informed about the range of analgesics available and the types of pain that may be responsive to those analgesics.

A. Non-opioid medications

When using non-opioid medications in pain management, HCPs should be knowledgeable about the following:

1. Mechanism of action of analgesic effect
2. Indications and uses for pain management
3. Routes of administration and formulations used in pain management
4. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia
5. Contraindications
6. Adverse events, with emphasis on labeled warnings
7. Drug interactions — both pharmacodynamic and pharmacokinetic

B. Opioid analgesic medications

Opioid analgesic medications can be used successfully as a component of pain management. However, opioids carry risks not present with most non-opioid analgesics, specifically the risks

[12] For example, see https://nccih.nih.gov. Accessed July 2018.

of addiction, abuse and misuse, which can lead to respiratory depression, overdose and death. Therefore, it is the responsibility of HCPs to be knowledgeable, not just about the presence of such risks, but about how to weigh these risks before prescribing an opioid and about how to properly manage patients who are prescribed opioids, both for short-term and long-term use. When using opioid analgesics as part of pain management, HCPs should be knowledgeable about the following:

1. General precautions
   a. Even at prescribed doses, opioid analgesics carry the risk of misuse, abuse, opioid use disorder, overdose, and death
   b. Importance of the appropriate use of PDMPs[13] and their use as a clinical decision support tool
   c. DSM-5 (R) criteria (or the most recent version) for OUD and the concepts of abuse (taking an opioid to get high) vs. misuse (taking more than prescribed for pain or giving to someone else in pain)[14]
   d. The concepts of tolerance and physiological dependence and how they differ from OUD (addiction)
   e. Recognition that some opioid analgesics (e.g., Transmucosal Immediate Release Fentanyl products, some ER/LA products) are safe only for opioid-tolerant patients

2. Mechanism of action and analgesic effect

3. Types of opioids (full agonists, partial agonists)

4. Indications and uses for pain management

5. Range of opioid analgesic products available for pain management and their related safety concerns
   a. Routes of administration including oral, transmucosal, transdermal
   b. Release characteristics of immediate release (IR), extended-release (ER), long-acting (LA)
   c. Abuse-deterrent formulations (ADFs)
      - Definition of ADF based on the FDA guidance for industry, *Abuse-Deterrent Opioids – Evaluation and Labeling*[15]
      - Recognition that all ADFs have the same potential for addiction and overdose death as non-abuse-deterrent opioids
      - How to understand FDA-approved ADF product labeling

6. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia
   a. Concepts and limitations of the conversion charts in labeling and the limitations of relative potency or equianalgesic dosing tables in literature

[13] SAMHSA Prescription Drug Monitoring Programs: A Guide for Healthcare Providers. Accessed July 2018.

[14] American Psychiatric Association DSM-5-Opioid Use Disorder Diagnostic Criteria. Accessed July 2018.

[15] See FDA guidance for industry *Abuse-Deterrent Opioids —Evaluation and Labeling*. Accessed July 2018.

b. Interindividual variability of response
c. Special populations
    - Pregnant, postpartum, breastfeeding, and neonatal opioid withdrawal syndrome
    - Renal and hepatic impairment
    - Children and adolescents
    - Genetic and phenotypic variations
    - Older adults
    - Sleep disorders
    - Common and uncommon psychiatric disorders

7. Contraindications

8. Adverse Events
    a. Medication errors
    b. Periods of greater risk for significant respiratory depression, including at treatment initiation and with dose increases
    c. Serious adverse drug reactions (including overdose and death)
    d. Labeled warnings
    e. Common adverse drug reactions

9. Drug interactions
    a. Pharmacokinetic interactions based on metabolic pathway
    b. Pharmacokinetic and pharmacodynamic interactions with alcohol
    c. Concerns with particular drug–drug interactions, including, but not limited to:
        - Benzodiazepines and other central nervous system depressants, including alcohol
        - Monoamine oxidase inhibitors
        - Antidiuretic hormone drugs

10. Key safety strategies for use with opioid medications
    a. Dosing instructions including daily maximum
    b. Safe storage to reduce risk of accidental exposure/ingestion by household contacts, especially children/teens and to reduce risk of theft
    c. Naloxone products for use in the home to reduce risk of overdose deaths in patients and household contacts
    d. Proper disposal of used (e.g., transdermal systems) and unused opioids
    e. Pain management after an opioid overdose
    f. Driving and work safety

IV. MANAGING PATIENTS ON OPIOID ANALGESICS

HCPs should be knowledgeable about the appropriate use of opioids in patients with acute and chronic pain, including the importance of balancing potential benefits with the risks of serious adverse outcomes such as overdose and death.

A. Initiating treatment with opioids — acute pain

1. Patient selection — consider when an opioid is an appropriate option and consult the PDMP

2. Dosing — as needed vs. around-the clock dosing, prescribing an appropriate quantity based on the expected duration of pain, i.e., the least amount of medication necessary to treat pain and for the shortest amount of time

3. Naloxone for home use — prescribe and discuss the use of naloxone products and the various means of administration

4. Screening tools for risk of abuse

B. Initiating treatment with opioids — chronic pain

1. Patient selection
   a. Differences in benefit and risk and expected outcomes for patients with chronic pain, palliative care, or end-of-life care
   b. Differences in initiating treatment in opioid nontolerant vs. opioid-tolerant patients

2. Dosing
   a. As needed vs. around-the-clock
   b. How to determine a safe initial dose
   c. Safe conversion from other opioids

3. Considerations in opioid selection
   a. IR or ER/LA
   b. Special precautions with methadone
   c. Products restricted to opioid-tolerant patients

4. When and how to use an opioid or non-opioid analgesic to supplement pain management

C. Ongoing management of patients on opioid analgesics

1. Periodic review of pain and functional goals

2. Review adverse events at each visit
   - Eliciting signs or symptoms of opioid abuse
   - Screening for endocrine function may be recommended

- Importance of adverse event reporting and mechanisms to report

3. Review refill history/review PDMP

4. How to determine when an opioid analgesic is no longer necessary/beneficial

D. Long-term management

1. Evaluation of the patient with worsening pain for changes in underlying condition and for signs of OUD before increasing opioid dosage

2. Changing opioid medications
   - Concept of incomplete cross-tolerance when converting patients from one opioid to another
   - Concepts and limitations of the conversion charts in labeling and the limitations of relative potency or equianalgesic dosing tables in literature

3. Monitoring of patient adherence to the treatment plan, especially regarding misuse and abuse:
   - Perform medication reconciliation — recognize, document, and address aberrant drug-related behavior
   - Determine if nonadherence is due to inadequate pain management
   - Understand the utility and interpretation of urine drug testing (e.g., screening and confirmatory tests) and use as indicated
   - Screen and refer for substance use disorder treatment when concerns arise

E. How to recognize and intervene upon suspicion or identification of an OUD

HCPs should understand how to monitor patients taking opioid analgesics and identify the signs and symptoms of opioid misuse, abuse, and OUD and be knowledgeable about how to begin the process of intervention upon suspicion of an OUD.

F. When to consult with a pain specialist

HCPs should be knowledgeable about when referral to a pain management specialist is indicated, including identifying patients at high risk for OUD and patients unable to achieve adequate pain management.

G. Medically directed opioid tapering

HCPs should be knowledgeable about how to safely taper opioid analgesics, including how to recognize and manage signs and symptoms of opioid withdrawal. HCPs should be knowledgeable about the particular risks associated with tapering during pregnancy.

H. Importance of patient education

HCPs should recognize their role in reducing the risks associated with opioid analgesics through patient education at initiation of an opioid and throughout long-term management.

1. Inform patients about pain management expectations and managing pain through different pharmacologic and nonpharmacologic modalities.

2. Use the *Patient Counseling Guide: What You Need to Know About Opioid Pain Medicines* as part of discussion with patients and caregivers when prescribing opioid analgesics.

3. Counsel the patient about the following:
   a. Importance of adherence to prescribed dosing regimen
   b. Patients should use the least amount of medication necessary to treat pain and for the shortest amount of time
   c. The risk of serious adverse events that can lead to death
   d. The risk of addiction that can occur even when product is used as recommended
   e. Known risk factors for serious adverse events, including signs and symptoms of overdose and opioid-induced respiratory depression, GI obstruction, and allergic reactions, among others
   f. The most common side effects, along with the risk of falls, working with heavy machinery, and driving
   g. When to call the prescriber (e.g., managing adverse events, ongoing pain)
   h. How to handle missed doses
   i. The importance of full disclosure of all medications and supplements to all HCPs and the risks associated with the use of alcohol and other opioids/benzodiazepines
   j. Product-specific concerns, such as not to crush or chew ER products; transdermal systems and buccal films should not be cut, torn, or damaged before use, etc.
   k. How to safely taper dose to avoid withdrawal symptoms
   l. Safe storage and disposal, risks of theft by family members and household visitors
   m. Never share any opioid analgesic with another person
   n. How and when to use naloxone products and their various means of administration
   o. Seeking emergency medical treatment if an opioid overdose occurs
   p. How to report adverse events and medication errors to FDA (1-800-fda-1088 or via http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)

V. ADDICTION MEDICINE PRIMER

HCPs should be knowledgeable about the basic elements of addiction medicine and be familiar with the definition, neurobiology, and pharmacotherapy of OUDs. In particular, stigmatizing or blaming language should be replaced with language that acknowledges that addiction,

reclassified as *substance use disorder*[16] in the revised Diagnostic Statistical Manual–V, is a disease. The term *opioid use disorder* [17] should be used when referring to the use of opioids, rather than other substances.

It should also be noted that there may be a different approach with a patient who misuses an opioid analgesic by taking the product differently than prescribed for the purpose of managing pain, in contrast to the patient who abuses an opioid analgesic with the intent of getting high. HCPs should be familiar with the following:

1. The neurobiology of OUD (addictive cycle)

2. Use of screening tools to identify patients at risk, based on known risk factors, and to identify patients developing signs of opioid dependence or addiction as early as possible.

3. Management of OUD, including the types of pharmacologic and nonpharmacologic treatments available and when to refer to an addiction medicine specialist.

[16] Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (Copyright 2013). American Psychiatric Association.

[17] Id.

1. REMS Outreach and Communication

    a. For each healthcare provider (e.g., prescriber, pharmacist) to be sent information regarding REMS-compliant accredited continuing education (CE), provide the date when the letters were sent; the number of letters electronically sent, received, undeliverable, and opened; and the number of letters mailed and undeliverable

    b. For each professional society, association, and licensing board to be sent information regarding REMS-compliant accredited CE, provide the number of letters electronically sent, received, undeliverable, and opened; and the number of letters mailed and undeliverable

2. REMS Implementation and Operations

    a. Status of grants

        i. The status of the request for proposals for grants for REMS-compliant accredited CE including:

            1. Request for Application (RFA) issued: date and number of applications submitted in response to each RFA

            2. RFAs awarded: date, number, and name of grantee

            3. Date/timeframe next RFA to be issued

        ii. The status of the requests for proposals for any grants to CE Providers or other CE organizations with expertise in assessing CE outcomes who agree to conduct evaluations of health care providers who have taken REMS-compliant accredited CE funded under this REMS.

    b. Grant review committee

        i. Individuals from the REMS Program Companies (RPC) reviewing grants will include the following clinical licensures: pharmacists, nurses, physicians. Additionally, there will be involvement by individuals with regulatory and pharmacovigilance experience. The job title, licensure, and professional degree of individuals will be provided for each grant review cycle.

        ii. Include any external members (non-RPC) involved in the grant review, including those from the broad-based CE community. Provide the job title,

licensure and professional degree of the individual for each grant review cycle

c. For CE programs awarded during the assessment period:

   i. Description of each grantee and projected number of completers

   ii. For the first assessment, the date the first program based upon the FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint"), became available

   iii. Description of CE program:

      1. Level of outcome the activity[1] is designed to impact
      2. CE format (live, webinar, etc.)
      3. Duration of activity for live or webinar activities
      4. Average duration to complete for internet/enduring activities
      5. Education methods and tools (case-based, multimedia, didactic, interactive, adaptive, etc.)[1,2]

   iv. All reports submitted to the RPC by CE grantees during the assessment period.

d. Number of completers of OA REMS Continuing Education activities during the assessment period; provide description of learners by standard learner category data.[3]

   i. Summary of reports from any CE Provider that tracks participants that begin an activity but do not complete it; only provide when insight on lack of completion is available (e.g., participant didn't complete because activity too long, too difficult, etc.)

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[1] Stevenson R, Moore DE. Ascent to the Summit of the CME Pyramid. *JAMA* 2018;319(6):543-544 [2] Cervero R, Gaines J. The Impact of CME on Physician Performance and Patient Health Outcomes: An Updated Synthesis of Systematic Reviews *J Contin Educ Health Prof* 2015;35(2):131–138

[2] Agency for Research Health and Quality. (2007). *Effectiveness of Continuing Medical Education*. Retrieved May 9, 2018, from https://archive.ahrq.gov/downloads/pub/evidence/pdf/cme/cme.pdf

[3] Standard Continuing Education (CE) learner data to be captured by all CE Providers for Opioid Analgesic REMS includes geographic location (state of primary practice), DEA prescriber status (individual registration or institutional authorization), profession, practice area, and length of time in practice.

e. Independent Audit: The results of independent audits of the CE. Audits must be conducted on a random sample of at least 10% of the REMS-compliant accredited CE funded under the Opioid Analgesic REMS and must include/evaluate:

    i. a description of the organization(s) conducting the audit(s)

    ii. whether the content of the REMS-compliant accredited CE covers all elements of the FDA Blueprint approved as part of the REMS;

    iii. whether the integrated or post-course knowledge assessment measures knowledge of all sections of the FDA Blueprint; and

    iv. whether the REMS-compliant accredited CE was conducted in accordance with the Accreditation Council for Continuing Medication Education (ACCME) standards for CE or appropriate standards for accreditation bodies

f. Concurrent Educational interventions

    i. For the year prior to the assessment period through the assessment period, provide an evaluation of the overall pain/opioid CE landscape including but not limited to:

        1. States requiring prescribers, pharmacists or nurses to complete opioid or pain management continuing education for licensing/renewal of licensing:

            a. Enumeration of these states and their requirements for continuing education on either pain or safe opioid use,
            b. estimates of annual licensed prescribers in those states
            c. which, if any, opioid analgesic or ER/LA Opioid Analgesics REMS CE were permissible in which states, for prescribers to meet requirements

        2. Health systems, including government (DOD, VA, IHS, etc.), that require opioid or pain management continuing education; include number of completers if available

        3. Any additional available data on continuing education programs available during this time with a focus on pharmacological pain management or safe opioid use

3. Health Outcomes and/or Surrogates of Health Outcomes

a. Surveillance and monitoring of data relating to opioid analgesic use, misuse, abuse, overdose, addiction, and death. Surveillance data should include the following:

    i. Nationally representative data or data from large stable populations on opioid analgesic misuse, abuse, addiction, overdose, and death, to allow reliable assessment of national trends and demographic patterns (e.g., age group specific rates and trends)

    ii. Both overall and drug-specific outcome rates, as available, in each data source

    iii. Data on trends and patterns of illicit opioid (e.g., heroin) use and related morbidity and mortality

b. Evaluation of drug utilization patterns: Nationally-projected data on drug utilization trends and patterns, including an evaluation of trends in:

    i. Dispensing of opioid analgesics subject to the Opioid Analgesic REMS, by drug, age group, prescriber specialty

    ii. An evaluation of opioid tolerance for products that require patients to be opioid tolerant prior to use

    iii. An evaluation of concomitant prescribing of gabapentinoids, benzodiazepines, and other CNS depressants with opioid analgesics

c. Evaluation of patient experiences around pain management

d. An evaluation of patients' experiences with acute and chronic pain management in various settings: this may include a survey, focus group, or other assessment of patient experience, including but not limited to access to coordinated pain management care, non-pharmacological options, and judicious and informed prescribing of opioids. The evaluation may also include an assessment of negative patient experiences, such as perceived overprescribing of opioids, providers' refusal to provide care, or forced rapid tapering or discontinuation.

e. Evaluation of prescriber behavior and patient outcomes: The results of an evaluation of the effect of REMS-compliant CE on prescriber behavior and patient outcomes. This evaluation should include the following:

    i. Development and use of metrics that assess prescriber behaviors and patient outcomes relating to key messages in FDA Blueprint. The assessment should also include an evaluation of potential unintended adverse patient

outcomes resulting from changes in prescribing practices (e.g., withdrawal symptoms or increased pain due to inappropriate rapid opioid tapering, patient abandonment, seeking of illicit opioids, suicide attempts/completion)

ii. Use of an appropriate control group (i.e., providers who have not completed REMS-compliant accredited CE), and rigorous control for confounding, to allow an assessment of whether any observed changes in prescriber behaviors or patient outcomes can be attributed to the CE

f. Evaluation of healthcare providers' perceptions of the key influences (e.g., education, state legislation, system-level policies, fear of reprimand or litigation, insurance reimbursement, time constraints) on pain management practices for prescribers and other members of the healthcare team and what the impacts have been on patient outcomes. For the 24-month assessment,

i. Conduct a literature review and summarize previous work in this area

ii. Propose a study or studies to address the evaluation of the key influences on a sample of opioid prescribers. These studies may employ mixed-methods approaches and other emerging research methodologies most appropriate for answering the question.

4. Knowledge

a. Evaluation of CE participants: The results of evaluations to determine the impact of REMS-compliant accredited CE on participants' knowledge, attitudes, and self-reported behavior around pain management and appropriate opioid prescribing. All evaluations should be representative and generalizable to the targeted health care professionals taking the REMS-compliant accredited CE and assess understanding of key elements from all sections of the FDA Blueprint. Multiple methodologies should be used, including but not limited to the following:

i. These assessments could be integrated into live, online, or multimedia formats using interactive approaches to enhance the educational value of the activity. Different versions or subsets of questions from a standardized assessment tool could be employed to cover all key messages and sections of the FDA Blueprint, in aggregate, while reducing the time burden for individual participants and allowing the assessment to be tailored for different types of healthcare professionals.

ii. A long-term follow-up evaluation of participants to assess retention of knowledge and skills, application of learning to clinical practice, self-reported change in behavior, and barriers to change. Consider incentivizing participation in follow-up assessment, for example through additional CE credits.

b. Evaluation of Patient Understanding: The results of an evaluation of patients' and caregivers' understanding of the serious risks of opioid analgesics and their understanding of how to use these products safely. This evaluation may include, for example, surveys of patients from a representative sample of patients taking opioid analgesics with respect to education level, insurance status, and geographic location.

5. During transition from the ER/LA Opioid Analgesics REMS to Opioid Analgesic REMS, data to be included until the last enduring activity has been reported:

   a. For each CE activity released under the ER/LA Opioid Analgesics REMS that remains active, provide the name of the CE Provider, the title of the activity, and the date the activity will expire

   b. Aggregate data on participants and completers should be collected using original MEMS 2.0 definitions

6. Methodologies: A timeline for submission of the assessment protocols, including data sources and the methodologies used to conduct all the above described analyses. Each assessment report should update the dates of submission for each component of the assessment.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

Appendix 28 Evaluation of the Impact of REMS-Compliant Accredited CE White Paper

Options for Evaluating the Impact of REMS-Compliant Continuing Education on Opioid Prescribing Practices, Patient Management and Patient Outcomes

Prepared for the Opioid Analgesic REMS Program Companies

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TABLE OF CONTENTS

LIST OF TABLES 2

LIST OF FIGURES 3

1. SUMMARY 4

2. BACKGROUND 5

3. PRIOR WORK BY RPC 6

4. PLAN 8

4.1 Conceptual Framework 8
4.2 Structure for Analyses 10

5. A SUITE OF ANALYSES TO ASSESS THE IMPACT OF CE 13

5.1 Overview 13
5.2 Required Data 13
5.3 Determinants of Prescribing Practice 13
5.4 Factors That Influence the Management of Patients Receiving Prescription Opioids 15
5.5 Determinants of the Uptake of CE 16
5.6 Combining Predictors of CE with Predictors of Prescribing and of Patient Management 17

6. CONDUCT 18

6.1 Research Venues 18
6.2 Provider Identification 18
6.3 Restriction to Informative Providers 19
6.4 Provider Education That Is Not REMS-Compliant 19
6.5 Why Not Direct Assessment of CE Participants? 20

7. DISCUSSION 21

8. CONCLUSION 23

9. REFERENCES 24

10. Appendix A. CDC Guidelines 27

11. Appendix B. The IQVIA RWD Prescription Claims Database 30

12. Appendix C. Doctor and Pharmacy Shopping 31

13. Appendix D. Components of a US Health Insurance Claims Database 32

LIST OF TABLES

Table 1. Format of a generic analytic result 11

Table 2. Available predictors of provider prescription semester volume and provider practices in a dispensing database 14

Table 3. Additional characteristics in an insurance or EHR database that can serve as outcomes in an evaluation of patient management 15

Table 4. Available predictors and outcome measures for provider uptake of CE in a dispensing database 16

Table 5. Correspondence between conclusions from the Conceptual Model and the proposed analyses 21

Table A1. Measures to assess CDC Guidelines 29
Table C1. Definitions of levels of doctor and pharmacy shopping over 18 months of follow-up.31

LIST OF FIGURES

Figure 1. Possible causal pathways for prescribing practice, patient selection and patient outcomes in the absence of REMS-compliant CE 8
Figure 2. Possible causal pathways for the evaluation of CE interventions.....9

1. SUMMARY

The purpose of this paper is to propose methods and venues for evaluating the effectiveness of REMS-compliant continuing education (CE), a component of a Risk Evaluation and Mitigation Strategy (REMS) that has been agreed upon by the Food and Drug Administration (FDA) and the Opioid Analgesic REMS Program Companies (RPC). New REMS-compliant CE programs based on the revised FDA Blueprint have been established following an FDA decision to expand the REMS program to include all opioids prescribed for the treatment of pain and to extend REMS-compliant CE to the broader healthcare teams including nurses and pharmacists. This proposal's focus is on measuring the effect of REMS-compliant CE on prescribing and on indices of good management of patients who receive opioids. The statistical models within which REMS-compliant CE is to be evaluated include an accounting for local secular trends in opioid prescribing and patient management.

In work conducted when extended-release/long-acting (ER/LA) opioids were the focus of regulatory concern, RPC's evaluation of a single large vendor's professional education program did not show an impact on the volume of prescribing or on the frequency of discouraged patient management activities, such as treating opioid-naïve patients with high-dose opioids or ER/LA opioids. Further findings from the analysis were that participants in educational programs came overwhelmingly from primary care, that among participants in the programs and comparison practitioners, many prescribed opioids rarely or not at all. The choice to pursue CE for opioid prescribing may have been positively related to a practitioner's *a priori* likelihood of using opioids.

The future analyses proposed here are derived from a conceptual framework that sees opioid prescribing as a function of past prescribing habits, prescriber and patient characteristics, and environmental factors, as well as prescriber-specific factors and secular trends. All the determinants act in addition to the professional education program. Under the framework, the impact of the program may change with time after completion of training and it may operate differently in different categories of prescribers. The proposed analysis takes as its principal endpoints measures proposed in CDC guidelines for population-level assessment of safe opioid prescribing and patient management (Appendix A). The analysis employs covariates that both are suggested by the conceptual framework, and are available in the assumed study settings.

The first cut of research into the factors that drive opioid prescribing and patient management can be accomplished before NPI-linked data are available. After there is a detailed picture of the dynamics of the outcomes in the populations to be studied, data describing prescriber-participants in REMS-compliant CE can be layered on to provide for a well-controlled assessment of the program's impact.

2. BACKGROUND

Educating healthcare providers about the use of opioids has the clinical goals of giving patients needed pain relief and eliminating prescribing that results in opioid misuse or abuse. Most US state medical boards mandate prescriber education for safe opioid prescribing, but the specifics vary from state to state. [1] The FDA has provided guidelines (the "FDA Blueprint") for the content of REMS-compliant accredited CE for prescribers and members of the broader healthcare team. [2] The range of the FDA's specified areas for education is broad, covering concepts in pain management and opioid use disorder, patient evaluation, the place of opioids in management plans for acute and chronic pain, patient counseling about safe use, referral of patients to pain specialists and identification and management of opioid use disorders.

RPC gained experience with a single education vendor (Pri-Med®) for a program that addressed use of ER/LA opioids in 2012 through 2017. In 2018, RPC awarded grants for 14 new REMS-compliant CE programs following the revised FDA Blueprint. In contrast to the earlier efforts, which were focused on ER/LA opioids, the program now encompasses prescription practice for all opioid products.

In what follows, we will use the term "REMS-compliant CE" to designate healthcare provider accredited continuing education programs developed under the sponsorship of RPC and verified as covering the topics in the FDA Blueprint. We will use terms such as "professional education" to refer to non-sponsored programs.

Integral to the REMS-compliant CE programs will be immediate assessment of the healthcare providers' understanding. Longer-term evaluations, up to 48 months, were also carried out under the ER/LA REMS program.[3] RPC will present elsewhere the plans for both short and long-term evaluations under the current REMS program.

The purpose of this discussion is to propose measures, techniques and venues to evaluate the impact of REMS-compliant CE programs on healthcare providers' practice and on patient outcomes. The measures rely heavily on the assessment standards set out in the US Centers for Disease Control (CDC) 2018 guidelines for safe prescribing practices for opioids (Appendix A).[4] The techniques are multivariable procedures that can accommodate time-varying and time-invariant predictors, secular trends and repeated measures. The venues are all ones for which there is substantial experience in the conduct of observational studies of drug utilization and drug effects.

RPC will prepare full protocols for the analysis of the impact of REMS-compliant CE on prescribers of opioids. The protocols will describe timelines, study venues, data to be ascertained, hypotheses and measures, analytic techniques, and the relation of actionable conclusions to the possible results.

Because the FDA's critique of prior RPC efforts went to fundamental issues of study conception, RPC felt it appropriate to commission this white paper, which would lay out how RPC might formulate studies that meet the Agency's intent. With REMS-compliant CE programs based on the 2018 FDA Blueprint starting just now, there is time to create a study that will assess REMS-compliant CE as a key component of the current REMS program that covers all opioids.

3. PRIOR WORK BY RPC

RPC contracted with the medical informatics company IQVIA™ to assess the Pri-Med prescriber education program's impact on opioid prescribing in 2012 through 2017. The results were provided to the FDA as "RPC Report #7." [5] Key portions of RPC Report #7 are to be summarized in a manuscript for publication.[6]

> RPC Report #7 used IQVIA's Real-World Data (RWD) Prescription Claims file (formerly called the "Longitudinal Prescription" – "LRx" – file). The Prescription Claims file captures about 90% of drug dispensings in the US. See Appendix B. A patient population was defined as one with evidence of continuous representation in the file from June 2012 through December 2017. The prescribers of all opioid products dispensed to the patients in the population were identified. The prescriber file was linked to Pri-Med's records of CE completion using the National Prescriber Index (NPI™). Pri-Med provided the completion date for each prescriber.

The unit of analysis in RPC Report #7 was the dispensing of an opioid. Each dispensing had associated drug characteristics such as substance, dose and formulation derived directly from the National Drug Code (NDC™) number or contextual characteristics, such as dispensing an ER/LA opioid to an opioid-naïve patient. The evaluation of the impact of prescriber education rested on classifying each dispensing as to whether it had occurred in the year following the prescriber's completion of the Pri-Med program. There were two kinds of comparisons.

1. Pre-post. Population-level summary measures of opioid dispensing characteristics in the year after prescriber education completion were compared to the same measures in the same prescribers during the year before prescriber education completion.
2. Contemporaneous. Providers who had not completed Pri-Med prescriber education were compared to those who had done so, with matching on a date corresponding to prescriber education completion and further matching by categories of age, gender, specialty, region, numbers of dispensings of ER/LA and immediate-release or short-acting (IR/SA) opioids, and number of opioid-treated patients for each prescriber. The outcome measures were assessed over the year following prescriber education completion among the completers and the matched comparison group.

Both kinds of comparison were applied to purely descriptive measures (item 1 below), direct assessments of change in practice (item 2), and indices of prescribing practices that are discouraged as being unsafe (items 3 and 4). The measures were:

1. Number of dispensings of ER/LA or IR/SA opioids or celecoxib
2. Instances of switching from ER/LA opioids to IR/SA opioids, celecoxib or tramadol
3. Dispensings of ER/LA opioids indicated for use in opioid-tolerant patients or dispensings of more than 100 morphine milligram equivalents per day to patients with no dispensing history that would predict opioid tolerance
4. Dispensings of ER/LA opioids concomitantly with CNS depressive agents

Neither the pre-post nor the contemporaneous comparison supported a supposition that prescriber education had an impact on prescribing practice. For each of the measures, there were no meaningful differences either between the pre-post populations of dispensings or between the populations of dispensings in persons who had completed prescriber education versus those who had not.

RPC Report #7 presented other findings relevant to interpreting its results on the impact of prescriber education and which will be useful to the planning of future assessments:

1. One-third of the prescribers were associated with zero dispensings of opioids in the one-year baseline period and another one-third with up to 25 dispensings in the one-year baseline period. Less than one-third of the prescribers had associated dispensings at least on a weekly basis during the baseline year.

2. Over 90% of prescribers were engaged in primary care (including nurse practitioners and physicians' assistants) and fewer than three percent were in specialties in which pain management is a central aspect of practice.
3. Despite baseline matching on categories of opioid prescription volume, the matched analysis indicated 20-25% lower opioid prescription volume associated with the providers who had not undergone prescriber education training than among those who did.
4. Ninety-three percent of the dispensings were paid for by commercial insurance, Medicare or Medicaid.

The first of these results suggests that the studied population included prescribers in whom it might be futile to attempt an assessment of prescribing practice as a measure of the impact of prescriber education. The second finding is encouraging in that it confirms that primary caregivers, who presumably are most in need of information, form a large part of the completing community for prescriber education programs. The fact that prescribers who completed prescriber education had more prescription volume, even within the categories of matching (point 3 above), suggests that the decision to undergo the training may have been correlated with a higher expectation of opioid prescription in practice. The last finding, that almost all dispensings were covered by insurance, implies that research venues that depend on data from insurance claims should be useful data sources in the future.

The authors of RPC Report #7 noted that the analysis did not control for secular trends. "These factors may have confounded both the pre-/post- and matched analyses. Potential factors include expanded prescription coverage under the Affordable Care Act, state-specific legislation and prescription-monitoring programs, changes to insurance adjustment policies (e.g., dosage strength prior authorizations) and changes to opioid analgesic formulations that resist tampering" (RPC Report #7, p. 70). In addition, neither the pre-post nor the matched analysis adjusted for the characteristics of the patients to whom the opioids were dispensed.

In summary, RPC Report #7 provided a variety of measures that would plausibly be indicative of a beneficial effect of a prescriber education program. None of these measures supported the hypothesis that prescriber education affected prescribing practice. The report did not go into possible differences in prescriber education impact across different groups of patients.

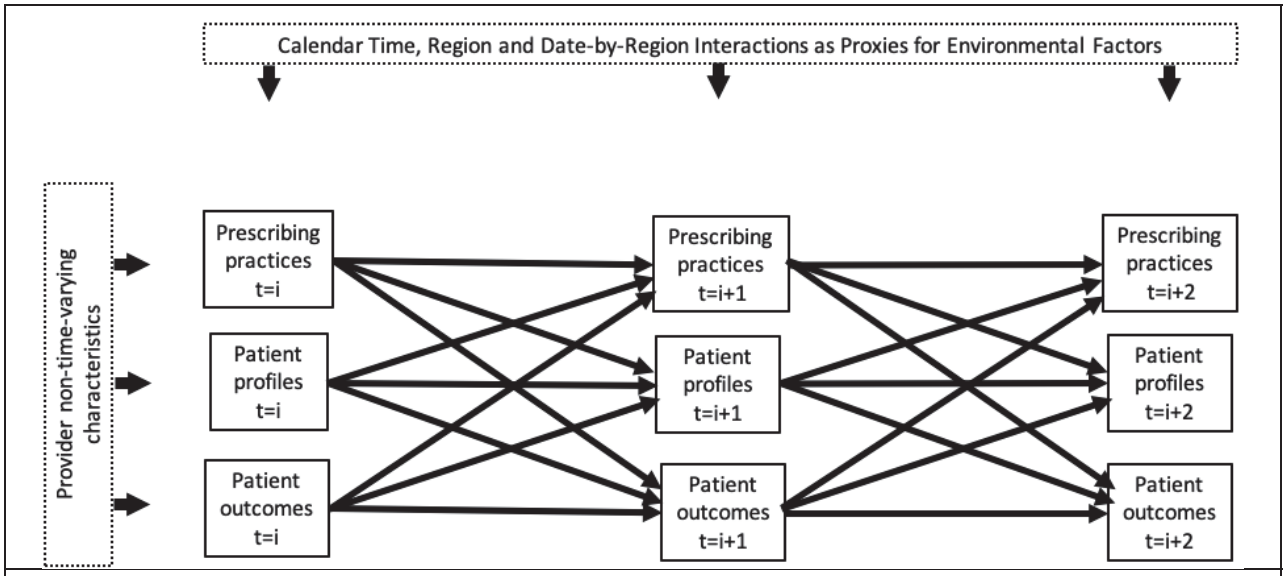
4. PLAN

4.1 Conceptual Framewor

As noted by the FDA in subseu ent comments, RPC Report #7 did not tie together the measures that it examined under an articulated model of how prescriber education programs might be expected to affect prescriber behavior. The report therefore left open the ue stion of whether other metrics or techniques of analysis might be more informative. To organize the consideration of future analyses and in response to the Agency's concern that those analyses should fit into an overarching picture of opioid prescribing, we propose the conceptual framework outlined in Figure 1.

Figure 1 depicts the flow of influences on the prescribing practice of a single provider. In Figure 1, there is no REMS-compliant CE. Time flows from left to right, and is divided into chunks, labeled *i*, *i*+1, *i*+2, On the far left are characteristics of the provider that vary slowly or not at all with time, such as specialty, age and gender. Heavier arrows pointing to the right depict the extended influence of provider characteristics over time. The tangle of arrows leading from each time chunk to the next is a diagrammatic portrayal of a statement that all aspects of an individual's medical practice are potentially affected by all aspects of an individual's practice history. Environmental factors (the box at the top of the diagram) can vary over time and by region. Analogously to the provider characteristics, a single downward heavy arrow at each time point, indicating influence on all the boxes below, portrays the influence of environmental factors.

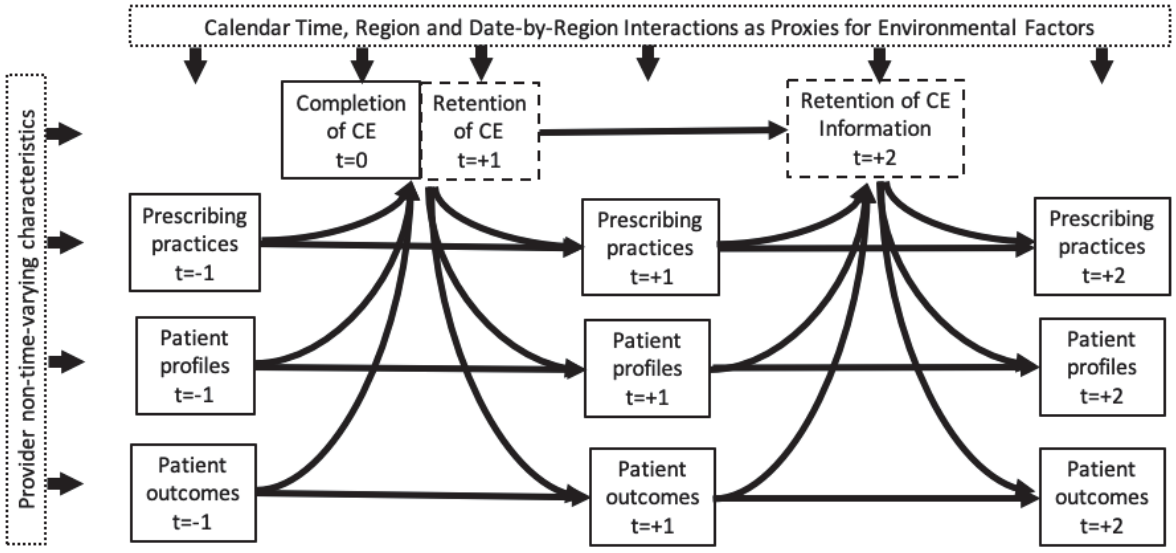
Figure 1. Possible causal pathways for prescribing practice patient selection and patient outcomes in the absence of REMS-compliant CE



Prescribing practices, patient profiles, and patient outcomes are all measurable at t=*i, i*+1, *i*+2,
Calendar time (date), region and date-by-region interactions are proxies for environmental factors.
Provider non-time-varying characteristics are known by the proxies of specialty, age, sex.
Boxes with solid outlines refer to observables. Dotted lines enclose factors that are not observed directly.

Figure 2 elaborates on the pathways of Figure 1 by adding an effect of REMS-compliant CE. For readability, the tangles of Figure 1 between time chunks have been reduced to single arrows. The decision to undertake a REMS-compliant CE program may be related to provider and environmental characteristics, as well as the preceding aspects of prescribing practices, patient selection and patient experience.

Figure 2. Possible causal pathways for the evaluation of CE interventions



Completion date REMS-compliant CE is known for each caregiver. This determines t=0
Prescribing practices, patient profiles, and patient outcomes are all measurable at t=-1, 0, +1.
Calendar time (date), region and date-by-region interactions are proxies for environmental factors.
Provider non-time-varying characteristics are known by the proxies of specialty, age, sex.
Boxes with solid outlines refer to observables. Dotted lines enclose factors that are not observed directly.

Note that Figure 2 does not include the components of the CE intervention itself (e.g. message, repetition of the message in the intervention, duration of the message, method of administration or other factors associated with it), nor does Figure 2 include the assessments of comprehension or retention of the messages. The conceptual model for behavior assessment in Figure 1 and Figure 2 is restricted to prescribing practices and other elements provided by large-scale health insurance and pharmacy claims data, such as characteristics of patients.

The following design considerations emerge from the framework.

1. The full effect of CE may not be immediate. The ultimate practices, profiles and outcomes (represented by t=+2 in Figure 1) may be affected by immediate post-CE changes (t=+1) in these same variables, both directly and through their effect on retention of CE learnings.
2. Calendar time, region and date-by-region interactions stand in as proxy measures for the environmental factors that evolve over time.
3. REMS-compliant CE can affect patient outcomes through mechanisms other than prescribing patterns. Providers can change risk for example through patient counseling, selection and retention of patients into their practices or referral of high-risk patients for specialized pain management.
4. Caregivers' historical prescribing practices and the characteristics of their patients (including the prior patient experience) are potential confounding factors.
5. Caregivers' historical prescribing practices and the characteristics of their patients are potential sources of heterogeneity in the apparent effect of CE. For example, providers who prescribe opioids daily may have previously acquired detailed knowledge that encompasses the material in the FDA Blueprint. Conversely, providers who do not typically see patients with serious pain and who have not historically prescribed opioids are unlikely to have measurable changes in prescribing practice.

The considerations above lead to specific analytic constraints.

1. Analysis should allow time-varying effects of REMS-compliant CE, such as a consolidation period before the onset of the effect and a decay over time.

2. External information may be required to interpret calendar time and region as proxies for environmental factors. Nationally, changes in opioid abuse coincided with the introduction of the ER/LA Opioid REMS program. [7] Examples of local factors that may affect secular trends differently by region include the effectiveness of state Prescription Drug Monitoring Programs (PDMPs), and the extent of local penetration of state-mandated training programs. [8, 9]
3. In addition to prescribing practices, outcomes to be examined should include measures of patient characteristics and patient experience.
4. The model predicting the level of any measure should incorporate as predictors: the same measures as observed earlier; prescriber characteristics; calendar time and region.
5. There should be systematic exploration of statistical interactions between important predictors.

A further constraint arises in the translation of the conceptual model for individuals to a population model for analysis.

6. If CE is very widespread, all programs need to be accounted for. Otherwise, CE itself may masquerade as a time-varying environmental factor.

In the sections that follow, we will propose that analysis be conducted with the unit of observation being the prescriber-semester, a six-month observation period of the activity of a single prescriber. Prescriber-semesters, ending each June 30 and December 31, accrue while there is eligibility and data. Outcomes and predictive factors are measured within each prescriber-semester.

4.2 Structure for Analyses

Figure 1 and Figure 2 portrayed the temporal flow of influence between measurable states for a single prescriber. Each figure can also be interpreted as a diagram of predictive influences in groups of prescribers, observed repeatedly and in the case of Figure 2, aligned so that t=0 for each person is the date of completion of REMS-compliant CE. For the analysis that will follow, each arrow in Figure 1 and Figure 2 corresponds to a possible coefficient of a predictive equation in which the various factors may represent predictors, outcomes or both. (For variable types that can be both predictors and outcomes, the variable-as-predictor always precedes in time the variable-as-outcome, so there is no circularity.)

Each box in Figure 1 and Figure 2 represents either a continuous variable, such as total morphine milligram equivalents (MMEs) dispensed in a provider-semester or a binomial variate such as percent of new opioid prescriptions that are for IR/SA opioids. In each case, the multivariable regression is a repeated measures analysis with prescriber-semesters as the unit of observation and prescriber as the indicator within which repetition occurs.

Table 1 presents the format of a generic result. In the Discussion (Section 7), we will tie the results of such analyses to the analytic requirements described above. As will be pointed out in the next sections, a plausible research strategy could be to investigate all the determinants of conformance to recommended opioid prescribing and patient management practices, before any consideration of the impact of REMS-compliant CE. The next step then would be to look at the determinants of REMS-compliant CE completion. Controlling for the predictors of REMS-compliant CE, the final step is to create combined models that examine the added impact of REMS-compliant CE programs. The rows corresponding to the impact of REMS-compliant CE appear in gray in Table 1, to emphasize that the introduction of REMS-compliant CE into any statistical model should come after detailed investigation of other predictors.

The rightmost three columns of Table 1 correspond to an extract from the output of a generalized estimate equations (GEE) model, such as would be available from PROC GENMOD in SAS. The unit of observation is the provider-semester. The values of outcome, predictors (left hand column of Table 1) and provider ID are known. All provider-semesters are included, irrespective of whether the provider ever completes REMS-

compliant CE. The "repeated" variable for the GEE is provider ID, and the model statement includes all the predictors.

Table 1. Format of a generic analytic result

Characteristic	Level	No. of provider-semesters	Outcome Average value	Mutually Adjusted Estimates		
				Point Estimate	Lower Bound	Upper Bound
Total	**All**	N_{total}				
Calendar year	**2019**	N_{2019}	AV	FV-RL		
	2020	N_{2020}	AV	Delta V		
	etc.	N_{year}	AV	Delta V		
Region (e.g. State)	**AA**	N_{AA}	AV			
	BB	N_{BB}	AV			
	etc.	N_{region}	AV			
Prior outcome values (continuous) by lag time in semesters	**-1**	N_{total}		Reg Coeff		
	-2	N_{total}		Reg Coeff		
Levels of predictor X	**1**	$N_{x=1}$	AV	FV-RL		
	2	$N_{x=2}$	AV	Delta V		
	etc.	$N_{x=etc}$	AV	Delta V		
Levels of predictor Y	**1**	$N_{y=1}$	AV	FV-RL		
	2	$N_{y=2}$	AV	Delta V		
	etc.	$N_{y=etc}$	AV	Delta V		
Etc.						
Time since CE completion in calendar semesters	**Never**	N_{total}	AV	FV-RL		
	Same	N_{total}	AV	Delta V		
	1	N_{total}	AV	Delta V		
	2	N_{total}	AV	Delta V		
	etc.	N_{total}	AV	Delta V		

Provider-semester – A completed six-month period of observation of a provider. Each provider-semester is associated with a value for the outcome and a value for each predictor
CE – REMS-Compliant Accredited Continuing Education
Fitted and adjusted values from a regression procedure (repeated measures within prescriber, autocorrelative working matrix)
At the specified level of the specified characteristic:
N – Number of provider-calendar-semesters giving information for the corresponding row of the table
AV – Observed average value of the outcome for the corresponding row
FV-RL – Fitted value of the outcome at the reference level for categorical predictors, i.e. Level 1 in the table
Delta V – Fitted regression coefficient for each level of each categorical predictor, vs. the corresponding reference level
Reg Coeff – Fitted regression coefficient for continuous predictors.
Lower Bound, Upper Bound – Lower and upper 95% confidence bounds to the adjusted point estimate

Because there is no restriction on eligibility other than the availability of information, the temporal and regional effects as well as the effects of possibly time-varying predictors and the auto-correlative impact of past outcome values are all estimated using all experience of all providers. In any venue that will be considered for this work, "all providers who prescribe opioids" is a large number, and the effect estimates will have good statistical precision.

The analysis laid out in Table 1 does not account for fulfillment of state-mandated CE programs whose completion records might not be available for analysis. State medical board requirements range from two hours of coursework every two years (many states) to 12 hours every two years (California only).[1] The

requirements do not mandate that courses follow the FDA Blueprint, but many programs may do so. In the schema of Figure 2, the effect of non-REMS-associated programs would have to be considered an Environmental Factor, captured only in the date and region variables. If such programs have an important individual impact on prescribing practices, it would be necessary to limit the provider-semesters to those belonging to a provider who has at some point completed a REMS-compliant CE, on the assumption that the provider will not also pursue other programs. In this context, it is still possible model trends over calendar time as a predictor of prescription practice, but only with added assumptions. See Section 6.4, Provider Education That Is Not REMS-Compliant.

5. A SUITE OF ANALYSES TO ASSESS THE IMPACT OF CE

5.1 Overview

The sequence of analyses that we propose encompasses evaluation of the determinants of each of the outcomes in the absence of REMS-compliant CE, finding the predictors of REMS-compliant CE and then synthesizing the results into a combined predictive equation.

The first steps are to investigate

1. Determinants of prescribing practice
2. Factors that influence the management of patients receiving prescription opioids, and
3. Determinants of the uptake of REMS-compliant CE

The last step is to synthesize the information derived from the first three.

4. Incorporate predictors of REMS-compliant CE with predictors of prescribing and patient management into a covariate-controlled assessment of the impact, in which variables representing REMS-compliant CE are present, along with a range of potentially confounding factors or modifiers of the program effect.

5.2 Required Data

For the evaluation of the impact of REMS-compliant CE on opioid prescribing and patient management going forward, the setting assumed here includes availability of the following information.

1. From providers of REMS-compliant CE, there is a list of the National Provider Index (NPI) numbers of prescribers who have completed CE, together with the date of completion of CE for each.
2. A data resource that can be linked to the NPI, that
    a. Includes information at the level of National Drug Code (NDC) for all or almost all dispensings associated with a provider, and that may
    b. Include information on patient demographics and all or nearly all patient diagnoses, medical care encounters and procedures and drug dispensings.

Data sources that lack information on CE completion (criterion 1 above) may still be useful for examining determinants of opioid prescribing and patient management. Data source that meet criterion 2a but not 2b will be sufficient to assess determinant of prescribing practice and of the uptake of CE, but not factors that influence management.

An ability to link the identity of providers (item 1) to corresponding information in the data resource (item 2) is crucial. See Section 6.2.

5.3 Determinants of Prescribing Practice

We propose that studies be conducted among providers for such time, as they are associated with a minimum evaluable number of opioid dispensings in the preceding two semesters. For specificity, we might consider setting the entry requirement for analysis at six dispensed opioid prescriptions in each of the preceding two semesters. A provider would come into analysis as of the first semester for which at least six dispensed prescriptions for opioids have occurred in each of the two preceding semesters. See also Section 6.3.

The right-hand column of Table 2 describes measures extracted from the CDC's guidelines that can also be implemented in a dispensing-only database.

As in Table 1, possible CE-specific elements are presented in gray in Table 2.

Table 2. Available predictors of provider prescription semester volume and provider practices in a dispensing database.

Predictors identified within the provider-semester	Outcome measures identified within the provider-semester
Provider characteristics	Volume and MME of
Age	All opioid dispensings
Sex	IR/SA opioid dispensing
Specialty	ER/LA opioid dispensings
Provider prescribing history for each of the two p receding semesters	Percentage of patients among those with a new opioid prescription whose dispensing is for …
Type (IR/SA Schedule II or III, ER/LA)	IR/SA opioid
Total MME dispensed	≤ 3 days' supply
Non-opioid analgesics, by class	Among patients on long-term opioid therapy, percentage who receive dispensings for
Environmental factors	>50 MME/day
Region	>90 MME/day
Calendar year	Benzodiazepines
Region by calendar year	Cash payment [a]
Characteristics of CE	
Time since completion	
CE vendor	
CE accreditor	

Provider-semester – A completed six-month period of observation of a provider. Each provider-semester is associated with a value for the outcome and a value for each predictor
Rows relating to CE have been grayed out to indicate that this factors would be added only after evaluating all other predictors and after identifying the factors that predict uptake of CE.
a Patient payment for the entirety of a dispensing ("Cash payment") is available in one dispensing database (IQVIA Prescription Claims), but is not available in insurance-based dispensing databases
CE – REMS-compliant continuing education
MME – Morphine milligram equivalents
IR/SA – Immediate-release or short-acting
ER/LA – Extended-release or long-acting

To use the predictors in Table 2 to achieve an output that could populate tables in the format of Table 1, the investigator would start with a pharmacy claims database, limiting analyses to providers for such provider-semesters that the database contained the provider's prescription activity and that were furthermore characterized by at least six opioid dispensings in each of the two preceding provider-semesters. From the longitudinal provider claims histories, one would construct both the outcome and predictor variables of Table 2, for each provider-semester. The model would be as described under *Structure for Analyses.* Each of the outcome measures in the right-hand column of Table 2 would be taken in sequence as the predicted variable, with a distribution specified to be either "normal" (for the continuous measures) or "binomial" (for the proportions). The model statement would include the predictors in the left-hand column. Provider ID is the variable used to gather repeated measures.

The next subsection, dealing with patient management and outcomes, is set within the context of large databases of medical insurance claims or electronic health records (EHRs). For compactness, we have not repeated the discussion of the factors in Table 2.

5.4 Factors That Influence the Management of Patients Receiving Prescription Opioids

Many of the CDC Guidelines require information on patients and patient management. Patient characteristics and patient management characteristics that can be derived from insurance claims or EHRs, relevant to implementing CDC measures to evaluate the guidelines are listed in Table 3.

Under the heading "Other Measures," Table 3 also identifies candidate outcome measures for appropriate prescribing practices. These are derived from publications describing work conducted for OPC PMR Studies 3033-6 and 3033-8. PMR 3033-6 yielded a straightforward definition of opioid overdose in insurance claims data as the existence of any service carrying a corresponding ICD code. [10] PMR 3033-8 derived an empirical definition of doctor-and-pharmacy shopping. [11, 12] The measure is defined in Appendix C. Shopping behavior in relation to opioids is predictive of opioid overdose and death. [13, 14, 15, 16, 17]

Table 3. Additional characteristics in an insurance or EHR database that can serve as outcomes in an evaluation of patient management

Predictors [a]	Outcome measures identified within each provider-semester (percent of treated patients having each of the characteristics)
As in Table 2	*Derived from CDC Guidelines*
	Management in relation to first dispensing. Percent of patients with
	Urine test performed before
	Follow-up visit within four weeks
	Management in relation to long-term dispensing. Percent of patients with
	Follow-up visit each quarter (yes/no)
	Pain and functional assessments (EHR only)
	Percent of patients for whom there is documentation that PDMP was checked (EHR only)
	Other Measures
	Occurrence of opioid overdose
	Proportion of dispensings going to patients with behaviors consistent with presumptive opioid use disorder
	Characteristics of patients, proportions with [b]
	Demographics
	Comorbidities
	Prior opioid experience
	Doctor/pharmacy shopping

[a] Provider characteristics and prescribing history would be re-evaluated at the beginning of each calendar semester for which the prescriber is enrolled throughout the semester.
[b] Patient characteristics are an outcome variable in this context because the composition of the provider's panel of patients is fluid and reflects the provider's choices about whom to treat.

Whereas the analyses proposed for Table 2 were of the six-month percentages among dispensings from providers with various characteristics, the analyses required for Table 3 would be of the percentages of patients who had received a dispensing from a provider and who exhibited the various outcome characteristics listed. The analyses would extend over all available provider-semesters of observation.

5.5 Determinants of the Uptake of CE

The proposed sequence of analysis requires first full characterization of the predictors of opioid prescribing and patient management in the available data. The next step is to describe the factors that lead a prescriber to pursue a REMS-compliant CE program.

Predictive characteristics for the uptake of a REMS-compliant CE that could readily be identified in a dispensing database are listed in the left-hand column of Table 4. The information in Table 4 would be obtained for all provider-semesters in the available data, omitting only those for which there was a prior completion of REMS-compliant CE. The evaluative step for describing uptake would be to quantify the fraction of physicians completing REMS-compliant CE per provider-semester as function of each the predictor characteristics in Table 4.

Table 4. Available predictors and outcome measures for provider uptake of CE in a dispensing database

Predictors [a]	Outcome Measures
Provider characteristics	Is there completion of CE in this provider-semester?
Age	
Sex	
Specialty	
Provider prescribing history for each of the two preceding semesters	
Number of opioid prescriptions dispensed	
Number by Type of opioid prescriptions dispensed (IR/SA Schedule II, IR/SA Schedule III, ER/LA)	
Total MME dispensed	
Number of Non-opioid analgesics, by class	
Environmental factors affecting both provider and patient	
Region	
Calendar year	
Number of patients with overdose in each of the preceding two semesters	
Number of patients with a provider-assigned code of opioid use disorder in each of the preceding two semesters	

[a] Provider characteristics and prescribing history would be re-evaluated at the beginning of each calendar semester for which the prescriber is enrolled at both the beginning and end of the semester.
CE – REMS-compliant continuing education
MME – Morphine milligram equivalents
IR/SA – Immediate-release or short-acting
ER/LA – Extended-release or long-acting

Preliminary tabulations might reveal prescriber populations in which the fraction pursuing CE is close to zero, and which can therefore be omitted from subsequent modeling exercises. Ultimately, a descriptive model would be derived by logistic regression over the calendar semesters of available data. The predicted variable for each provider-semester is whether CE occurred during the semester.

If prescriber groups with low uptake of CE are included, the modeling might include zero-inflation estimates, which provide a separate accounting of groups in which the outcome event does not occur, and which in so doing improve variance estimates for other predictors. [18]

5.6 Combining Predictors of CE with Predictors of Prescribing and of Patient Management

With information on the global determinants of targeted practices for prescribing and for patient management (Table 2 and Table 3), and on the determinants of REMS-compliant CE (Table 4), the estimates of impact of REMS-compliant CE can be derived by adding CE characteristics to the global regressions. The population of provider-semesters studied would incorporate all available data. If the analysis were limited to CE and the covariates in Table 2 (prescription claims data), a full prescription claims database could be used. An analysis that included patient and management characteristics as both predictors and outcomes (Table 3), as drawn from an insurance claims database or an EHR would necessarily be restricted to provider-semesters characterized by available data.

Covariates that must be included to obtain unconfounded estimates are any that are shared between the two sets of regressions. To maintain information on the non-CE predictors of outcomes, the analyst may wish to retain some or all of them, even if they are not required for confounder control. It will be advisable to explore interactions between CE and other predictors to identify subsets of the prescriber population in which CE has differing impacts.

The effect on opioid prescribing of REMS-compliant CE at different intervals since completion can be estimated with respect to no REMS-compliant CE. The estimated effect is drawn in part from between-provider comparisons, when the providers differ in their completion levels or times since completion. The effect of REMS-compliant CE is also drawn from within-provider comparisons, comparing provider-semesters before and after completions. In every case, estimated effects are adjusted for the levels of other predictors of prescribing, whose effects are drawn from the contrast between provider-semesters at different levels of the covariates.

Depending on the presumed influence of non-REMS-compliant CE in the population, it may be necessary to restrict analysis to provider-semesters that precede or follow completion of REMS-compliant CE. See Section 6.4.

6. CONDUCT

6.1 Research Venues

The two components for any evaluation of the impact of REMS-compliant CE must be (1) a substantial number of participants whose identities can be linked to (2) a system for measuring prescribing practice and a description of the patients who are being cared for. The first of these is an anticipated product of the 2018 round of RPC's vendor contracting.

The second component requires administrative data that cover the medical environment in which the prescribers work. The IQVIA RWD Prescription Claims data (Appendix B) provides the opportunity to examine prescription practice for nearly all US prescribers. Many large insurance data resources that are used for drugs research, such as the FDA Sentinel initiative and its contributors. [19]

On a smaller but still national scale, there are currently many options for studying opioid dispensing in environments for which extensive patient information is derivable from insurance claims. Information can also be derived from settings in which patient care falls under a unified EHR. US health insurers keep transactional information in the broad categories set out in Appendix D. The FDA's Sentinel Initiative is currently accruing data on some 70 million Americans. [20] Other large resources are Optum (UnitedHealthcare, 21 million), HealthCore (Anthem, 22 million) and the Centers for Medicaid and Medicare Services (CMS) Medicaid Analytic Extract (MAX) database, with validated linkages between fee-for-service and comprehensive managed care for Medicaid recipients in 22 states. [21, 22, 23] IQVIA's PharMetrics Plus database includes data on 80 million persons, past and present, in a variety of commercial insurance plans. IBM Marketscan is also a compilation of data from various insurers, with data on 100 million persons, past and present. For each of these last two, current enrollees comprise only a fraction of the total, so that their effective size for future data accrual would have to be gauged *ad hoc.*

Important regional data sources with complete EHR data and deep research experience include the Kaiser-Permanente programs in California, Oregon, Washington; the Geisinger Clinic (Pennsylvania); Harvard Pilgrim Healthcare (Massachusetts); and Hackensack Meridian Health (New Jersey). [24]

6.2 Provider Identification

All the work proposed here depends crucially on having the NPIs of essentially all healthcare providers who have completed the RPC-funded REMS-compliant accredited CE programs. Under suitable confidentiality protections, the NPIs need to be linked to one or more of the data resources described in Section 6.1.

Within a single healthcare system, such as one of the Kaiser-Permanente programs, it may be possible for the system administrators to link provider IDs in the EHR directly to documentation of completion of REMS-compliant CE.

Sharing NPI numbers proved feasible in work with Pri-Med for RPC Report #7. However, RPC's experience has been that other providers of CE programs have been reluctant to share with industry the NPI numbers of prescribers who complete their programs. In a letter to RPC dated February 14, 2019, the Conjoint Committee on Continuing Education indicated that "A key reality imbued in attracting health professionals to CE funded through pooled RPC funds is the assurance that the learners will not be identified out of fear of becoming the targets of marketing by the opioid manufacturers." [25]

One of the data vendors described in Section 6.1 has developed a system for preserving patient anonymity that could be adapted to preserving prescriber anonymity as well, while still allowing full linkage of diverse data streams.[26] (See Appendix B.) The technique is to perform an irreversible encryption of identifiers in the data to be linked (NPI numbers from CE vendors) and to perform the same encryption of the corresponding identifiers in the database that provides covariates and outcomes. The encrypted identifiers ("tokens") serve for linkage.

Since the sharing of unencrypted NPI numbers for prescribers is consistent with existing patient privacy legislation in the US, a first step to linkage might be for the FDA to take a position that such sharing is in the national interest. The FDA might also encourage providers of REMS-compliant CE programs to enter arrangements that could secure prescriber privacy and still permit program evaluation. The encryption of NPI numbers could be a further part of such a proposal.

6.3 Restriction to Informative Providers

REMS-compliant CE that follows the FDA Blueprint is likely to make the prescription of opioids more selective and less frequent. Providers who do not prescribe opioids cannot provide information on prescribing practices and very little information on the management of patients who have been prescribed opioids. This practical consideration does not mean that education following the FDA Blueprint is not of use to caregivers who do not regularly prescribe opioids. There may be between-provider or community impacts of education. There could be influences on a caregivers' subsequent choice of patients to retain or refer. Patients prescribed opioids by pain specialists may nonetheless be managed by non-prescribing healthcare providers who would benefit from education on the management of patients receiving opioids. Nonetheless, the impact of REMS-compliant CE in low-volume prescribers is likely to be poorly assessable under the schema of Figure 2.

A recommendation in Section 5.3 was to omit from analysis any provider-semester that was not preceded by at least two semesters in which the provider wrote prescriptions for at least six opioid dispensings, i.e. an average of one per month. This follows from the consideration of the possibility of measurable impact of REMS-compliant CE in such prescribers.

6.4 Provider Education That Is Not REMS-Compliant

The recommendations have focused on a design that includes all active prescribers of opioids, irrespective of whether they undertake REMS-compliant CE. This choice is based on some core advantages.

1. System-based assessment offers the easy availability of information on prescribers who have not elected to pursue the REMS-compliant CE.
2. Comprehensive analyses can be undertaken that include both between-prescriber and between-eras comparisons simultaneously, with statistical control for factors identified in the conceptual framework that may vary between prescribers or over time. The statistical control for characteristics that could have been matching factors serves the same purpose of comparing completers to otherwise similar providers who did not complete REMS-compliant CE. At the same time, inclusion as covariates of the prior states of all outcomes as predictors of the current state of the same outcomes creates pre-post control in the analysis of the impact of CE.
3. There may be secular trends in practice. Including all prescribers permits highly precise control for environmental trends, even at the level of geographical region.

In the RPC survey of providers who had prescribed ER/LA opioids, both providers who reported having undergone CE that was not known to be REMS-compliant, and providers who had undergone REMS-compliant CE scored higher on some measures of safe prescribing and patient management practices than did providers who did not report having pursued CE on opioid prescription and patient management.[3] The survey was a highly self-selected sample of eligible prescribers, and may have suffered from biased estimates on that account. Nonetheless, it raises the possibility that non-REMS-compliant CE may affect prescriber behavior.

Considering the survey results from ER/LA prescribers, the widespread requirements that US prescribers obtain and revisit CE in safe opioid prescription raises a concern that one "environmental" factor affecting all the outcomes proposed here is CE from sources not documented as REMS-compliant CE. An analysis

restricted to those who eventually complete a REMS-compliant CE program is attractive, as these prescribers are unlikely to have pursued another program at about the same time.

The analyses described here could be carried out in the population of prescriber-semesters for which the prescriber eventually chose REMS-compliant CE. For tighter control of region and other time-invariant prescriber characteristics, one could add matching by provider ID to all the analyses that yielded estimates of effect. Retaining calendar year as a predictor would permit limited control for secular effects, under two assumptions

1. The number of providers who elect REMS-compliant CE is large enough to permit stable estimates of temporal effects, adjusting for REMS-compliant CE status.
2. The period of observation for each of the providers covers the calendar years used for the evaluation of CEs overall, so that there are concurrent estimates of trend.

6.5 Why Not Direct Assessment of CE Participants?

A key part of CE programs is the assessment of what knowledge has been absorbed and later retained by participants. The information provides a primary measure of the program's ability to communicate to the participants in terms that are accessible and memorable. As noted in Section 4.1, retention is a first step toward impact on practice.

Questionnaires on practice can be folded into the knowledge assessments. A concern is that volunteered responses would be influenced by the provider's awareness of the desired effects of the training. In another setting marked by passionate public debate (the controversy over the safety of so-called third generation oral contraceptives), prescribing practice did not reflect the practitioners' asserted beliefs, which coincided with standard views of indication and safety. [27, 28]

7. DISCUSSION

Extended follow-up of large numbers of opioid prescribers provides a rich environment for assessing the impact of CE programs. We have proposed here that there be six-month updates of prescribers' historical practice patterns and experience, as well as their current prescribing practices and indices of good patient management. Added to these data would be other covariates including physician characteristics and calendar time and region as proxies for environmental features.

Implementation of the proposed impact analysis presupposes a minimal favorable setting, one with a list of the NPI numbers of all prescribers who have completed CE, together with the date of completion of CE for each together with a data resource that is linkable to the NPI. If the resource includes information at the level of National Drug Code (NDC) all or almost all dispensings associated with a provider, it is possible to study all proposed opioid dispensing practices. If the resource additionally includes information on patient demographics and all or nearly all the patient's diagnoses, medical care encounters and procedures and drug dispensings, a richer assessment of the management of patients who receive opioids is possible.

Table 5 compares aspects of the proposed analyses to the analytic constraints presented in Section 4.1.

Table 5. Correspondence between conclusions from the Conceptual Model and the proposed analyses

Constraint	Predictors	Model structure
The full effect of CE may not be immediate.	Immediate and lagged effects of CE completion and lagged prior values of the outcome measure	Repeated measures over time, within prescriber.
CE may affect patient outcomes through mechanisms other than prescribing patterns.	Patient overdose, shopping incorporated as both endpoint and lagged predictors	Repeated measures analysis accounts for within-prescriber, between-period correlations, beyond those modeled directly through covariates.
Caregivers' historical prescribing practices and the characteristics of their patients are potential confounding factors.	Covariates to be included as predictors whenever they predict both CE and an outcome and so are confounders.	← See "Predictors."
Caregivers' historical prescribing practices and the characteristics of their patients are potential effect modifiers.	Systematically examine interaction terms between important predictors.	← See "Predictors."
Calendar time and region stand in as proxy measures.	Include calendar year and region in all models.	Check for interactions between calendar year and region.
CE may be widespread	Effect of time-varying environmental factors may be limited by "contamination" from concurrent unrecorded CE.	Restrict analysis to individuals known to have completed CE, and therefore are unlikely to have pursued other CE.
CE – REMS-compliant CE		

The proposed analyses moreover incorporate most of the guidelines set out by the CDC for the evaluation of safe prescribing of opioids (Appendix A). Table A1 indicates which of the guidelines can be met. The elements that have been missed are ones that currently would require human reading of the medical record. The application of natural language processing to sufficiently well-structured EHRs may in the future provide a route into such questions.[29] At present, reliance on such systems may be premature. [30, 31]

An effect of the general diffusion of knowledge about opioid prescribing practices that results from public attention and widespread CE may appear as regional-temporal trends in opioid prescribing practices. A useful

aspect of the modeling proposed above is that the proposed covariates can be investigated as predictors of each of the outcomes in the absence of any CE data. Knowledge of predictors of undesirable opioid prescription practice and failure to meet management guidelines might provide nuance as to which of the elements in the FDA Blueprint required special consideration in possibly idiosyncratic target populations.

As with RPC Report #7, it is possible that no amount of analysis will be tease out an independent effect of REMS-compliant CE on opioid prescription or on patient management. The near-universal requirement for education on opioid prescribing from state boards of medicine means there will be few providers who have not received formal training as part of their medical accreditation. The heavy focus on the opioid epidemic by medical and lay media in the US means that no prescriber will be unaware of the concerns. Environmental factors that are not well characterized in available data may overwhelm the documentable effects of REMS-compliant CE.

The CDC guidelines' authors have pointed out that restrictions on opioid prescribing can be misapplied, to the detriment of patients.[32] The possible benefits or harms to patients do not form part of this proposed analysis of the behavior of prescribers.

8. CONCLUSION

Existing data systems provide a rich basis for the evaluation of safe opioid prescribing as described in CDC guidelines. Evaluations of predictors and of state-by-state trends could be done now. Added evaluation of educational programs that meet the FDA Blueprint is a matter of identifying program completers and linking their identifiers into the presently available data systems.

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10. APPENDIX A. CDC GUIDELINES

See reference 4: Centers for Disease Control and Prevention. *Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain.* 2018. National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention, Atlanta, GA.

Full text

1. **Opioids are not first-line therapy.**

   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. **Establish goals for pain and function.**

   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. **Discuss risks and benefits.**

   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.

4. **Use immediate-release opioids when starting.**

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

5. **Use the lowest effective dose.**

   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 ≥ 50 morphine milligram equivalents (MME) per day, and should avoid increasing dosage to ≥ 90 MME per day or carefully justify a decision to titrate dosage to ≥ 90 MME per day.

6. **Prescribe short durations for acute pain.**

   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. **Evaluate benefits and harms frequently.**

   Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every three 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.

8. **Use strategies to mitigate risk.**

   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 (≥ 50 MME per day), or concurrent benzodiazepine use, are present.

9. **Review prescription drug monitoring program (PDMP) data.**

   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 three months.

10. **Use urine drug testing.**

    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. **Avoid concurrent opioid and benzodiazepine prescribing.**

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

12. **Offer treatment for opioid use disorder.**

    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.

In addition to formulating the guidelines above, the CDC expert committee presented the following measures for assessing conformance to the guideline. We have added annotation as to which of these measures can be ascertained in a dispensing database and which require a full insurance claims on EHR database.

Table A1. Measures to assess CDC Guidelines		
		Feasible for testing in a claims or EHR environment -- ♠ Feasible for testing with dispensing-only data -- ♠
Short-term opioid therapy		
1.	The percentage of patients with a new opioid prescription for an immediate-release opioid.	♠♠
2.	The percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.	
3.	The percentage of patients with a new opioid prescription for chronic pain with documentation that a urine drug test was performed prior to prescribing.	♠♠
4.	The percentage of patients with a follow-up visit within four weeks of starting an opioid for chronic pain.	♠
5.	The percentage of patients with a new opioid prescription for acute pain for a three days' supply or less.	♠♠
Long-term opioid therapy		
6.	The percentage of patients on long-term opioid therapy who are taking 50 MMEs or more per day.	♠♠
7.	The percentage of patients on long-term opioid therapy who are taking 90 MMEs or more per day.	♠♠
8.	The percentage of patients on long-term opioid therapy who received a prescription for a benzodiazepine.	♠♠
9.	The percentage of patients on long-term opioid therapy who had a follow-up visit at least quarterly.	♠
10.	The percentage of patients on long-term opioid therapy who had at least quarterly pain and functional assessments.	♠
11.	The percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly.	
12.	The percentage of patients on long-term opioid therapy who the clinician counseled on the risks and benefits of opioids at least annually.	
13.	The percentage of patients on long-term opioid therapy with documentation that a urine drug test was performed at least annually.	♠
14.	The percentage of patients with chronic pain who had at least one referral or visit for nonpharmacologic therapy as a treatment for pain.	♠
15.	The percentage of patients on long-term opioid therapy who were counseled on the purpose and use of naloxone, and either prescribed or referred to obtain naloxone.	
16.	The percentage of patients with an opioid use disorder (OUD) who were referred to or prescribed medication-assisted treatment (MAT).	♠

11. APPENDIX B. THE IQVIA RWD PRESCRIPTION CLAIMS DATABASE

The IQVIA RWD Prescription Claims database has information on approximately 90% of prescription claims in the United States, covering retail, mail and long-term care facilities. IQVIA updates the Prescription Claims database with approximately four billion paid claims per year. Data are available from 2001 to the present. From each of the outlets in its panel, the database captured all fills, both in person and through the mail, both paid by insurance and paid entirely by the consumer. RWD Prescription Claims distinguishes unique pharmacies, unique prescribers and unique medical practices and can capture records generated by patients who filled prescriptions in more than one state. Prescriber National Provider Identifier (NPI) numbers are available for the prescriber associated with each prescription claim. Prescription claims are longitudinally linked to an anonymous patient token and so can be linked to events within the data set itself and across other IQVIA patient data assets.

12. APPENDIX C. DOCTOR AND PHARMACY SHOPPING

OPC PMR Study 3033-8 developed an empirical measure of doctor and pharmacy shopping for opioids (see reference 13). Simple counts of dispensings that derived simultaneously from different pharmacies and different prescribers proved the best discriminator of possible aberrant behavior in opioid recipients as compared to a control group of persons filling prescriptions for diuretics. The categories are defined by the number of prescriber practice sites from which opioid prescriptions were obtained in the 18-month observation period and the number of pharmacy outlets that filled the prescriptions (Table C1). Applied to 164,923 persons who had received two or more opioid dispensings over 18 months, a definition that substituted prescribers for prescribing practices yielded almost the same classification as the practice-driven definition.

Table C1. Definitions of levels of doctor and pharmacy shopping over 18 months of follow-up

Level	Definition
None	(No contributory dispensings) OR (2 practices and 2 outlets)
Minimal	(2 practices AND >2 outlets) OR (2 outlets AND >2 practices)
Moderate	(3 practices AND ≥3 outlets) OR (4 practices AND (3 or 4 outlets) OR (5 practices and 3 outlets)
Extensive	(4 practices AND ≥5 outlets) OR (5 practices AND ≥4 outlets) OR (≥6 practices AND ≥3 outlets)

13. APPENDIX D. COMPONENTS OF A US HEALTH INSURANCE CLAIMS DATABASE

Transactions can be linked to one another and to individuals through shared identification numbers, which are encrypted when the data is used for research purposes.

Population descriptors. Eligibility files provide dates of enrollment and exit from coverage and basic demographic information. These files also have personal identifying information that can be used, with appropriate permission, for linkage to external data sources.

Drug exposures. Claims for reimbursement of all drugs dispensed include date of dispensing; the name, dose and form of the product dispensed; and the quantity dispensed.

Health Outcomes. Hospitals and health-care centers use the US Center for Medicare and Medicaid Services (CMS)-1450 form when submitting bills to Medicare and third-party payers. Relevant fields on the CMS-1450 are patient and provider identifiers, patient characteristics, dates of service, a principal and other discharge diagnoses codes, procedures, admission diagnosis, and discharge status. Typically, facility claims do not include medications dispensed in hospital.

Appendix 10 Concurrent Education Interventions Report

Continuing Education: Pain Management and Safe Opioid Prescribing

July 2019

TABLE OF -CONTENTS

LIST OF TABLES **3**

1. INTRODUCTION **4**

1.1 Overview 4
1.2 Methodology 4
1.2.1 Determining State CE Requirements 4
1.2.2 Ascertaining Estimates of Annual Licensed Prescribers 5
1.2.3 Health Systems Requiring Opioid or Pain Management CE 5
1.2.4 Determining Adequacy of REMS CE to Meet CE Requirements 5
1.2.5 Additional Data on Available CE Programs 5

2. STATE CONTINUING EDUCATION REQUIREMENTS **6**

2.1 Medical Doctors and Doctors of Osteopathy 6
2.2 Physician Assistants 7
2.3 Podiatrists 8
2.4 Naturopathic Physicians 9
2.5 Nurses 9
2.6 Dentists 9
2.7 Optometrists 10
2.8 Pharmacists 10

3. LARGE SYSTEM CONTINUING EDUCATION REQUIREMENTS **12**

4. SUFFICIENCY OF REMS EDUCATION PROGRAMS **14**

5. ADDITIONAL CONTINUING EDUCATION PROGRAMS AVAILABLE **17**

APPENDIX A: "NUMBER OF AFFECTED PRESCRIBERS" LEGEND FOR APPENDICES B-I **18**

APPENDIX B: STATE PAIN AND OPIOID CE REQUIREMENTS-MEDICAL DOCTORS AND DOCTORS OF OSTEOPATHY **19**

APPENDIX C: STATE PAIN AND OPIOID CE REQUIREMENTS-PHYSICIAN ASSISTANTS **29**

APPENDIX D: STATE PAIN AND OPIOID CE REQUIREMENTS-PODIATRISTS **35**

APPENDIX E: STATE PAIN AND OPIOID CE REQUIREMENTS-NATUROPATHS **40**

APPENDIX F: STATE PAIN AND OPIOID CE REQUIREMENTS-NURSES **42**

APPENDIX G: STATE PAIN AND OPIOID CE REQUIREMENTS-DENTISTS **49**

APPENDIX H: STATE PAIN AND OPIOID CE REQUIREMENTS-OPTOMETRISTS **53**

APPENDIX I: STATE PAIN AND OPIOID CE REQUIREMENTS-PHARMACISTS **56**

APPENDIX J: SUFFICIENCY OF REMS EDUCATION, BY STATE **59**

APPENDIX K: CONTINUING EDUCATION PROGRAMS **64**

LIST OF TABLES

Table 1: Number of States in Which Standard REMS CE is Sufficient to Meet State Requirements..... 16

1. INTRODUCTION

1.1 Overview

In July 2012, the United States Food and Drug Administration (FDA) approved the initial Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of ER and LA opioid analgesics used in the outpatient setting outweigh the risks. In September 2018, FDA released its updated Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain.

As part of an effort to evaluate the effectiveness of the Extended-Release/Long-Acting (ER/LA) REMS program, the Opioid Analgesic REMS Program was mandated by FDA to provide an evaluation of the overall pain/opioid CE landscape. This mandate included the following directions:

> "For the year prior to the assessment period through the assessment period, provide an evaluation of the overall pain/opioid CE landscape including but not limited to:
>
> 1. States requiring prescribers, pharmacists or nurses to complete opioid or pain management continuing education for licensing/renewal of licensing:
>
> a. Enumeration of these states and their requirements for continuing education on either pain or safe opioid use;
>
> b. estimates of annual licensed prescribers in those states;
>
> c. which, if any, opioid analgesic or ER/LA Opioid Analgesics REMS CE were permissible in which states, for prescribers to meet requirements;
>
> 2. Health systems, including government (DOD, VA, IHS, etc.), that require opioid or pain management continuing education; include number of completers if available; and
>
> 3. Any additional available data on continuing education programs available during this time with a focus on pharmacological pain management or safe opioid use"

The assessment period referenced above extends from September 18, 2018 through July 17, 2019.

The Opioid Analgesic REMS Program's Metrics Subteam contracted with RKT Consulting, LLC, to carry out the research needed to meet this FDA request. Presented in this report are the results of that research.

1.2 Methodology

1.2.1 Determining State CE Requirements

To determine each state's CE requirements, both in general and focused on pain management and safe opioid use, websites for the relevant licensing boards were accessed. Links to information for licensees about CE requirements were followed, as well as links to relevant sections of the state's statutes and regulations. Additionally, websites for national organizations representing the professions covered by the FDA request were reviewed, along with websites of independent CE providers whose posted information included lists of state CE requirements. In some cases, it was necessary to conduct additional internet searches focused on "controlled substance", "opioid", or "pain management" CE requirements. This redundant process revealed a number of cases in which the states' websites were not current and the follow-up process enabled the research team to have a high degree of confidence in the findings presented below. If a requirement needed clarification, the research team contacted the relevant licensing board.

Requirements for general CE were recorded, and exact language regarding the pain management/opioid CE requirements was copied and pasted into the report appendices.

1.2.2 Ascertaining Estimates of Annual Licensed Prescribers

Several sources were used to estimate the current number of licensed prescribers, nurses, and pharmacists:

- Each state's licensing board websites for each profession were reviewed for links to this information
- If the website did not contain information about the number of licensees, a telephone call and email contact was placed to the licensing board
- In many instances, licensing boards did not have this information readily available and required considerable time to produce the result.
- When unable to obtain the necessary information from the licensing board, the consultants accessed the United States Department of Labor's Bureau of Labor Statistics' Occupational Employment Statistics query system. This resource provided the number of employed professionals in each state, as opposed to the number of licensed professionals, but was considered the most accurate available estimate of the number of affected licensees

In some states, not all licensees are required to complete pain management/opioid CE. However, it was rare that licensing boards could provide information on what proportion of their licensees met the criteria obligating them to complete the CE requirements of interest. Superscripts defined in Appendix A are used in Appendices B through I to indicate any factors affecting the accuracy of the estimates provided.

1.2.3 Health Systems Requiring Opioid or Pain Management CE

Section 3 of this report describes efforts undertaken to determine if large health systems have relevant CE requirements for their prescriber, nurse, or pharmacist employees.

1.2.4 Determining Adequacy of REMS CE to Meet CE Requirements

The methodology used to determine if completing a REMS-compliant CE program would enable a licensee to meet the state's CE requirements is described at the beginning of Section 4 of this report.

1.2.5 Additional Data on Available CE Programs

Efforts undertaken to identify additional available CE programs are described in detail in Section 5 of this report.

2. STATE CONTINUING EDUCATION REQUIREMENTS

In order to evaluate the effectiveness and uptake of opioid analgesic REMS CE programming, FDA requested information about state requirements for prescriber, pharmacist, and nursing CE related to either pain management or safe opioid use. Specifically, FDA's request was:

> "For the year prior to the assessment period through the assessment period, provide an evaluation of the overall pain/opioid CE landscape including but not limited to:
>
> 1. States requiring prescribers, pharmacists or nurses to complete opioid or pain management continuing education for licensing/renewal of licensing:
>
> a. Enumeration of these states and their requirements for continuing education on either pain or safe opioid use,
>
> b. estimates of annual licensed prescribers in those states…"

While pharmacists and nurses represent singular professions, the term "prescribers" encompasses several distinct groups, including medical doctors, doctors of osteopathy, physician assistants, advanced practice nurses, podiatrists, naturopathic physicians, dentists, and optometrists, each of which may have a scope of practice including opioid prescribing.

The following sections present the findings of research conducted to fulfill FDA's request. For each profession, each jurisdiction's general CE requirements for licensees, specific requirements regarding pain management and opioid CE, and the best available estimate of the number of affected providers is presented. Highlights of the findings are also presented, both to summarize the CE requirement picture for that profession as well as to indicate provisions that are substantially different from the norm.

2.1 Medical Doctors and Doctors of Osteopathy

Medical Doctors (MDs) and Doctors of Osteopathy (DOs) are required by forty states to complete CE related to pain management, substance use disorder, or safe opioid prescribing. Details of state requirements may be found in Appendix B.

Highlights related to the forty states with such CE requirements include the following:

- Twenty-eight states require 3.5 hours or less of pain- and opioid-related CE for each licensure renewal period.
- Eight states have pain- and opioid-related CE requirements based on a practitioner's status as a pain specialist and/or employment at a pain management clinic. Of these, six states (Alabama, Arkansas, Ohio, South Carolina, Texas, Washington, and West Virginia) require additional CE due to a practitioner's status as a pain specialist and/or employment in a pain management clinic, while the other two states (Georgia and Tennessee) exempt pain specialists from obtaining CE that is otherwise required for non-specialists.
- Six states (California, Georgia, Louisiana, Oregon, Rhode Island, and Washington) have one-time pain- and opioid-related CE requirements that either are prerequisites to initial licensure or are required of all licensees one time within a certain timeframe.
- Three states (Kentucky, Nebraska, and Vermont) require that the pain- and opioid-related CE specifically cover topics related to use of the state's prescription drug monitoring program (PDMP).
- Seven states (Georgia, Massachusetts, New Mexico, Tennessee, Vermont, Washington, and Wisconsin) require that the pain- and opioid-related CE specifically cover information related to state and/or federal laws, rules, and guidelines.
- New York has no general CE requirement for MDs and DOs. However, all prescribers in the state with a DEA registration, as well as medical residents who prescribe controlled substances under a facility DEA registration, are required to complete at least three hours of CE in pain management, palliative

care, and addiction prior to each biennial license renewal. Eight separate topic areas must be included in the pain management CE.

- New Mexico has instituted a series of requirements that are very similar across all prescribing professions. The requirements for MDs and DOs are a good example of what is found for most other professions. MDs and DOs are required to complete five hours of CE every two years, covering a range of topics including a review of the medical board's rules regarding pain management.
- Oregon is another state with similar requirements spanning a number of professions. Each MD and DO must complete a 1-hour pain management CE course provided by the Oregon Pain Management Commission, plus an additional six hours of CE in the subjects of pain management or the treatment of terminally ill and dying patients. Note that this is a one-time requirement only.
- Similarly, Rhode Island has implemented identical mandatory CE across several professions. MDs, DOs, and other prescribers in the state have a one-time requirement to complete eight hours of CE on topics such as appropriate prescribing for pain, pharmacology, dependence potential, and alternatives to opioids for pain management. Those who have taken DATA 2000 training to prescribe buprenorphine are exempt from the eight-hour requirement.

2.2 Physician Assistants

Physician assistants (PAs) are required by thirty-four states to complete CE related to pain management, substance use disorder, or safe opioid prescribing. One additional state imposes a requirement for completion of pharmacology-specific CEs, although there is no specification that such education must involve opioid analgesics or any other controlled substance.

Details of state requirements may be found in Appendix C.

Highlights of these CE requirements include the following:

- Twenty-five states require 3.5 hours or less of pain- and opioid-related CE for each renewal period.
- Alabama requires holders of its state Controlled Substances Certificate to complete a 12-hour program approved by the Board of Medicine. After completing this program, physician assistants are required to complete four hours of CE every two years as part of their license renewal requirements.
- Arkansas has a complex requirement that includes five hours related to pain management for PAs prescribing hydrocodone-containing medications and three hours of prescribing education related to pain treatment for all PAs, every two years.
- Kentucky requires 4.5 hours every three years, related to use of the state's PDMP, pain management, addiction disorders, or some combination of these topics.
- Massachusetts imposes a requirement only for PAs prescribing controlled substances. Those individuals need four CE credits every two years, with topics coming from a lengthy list related to pain management and safe opioid use.
- Mississippi's standard for PAs is one of the most stringent for any profession, anywhere in the country. PAs are required to complete ten hours of CE related to prescribing medications every year, with "an emphasis on controlled substances". It should be noted that this requirement only applies to PAs authorized to prescribe controlled substances.
- New Mexico has instituted a series of requirements that are very similar across all prescribing professions. The requirements for PAs are a good example of what is found for most other professions. PAs are required to complete five hours of CE every two years, covering a range of topics including a review of the medical board's rules regarding pain management.
- New York has no general CE requirement for PAs. However, all prescribers in the state with a DEA registration, as well as medical residents who prescribe controlled substances under a facility DEA registration, must complete at least three hours of CE in pain management, palliative care, and

addiction prior to each biennial license renewal. Eight separate topic areas must be included in the pain management CE.

- Ohio's requirement is unique among PAs, in that the licensing board requires 12 pharmacology-specific CE credits, over and above the basic requirement of 100 hours every two years, in order to renew a Certificate to Prescribe. Although this requirement does not specifically tie to pain management or opioid therapy, it is nonetheless included here because completion of an opioid analgesic REMS CE program would help meet the requirement.
- Oregon is another state with similar requirements spanning a number of professions. Each PA must complete a 1-hour pain management CE course provided by the Oregon Pain Management Commission, plus an additional six hours of CE in the subjects of pain management or the treatment of terminally ill and dying patients. Note that this is a one-time requirement only.
- Pennsylvania has legislated an initial requirement for four board-approved CE hours, consisting of two hours in pain management or the identification of addiction, and two hours in the practices of prescribing or dispensing of opioids. Following completion of this initial requirement, for each subsequent renewal of the license, a PA must complete two hours of CE on pain management, identification of addiction, or prescribing practices.
- Similarly, Rhode Island has implemented identical mandatory CE across several professions. PAs and other prescribers there have a one-time requirement to complete eight hours of CE on topics such as appropriate prescribing for pain, pharmacology, dependence potential, and alternatives to opioids for pain management. Those who have taken DATA 2000 training to prescribe buprenorphine are exempt from the eight-hour requirement.
- South Carolina imposes no general CE requirement for PAs to renew their licenses, but those who prescribe controlled substances are mandated to complete four hours of CE every two years related to approved procedures of prescribing and monitoring controlled substances in Schedules II, III, and IV.
- Texas requires completion of ten hours of CE related to pain management, but only for PAs employed in registered pain management clinics.

2.3 Podiatrists

Doctors of podiatric medicine are required to obtain pain management/opioid use disorder/safe opioid use CE in twenty-nine states.

Details of these requirements may be found in Appendix D.

An overview of these requirements identifies:

- Twenty-four states require three or fewer hours of pain- and opioid-related CE for each renewal period.
- Michigan requires five hours of CE in pain and symptom management for each license renewal period.
- Mississippi requires five hours of CE for each two-year renewal cycle, related to controlled substance prescribing, but only for podiatrists holding a current DEA registration.
- Oregon requires completion of seven hours of CE, including one hour of CE consisting of a program provided by the Oregon Pain Management Commission.
- Texas requires ten hours of CE related to pain management, but only for providers employed by a registered pain management clinic. There is no requirement for providers employed elsewhere.
- Utah requires 3.5 hours of CE every two years. The content of this education must include all elements of the FDA blueprint for the ER/LA Opioid REMS program.
- Including the states mentioned above, five states permit some podiatrists to be exempt from these CE requirements. The criteria for exemption vary from state to state.

2.4 Naturopathic Physicians

Only five states and the District of Columbia allow naturopathic physicians to prescribe controlled substances, including opioid analgesics. Of these, four states have CE requirements related to pain management, substance use disorder, and/or safe opioid prescribing.

Details of these requirements may be found in Appendix E.

Summarized results include:

- Arizona requires three hours of CE related to opioid use disorder.
- California has a one-time requirement for 12 hours of CE in pain management and care of the terminally ill. This requirement now also specifically includes content on the risks of addiction associated with Schedule II drugs.
- Oregon requires all health care providers, including naturopaths, to complete seven hours of CE in pain management within two years of first licensure. One hour of this content consists of a course designed by the Oregon Pain Commission.
- Vermont requires two hours of CE each licensure period, covering a wide range of topics related to pain management, substance use disorder, and safe opioid prescribing.

2.5 Nurses

Several types of nurses may have prescriptive privileges that include opioid analgesics. These include Advanced Practice Registered Nurses (APRNs), Nurse Practitioners (NPs), Certified Registered Nurse Anesthetists (CRNAs), and Certified Nurse Midwives (CNM). Forty-five states and the District of Columbia require some or all of these types of nurses to accrue continuing education in pain management, substance use disorder, and/or safe opioid prescribing as a condition of license renewal. In several cases, these requirements have been instituted despite nurses generally having no CE requirements for license renewal.

Details regarding pain management/opioid CE requirements for nurses may be found Appendix F.

Following is a summary of key findings for nurses:

- Twenty-seven states and the District of Columbia impose requirements for CE in pharmacology for nurses with prescriptive authority. Often, these requirements are substantial, with many in the 10-to-15 hour range. Several of these states also specify that these CE hours must include content related to pain management, substance use disorders, or safe opioid use. Even though many of these requirements are solely focused on pharmacology, they have been retained in this analysis because an opioid REMS CE program would serve to partially fulfill that requirement.
- Seven states have no standard CE requirement for nurses, but have pain management/opioid CE requirements for APRNs. Note that five of those seven states require APRNs to maintain national certification, which may entail completing CE requirements.
- Nurses in Texas are required to obtain pain management/opioid CE only if they are employed by a registered pain management clinic.
- Massachusetts sets out requirements for APRN pain management/opioid CE, but it does not specify the minimum number of CE hours required.
- Delaware, Michigan, New Jersey, Oregon, Rhode Island, Texas (only if employed in a registered pain management clinic), Utah, and Vermont have pain management/opioid CE requirements for all nurses, not just for the subset eligible to prescribe controlled substances.

2.6 Dentists

Thirty-two states impose a CE requirement related to pain management and/or safe opioid use as a condition of license renewal for dentists.

Details of requirements for dentists can be found in Appendix G.

Following is a summary of key findings regarding required CE for dentists:

- Nearly all state dental licensing boards require either two or three hours of CE focused on pain management, substance use disorders, and/or safe opioid use, during each license renewal period.
- Only two boards require more than three hours:
  - Utah requires 3.5 hours of CE every two years, focused on controlled substance prescribing. The required content of this CE includes all elements of the ER/LA Opioid REMS.
  - Rhode Island requires completion of eight hours of Category 1 CE for any dentist with a Schedule II DEA registration. However, this is a one-time requirement, and there is no provision requiring further pain management or safe opioid use CE for subsequent license renewals.
- Four states limit this CE requirement to subsets of dentists either who prescribe controlled substances in general, or who specifically prescribe opioid analgesics.

2.7 Optometrists

Optometrists are permitted to prescribe controlled substances, including opioid analgesics, in every state and the District of Columbia. Eighteen states require CE focused on pain management and/or safe opioid use.

Details of the requirements can be found in Appendix H.

A summary of the key findings for those 18 states includes:

- Only Rhode Island and Utah have requirements that exceed three hours per license renewal period.
  - Utah requires 3.5 hours of CE every two years, focused on controlled substance prescribing. The required content of this CE includes all elements of the ER/LA Opioid REMS Continuing Education Blueprint.
  - Rhode Island requires completion of eight hours of Category 1 CE for any optometrist who prescribes a Schedule II opioid. However, this is a one-time requirement, and there is no provision requiring further pain management or safe opioid use CE for subsequent license renewals.
- Arizona limits its CE requirement to optometrists who are authorized to prescribe Schedule II hydrocodone products.
- West Virginia limits its CE requirement to optometrists who have prescribed, administered, or dispensed controlled substances during the previous two years. Licensees who certify that they have not prescribed, administered, or dispensed controlled substances during the entire preceding two-year period are exempt from the requirement.

2.8 Pharmacists

Although pharmacists in some states may play a role in prescribing through collaborative practice agreements, most of their work related to pain management and safe opioid use involves accurately dispensing medications pursuant to a legal and appropriate prescription, in accordance with the "corresponding responsibility" language found in the federal Controlled Substances Act. Additionally, pharmacists may counsel patients for whom opioids are prescribed about safe use, secure storage, and appropriate disposal. Given their important role, states are beginning to establish pain management/opioid CE requirements for pharmacists

State CE requirements for pharmacists, related to safe opioid use or pain management, can be found in Appendix I.

A summary of the findings follows:

- Fourteen states and the District of Columbia have pharmacist CE requirements related to pain management and/or opioid use.

- Only three of these requirements are for more than three hours of CE every renewal period:
  - Mississippi requires five hours of CE each year, related to opioid abuse and prevention of some other drug of abuse or addiction-related issue.
  - Oregon has a one-time requirement to complete seven CE hours within 24 months of the licensee's first license renewal; one hour must be the module from the Oregon Pain Management Commission.
  - Pennsylvania requires four hours of Board-approved education consisting of two hours in pain management or the identification of addiction and two hours in the practices of prescribing or dispensing of opioids, every two years.
- Although the required topics are relatively evenly divided, there is a slight preference for CE focused on preventing, detecting, and treating opioid misuse, abuse, and addiction, over a focus on pain management.

3. LARGE SYSTEM CONTINUING EDUCATION REQUIREMENTS

FDA requested that RPC produce information regarding CE requirements by health systems. The specific language of the request was as follows:

> "For the year prior to the assessment period through the assessment period, provide an evaluation of the overall pain/opioid CE landscape including but not limited to…
>
> > 2. Health systems, including government (DOD, VA, IHS, etc.), that require opioid or pain management continuing education; include number of completers if available."

Consultants contacted sources within the Department of Defense (DOD), Veterans Administration (VA), and Indian Health Service (IHS), inquiring about such requirements. It was determined that opioid or pain management continuing education requirements at these three agencies are as follows:

- DOD: The Department of Defense requires prescribers and pharmacists to complete a two-hour CE program every three years. The current iteration of this program is titled, "DoD Opioid Prescriber Safety Training Program". It can be accessed at https://events-na7.adobeconnect.com/content/connect/c1/1124277231/en/events/event/shared/1959741235/event_registration.html?connect-session=na7breez3zhbxwab8y3stzxv&sco-id=1959741152&_charset_=utf-8
- VA: The Veterans Administration currently has no requirement for opioid or pain management continuing education for any of its staff.
- IHS: The Indian Health Service requires that all IHS prescribers, contractors, clinical residents, and trainees complete its Essential Training on Pain and Addiction course within the first six months of employment. Refresher training must be completed every three years. This course may be accessed at https://www.ihs.gov/painmanagement/trainingopportunities/essentialtraining/.

No information is available regarding the number of providers who have completed these training programs.

Additionally, the contractor attempted to contact the largest private health systems in the United States, to determine if they imposed any requirements on their employees. Searches for the largest systems, based on annual revenue and on number of facilities, turned up slightly different list memberships. The following 13 systems made up a combined list:

- HCA
- Ascension Health
- Catholic Health Initiatives
- Dignity Health
- Trinity Health
- Providence St. Joseph Health
- Tenet Healthcare
- Community Health Systems
- University of California Health
- Universal Health Services
- Kaiser Permanente
- UPMC Health System
- Carolinas Healthcare System Atrium Health

Each of these health systems was contacted through two routes. First, the website of each system was searched for a point of contact. These searches yielded two types of contacts: public relations staff, and webforms allowing users to post a message to a source within the system. Second, searches were conducted on LinkedIn for the Chief Medical Officers (or individuals with substantially similar roles) within each system. Individuals at ten health systems were identified through these searches. Messages were sent to all

identified points of contact, using email addresses and webforms from the websites and LinkedIn's messaging function, requesting information related to pain management or opioid CE requirements for employees of the systems.

Of the 13 systems, only Trinity Health responded. The contact at Trinity Health reported that the system has established a requirement for two hours of accredited CE related to pain management and/or safe opioid use for all opioid prescribers, as well as a one-hour requirement for nurses and pharmacists. Additionally, all staff must adhere to CE requirements established by their respective licensing boards. The Trinity Health contact indicated that tracking completion of this educational requirement is challenging; each institution typically carries it out, and there is no central reporting mechanism in place.

4. SUFFICIENCY OF REMS EDUCATION PROGRAMS

Nearly every state regulatory board overseeing prescribers, pharmacists, and nurses requires its licensees to complete CE as a means of maintaining and enhancing their competency to provide health care. Over the past five to ten years, most licensing boards, either acting independently or in response to legislative mandate, have added specific requirements focused on pain management and/or safe opioid use. This report details those requirements above.

FDA has made the following request:

> "For the year prior to the assessment period through the assessment period, provide an evaluation of the overall pain/opioid CE landscape including but not limited to:
>
> 1. States requiring prescribers, pharmacists or nurses to complete opioid or pain management continuing education for licensing/renewal of licensing:…
>
> c. which, if any, opioid analgesic or ER/LA Opioid Analgesics REMS CE were permissible in which states, for prescribers to meet requirements"

To conduct this evaluation, two individual reviewers experienced with CE and opioid analgesic policy analyzed each pain/opioid CE requirement in each state and the District of Columbia, for each discipline, comparing those requirements to the FDA's 2018 REMS Education Blueprint. Each reviewer independently determined whether each licensing board CE requirement would be fulfilled if a practitioner took a CE course of sufficient length, designed to comply with the 2018 REMS Education Blueprint ("standard REMS CE").

- If all of the state's content requirements were contained in the 2018 REMS Blueprint, the requirement was rated "meets", indicating that CE programs derived solely from the REMS Blueprint can meet the state requirements.
- If some, but not all, of the state's content requirements were contained in the 2018 REMS Blueprint, the requirement was rated "partially meets", indicating that CE programs derived solely from the REMS Blueprint can only partially meet the state requirements.
- Finally, if none of the state's content requirements were contained in the 2018 REMS Blueprint, the requirement was rated "does not meet", indicating that CE programs derived solely from the REMS Blueprint cannot meet the state requirements.

Note that this assessment does not evaluate time-based aspects of the states' requirements, as CE programs based on the 2018 REMS Blueprint could vary in length.

The two reviewers reconciled their findings, and then discussed and resolved any inconsistent determinations.

A summary of findings shows that some form of pain/opioid CE is required in nearly every state for at least one discipline, and very often across most licensed disciplines within a state.

Only four states require no pain/opioid CE of any kind: Colorado, Kansas, Missouri, and South Dakota.

Of the 47 jurisdictions that do require pain/opioid CE, the most common reasons that a state requirement would not be fulfilled by a standard REMS CE program are that the state requires:

- Information on federal and state law and regulations
- Dosage level and duration of prescribing recommendations
- Diversion training
- Prescription drug monitoring program education
- Palliative care and/or end-of-life and/or discipline-specific education

Following is a summary of highlights related to the sufficiency of REMS CE as compared to state requirements, by discipline. These findings are summarized in Table 1. Detailed data are presented in Appendix J.

Doctor of Medicine/Osteopathy

Of the 40 states with physician CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in 26 states, partially fulfill the requirement in 10 states, and fail to fulfill the requirement in four states.

Physician Assistant

Of the 35 states with physician assistant CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in 23 states, partially fulfill the requirement in ten states, and fail to fulfill the requirement in two states.

Podiatrist

Of the 29 states with podiatrist CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in 22 states, partially fulfill the requirement in four states, and fail to fulfill the requirement in three states.

Naturopathic Physician

Of the four states with naturopathic physician CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in one state, partially fulfill the requirement in two states, and fail to fulfill the requirement in one state.

It is important to note that there are very few CE requirements related to pain/opioids for naturopathic physicians because these practitioners are not licensed in every state, nor may they prescribe controlled substances in every state in which they are licensed. Only 22 states and the District of Columbia have laws regulating naturopathic doctors, and only six jurisdictions allow naturopathic physicians to prescribe controlled substances. Two of those jurisdictions have no specific pain/opioid CE requirements for naturopathic physicians.

Nurse

Of the 46 states with nurse CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in 35 states, partially fulfill the requirement in five states, and fail to fulfill the requirement in 6 states.

In most cases, though not all, pain/opioid CE requirements will apply to only those nurses who hold prescriptive authority (most often known as nurse practitioners). Some states have extended their pain/opioid requirements to all nurses, with or without prescriptive authority.

In some cases, nurses with prescriptive authority are required to take a relatively large number of CE credits related to pharmacology/pharmacotherapeutics. While these are not specific pain/opioid CE requirements, these requirements may be fulfilled by standard REMS CE, as opioid education is generally considered a subset of pharmacology. Thus, pharmacology-specific CE requirements were included for purposes of this evaluation.

Dentist

Of the 32 states with dentist CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in 21 states, partially fulfill the requirement in six states, and fail to fulfill the requirement in 5 states.

Optometrist

Of the 18 states with optometrist CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in 15 states, partially fulfill the requirement in one state, and fail to fulfill the requirement in two states.

Pharmacist

Of the 15 states with pharmacist CE requirements related to pain/opioids, standard REMS CE would totally fulfill the requirement in eight states, partially fulfill the requirement in two states, and fail to fulfill the requirement in five states.

Table 1: Number of States in Which Standard REMS CE is Sufficient to Meet State Requirements

	Requirements Met	Requirements Partially Met	Requirements Not Met	No Requirements
MD/DO	26	10	4	12
Physician Assistant	23	10	2	16
Podiatrist	22	4	3	22
Naturopath	1	2	1	47
Nurse	35	5	6	5
Dentist	21	6	5	19
Optometrist	15	1	2	33
Pharmacist	8	2	5	36

5. ADDITIONAL CONTINUING EDUCATION PROGRAMS AVAILABLE

FDA requested additional data on continuing education programs, as follows:

> "For the year prior to the assessment period through the assessment period, provide an evaluation of the overall pain/opioid CE landscape including but not limited to…
>
> > 3. Any additional available data on continuing education programs available during this time with a focus on pharmacological pain management or safe opioid use."

This request was interpreted to mean that FDA seeks information about currently available CE programs focused on the specified topics. Given that there is no central repository of all available CE programs, internet searches were undertaken seeking CE programs on pain management (including non-pharmacological pain management if it was presented as a means to reduce opioid use) and/or safe opioid use.

Extensive searching using the Google search engine and the terms "opioid continuing education," "pain continuing education," and "opioid REMS continuing education" identified 273 programs. The titles, sponsors, and CE credit hours associated with each program are listed in Appendix K. All of these programs were available during the time frame specified by FDA. While the search strategies used were comprehensive, it is likely that other programs are available, but were not identified. Additionally, there may have been programs available during earlier portions of the FDA-designated window that have since closed and been removed from the internet.

Appendix A: "Number of Affected Prescribers" Legend for Appendices B-I

The number found in the "Number of Affected Prescribers" column represents the most accurate figure available regarding the number of prescribers within a state that are subject to the "Pain and Opioid CE Requirements" column.

The number included in this column is as up to date as possible, with many numbers being reported directly from licensing boards as the "real-time" number of active licensees in July 2019. In other cases, numbers were obtained from official state documents, state websites, and/or professional associations.

Numbers that are not qualified with any additional labels (see Legend, below) are figures that are from no earlier than 2016, are not subject to any specific limitations, and accurately represent the number of practitioners affected by the "Pain and Opioid CE Requirements" column. However, while the states have come up with a number of ways to limit who must obtain pain/opioid CE, they don't often have figures available for these specific requirements, instead only maintaining records of their total numbers of licensees. Therefore, a number of labels have been employed to clarify when a number provided will not be an entirely accurate representation of the number of prescribers affected by the pain/opioid CE requirement.

Legend:

[1]While the number provided represents the total number of licensees, only those licensees who **actively prescribe controlled substances** must obtain the required pain/opioid CE.

[2]While the number provided represents the total number of licensees, only those licensees who **actively prescribe opioids** must obtain the required pain/opioid CE.

[3]While the number provided represents the total number of licensees, only those licensees who **prescribed an opioid during the last licensure renewal cycle** must obtain the required pain/opioid CE.

[4]While the number provided represents the total number of licensees, only those licensees who are **registered with the state to prescribe (hold "prescriptive authority") and/or dispense controlled substances** must obtain the required pain/opioid CE. This additional state-based requirement is not commensurate with DEA registration.

[5]While the number provided represents the total number of licensees, only those licensees who **practice in a pain management clinic and/or qualify as pain management specialists** must obtain the required pain/opioid CE.

[6]The number provided represents the total number of licensees, and **all licensees are subject to at least one requirement** related to pain/opioids/controlled substances/pharmacology/etc. However, there is an **additional pain/opioid requirement which will only apply to the subset of those licensees who prescribe controlled substances**.

[7]The number represents the **total number of licensees from 2015**, as more recent data was unavailable.

[8]While the number provided represents the total number of licensees, those licensees who **qualify as pain specialists are exempt** from obtaining the required pain/opioid CE.

[9]No number was available from a reliable state-based source, so data from the United States **Department of Labor's** Bureau of Labor Statistics' Occupational Employment Statistics query system was utilized. **Figures are from 2018 and represent the number of employed practitioners, not the number of licensed practitioners.**

Appendix B: State Pain and Opioid CE Requirements-Medical Doctors and Doctors of Osteopathy

State Pain and Opioid CE Requirements-Medical Doctors and Doctors of Osteopathy

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
Alabama	25 AMA PRA Category 1 CMEs every year	All Alabama Controlled Substance Certificate holders must obtain 2 AMA PRA Category 1 or equivalent CMEs every 2 years beginning in 2018. Acceptable programs confer Category 1 CMEs in the areas of: (1) controlled substance prescribing practices, (2) recognizing signs of the abuse or misuse of controlled substances, or (3) controlled substance prescribing for chronic pain management. No course pre-approval is required. Medical Directors of pain management clinics can qualify by completing 40 in-person; live participatory AMA PRA Category 1 CEs in pain management within 3 years prior to serving as a medical director.	7,160 [4,5,9]
Alaska	50 AMA PRA Category 1 CMEs every 2 years, or Category 1 or 2 AOA every two years	For license renewals for those with a DEA registration, at least 2 of the total CMEs required to qualify for renewal must be specific to pain management and opioid use and addiction. AMA PRA Category 1 education qualifies.	1,310 [9] MD 446 DO
Arizona	For MDs, 40 CMEs every 2 years. For DOs, not more than 8 hours of annual CMEs may be obtained by completing AMA PRA Category 1 (they need 24 AOA CMEs).	A.R.S. § 32-3248.02 requires all healthcare professionals who hold Drug Enforcement Administration certifications to complete a minimum 3 CMEs in an opioid related, substance-use disorder related, or addiction related course each renewal cycle as part of the annual continuing education requirement for licensure.	12,030 [9]
Arkansas	20 CMEs every year. 50% must be Category 1 and in the physician's primary area of practice.	For physicians who primarily treat pain, at least 10 CMEs annually must relate to pain. Physicians operating a pain management program should meet the following: 3 years' experience in the interdisciplinary management of persons with chronic pain; participation in active education on pain management at a local or national level; Board certification in a medical specialty or completion of training sufficient to qualify for examinations by members of the American Board of Medical Specialties; 2 years' experience in the medical direction of an interdisciplinary Chronic Pain Program or at least 6 months of pain fellowship. The physician must have completed at least one of the following: attendance at one meeting per year of a regional and national pain society; presentation of an abstract to a regional or national pain society; publication on a pain topic in a peer-reviewed journal; membership in a pain society at a regional or national level.	6,567 [5,6] MD 438 [5,6] DO
California	MD requires 50 AMA PRA Category 1 CMEs every 2 years; DO requires 100 AMA PRA Category 1 CMEs every 2	There is a one-time requirement of 12 CMEs in pain management and care of the terminally ill (except for Pathologists and Radiologists) that must be completed by the physician's second license	64,140 [9]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
	years, but 40 credits must be AOA1-A or AOA1-B.	renewal date or within 4 years, whichever comes first. The 12 CMEs may be divided in any way that is relevant to the physician's specialty and practice setting. The Medical Board will accept any combination of the two topics totaling 12 hours. For physicians and surgeons licensed on or after 01 January 2019, the course must include the subject of risks of addiction associated with the use of Schedule II drugs. As an alternative to the above 12-hour requirement, a physician or surgeon may complete a one-time continuing education course of 12 CMEs in the subjects of treatment and management of opiate-dependent patients, including 8 hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders.	
Connecticut	50 CMEs (AMA PRA Category 1, AOA, etc.) every 2 years. One CME means a minimum of 50 minutes of continuing education activity. Continuing medical education shall be in an area of the physician's practice.	During the first renewal period and not less than every six years thereafter, there is a 1-hour "risk management" requirement. This requirement can be fulfilled with a CME on prescribing controlled substances and pain management. CME shall be in an area of the physician's practice.	17,418 MD 808 DO
Florida Medical	40 AMA PRA Category 1 CMEs every 2 years	2 hours of AMA Category 1 or AOA Category 1-A CMEs on prescribing controlled substances, every 2 years	78,050
Florida Osteopathic	40 CMEs every 2 years	2 hours of AMA Category 1 or AOA Category 1-A CMEs on prescribing controlled substances, every 2 years	8,644
Georgia	40 AMA PRA Category 1 CMEs every 2 years	Every physician not subject to Rule 360-15-.01(3) who maintains an active DEA certificate and prescribes controlled substances, except those holding a residency training permit, shall complete at least one time 3 or more hours of AMA/AOA PRA Category 1 CME that is designed specifically to address controlled substance prescribing practices. The controlled substance prescribing CME shall include instruction on controlled substance prescribing guidelines, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management. The certification of such completion must occur at the first renewal following January 1, 2018 or the first renewal following licensure. Completion of this requirement may count as three hours toward the CME requirement for license renewal. Rule 360-15-.01(3) states: "Physicians who do not hold a certification in pain management or palliative medicine, and whose opioid pain management patients comprise 50% or more of the patient population must demonstrate competence by biennially obtaining 20 (twenty) hours of	15,110 [1,6,8,9]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
		continuing medical education ("CME") pertaining to pain management or palliative medicine."	
Illinois	150 CMEs every 3 years, 60 of which must be AMA PRA Category 1	Beginning in 2020, 3 CMEs on safe opioid prescribing practices offered or accredited by a professional association, state government agency, or federal agency every licensing period	23,250 [9]
Indiana	No CME requirement for MDs and DOs, except for new requirement for opioids	Beginning in 2019, 2 CMEs addressing the topic of opioid prescribing and opioid abuse every licensing period	14,700 [9]
Iowa	40 AMA PRA Category 1 CMEs every two years	2 CMEs in Chronic Pain Management every 5 years	5,560 [9]
Kentucky	60 CMEs every 3 years. Of the 60 CMEs, 30 must be AMA PRA Category 1 or AOA Category 1 by an organization accredited by the Accreditation Council on Continuing Medical Education or the AOA Council on Continuing Medical Education.	Minimum of 4.5 hours of HB1 (House Bill 1) approved CMEs for physicians authorized to prescribe or dispense controlled substances every licensing period. The education must relate to the use of KASPER, pain management, addiction disorders, or a combination of two or more of those subjects. The requirement may be met with one, 4.5 hour course or multiple courses totaling 4.5 hours.	6,060 [9]
Louisiana	20 AMA PRA Category 1 CMEs every year	One time requirement: Effective 01 January 2018, as a condition to license renewal, all practitioner licensed to prescribe controlled substances are required to obtain CMEs pertaining to drug diversion training, best practices regarding prescribing of controlled substances, appropriate treatment of addiction, and any other matters pertaining to the prescribing of controlled substances that are deemed appropriate by the board.	17,664 MD 563 DO
Maine	100 CMEs every 2 years. For MDs, 40 CMEs must be AMA Category 1. For DOs, 40 CMEs must be AOA Category 1. All must be Category 1 if an osteopathic specialist.	Effective 31 December 2017, 3 CMEs of opioid prescribing required every 2 years for all clinicians who prescribe opioids. 3 CMEs of any Category 1 AMA approved program on the prescribing of opioids suffice.	3,840 [2,9]
Maryland	50 AMA PRA Category 1 CMEs every 2 years	1 CME every 2 years on opioid prescribing	37,853 MD 1,764 DO
Massachusetts	100 CMEs every 2 years. Of that 100, 40 must be AMA PRA Category 1 or AOA.	10 CMEs on Risk Management (Minimum of 4, Category 1 CMEs); 3 CMEs on opioid education and pain management for renewals. Risk management study must include instruction in medical malpractice prevention such as risk identification, patient safety, and loss prevention. It may include courses in medical ethics, quality assurance, medical-legal issues, patient relations, non-economic aspects of practice management, or	27,340 [9]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
		courses designed to reduce the likelihood of medical malpractice through means other than increasing the licensee's medical education and technical competence. Risk management study also includes review of the Board's Patient Care Assessment regulations (243 CMR 3.01-3.16) and participation on designated peer review committees dealing with quality assurance. Effective 01 February 2012, physicians applying to renew a license or obtain a new license must complete at least 3 CMEs in pain management and opioid education. The requirement applies to all physicians who prescribe controlled substances (Schedules I through VI). According to state regulations, such education includes training in effective pain management, identification of patients at high risk for substance abuse, counseling patients about side effects, and the addictive nature and proper storage and disposal of prescription drugs. These CEUs will qualify as either Category 1 or Category 2, and may be counted as risk management credits.	
Michigan Medical	150 CMEs every 3 years. Of those, a minimum of 75 must be AMA PRA Category 1	3 CME (of the 150) must be earned in the area of pain and symptom management	34,559
Michigan Osteopathic	150 CMEs every 3 years; 60 must be Category 1	3 CME (of the 150) must be earned in the area of pain and symptom management	8,281
Minnesota	75 AMA PRA Category 1 CMEs every 3 years	Effective 01 January 2020, licensees with the authority to prescribe controlled substances must obtain at least 2 CMEs on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the continuing education requirements for licensure renewal.	15,438 [7]
Mississippi	40 AMA PRA Category 1 CMEs every 2 years	5 CME related to prescribing medications, with emphasis on controlled substances required for licensees with active DEA certificates	3,330 [9]
Nebraska	50 AMA PRA Category 1 CMEs every 2 years	Effective 01 October 2018, 3 hours every 2 years regarding prescribing opiates. This may include education regarding prescribing and administering opiates, risks and indicators regarding opiate addiction development and emergency opiate situations. 1/2 hour of the 3 shall cover the PDMP.	9,500 [1] MD 1,328 [1] DO
Nevada	40 AMA PRA Category 1 CMEs every 2 years for MDs. 35 AMA PRA Category 1 (or AOA 1-A) CMEs every year (10 must be AOA 1-A) for DOs.	2 CME relating specifically to the misuse and abuse of controlled substances, the prescribing of opioids or addiction during each period of licensure.	4,050 [9]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
New Hampshire	100 CMEs every 2 years. 40 must be AMA PRA Category 1.	3 opioid CMEs for physicians with a DEA license every 2 years. This requirement is not waived for anyone (even if his or her other CME requirements are waived). There is an approval process for this education.	7,496
New Jersey	100 CMEs every 2 years. 40 must be AMA PRA Category 1.	Effective with 2019 and subsequent renewals, for all prescribers, 1 CME concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.	22,800 [9]
New Mexico Medical	75 AMA PRA Category 1 CMEs every 2 years	5 CME in pain management. Appropriate courses should include a review of NM Medical Board Rule 16.10.14 NMAC on pain management; an understanding of the pharmacology and risks of controlled substances, a basic awareness of the problems of abuse, addiction and diversion, and awareness of state and federal regulations for the prescription of controlled substances.	3,300 [9]
New Mexico Osteopathic	75 Category 1 CMEs every 2 years	6 CME in pain management. Appropriate courses should include a review of 16.17.5 NMAC, management of the treatment of pain, an understanding of the pharmacology and risks of controlled substances, a basic awareness of the problems of abuse, addiction and diversion, and awareness of state and federal regulations for the prescription of controlled substances.	654
New York	No general CME requirement.	All prescribers licensed to treat humans who have a DEA registration to prescribe controlled substances, as well as medical residents who prescribe controlled substances under a facility DEA registration, must complete at least 3 hours of course work or training in pain management, palliative care, and addiction. The following 8 topic areas must be included: New York State and federal requirements for prescribing controlled substances; pain management; appropriate prescribing; managing acute pain; palliative medicine; prevention, screening, and signs of addiction; responses to abuse and addiction; end of life care.	59,140 [9]
North Carolina	60 Category 1 CMEs that are “relevant to the physician's current or intended specialty or area of practice” every 3 years	Every physician who prescribes controlled substances, except those with residency status, shall complete at least 3 Category 1 CMEs (counts toward the overall 60) that are specifically designed to address controlled substance prescribing practices. The course shall include instruction on controlled substances prescribing practices, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management.	19,180 [1,9]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
Ohio	100 CMEs every 2 years. 40 must be AMA PRA Category 1.	Each physician owner of a pain management clinic shall complete at least 20 hours of category I CMRs in pain medicine every 2 years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the Category I requirement for certificate of registration renewal for the physician.	30,400 [5,9]
Oklahoma	For MD, 60 AMA PRA Category 1 CMEs every 3 years; for DOs, 16 AOA 1-A or B CMEs every year.	For MDs, 1 CME in pain management or 1 CME in opioid use or addiction each year preceding renewal of a license, if holding a DEA registration. For DOs, 1 CME every other year on prescribing, dispensing, and administering controlled substances.	6,070 [9]
Oregon	60 AMA PRA Category 1 CMEs every 2 years. CMEs must be relevant to the provider's current practice.	Within the first year of licensure, licensees must complete CMEs on pain management. A 1-hour course provided by the Oregon Pain Management Commission is required plus at least 6 more CMEs in pain management or the treatment of terminally ill and dying patients. Those 6 CMEs may be made up of any combination of CME coursework focusing on pain management and/or treatment of terminally ill and dying patients. This is a one-time requirement, but licensees may choose to obtain additional hours on these topics throughout their careers. The topic of pain management is legally considered relevant for all licensees, regardless of their specialty.	13,113 MD 1,382 DO
Pennsylvania Medical	100 CMEs every 2 years. At least 20 of the 100 CMEs must be AMA PRA Category 1.	4 Board-approved CMEs consisting of 2 CMEs in pain management or the identification of addiction and 2 CMEs in the practices of prescribing or dispensing of opioids; subsequent renewals require 2 CMEs on pain management, identification of addiction, or prescribing practices.	48,463
Pennsylvania Osteopathic	100 CMEs every 2 years. At least 20 of the 100 CMEs must be Category 1.	4 Board-approved CMEs consisting of 2 CMEs in pain management or the identification of addiction and 2 CMEs in the practices of prescribing or dispensing of opioids; subsequent renewals require 2 CMEs on pain management, identification of addiction, or prescribing practices.	Not available
Rhode Island	40 AMA PRA Category 1 (or AOA 1-A) CMEs every 2 years	8 CMEs on topics such as: appropriate prescribing for pain, pharmacology, potential for dependence, and alternatives to opioids for pain management. Those who have taken DATA 2000 training to prescribe buprenorphine will be exempt from the 8-hour continuing education requirement. Training must be completed at least once per career and must occur before the next renewal of your controlled substance registration in June of 2018.	5,019 MD 400 DO
South Carolina	40 AMA PRA Category 1 CMEs every 2 years. At least thirty CMEs must be	2 CMEs related to approved procedures of prescribing and monitoring controlled substances	22,000 [5,6]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
	related directly to the licensee's practice area.	listed in Schedules II, III, and IV for all licensees. Further, at least 30 of the general CMEs must be related directly to the licensee's practice area, so pain specialists need 30+ pain-related CMEs.	
Tennessee	For MDs, 40 hours AMA PRA Category 1 CMEs every 2 years. For DOs, 40 hours AOA 1A or 2A CMEs every 2 years.	2 CMEs that must include instruction in: the Department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol; topics such as medicine addiction, risk management tools, and other topics approved by the Board. Providers of intractable pain treatment must have specialized CMEs in pain management. If you do not have a DEA registration and do not prescribe, at least 2 of the 40 required hours shall be in a course or courses designated specifically to address prescribing practices. Medical doctors and osteopathic physicians who are board certified by the American Board of Medical Specialties, American Osteopathic Association or the American Board of Physician Specialties in 1 or more of the following specialties or subspecialties do not have to complete the 2 CME on controlled substance prescribing: Pain management, Anesthesiology, Physical medicine and rehabilitation, Neurology, or Rheumatology.	9,900 [8,9]
Texas	48 CMEs every 2 years. Of the 48, at least 24 must be AMA/PRA/ACCME/AOA courses.	Per Board rule 195.4(e), the medical director of a pain management clinic must, on an annual basis, ensure that all personnel (including the medical director) are properly licensed, and if applicable, trained to include 10 CMEs related to pain management. This CME requirement applies to all personnel providing medical services to the patients (including, but not limited to: PAs, x-ray techs, phlebotomists, RNs, MAs, etc.).	45,250 [5,9]
Utah Medical	40 CMEs every 2 years. 34 CMEs must be AMA PRA Category 1. 6 CMEs may be from Division of Occupational and Professional Licensing.	3.5 CMEs every 2 years on controlled substance prescribing. The 3.5 CMEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published 09 July 2012, or as it may be subsequently revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	5,620 [9]
Utah Osteopathic	40 CMEs every 2 years. 34 CMEs must be AMA PRA Category 1. 6 CMEs may be from Division of Occupational and Professional Licensing.	3.5 CMEs every 2 years on controlled substance prescribing. The 3.5 CMEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's	1,183

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
		Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published 09 July 2012, or as it may be subsequently revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	
Vermont Medical	30 AMA PRA Category 1 CMEs every 2 years	1 CME every licensing period for all licensees shall be on the topic of hospice care, palliative care, or pain management services, or a combination of these. One additional CME on the appropriate use of opioids, including the use of complementary and alternative therapies instead of opioid controlled substances to treat chronic pain is required by licensees who prescribe or are likely to prescribe opioid controlled substances, as determined by the Board, every licensing period.	3,739 [2,6]
Vermont Osteopathic	30 CMEs every 2 years; a minimum of 12 CMEs must be osteopathic medical education	2 hours of continuing education for each full licensing period on the topics of: the abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; the appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant State and federal laws and regulations concerning the prescription of opioid controlled substance.	260
Virginia	60 CMEs every 2 years. At least 30 must be AMA PRA Category 1.	2 CME related to pain management, proper prescribing of controlled substances, and the diagnosis and management of addiction every 2 years.	44,844
Washington	For MDs, 200 CMEs every 4 years, at least 120 must be Category 1 credits (AMA PRA Category 1). For DOs, 150 CMEs every 3 years, at least 60 must be Category 1 (AMA PRA Category 1 accepted).	For MDs: WSMA's one-hour webinar, “Preparing for New State Opioid Prescribing Rules”, fulfills the state CMEs on opioid prescribing. This activity has been approved for AMA PRA Category 1 Credit. Also, allopathic physician and PA prescribers should note that simply reading the new rules will meet the new state requirement for opioid continuing medical education. For DOs: In order to prescribe an opioid in Washington state, an osteopathic physician licensed to prescribe opioids shall complete a one-time CME regarding best practices in the prescribing of opioids and the current opioid prescribing rules in this chapter. The continuing education must be at least one hour in length. WAC 246-853-685	12,470 [9]

State Boards	Total CME Hours (CMEs) Required	Pain and Opioid CME Requirements	Number of Affected Prescribers
West Virginia	For MDs, 50 AMA PRA Category 1 CMEs every 2 years, 30 of which must be related to the provider's area or areas of specialty. For DOs, 32 CMEs every 2 years, 16 of which must be AOA 1-A or 1B.	Pain specialists need to have 30 pain-related CMEs every 2 years. Further, for all providers, unless they have completed and timely provided to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every physician as a prerequisite to license renewal shall complete a minimum of 3 CMEs of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period, of which 3 such CMEs may be provided only by a Board-approved program	3,220 [5,6,9]
Wisconsin	30 AMA PRA Category 1 or AOA Category 1 CMEs every 2 years	2 CMEs on the Wisconsin Medical Examining Board Opioid Prescribing Guideline during the 2016-2017 and 2018-2019 CME cycles	10,170 [9]

Appendix C: State Pain and Opioid CE Requirements-Physician Assistants

State Pain and Opioid CE Requirements-Physician Assistants

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Alabama	25 AMA PRA Category 1 CEs annually	To renew a Qualified Alabama Controlled Substances Certificate: Must have 4 AMA PRA Category 1 CEs every 2 years (after original 12 hours of state-sponsored CEs). The courses must be pre-approved by the Board. The initial 12 CEs include: 8 AMA PRA Category 1 CEs from "Prescribing Controlled Drugs; Critical Issues and Common Pitfalls"; and, 4 AMA PRA Category 1 CEs that include advanced pharmacology and prescribing trends relating to controlled substances.	750 [4,9]
Alaska	50 AMA PRA Category 1 CEs every 2 years	For license renewals, at least 2 of the required CEs for renewal must be specific to pain management and opioid use and addiction. AMA PRA Category 1 CEs qualify. For a physician assistant, it may instead be earned in a NCCPA-approved continuing medical education program.	623
Arizona	40 CEs every 2 years	A.R.S. § 32-3248.02 requires all healthcare professionals who hold Drug Enforcement Administration certifications to complete a minimum 3 CEs in an opioid-related, substance-use disorder related, or addiction related course each renewal cycle as part of the annual continuing education requirement for licensure.	2,100 [9]
Arkansas	20 CEs annually. CEs hours do not have to be in a particular category.	PAs authorized to prescribe Schedule II hydrocodone combination products reclassified from Schedule III to Schedule II (in 2014) must complete at least five (5) CE hours in the area of pain management. Each year, each physician and physician assistant shall obtain at least one (1) hour of CME credit specifically regarding the prescribing of opioids and benzodiazepines. Within the first two (2) years of licensure, a prescriber shall obtain a minimum of three (3) hours of prescribing education approved by the Arkansas State Medical Board.	511
Connecticut	100 CEs every 2 years, 50 of which must be Category 1 (This mirrors the CE requirement of the National Commission on Certification of Physician Assistants (NCCPA)).	Connecticut licensed physician assistants must complete not less than 1 CE in prescribing controlled substances and pain management during each two-year renewal period.	2,300 [9]
Florida	100 CEs every 2 years	Prescribing PAs must have 3 CEs every 2 years on safe and effective prescribing of controlled substances. In addition to the above requirements, prescribing physician assistants must complete 10 hours of CEs in each specialty area of the supervising physician. These hours are included in the general CEs. Effective 01 January 2017, 3 of the 10 specialty hours must consist of a course on the safe and effective prescribing of controlled substance medications given by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category I credit or designated by the American Academy of Physician Assistants as a Category I credit.	9,762

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Indiana	100 CEs every 2 years	Effective 01 July 2019, pursuant to Senate Enrolled Act 225-2018, a practitioner, licensed by a board and applying for registration or re-registration to distribute or dispense a controlled substance, must have completed 2 CEs during the previous 2 years addressing the topic of opioid prescribing and opioid abuse.	1,550 [9]
Iowa	100 AMA PRA Category 1 CEs every two years	A licensee who has prescribed opioids to a patient during the renewal cycle shall complete a minimum of 2 CEs regarding the guidelines for prescribing opioids for chronic pain, as issued by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, including recommendations on limitations on dosages and the length of prescriptions, risk factors for abuse, and nonopioid and nonpharmacologic therapy options, as a condition of license renewal. These CEs may count toward the 100 CEs required for license renewal. The licensee shall maintain documentation of these hours, which may be subject to audit.	1,000 [3]
Kentucky	60 CEs every 3 years. Of the 60 CEs required, 30 must be AMA PRA Category 1 or AOA Category 1 by an organization accredited by the Accreditation Council on Continuing Medical Education or the AOA Council on Continuing Medical Education.	Minimum of 4.5 CEs of HB1 (House Bill 1) approved CEs for physicians authorized to prescribe or dispense controlled substances. The education must relate to the use of KASPER (their prescription monitoring program), pain management, addiction disorders, or a combination of two or more of those subjects. The requirement may be met with one 4.5 CE course or multiple courses totaling 4.5 CEs.	1,070 [9]
Louisiana	100 CEs every 2 years	Practitioners with a Controlled Dangerous Substance (CDS) license are required to complete at least 3 Board-approved CEs on the best practices for the prescribing of CDS, drug diversion training, appropriate treatment for addiction, and the treatment of chronic pain.	1,291
Maine	100 CEs every 2 years	Effective 31 December 2017, 3 CEs of opioid prescribing required every 2 years for all clinicians that prescribe opioids. 3 CEs of any Category 1 AMA approved program on the prescribing of opioids will suffice	720 [2,9]
Maryland	50 CEs every 2 years or maintenance of NCCPA certification	One-time requirement for 2 CEs if holding a CDS registration, starting 01 October 2018. Must relate to prescribing or dispensing controlled substances. Must be recognized by the provider's professional board or accredited by ACCME.	7,268
Massachusetts	100 CEs every 2 years, 40 of which must be Category 1	If prescribing controlled substances, must complete 4 CEs in the following topics: effective pain management; the risks of abuse and addiction associated with opioid medication; identification of patients at risk for substance use disorders; counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications; appropriate prescription quantities for prescription medications that have an increased risk of abuse; and opioid antagonists, overdose prevention treatments and instances in which a patient may be advised on both the use of and ways to access opioid antagonists and overdose prevention treatments.	3,720 [1,9]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Minnesota	50 AMA PRA Category 1 CEs every 2 years or maintenance of NCCPA certification	Effective 01 January 2020, licensees with the authority to prescribe controlled substances must obtain at least 2 CEs on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the continuing education requirements for licensure renewal.	1,980 [9]
Mississippi	50 CEs annually. Of the 50 CEs required, 20 must be AMA PRA Category 1. NCCPA certification waives requirement	10 CEs of AMA, AOA, or AAPA Category 1 CEs related to prescribing medications, with emphasis on controlled substances, required for PA authorized to prescribe controlled substances.	200 [9]
Nebraska	50 CEs of ACCME, AOA, or AAPA Category 1 CEs every 2 years, or maintenance of NCCPA certification	Effective 01 October 2018, 3 hours every 2 years regarding prescribing opiates. This may include education regarding prescribing and administering opiates, risks and indicators regarding opiate addiction development and emergency opiate situations. 1/2 hour of the 3 shall cover the PDMP	1,454 [2]
Nevada	40 AMA PRA Category 1 CEs every 2 years.	2 CEs relating specifically to the misuse and abuse of controlled substances, the prescribing of opioids, or addiction during each period of licensure.	650 [9]
New Hampshire	Must maintain NCCPA certification	All prescribers required to register with the program who possess a U.S. Drug Enforcement Administration (DEA) license number shall complete 3 CEs of free, appropriate prescriber's regulatory board-approved online continuing education or pass an online examination, in the area of pain management and addiction disorder or a combination, as a condition for license renewal.	889
New Jersey	50 CEs every 2 years; must be Category 1 AMA, AAPA, AOA, or ACCME	Effective with 2019 and subsequent renewals, for all prescribers, 1 CE concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.	2,810 [9]
New Mexico	Must maintain NCCPA certification	5 CEs in pain management. Appropriate CEs should include: a review of NM Medical Board Rule 16.10.14 NMAC on pain management; an understanding of the pharmacology and risks of controlled substances; a basic awareness of the problems of abuse, addiction, and diversion; and awareness of state and federal regulations for the prescription of controlled substances.	680 [9]
New York	No general CE requirement; see Pain/Opioid CE.	All prescribers licensed to treat humans who have a DEA registration to prescribe controlled substances, as well as medical residents who prescribe controlled substances under a facility DEA registration, must complete at least 3 CEs in pain management, palliative care, and addiction. The following 8 topic areas MUST be included: New York State and federal requirements for prescribing controlled substances; pain management; appropriate prescribing; managing acute pain; palliative medicine; prevention, screening, and signs of addiction; responses to abuse and addiction; and end of life care. All 8 topics must be completed prior to attestation; the topics can be completed in a single presentation or in individual segments for a total of at least 3 hours. The coursework may be	12,060 [9]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
		live, online, or obtained from a publication or journal. There is no minimum amount of time that must be spent on each of the eight topics. The CE does not have to be pre-approved, as prescribers merely complete an attestation saying that they completed the appropriate work.	
North Carolina	50 CEs of AAPA Category 1 CE every 2 years; active NCCPA certification waives requirement; NCCPA certification waives this requirement, but not the controlled substance requirement	Beginning 01 July 2017, 2 hours of CEs specifically designed to address controlled substance prescribing practices. The CEs shall include instruction on controlled substances prescribing practices, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management.	5,010 [9]
Ohio	100 CEs every 2 years + 12 pharmacology every 2 years plus NCCPA certification	12 pharmacology-specific CEs over and above the required 100 CEs in order to renew a Certificate to Prescribe.	4,430 [9]
Oklahoma	20 CEs annually	1 CE each year shall be concerning the topic of substance abuse	1,390 [9]
Oregon	60 CEs of AMA, APMA, AAPA, or AOA Category 1 or AOA Category 1A or 2A every 2 years	Within the first licensure year, licensees must complete CEs on pain management. A 1-hour course provided by the Oregon Pain Management Commission is required plus at least 6 more CEs in the subjects of pain management or the treatment of terminally ill and dying patients. This is a 1-time requirement, but licensees may choose to obtain additional hours on these topics throughout their careers. Furthermore, the topic of pain management is legally considered relevant for all licensees, regardless of their specialty.	2,152
Pennsylvania	Must hold current NCCPA certification.	4 Board-approved CEs consisting of 2 CEs in pain management or the identification of addiction and 2 CEs in the practices of prescribing or dispensing of opioids; subsequent renewals require 2 CEs on pain management, identification of addiction, or prescribing practices.	8,832
Rhode Island	20 CEs every 2 years	8 CEs on topics such as: appropriate prescribing for pain, pharmacology, dependence, potential, and alternatives to opioids for pain management. Those who have taken DATA 2000 training to prescribe buprenorphine will be exempt from the 8 CEs. Training must be completed at least once per career and must occur before the next renewal of your controlled substance registration in June of 2018.	588
South Carolina	No requirement, except as noted for those prescribing controlled substances	4 CEs every 2 years related to approved procedures of prescribing and monitoring controlled substances in Schedules II, III, and IV.	1,430 [9]
Tennessee	100 CEs every 2 years	2 CEs related to controlled substance prescribing, which must include instruction in the Department's treatment guidelines (i.e., Tennessee Chronic Pain Guidelines) on opioids, benzodiazepines, barbiturates, and carisoprodol and may include topics such as medicine addiction, risk management tools, and other topics approved by the PA Committee.	2,010 [9]
Texas	40 CEs every 2 years	Per Board rule 195.4(e), the medical director of a pain management clinic must, on an annual basis, ensure that all personnel (including the medical director) are properly licensed,	7,930 [5,9]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
		and if applicable, trained to include 10 CEs related to pain management. This CE requirement applies to all personnel providing medical services to the patients (including, but not limited to: PAs, x-ray techs, phlebotomists, RNs, MAs, etc.).	
Utah	40 CEs every 2 years; NCCPA certification waives requirement	3.5 CEs every 2 years on controlled substance prescribing. The 3.5 CEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, published 09 July 2012, or as it may be revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	1,090 [9]
Vermont	100 CEs every 2 years, 50 of which must be Category 1; NCCPA certification waives this requirement	2 CEs on controlled substances prescribing. The activity must be accredited as AMA PRA Category 1 CEs or American Academy of Physician Assistants Category 1 training. Required topics include: abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant State and federal laws and regulations concerning the prescription of opioid controlled substance. Each licensee who is registered with the D.E.A. and who holds a D.E.A. number to prescribe controlled substances, or who has submitted a pending application for one, is presumed to prescribe controlled substances and must meet this requirement.	425
Virginia	Must maintain NCCPA certification	2 AMA/PRA Category 1 CEs related to pain management, proper prescribing of controlled substances, and the diagnosis and management of addiction every 2 years. There is no exemption from this CE requirement for doctors of medicine, osteopathy, podiatry, physician assistants, and nurse practitioners who hold active licenses.	3,958
Washington	100 CEs every 2 years. A minimum of 40 CEs must be Category 1. NCCPA certification waives this requirement	If the practitioner prescribes opioids in Washington, they must complete a CE. The course is one-time for at least one hour. It must be completed by the end of your first full CE reporting period after 01 January 2019. WSMA's one-hour webinar, “Preparing for New State Opioid Prescribing Rules”, fulfills the new state requirement for CE on opioid prescribing. This activity has been approved for AMA PRA Category 1 Credit. Also, allopathic physician and PA prescribers should note that simply reading the new rules will meet the new state requirement for opioid continuing medical education.	2,470 [2,9]
West Virginia	100 CEs every 2 years; at least 50 must be Category 1	A physician assistant who has prescribed, administered, or dispensed any controlled substance pursuant to a West Virginia license during the reporting period shall complete a Board-approved CE activity for a minimum of 3 hours of drug diversion training and best practice prescribing of controlled substances training.	770 [1,9]

Appendix D: State Pain and Opioid CE Requirements-Podiatrists

State Pain and Opioid Requirements-Podiatrists

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Alabama	12 CEs annually	All Alabama Controlled Substance Certificate holders must obtain 2 AMA PRA Category 1 or equivalent CEs every 2 years beginning in 2018. Acceptable CEs confer Credit in the areas of: controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management. No pre-approval of the courses is required.	155
Alaska	50 AMA PRA Category 1 CEs every 2 years. Podiatrist credits may instead be earned in a CE program from a provider that is approved by the Council on Podiatric Medical Education (CPME).	For license renewals for those with a DEA registration, at least 2 of the total CEs required to qualify for renewal must be specific to pain management and opioid use and addiction. AMA PRA Category 1 education qualifies.	29
Arizona	25 CEs annually	A.R.S. § 32-3248.02 requires all healthcare professionals who hold Drug Enforcement Administration certifications to complete a minimum 3 CEs in an opioid-related, substance-use disorder related, or addiction related course each renewal cycle as part of the annual continuing education requirement for licensure.	429
Florida	40 CEs every 2 years	2 CEs on prescribing controlled substances if holding DEA registration	1,787
Iowa	40 CEs every 2 years	A licensee who has prescribed opioids to a patient during a renewal cycle shall have obtained a minimum of 1 CE regarding the United States Centers for Disease Control and Prevention guideline for prescribing opioids for chronic pain, including recommendations on limitations on dosages and the length of prescriptions, risk factors for abuse, and nonopioid and nonpharmacologic therapy options.	243 [3]
Kentucky	20 CEs annually	Beginning on 01 July 2012, and annually thereafter, each podiatrist licensed by the board shall complete at least 1.5 CEs related to the use of the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER), pain management, or addiction disorders.	204
Louisiana	20 CEs annually	3 CEs on opioid management required one time in career, starting in 2018, if prescribing, administering, or dispensing a controlled substance; otherwise exempt	190
Maine	25 CEs every 2 years	3 Category 1 CEs every 2 years on the prescribing of opioid medication as a condition of prescribing opioid medication.	83
Maryland	50 CEs every 2 years	1 CE per renewal cycle on prescribing pain medications (starting 2018-2019).	460
Massachusetts	15 CEs annually	At least 1 CE in the previous one year shall be in pain management training, pursuant to St. 2010, c. 283. Pain management training shall include, but not be limited to: training how to identify patients at high risk for substance abuse, training how to counsel patients on the side effects,	544

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
		addictive nature, and proper storage and disposal of prescription medicines.	
Michigan	150 CEs every 3 years	5 CEs in pain and symptom management in each renewal period pursuant to section 16204(2), MCL 333.16204(2), of the code. Courses in pain and symptom management may include, but are not limited to, courses in: behavior management, pharmacology, behavior modification, stress management, clinical applications, and drug interventions as they relate to professional practice.	806
Minnesota	40 CEs every 2 years	Effective 01 January 2020: Licensees with the authority to prescribe controlled substances must obtain at least 2 CEs on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the continuing education requirements for licensure renewal.	250
Mississippi	40 CEs every 2 years	If the podiatrist has a current DEA certificate, 5 CEs must be in the prescribing of controlled substances.	96
Nebraska	48 CEs every 2 years	Effective 01 October 2018, 3 CEs every 2 years regarding prescribing opiates. This may include education regarding prescribing and administering opiates, risks and indicators regarding development of addiction to opiates, and emergency opiate situations. 1/2 hour of the 3 shall cover the PDMP.	109 [1]
Nevada	50 CEs every 2 years	Each holder of a license to practice podiatry who is registered to dispense controlled substances pursuant to NRS 453.231 shall complete at least 2 CEs relating specifically to the misuse and abuse of controlled substances, the prescribing of opioids or addiction during each period of licensure.	148 [4]
New Jersey	100 CEs every 2 years	Effective with 2019 and subsequent renewals, for all prescribers, 1 CE concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.	1,220
New Mexico	16 CEs annually	2 CEs in appropriate courses: an understanding of the pharmacology and risks on controlled substances; a basic awareness of the problems of abuse, addiction and diversion; awareness of state and federal regulations for the prescription of controlled substances; and management of the treatment of pain. Courses may also include a review of this rule (16.21.9 NMAC).	369
New York	50 CEs every 3 years	All podiatrists (and any other person licensed under Title 8) who have a DEA registration number and all residents prescribing with a facility DEA registration number will be required to take 3 CEs approved by the DOH in pain management, palliative care and addiction.	2,448
North Carolina	25 CEs annually	At least 1 CE consists of a course designed specifically to address prescribing practices. The course shall include, but not be limited to, instruction on controlled substance prescribing practices and controlled substance prescribing for chronic pain management.	415

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Oregon	60 CEs every 2 years	By 2009 or within the first year of licensure, licensees must complete CEs on pain management. The requirements and exemptions are detailed in OAR 847-008-0075. 1 CE provided by the Oregon Pain Management Commission is required plus at least 6 CEs in the subjects of pain management or the treatment of terminally ill and dying patients.	173
Pennsylvania	50 CEs every 2 years	2 CEs in pain management, the identification of addiction, or the practices of prescribing or dispensing of opioids.	1,602
South Carolina	24 CEs every 2 years	If a podiatrist is authorized pursuant to state and federal law to prescribe controlled substances, 2 of the requisite biennial CEs must be related to approved procedures of prescribing and monitoring controlled substances listed in Schedules II, III, and IV of the schedules provided for in Sections 44-53-210, 44-53-230, and 44-53-250.	200
Tennessee	15 CEs annually	1 of the 15 required CEs shall, every other calendar year, be a course designed specifically to address prescribing practices	230
Texas	50 CEs every 2 years	Per Board rule 195.4(e), the medical director of a pain management clinic must, on an annual basis, ensure that all personnel (including the medical director) are properly licensed, and if applicable, trained, to include 10 hours of continuing medical education related to pain management. This requirement applies to all personnel providing medical services to the patients (including, but not limited to: PAs, x-ray techs, phlebotomists, RNs, MAs, etc.).	1,152 [5]
Utah	40 CEs every 2 years	3.5 CEs every 2 years on controlled substance prescribing. The 3.5 CEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published 09 July 2012, or as it may be subsequently revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	244
Vermont	30 CEs every 2 years	All podiatry licensees who prescribe controlled substances shall certify at the time of each renewal that they have completed at least 2 CE activities on controlled substances prescribing. The CE must be accredited as AMA PRA Category 1 Credit training or Council on Podiatric Medical Education approved training. The following topics must be covered, as required by Vermont law: abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; the appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and relevant State and federal laws and regulations concerning the prescription of opioid controlled substances. Each licensee who is registered with the U.S. Drug Enforcement Agency (D.E.A.) and who	35

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
		holds a D.E.A. number to prescribe controlled substances, or who has submitted a pending application for one, is presumed to prescribe controlled substances and must meet this requirement. Any podiatrist who is required to certify completion of this CE to renew, but who cannot, will be subject to the provisions regarding makeup of missing CE in 22.3 and 22.4.	
Virginia	60 CEs every 2 years	Every 2 years, licensees with prescriptive authority must complete 2 CEs in pain management, proper prescribing of controlled substances, and the diagnosis and management of addiction.	543
West Virginia	50 CEs every 2 years	Unless a podiatrist has completed and timely provided to the Board a Board-developed certification waiver form attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every podiatrist as a prerequisite to license renewal shall complete a minimum of 3 CEs of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period. The 3 CEs shall be part of the 50 total hours of continuing education required and not 3 additional hours.	115 [1]
Wisconsin	50 CEs every 2 years	2 of the 50 podiatric CEs required under sub.(1) shall be an educational course or program related to opioid prescribing; only required if podiatrist holds DEA registration	384

Appendix E: State Pain and Opioid CE Requirements-Naturopaths

State Pain and Opioid CE Requirements-Naturopaths

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Arizona	30 CEs annually	3 CEs in opioid-related substance use disorder or addiction	1,020
California	60 CEs every 2 years	There is a one-time requirement of 12 CEs in pain management and care of the terminally ill (except for Pathologists and Radiologists) that must be completed by the physician's second license renewal date or within four years, whichever comes first. The 12 CEs may be divided in any way that is relevant to the physician's specialty and practice setting. The Medical Board will accept any combination of the two topics totaling 12 CEs. For physicians and surgeons licensed on or after 01 January 2019, the course must include the subject of risks of addiction associated with the use of Schedule II drugs. As an alternative to the above 12-CE requirement, a physician or surgeon may complete a 1-time CE of 12 hours in the subjects of treatment and management of opiate-dependent patients, including 8 hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders.	915
Oregon	32 CEs annually	7 CEs on pain management, within the first 2 years of licensure	1,090
Vermont	30 CEs every 2 years	2 CEs for each full licensing period beginning on or after 08 June 2016 on the topics of: the abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; the appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant State and federal laws and regulations concerning the prescription of opioid controlled substance.	337

Appendix F: State Pain and Opioid CE Requirements-Nurses

State Pain and Opioid CE Requirements-Nurses

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Alabama	24 CEs every 2 years	As a part of the 24 Board-approved or -recognized CEs for license renewal [610-X-4-.08], Certified Registered Nurse Practitioners (CRNP) and Certified Nurse Midwives (CNM) with prescriptive authority shall earn 6 CEs of pharmacology content specific to prescriptive practice in the approved area for collaborative practice. Certified Registered Nurse Anesthetists (CRNA) shall earn 6 CEs of pharmacology.	3,680 [4,9]
Alaska	30 CEs every 2 years	For APRNs with general prescriptive authority, 15 CEs in advanced pharmacotherapeutics are required each licensing period. For those with Controlled Substances Prescriptive Authority (those holding a DEA registration), 2 additional CEs (beyond the 15) are required in pain management and opioid use each licensing period.	440 [6,9]
Arizona	0 CEs every 4 years	A.R.S. § 32-3248.02 requires all healthcare professionals who hold Drug Enforcement Administration certifications to complete a minimum 3 of CEs in an opioid-related, substance-use disorder related, or addiction related courses each renewal cycle as part of the annual continuing education requirement for licensure.	3,510 [6.9]
Arkansas	15 CEs (or National Certification) every 2 years	Initial Applicants: APRNs issued a certificate of prescriptive authority after 31 December 2015 shall obtain a minimum of 3 CEs of prescribing education, which include information on maintaining professional boundaries and the prescribing rules, regulations and laws that apply to APRNs in the state of Arkansas within 2 years of issuance of the prescriptive authority certificate. Renewals: APRNs with prescriptive authority shall complete 5 pharmacotherapeutics CEs in the APRN's area of certification each biennium prior to license renewal. Effective 01 January 2017, 2 of the 5 hours must contain information related to maintaining professional boundaries and the prescribing rules, regulations and laws that apply to APRNs in the State of Arkansas.	1,900 [4,9]
California	30 CEs every 2 years	Nurse Practitioners (NPs) with Schedule II furnishing privileges must complete a 3-hour online Schedule II course through the CA Association for Nurse Practitioners. Certified Nurse Midwives (CNMs) with Schedule II furnishing privileges must complete a 2-hour online Schedule II course through the CA Association for Nurse-Midwives.	13,420 [4,9] NP 700 [4,9] CNM
Connecticut	50 CEs every 2 years	CEs shall: be in an area of the APRN's practice; reflect the professional needs of the licensee in order to meet the health care needs of the public; include at least 5 contact hours of training or education in pharmacotherapeutics; and include at least 1 contact hour of training or education in substance abuse, including, but not limited to, prescribing controlled substances and pain management.	5,382
Delaware	National Certification plus 10 pharmacology CEs for APRN every 2 years	3 hours related to substance abuse for all nurses (not just those with prescriptive authority). APRNs with authority to prescribe controlled substances must complete the 1-hour Mandatory training on Delaware law, regulation and programs on prescribing and distribution of controlled substances, and 10 CEs in pharmacology/pharmacotherapeutics in the past 2 years.	760 [9] APRN 11,840 [9] RN

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
District of Columbia	24 CEs every 2 years	APRNs must complete 15 CEs related to pharmacology (of the 24 required hours)	840 [9]
Florida	24 CEs (or National Certification) every 2 years	3 CEs of Safe and Effective Prescription of Controlled Substances for APRNs each licensing period. (Must be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, the American Nurses Credentialing Center, the American Association of Nurse Anesthetists, or the American Association of Nurse Practitioners and may be offered in a distance-learning format.)	31,183
Hawaii	30 CEs every 2 years	For APRN with prescriptive authority, 8 contact hours in pharmacology related to clinical practice specialty area and approved by a Board-recognized certifying body each licensing period.	410 [4,9]
Idaho	30 CEs every 2 years	For APRN with prescriptive authority, 10 contact hours in pharmacology for license renewal. All new initial applicants must provide documentation of 30 hours of pharmacotherapeutic coursework (either formal academic education or CE).	750 [9]
Illinois	20 CEs for RN and LPN; 80 CEs for APN every 2 years	APRNs shall obtain, each 2-year licensing period, no less than 20 CEUs of pharmacotherapeutics, including 10 hours of opioid prescribing or substance abuse education.	5,540 [9]
Indiana	0 hours for RNs; 30 hours for APRNs every year	APRNs with prescriptive authority must include 8 hours in pharmacology. Effective 01 July 2019, a practitioner who is licensed by a board and applies for controlled substance registration or re-registration must have completed 2 hours of CEUs during the previous 2 years addressing the topic of opioid prescribing and opioid abuse.	7,560
Iowa	36 CEs for RN or LPN; National Certification for APRN every 3 years	For ARPN who prescribed opioids to a patient during the renewal cycle: a minimum of 2 CEs regarding the CDC guideline for prescribing opioids for chronic pain (at each renewal).	4,869 [3]
Kentucky	14 CEs or National Certification every 1 year	5 contact hours of approved pharmacology CEs must be earned by all APRNs each licensure period. CE certificates should reflect specific pharmacology contact hours awarded. For APRNs with prescriptive authority for controlled substance, of the 5 approved pharmacology contact hours required for renewal, 1.5 of approved contact hours must be on the use of KASPER, pain management, or addiction disorders each licensure period. These hours may count as part of the required 5 pharmacology hours.	3,572 [6]
Louisiana	For RN, 5-15 CEs (depending on hours spent practicing); for APRNs whose role and population focus does not provide for certification/recertification, 30 contact hours related to advanced practice nursing every 1 year	Each year an APRN with prescriptive authority shall obtain 6 contact hours of CEs in pharmacotherapeutics in their advanced nursing role and population foci.	3,322 [4]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Maine	0 CEs for RN and LPN; 75 CEs for APRN every 2 years	15 contact hours of CEs in pharmacology every two years	1,240 [9]
Maryland	0 CEs for RNs; National Certification for APRN every 2 years	1-time requirement for 2 hours if holding a CDS registration, starting 01 October 2018. Must relate to prescribing or dispensing of controlled substances. Must be recognized by the provider's professional board or accredited by ACCME.	3,710 [4,9]
Massachusetts	15 CEs for RN and LPN; National Certification for APRN every 2 years	To apply for prescriptive authority from MA Controlled Substance Registration (MCSR) and to renew APRN authorization every 2 years, all prescribers must complete education relative to: effective pain management; risks of abuse and addiction associated with opioid medication; identification of patients at risk for substance use disorders; counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications; appropriate prescription quantities for prescription medications that have an increased risk of abuse; and, opioid antagonists, overdose prevention treatments and instances in which a patient may be advised on both the use of and ways to access opioid antagonists and overdose prevention treatments. M.G.L. c. 94C s.18 (e) does not specify a minimum number of contact hours to comply with this education requirement.	6,200 [1,9]
Michigan	25 CEs for RNs; National Certification for APRN every 2 years	Each licensing period, every nurse (both with and without prescriptive authority) must complete at least two 2 CE in pain and symptom management, in courses or programs approved by the Board. These count toward the 25 CE requirement.	22,596 APRN 155,436 RN
Minnesota	24 CEs for RN; 12 CEs for LPN; National Certification for APRN every 2 years	Effective 01 January 2020: Licensees with the authority to prescribe controlled substances obtain at least 2 CEs on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the CE requirements for licensure renewal.	7,780
Mississippi	0 CEs for RN; 40 CEs for APRN every 2 years	For APRNs, 2 of the 40 CEs must be related to the prescribing of controlled substances.	6,703
Montana	24 CEs every 2 years	For APRNs with prescriptive authority, 12 (of the 24) CEs must be in the area of pharmacotherapeutics.	640 [4,9]
Nebraska	20 CEs for RN and LPN; 40 CEs for APRN-NP /every 2 years	10 CEs related to pharmacology for APRN-NP. Effective 01 October 2018, 3 CEs every 2 years regarding prescribing opiates. This may include education regarding prescribing and administering opiates, risks and indicators regarding development of addiction to opiates, and emergency opiate situations. 1/2 hour of the 3 shall cover the PDMP.	2,288 [6]
Nevada	30 CEs for RNs; 45 CEs for APRNs every 2 years	APRNs that have dispensing or prescribing privileges must complete 2 CEs related to the use and misuse of controlled substances also within each renewal period.	710 [4,9]
New Hampshire	30 CEs for RN and LPN; 30 additional CEs (60 total) related to specialty for APRN every 2 years	For all APRNs, 5 CEs must be related to pharmacology. For APRNs with an active DEA number for prescribing, 3 of the 5	1,140 [6,9]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
	(For APRN, current certification in specialty will meet requirements for 30 CEs for RN licensure)	CEs must address opioid prescribing, pain management, or substance abuse disorder.	
New Jersey	30 CEs for RN and LPN; National Certification for APN every 2 years	All professional nurses, practical nurses, and certified nurse midwives: 1 CE each licensing period related to prescription opioid drugs, including alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. Advanced Practice Nurses: 6 CEs in pharmacology related to controlled substances, including pharmacologic therapy, addiction prevention and management, and issues concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.	4,000
New Mexico	30 CEs for RN and LPN; 50 CEs for APRN every 2 years	15 CEs related to pharmacology for all APRNs each licensing period. For APRNs with DEA registration and prescriptive authority, 5 of 15 pharmacology hours must be related to management of non-cancer or chronic pain.	980 [6,9]
New York	0 CEs for RN; National Certification for APRN every 2 years	All NY practitioners with a DEA registration number to prescribe controlled substances are required to complete at least 3 CEs of course work or training in pain management, palliative care, and addiction by 01 July 2017, and once every 3 years thereafter.	13,710 [9]
North Carolina	15-30 CEs for RNs (depending on other activities) every 2 years. 50 CEs for APRNs (depending on other activities) every 2 years.	For those Nurse Practitioners who prescribe controlled substances, at least 1 CE (of the 50) shall address controlled substance prescribing practices, signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management.	4,760 [1,9]
North Dakota	12 CEs every 2 years, plus National Certification for APRN	15 CEs related to pharmacology for APRN with prescriptive authority (fulfills the 12 CE renewal requirement)	1,183
Ohio	24 CEs for RNs; 48 CEs (36 for those with National Certification) for APRNs	For an APRN-CNP, APRN-CNS, or APRN-CNM, at least 12 of the total required CEs must include CE in advanced pharmacology.	16,760
Oklahoma	RNs must meet 1 of 5 options for license renewal. One option is 24 CEs every 2 years. National Certification for APRNs.	15 contact hours or 1 academic credit hour related to pharmacology for CNP, CNM, CNS with prescriptive authority each licensing period.	1,590 [4,9]
Oregon	National certification for APRN. If not certified, then 45 CEs every 2 years; for CNS who isn't certified, 40 CEs every 2 years.	1-time requirement of 7 CEs related to pain management for RN, LPN, and APRN (1 hour must be a course to be provided by the Oregon Pain Management Commission. The remaining six hours can be nurse's choice of pain management topics.). Of the 45 hours required for an APRN, 15 must be focused on pharmacotherapeutic content.	5,559 APRN 64,093 RN 5,728 LPN

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Pennsylvania	30 CEs for RN, CNS, and CRNP every 2 years	16 CEs related to pharmacology for CRNP with Prescriptive Authority each licensing period. CRNPs with prescriptive authority approval must complete a one-time requirement of 2 CE in pain management, the identification of addiction and 2 CE in the practices of prescribing or dispensing of opioids.	7,280 [4,9]
Rhode Island	10 CEs for RN and LPN; National Certification for APRN every 2 years	2 of the 10 CEs required must be about substance abuse.	13,320 [9]
South Carolina	0 CEs every 2 years for APRN, plus National Certification.	APRNs with prescriptive authority will need 45 contact hours of pharmacotherapeutics at initial licensure (15 of which must be in controlled substance pharmacology for NPs wishing to prescribe these drugs).	2,260 [4,9]
Tennessee	0 CEs every 2 years for APRN, plus National Certification.	2 CEs designed specifically to address controlled substance prescribing practices including the Tennessee Chronic Pain Guidelines.	7,010 [4,9]
Texas	20 CES every 2 years or National Certification.	Per Board rule 195.4(e), the medical director of a pain management clinic must, on an annual basis, ensure that all personnel (including the medical director) are properly licensed, and if applicable, trained to include 10 hours of continuing medical education (CE) related to pain management. This CE requirement applies to all personnel providing medical services to the patients (including, but not limited to: PAs, x-ray techs, phlebotomists, RNs, MAs, etc.). Furthermore, Advance Practice Nurses (APNs) are required to complete CE within their advanced specialty area and role recognized by the BON. APNs with limited prescriptive authority must also complete an additional five contact hours in pharmacotherapeutics. APRNs that have prescriptive authority and prescribe controlled substances must complete at least 3 additional contact hours of continuing education related to prescribing controlled substances.	12,020 [5,6,9]
Utah	30 CEs, or 200 practice hours and 15 CEs, or 400 practice hours every 2 years	3.5 CEs every 2 years on controlled substance prescribing. The 3.5 CEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published 09 July 2012, or as it may be subsequently revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	2,158 [7]
Vermont	0 CEs every 2 years; National Certification for APRN	2 CEs for each full licensing period beginning on or after 08 June 2016 on the topics of: abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant state and federal laws and regulations concerning the prescription of opioid controlled substance.	992

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Virginia	15 CEs and 640 practice hours (or 30 contact hours) every 2 years for RN and LPN; National certification for Nurse Practitioner licensed after 08 May 2002 (if licensed as an NP before 08 May 2002, certification or 40 contact hours related to specialty area is required)	2 CEs related to pain management, proper prescribing of controlled substances, and the diagnosis and management of addiction every 2 years. There is no exemption from this CE requirement for doctors of medicine, osteopathy, podiatry, physician assistants, and nurse practitioners who hold active licenses. APRNs with prescriptive authority must also have 8 CEs in pharmacology or pharmacotherapeutics for each biennium.	10,038 [4]
Washington	531 practice hours and 45 contact hours every 3 years for RN and LPN; National Certification, 30 contact hours, and 250 independent clinical practice hours for ARNP	15 additional contact hours in pharmacotherapeutics for all ARNPs with prescriptive authority each licensing period. Under new law (WAC 246-840-4655), in order to prescribe an opioid, an ARNP licensed to prescribe opioids shall complete a 1-time continuing education requirement regarding best practices in the prescribing of opioids that is at least 4 hours in length. The 1-time continuing education requirement by the end of the first full continuing education reporting period after 01 January 2019, or during the first full continuing education reporting period after initial licensure, whichever is later.	3,430 [9]
West Virginia	12 CEs per 1 year for RN; 24 CEs and 400 practice hours every 2 years for LPN; 24 CEs every 2 years for APRNs	3 CEs initially and then 1 contact hour, thereafter, annually of CE for best prescribing and drug diversion training if you prescribe, administer or dispense controlled substances. APRNs must obtain 12 hours in pharmacotherapeutics (out of the 24 total required).	1,080 [4,9]
Wisconsin	0 CEs every 2 years	Advanced Practice Nurse Prescribers: 16 contact hours per biennium in clinical pharmacology or therapeutics relevant to the area of practice, including at least 2 contact hours in responsible prescribing of controlled substances.	3,030 [9]
Wyoming	30 hours, or 15 hours and 200 hours of employment, or 400 hours of employment; In addition, for APRN, either National Certification, or 60 contact hours of CEs in practice area and 400 hours of employment.	APRNs with prescribing authority must obtain 15 CE in pharmacology and clinical management of drug therapy or pharmacotherapeutics per biennium.	568 [7]

Appendix G: State Pain and Opioid CE Requirements-Dentists

State Pain and Opioid CE Requirements-Dentists

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Alabama	20 CEs annually	Effective 02 March 2019: 2 CEs on prescribing controlled substances every 4 years	1,160 [9]
Alaska	32 CEs every 2 years	For those with a DEA registration, at least 2 of the total CEs required to qualify for renewal must be specific to pain management and opioid use and addiction. AMA PRA Category 1 education qualifies.	787
Arizona	72 CEs every 3 years	A.R.S. § 32-3248.02 requires all healthcare professionals who hold DEA registrations to complete a minimum of 3 CEs in an opioid-related, substance-use disorder related, or addiction related course each renewal cycle as part of the annual continuing education requirement for licensure.	2,520 [9]
Connecticut	25 CEs every 2 years	The 25 CEs shall include not less than 1 CE in any 3 of the 10 mandatory topics for continuing education activities prescribed by the Commissioner; infection control in a dental setting; and prescribing controlled substances and pain management. The 10 mandatory CE topics are: prescribing controlled substances and pain management, record keeping/risk management, infection control, access to care, HIPAA compliance, medical emergencies in the dental office (including current training in CPR), sexual assault and domestic abuse, cultural competence, mental health conditions common to veterans, and diagnostic technology.	3,460
Florida	30 CEs every 2 years	2 CEs every 2 years on the safe and effective prescribing of controlled substance medications	15,552
Georgia	40 CEs every 2 years	1 CE on the impact of opioid abuse and/or the proper prescription writing and use of opioids in dental practice	5,888
Iowa	30 CEs every 2 years	If prescribing opioids, must complete at least 1 CE in the area of opioids. The training shall include the following: guidelines for prescribing opioids, including recommendations on limitations of dosages and the length of prescriptions; risk factors for abuse; and nonopioid and nonpharmacologic therapy options.	2,170 [2]
Kentucky	30 CEs every 2 years	3 CEs related to the use of KASPER, pain management, or addiction disorders	3,869
Louisiana	30 CEs every 2 years	Starting in 2018, 3 CEs on opioid management required one time in career if prescribing, administering, or dispensing a controlled substance; otherwise exempt	2,750 [1]
Maine	40 CEs every 2 years	3 CEs mandatory for dentists who prescribe opioids	470 [2,9]
Maryland	30 CEs every 2 years	2 Board-approved CEs on proper prescribing and dispensing of prescription drugs every other renewal cycle starting 2018-2019.	2,720 [9]
Massachusetts	40 CEs every 2 years	3 CEs mandated each renewal cycle. Practitioners who prescribe controlled substances, are required, to obtain or renew their professional licenses, to complete appropriate training relative to: effective pain management; the risks of abuse and addiction associated with opioid medication; identification of patients at risk for substance use disorders; counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications; appropriate prescription quantities for prescription medications that have an increased risk of abuse; and opioid antagonists, overdose prevention treatments, and instances in which a	3,160 [9]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
		patient may be advised on both the use of and ways to access opioid antagonists and overdose prevention treatments.	
Michigan	60 CEs every 3 years	3 Board-approved CEs in pain and symptom management related to the practice of dentistry. CEs in pain and symptom management, as they relate to the practice of dentistry, may include, but are not limited to: behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interactions.	7,943
Minnesota	30 CEs every 2 years	Effective 01 January 2020: Licensees with the authority to prescribe controlled substances obtain at least 2 CEs on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the continuing education requirements for licensure renewal.	1,800 [9]
Mississippi	40 CEs every 2 years	3 CEs every 2 years regarding the prescription of opioids.	1,612
Nebraska	30 CEs every 2 years	Effective 01 October 2018, 3 CEs every 2 years regarding prescribing opiates. This may include education regarding prescribing and administering opiates, risks and indicators regarding development of addiction to opiates, and emergency opiate situations. 1/2 hour of the 3 CEs shall cover the PDMP.	1,584 [1]
Nevada	20 CEs annually	2 CEs relating specifically to the misuse and abuse of controlled substances, the prescribing of opioids or addiction during each licensure period	1,220 [9]
New Hampshire	40 CEs every 2 years	Dentists who have a DEA number associated with New Hampshire and who prescribe Schedule II-IV controlled substances, shall complete 3 Board-approved CEs or pass an online examination, in the area of pain management and addiction disorder or a combination, as a condition for initial licensure and license renewal.	906
New Jersey	40 CEs every 2 years	Effective in 2019 and for subsequent renewals, for all prescribers, 1 CE concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.	3,670 [9]
New Mexico	60 CEs every 3 years	3 CEs every 3 years. CEs must include: an understanding of the pharmacology and risks on controlled substances; a basic awareness of the problems of abuse, addiction and diversion; awareness of state and federal regulations for the prescription of controlled substances; and management of the treatment of pain	1,510
New York	60 CEs every 3 years	All prescribers licensed to treat humans who have a DEA registration to prescribe controlled substances, as well as medical residents who prescribe controlled substances under a facility DEA registration, must complete at least 3 CEs in pain management, palliative care, and addiction. The following 8 topic areas must be included: New York State and federal requirements for prescribing controlled substances; pain management; appropriate prescribing; managing acute pain; palliative medicine; prevention, screening, and signs of addiction; responses to abuse and addiction; end of life care. All 8 topics must be completed prior to attestation; the topics can be completed in a single presentation or in individual segments for a total of at least 3 hours. CEs may be live, online, or obtained from a publication or	18,224

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
		journal. There is no minimum amount of time that must be spent on each topic. The CEs do not have to be pre-approved (NY Dept. of Health does not pre-approve individual CEs). Courses must be accredited.	
North Carolina	15 CEs annually	All licensees who have a current DEA registration must complete 1 CE annually that shall include, but not be limited to, instruction on controlled substance prescribing practice and controlled substance prescribing for chronic pain management.	5,386
Oregon	40 CEs every 2 years	All dentists licensed by the Oregon Board of Dentistry will complete a one-time 1 CE pain management course specific to Oregon provided by the Oregon Pain Commission of the Oregon Health Authority.	3,821
Pennsylvania	30 CEs every 2 years	2 CEs in pain management, the identification of addiction or the practices of prescribing or dispensing of opioids, if holding current DEA registration or using someone else's DEA registration to prescribe controlled substances	9,514
Rhode Island	40 CEs every 2 years	8 CEs on topics such as appropriate prescribing for pain, pharmacology, potential for dependence, and alternatives to opioids for pain management. One-time requirement for dentists with a Schedule II DEA registration	635 [6]
Tennessee	40 CEs every 2 years	2 CEs in the area of prescribing of controlled substances education that includes instruction in the Tennessee Chronic Pain Guidelines.	3,992
Utah	30 CEs every 2 years	3.5 CEs every 2 years on controlled substance prescribing. The 3.5 CEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published 09 July 2012, or as it may be subsequently revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	1,660 [9]
Vermont	30 CEs every 2 years	Effective 08 June 2016: 2 CEs for each full licensing period on the topics of: abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; the appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant State and federal laws and regulations concerning prescription of opioid controlled substance.	585
Virginia	15 CEs annually	2 CEs on pain management	7,112
Washington	63 CEs every 3 years	3 CEs on opioid prescribing required one time	6,708
West Virginia	35 CEs every 2 years	3 CEs regarding drug diversion training and best practice prescribing of controlled substances training and training on prescribing and administration of an opioid antagonist every licensing period	470 [9]
Wisconsin	30 CEs every 2 years	2 CEs in the topic of responsible prescribing of controlled substances for the treatment of acute dental pain every licensing period	1,930 [9]

Appendix H: State Pain and Opioid CE Requirements-Optometrists

State Pain and Opioid CE Requirements-Optometrists

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Alaska	40 CEs every 2 years	2 CEs must be on pain management, opioid use, and addiction if licensee holds a DEA registration; must be AMA Category 1 or AOA Category 1 or 2; must include all three topics	7
Arizona	32 CEs every 2 years	3 CEs on opioid-related, substance use disorder-related, or addiction-related topics each cycle (for those authorized to prescribe C-II; optometrists can prescribe C-II hydrocodone products only)	1,200 [4]
Florida	30 CEs every 2 years	2 CEs on prescribing controlled substances if holding a DEA registration	466
Kentucky	15 CEs annually for therapeutic licenses; 8 CEs for non-therapeutic licenses	Those with a DEA registration must complete a 2-CE course annually in pain management/addiction disorders.	373
Michigan	40 CEs every 2 years	2 Board-approved CEs in pain and symptom management related to the practice of optometry. May include: ethics and health policy related to pain; pain definitions; basic sciences related to pain, including pharmacology, psychology, sociology, and anthropology; clinical sciences related to pain, including specific pain conditions and pain in special contexts and settings; clinician-patient communications related to pain; management of pain, including evaluation and treatment and non-pharmacological and pharmacological management; ensuring quality pain care; and Michigan programs and resources relevant to pain.	1,773
Minnesota	40 CEs every 2 years	Effective 01 January 2020: Licensees with the authority to prescribe controlled substances must obtain 2 CEs on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the continuing education requirements for licensure renewal. This requirement was mandated via statute, and board rules have not yet been promulgated.	900 [9]
Nevada	30 hours annually for TPA certified; 18 hours for DPA certified	2 CEs annually related to misuse and abuse of controlled substances, prescribing of opioids, or addiction	294
New Hampshire	50 CEs annually; 15 CEs annually for non-TPA certified	3 CEs annually, completed online	292
New Jersey	50 CEs every 2 years	Of the 50 CEs biennially required under this section, at least 1 CE shall be for educational programs or topics that concern the prescription of hydrocodone, or the prescription of opioid drugs in general, including responsible prescribing practices, the alternatives to the use of opioids for the management and treatment of pain, and the risks and signs of opioid abuse, addiction, and diversion.	1,160 [9]
New Mexico	22 CEs annually	1 hour annually in pain management or a related topic	302
North Carolina	25 CEs annually	2 hours in a Board-approved opioid course	1,404
Oklahoma	25 CEs annually	1 hour in judicious prescribing annually	630 [9]

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Prescribers
Pennsylvania	30 CEs every 2 years	Effective 01 July 2017, 2 CEs in pain management or identification of addiction and 2 CEs in practices in prescribing or dispensing of opioids each licensing period	2.660
Rhode Island	60 CEs every 3 years if TPA certified; 48 if not TPA certified	Any practitioner who prescribes a C-II opioid is required to successfully complete 8 CEs of Category 1 CE in any or all of the following topics: appropriate prescribing of opioids for pain; pharmacology; adverse events; potential for dependence; tolerance; addiction; and alternatives to opioids for pain management. Although no one specific course is required, the Drug Addiction Treatment Act of 2000 (DATA 2000) waiver training course qualifies for the above requirement. This specific training requirement is required only once and must be completed before renewal of controlled substance registration or two (2) years, whichever is longer.	Not available
Tennessee	30 hours every 2 years	2 hours every 2 years	1,310
Utah	30 CEs every 2 years	3.5 CEs every 2 years on controlled substance prescribing. The 3.5 CEs shall include: the scope of the controlled substance abuse problem in Utah and the nation; all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published 09 July 2012, or as it may be subsequently revised; the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; patient record documentation for controlled substance and opioid prescribing; and office policies, procedures, and implementation.	470 [9]
Vermont	40 CEs for TPA; 20 CEs for non-TPA	Effective 08 June 2016: 2 CEs for each full licensing period on the topics of: abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant state and federal laws and regulations concerning the prescription of opioid controlled substance.	117
West Virginia	43 CEs every 2 years	3 CEs in drug diversion training and best practice controlled substance prescribing within 1 year of initial licensing; 3 CEs on same topic every 2 years if prescribing, dispensing, or administering controlled substances; if not prescribing, administering, or dispensing controlled substances, either 3 CEs on drug diversion and best practice prescribing or the licensee must certify that he/she has not prescribed, administered, or dispensed controlled substances during entire 2-year renewal cycle.	180 [1,9]

Appendix I: State Pain and Opioid CE Requirements-Pharmacists

State Pain and Opioid CE Requirements-Pharmacists

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Pharmacists
Arizona	30 CEs every 2 years	3 CEs must be opioid related, substance-use related or addiction related	7,812
Delaware	30 CEs every 2 years	At least 2 CEs every 2 years must relate to medication safety/errors. At least two 2 CEs every 2 years must relate to the distribution, dispensing, or delivery of controlled substances; or, the detection and recognition of abuse or illegal use of controlled substances.	1,060 [9]
District of Columbia	40 CEs every 2 years	At least two 2 CEs every 2 years must relate to medication/dispensing errors.	1,070 [9]
Florida	30 CEs every 2 years	2 CEs (of the 30) must be board-approved controlled substance CE	34,157
Michigan	30 CEs every 2 years	1 CE in pain and symptom management each licensing period	15,500
Mississippi	15 CEs annually	5 CEs each year must be related to opioid abuse and prevention or some other drug of abuse or addiction-related issue.	2,280 [9]
New Jersey	30 CEs every 2 years	1 CE (of the 30) in topics concerning prescription opioid drugs, including alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion	9,280 [9]
New Mexico	30 CEs every 2 years	2 (of the 30) CEs in the safe use of opioids. These 2 CEs in the safe use of opioids may also be used for New Mexico's patient safety CE requirement if indicated by the ACPE number.	3,078
Oregon	30 CEs every 2 years	One-time requirement to complete 7 CEs on pain management within 24 months of first license renewal; 1 CE must be the module from the Oregon Pain Management Commission.	4,360 [9]
Pennsylvania	30 hours every 2 years	4 CEs of Board-approved education consisting of 2 CEs in pain management or the identification of addiction and 2 CEs in the practices of prescribing or dispensing of opioids	23,738
South Carolina	15 CEs annually	1 CE (of the 15) must be related to approved procedures for monitoring controlled substances listed in Schedules II, III, and IV	8,600
Texas	30 CEs every 2 years	1 CE (of the 30) must be related to opioid abuse	21,250 [9]
Vermont	30 CEs every 2 years	2 CEs for each full licensing period beginning on or after 08 June 2016 on the topics of: abuse and diversion, safe use, and appropriate storage and disposal of controlled substances; appropriate use of the Vermont Prescription Monitoring System; risk assessment for abuse or addiction; pharmacological and nonpharmacological alternatives to opioids for managing pain; medication tapering and cessation of the use of controlled substances; and, relevant state and federal laws and regulations concerning the prescription of opioid controlled substance.	808
Virginia	15 CEs annually	In 2017, all pharmacists were required to obtain at least 1 CE in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration. The minimum requirement was part of the 15 hours of CE that was required during 2017. This was a one-time requirement; further action of the Board would be required to mandate CE in a specific topic in future years.	15,424

State Boards	Total CE Hours (CEs) Required	Pain and Opioid CE Requirements	Number of Affected Pharmacists
West Virginia	30 CEs every 2 years	3 CEs of drug diversion training and best practice prescribing of controlled substances training unless verifying he/she has not administered or dispensed controlled substances during the entire previous reporting period. "Drug diversion training and best practice prescribing of controlled substances training" means a training course of at least 3 CPE hours which includes, at a minimum, all of the following: Drug diversion, including West Virginia statistics on prescription drug abuse and resulting deaths; Epidemiology of chronic pain and misuse of opioids; Indication for opioids in chronic pain treatment including, at a minimum, general characteristics, toxicities, and drug interactions; Patient evaluation and risk assessment and tools to assess risk and monitor benefits. Initiation and ongoing-management of chronic pain in patients treated with opioid based therapies, including, at a minimum: treatment objectives; medication therapy management and collaborative practice; prescription of controlled substance agreements; urine screens and pill counts; patient education on safe use, storage and disposal of opioids; discontinuation of opioids; and documentation and medical records; Case study of a patient with chronic pain; Identification of diversion and drug seeking tactics and behaviors; Best practice methods for working with patients, prescribers, law enforcement, and others as appropriate, concerning patients suspected of drug seeking behavior and diversion; Compliance with controlled substances laws and rules; and How to Register with and use the West Virginia Controlled Substances Monitoring Program.	2,180 [9]

Appendix J: Sufficiency of REMS Education, by State

Sufficiency of REMS Education, by State

State	MD/DO	Physician Assistant	Podiatrist	Naturopath	Nurse	Dentist	Optometrist	Pharmacist
Alabama	Meets	Partially Meets	Meets	No State CE Requirement	Does Not Meet	Meets	No State CE Requirement	No State CE Requirement
Alaska	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	No State CE Requirement
Arizona	Meets	Meets	Meets	Meets	Meets	Meets	Meets	Meets
Arkansas	Partially Meets	Meets	No State CE Requirement	No State CE Requirement	Does Not Meet	No State CE Requirement	No State CE Requirement	No State CE Requirement
California	Partially Meets	No State CE Requirement	No State CE Requirement	Partially Meets	Does Not Meet	No State CE Requirement	No State CE Requirement	No State CE Requirement
Colorado	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement
Connecticut	Meets	Meets	No State CE Requirement	No State CE Requirement	Meets	Partially Meets	No State CE Requirement	No State CE Requirement
Delaware	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Does Not Meet	No State CE Requirement	No State CE Requirement	Does Not Meet
District of Columbia	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	Does Not Meet
Florida	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	Does Not Meet
Georgia	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement
Hawaii	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement
Idaho	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement
Illinois	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement
Indiana	Meets	Meets	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement

State	MD/DO	Physician Assistant	Podiatrist	Naturopath	Nurse	Dentist	Optometrist	Pharmacist
Iowa	Meets	Does Not Meet	Does Not Meet	No State CE Requirement	Does Not Meet	Does Not Meet	No State CE Requirement	No State CE Requirement
Kansas	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement
Kentucky	Partially Meets	Partially Meets	Meets	No State CE Requirement	Partially Meets	Meets	Meets	No State CE Requirement
Louisiana	Does Not Meet	Partially Meets	Meets	No State CE Requirement	Meets	Meets	No State CE Requirement	No State CE Requirement
Maine	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	No State CE Requirement	No State CE Requirement
Maryland	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	No State CE Requirement	No State CE Requirement
Massachusetts	Partially Meets	Meets	Meets	No State CE Requirement	Meets	Meets	No State CE Requirement	No State CE Requirement
Michigan	Meets	No State CE Requirement	Meets	No State CE Requirement	Meets	Does Not Meet	Does Not Meet	Meets
Minnesota	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	No State CE Requirement
Mississippi	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	No State CE Requirement	Meets
Missouri	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement
Montana	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement
Nebraska	Partially Meets	Partially Meets	Partially Meets	No State CE Requirement	Partially Meets	Partially Meets	No State CE Requirement	No State CE Requirement
Nevada	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	No State CE Requirement
New Hampshire	Meets	Meets	No State CE Requirement	No State CE Requirement	Meets	Meets	Meets	No State CE Requirement

State	MD/DO	Physician Assistant	Podiatrist	Naturopath	Nurse	Dentist	Optometrist	Pharmacist
New Jersey	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	Meets
New Mexico	Partially Meets	Partially Meets	Meets	No State CE Requirement	Meets	Partially Meets	Meets	Meets
New York	Partially Meets	Partially Meets	Does Not Meet	No State CE Requirement	Meets	Partially Meets	No State CE Requirement	No State CE Requirement
North Carolina	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	No State CE Requirement
North Dakota	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement
Ohio	Meets	Meets	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement
Oklahoma	Meets	Meets	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	Meets	No State CE Requirement
Oregon	Partially Meets	Partially Meets	Partially Meets	Partially Meets	Partially Meets	Does Not Meet	No State CE Requirement	Partially Meets
Pennsylvania	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	Meets	Meets
Rhode Island	Meets	Meets	No State CE Requirement	No State CE Requirement	Meets	Meets	Meets	No State CE Requirement
South Carolina	Meets	Meets	Meets	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	Does Not Meet
South Dakota	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement
Tennessee	Does Not Meet	Partially Meets	Meets	No State CE Requirement	Partially Meets	Partially Meets	Meets	No State CE Requirement
Texas	Meets	Meets	Meets	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	Meets
Utah	Partially Meets	Partially Meets	Partially Meets	No State CE Requirement	Partially Meets	Partially Meets	Partially Meets	No State CE Requirement
Vermont	Partially Meets	Does Not Meet	Does Not Meet	Does Not Meet	Does Not Meet	Does Not Meet	Does Not Meet	Does Not Meet

State	MD/DO	Physician Assistant	Podiatrist	Naturopath	Nurse	Dentist	Optometrist	Pharmacist
Virginia	Meets	Meets	Meets	No State CE Requirement	Meets	Meets	No State CE Requirement	Meets
Washington	Does Not Meet	Meets	No State CE Requirement	No State CE Requirement	Meets	Meets	No State CE Requirement	No State CE Requirement
West Virginia	Meets	Partially Meets	Partially Meets	No State CE Requirement	Meets	Meets	Meets	Partially Meets
Wisconsin	Does Not Meet	No State CE Requirement	Meets	No State CE Requirement	Meets	Does Not Meet	No State CE Requirement	No State CE Requirement
Wyoming	No State CE Requirement	No State CE Requirement	No State CE Requirement	No State CE Requirement	Meets	No State CE Requirement	No State CE Requirement	No State CE Requirement

Appendix K: Continuing Education Programs

Continuing Education Programs

Course	Source	Hours
REMS-Compliant Programs Funded by REMS Program Companies (RPC)		
ASA Pain: Anesthesiologists Tailored Approach to Patient Safety Considerations When Using Opioid Analgesics - Georgia	American Society of Anesthesiologists	3
SCOPE of Pain: Safer/Competent Opioid Prescribing Education	Boston University School of Medicine	2
SCOPE of Pain: Safe and Competent Opioid Prescribing Education	Boston University School of Medicine	2
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & American Academy of Hospice and Palliative Medicine	2.5
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & American Association of Nurse Practitioners	3
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & American Academy of Physician Assistants	3
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & American Osteopathic Association	3
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & American Society of Addiction Medicine	2
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & California Academy of Family Physicians	3
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & Nurse Practitioner Healthcare Foundation	3
Pain Management and Opioids: Balancing Risks and Benefits	CO*RE & Interstate Postgraduate Medical Association	2.5
Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS): Education for Healthcare Providers	Global Education Group and Rockpointe	3
Get SMART - Module 1: Basics of Pain & Pain Management	Johns Hopkins University, School of Medicine; DKBmed, & Postgraduate Institute for Medicine	1
Get SMART - Module 2: Principles of Opioids	Johns Hopkins University, School of Medicine; DKBmed, & Postgraduate Institute for Medicine	1
Get SMART - Module 3: Initiating Treatment and Ongoing Management	Johns Hopkins University, School of Medicine; DKBmed, & Postgraduate Institute for Medicine	1
NEJM Knowledge+: Pain Management and Opioids	Massachusetts Medical Society	10
Get SMART - Safe Means of Administering the Right Therapy (Get SMART REALCME) Tier 1	Postgraduate Institute for Medicine	1
Get SMART - Safe Means of Administering the Right Therapy (Get SMART REALCME) Tier 2	Postgraduate Institute for Medicine	1
SAFE Opioid Prescribing	PRI-Med	3.5
Get SMART - Safe Means of Administering the Right Therapy Module 1	University of Kentucky College of Medicine, DKBmed & Postgraduate Institute for Medicine	1

Course	Source	Hours
Get SMART - Safe Means of Administering the Right Therapy Module 2	University of Kentucky College of Medicine, DKBmed & Postgraduate Institute for Medicine	1
Opioid Analgesic: Risk Evaluation and Mitigation Strategy (REMS) and the New FDA Blueprint	University of North Texas Health Science Center	
REMS Activity 2	University of North Texas Health Science Center	1
REMS 3	University of North Texas Health Science Center	1
Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)	USF Health, Potomac Center for Medical Education, and Rockpointe	2.25
Programs Funded by Other Entities		
Pathways in Pain Management: Chronic Low Back Pain	American Academy of Physician Assistants, California Academy of Family Physicians, Healthcare Performance Consulting, Interstate Postgraduate Medical Association & Nurse Practitioner Healthcare Foundation	0.75
Advancements in Cancer Management	Academy for Continued Health Learning	3.25
Adult Medicine 8th Edition: 08 Chronic Pain Management	American Academy of Family Physicians	1
Care of Chronic Conditions 3rd Edition	American Academy of Family Physicians	1
Navigating the Challenges in an Era of Opioid Deprescribing: Behavioral Strategies for Patient Engagement and Success	American Academy of Pain Medicine	1
Pain Management for Women with Rheumatoid and Other Arthritic Conditions	American Academy of Pain Medicine	1
Preparing for 2019: Update on Coding and CMS Policy Changes Webinar	American Academy of Pain Medicine	1
Managing Aberrant Drug Taking Behaviors and Opioid Use Disorder	American Association of Nurse Practitioners	1.25
Neuropathic Pain: Pathophysiology, Diagnosis, and Treatment of Common Conditions	American Association of Nurse Practitioners	1.25
Non-Opioid Pharmacology for Pain Management	American Association of Nurse Practitioners	1.25
NP/PA 16-Hour Buprenorphine Waiver Training Part II Only	American Association of Nurse Practitioners	16
NP/PA 24-Hour Buprenorphine Waiver Training	American Association of Nurse Practitioners	24
Opioid Prescribers: Avoiding Practice Breakdown and Disciplinary Action	American Association of Nurse Practitioners	1
Opioid Prescribers: Avoiding Practice Breakdown and Disciplinary Action	American Association of Nurse Practitioners	1.25
Prescription Drug Monitoring Program: Past, Present and Future	American Association of Nurse Practitioners	1.25
Research-Based Clinical Strategies to Prevent and Address Adolescent Substance Use and Prescription Medication Misuse: Being Part of the Solution, Part 1	American Association of Nurse Practitioners	0.5

Course	Source	Hours
Research-Based Clinical Strategies to Prevent and Address Adolescent Substance Use and Prescription Medication Misuse: Being Part of the Solution, Part 2	American Association of Nurse Practitioners	0.5
Safe Opioid Prescribing Series: How to Safely and Effectively Treat Pain in Primary Care	American Association of Nurse Practitioners	2.25
Take ACTION: Opioid Overdose Prevention Education Training for Nurse Practitioners	American Association of Nurse Practitioners	1
ABFM Pain Management Clinical Self-Assessment	American Board of Family Medicine	4
ABFM Pain Management Knowledge Self-Assessment	American Board of Family Medicine	8
SAFE Opioid Prescribing	American College of Physicians	3.5
Safe and Responsible Prescribing of Opioid Analgesics	American Dental Association	2
A Primer on the Opioid Morbidity and Mortality Crisis: What Every Prescriber Should Know	American Medical Association	0.75
Treating Common Pain Conditions: Practical Guidance for Pain Management	American Medical Association	1.75
Treating Older Adults: Practical Guidance for Pain Management	American Medical Association	1
Using Opioids Safely: Practical Guidance for Pain Management	American Medical Association	2.5
Addiction Medicine-Advanced Essentials	American Osteopathic Academy of Addiction Medicine	16.5
Medication Assisted Treatment in The Emergency Room Setting	American Psychiatric Association	1
Recovery Support for Young People with Opioid Use Disorders	American Psychiatric Association	1
Rethinking Withdrawal Management	American Psychiatric Association	1
Telepsychiatry's Role in Medication Assisted Treatment	American Psychiatric Association	1
The Clinical and Public Health Utility of Mutual Aid Organizations in Addressing Addiction: What Does the Science Tell Us?	American Psychiatric Association	1
Tracking Drug Use Patterns	American Psychiatric Association	1
Vaccines for Opioid Use Disorder: Focusing on the Fentanyl Epidemic	American Psychiatric Association	1
Drug Diversion and Best Practice Prescribing of Controlled Substances	Berkeley Medical Center, WVU Medicine and Hospice of the Panhandle	3
Pediatric Pain and Opioid Education	Boston Children's Hospital & Harvard Medical School	5.5
Safe Opioid Prescribing for Acute Dental Pain	Boston University Henry M. Goldman School of Dental Medicine	1
A Patient-Centered Approach to Opioid Tapering	Boston University School of Medicine	0.5
Emergency Response: Safer Opioid Prescribing in the Emergency Department	Boston University School of Medicine	1.5
Managing Pain and Opioid Use: An Educational Program on Compliance with NYS Prescribing Laws	Boston University School of Medicine	1
Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists	Boston University School of Medicine	1.25

Course	Source	Hours
Safe and Competent Opioid Prescribing for Providers Working with Veterans and Military Service Personnel	Boston University School of Medicine	1.75
Safe and Competent Opioid Prescribing: Optimizing Office Systems	Boston University School of Medicine	0.5
Safer Opioid Prescribing for Pain in Adolescents and Young Adults in Outpatient Settings	Boston University School of Medicine	1
Safer Post-Operative Prescribing of Opioids	Boston University School of Medicine	0.5
From Prescription Drug Abuse to Street Heroin...The Tale of West Virginia's Drug Abuse Epidemic	CAMC Health Education and Research Institute	3
Shifting Perspectives on Pain Management in Oral Surgery	CME Outfitters & American Optometric Association	0.5
The Role that Gender Plays in Pain Perception, Treatment, and Addiction	CME Outfitters & Interstate Postgraduate Medical Association	0.25
Laboratory Director Continuing Education Program: The Toxicology Laboratory's Role in Pain Management	COLA	2
A Multidisciplinary Approach to the Care of Pregnant and Parenting Women with Opioid Use Disorders	Dartmouth-Hitchcock	1
An Infectious Disease Perspective: Opioid Use Disorder and Commonly Co-Occurring Conditions in Pregnant Women	Dartmouth-Hitchcock	1
Changing Opioid Medication Paradigms for Effective Living (COMPEL)	Dartmouth-Hitchcock	1
Collaborative Care Approach to Treating Opioid Use Disorder in Primary Care	Dartmouth-Hitchcock	1
From Hospital to Community: Responding to the Epidemic of Opioid Overdose and Addiction	Dartmouth-Hitchcock	1
Improving Care for Opioid-Exposed Newborns using the Eat, Sleep, Console (ESC) Care Approach	Dartmouth-Hitchcock	1
Initiating Treatment for Alcohol and Opioid Use Disorder in the Emergency Department	Dartmouth-Hitchcock	1
Integrating Opioid Use Disorder Treatment in HIV Clinical Care	Dartmouth-Hitchcock	1
Medicine Grand Rounds - Cannabis and Opioids in Pain Management: Alternatives? Complements? Pipe dream?	Dartmouth-Hitchcock	1
Opioid Prescribing for Acute Pain after Surgery	Dartmouth-Hitchcock	1
Opioid Use for Headache Treatment	Dartmouth-Hitchcock	1
Opioid Use in Orthopaedics	Dartmouth-Hitchcock	1
Perioperative Pain Control for the Opioid Tolerant Patient	Dartmouth-Hitchcock	1
Prescription Opioids: Social Policy Gone Awry	Dartmouth-Hitchcock	1
Screening for Opioid Use Disorder in the Oncology Setting	Dartmouth-Hitchcock	1
Screening, Brief Intervention and Referral for Treatment for Substance Use Disorder in the Oncology Setting	Dartmouth-Hitchcock	1
The Opioid Crisis and Women's Health	Dartmouth-Hitchcock	1
The Opioid Epidemic in Northern New England: The Story and Response Outside	Dartmouth-Hitchcock	1
Emergency Medicine Practice: Pain in the Emergency Department: Management Beyond Opioids	EB Medicine	4
Drug Diversion Training and Best Practice Prescribing of Control Substances Workshop	Family Medicine Foundation of WV	3
Florida Mandatory Opioid Prescribing CME Speaker: David Koo, MD	Florida Academy of Family Physicians	2
GOLD Neonatal Conference 2019: Clinical Pain Management in the Neonate	Gold Learning	1
Opioid Use Disorder Education Program - Collaborative Care Approaches for Mgmt. of OUD	Harvard Medical School	8
Opioid Use Disorder Education Program - Identification, Counseling, and Treatment of OUD	Harvard Medical School	8

Course	Source	Hours
Opioid Use Disorder Education Program - Understanding Addiction	Harvard Medical School	8
Project ECHO: Tele-mentoring Program for Treatment of OUD	Indiana State Medical Association	1
2019 Legal Update: Understanding the Most Recent Indiana Laws for Prescribers and How to Comply	Indiana State Medical Association	1
Changing the Culture of Prescribing: Providing Safe & Compassionate Care to the Opioid Tolerant Patient	Indiana State Medical Association	1
Changing the Game: Sports Medicine and the Opioid Crisis	Indiana State Medical Association	1
Chronic Pain Management and Integrative Treatment Methods	Indiana State Medical Association	1
Difficult Conversations with Patients Seeking Opioids	Indiana State Medical Association	1
INSPECT Integration: Data for Critical Prescribing Decisions	Indiana State Medical Association	1
Legislative & Legal Update on Opioid Prescribing	Indiana State Medical Association	1
Medication Assisted Treatment for Opioid Use Disorders	Indiana State Medical Association	1
Opioid Epidemic: Medical Societies' Views/Clinical Realities	Indiana State Medical Association	1
Psychological Considerations in Assessment and Treatment of Patients with Chronic Pain	Indiana State Medical Association	1
Screening & Treating Adolescents with Substance Use Disorder	Indiana State Medical Association	1
Strategies for Safe and Compassionate Opioid Weaning: Developing a Path to Success	Indiana State Medical Association	1
The Least, Last and Lost: Caring for Pregnant Women & Newborns Affected by Opioid Use Disorder	Indiana State Medical Association	1
The Opioid Epidemic: Impact on Peri-Operative Care	Indiana State Medical Association	1
Treating Controlled Substance Use & Abuse in the ED	Indiana State Medical Association	1
Responsible Opioid Prescribing	Interstate Postgraduate Medical Association	2.5
Association of Pharmacological Treatments with Long-term Pain Control in Patients with Knee Osteoarthritis: A systematic Review and Meta-analysis	JAMA	1
Medical Marijuana for Treatment of Chronic Pain and Other Problems	JAMA	0.5
Opioid Prescribing: Rising to the Challenge	JAMA	0.5
Opioids for Chronic Noncancer Pain: A systematic Review and Meta-analysis	JAMA	1
Urine Drug Screens to Monitor Opioid Use for Managing Chronic Pain	JAMA	1
Opioid Use by Patients After Rhinoplasty	JAMA Facial Plastic Surgery	1
Postoperative Opioid Use Among Patients Undergoing Plastic and Reconstructive Surgery	JAMA Facial Plastic Surgery	1
Association of Medical and Adult-Use Marijuana Laws With Opioid Prescribing for Medicaid Enrollees	JAMA Internal Medicine	1
Association of Opioid Prescriptions from Dental Clinicians for US Adolescents and Young Adults With Subsequent Opioid Use and Abuse	JAMA Internal Medicine	1
Improving Adherence to Long-term Opioid Therapy Guidelines to Reduce Opioid Misuse in Primary Care: A Cluster-Randomized Clinical Trial	JAMA Internal Medicine	1
Association of Long-term Opioid Therapy With Functional Status, Adverse Outcomes, and Mortality Among Patients With Polyneuropathy	JAMA Neurology	1
Effect of Intranasal Ketamine vs. Fentanyl on Pain Reduction for Extremity Injuries in Children: The PRIME Randomized Clinical Trial	JAMA Pediatrics	1

Course	Source	Hours
Opioid Use Disorder After Self-medicating Pain From Traumatic Brain Injury	JAMA Psychiatry	1
Association Between Long-term Opioid Use in Family Members and Persistent Opioid Use After Surgery Among Adolescents and Young Adults	JAMA Surgery	1
Defining Optimal Length of Opioid Pain Medication Prescription After Common Surgical Procedures	JAMA Surgery	1
Incidence and Predictors of Opioid Prescription at Discharge After Traumatic Injury	JAMA Surgery	1
Legal Advisor: Identifying Drug Dependence	Massachusetts Medical Society	1
New Opioid Prescribing Guidelines in Practice	Massachusetts Medical Society	1
Mayo Clinic Talks Podcast: Opioid Edition	Mayo Clinic School of Continuous Professional Development	3
Principles of Pain Management and Palliative Care: Essential Tools for the Clinician 2019	Mayo Clinic School of Continuous Professional Development	29
Opioid Prescribing: Safe Practice, Changing Lives	Medscape	2
Treating Pain and Addiction	Michigan Center for Clinical Systems Improvement	6
Prescribing Opioids, Providing Naloxone, and Preventing Drug Diversion: The West Virginia Requirement	NetCE	3
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Northern West Virginia Rural Health Education Center	3
Pathways in Pain Management: Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation	0.75
Pathways in Pain Management: Effectively Addressing Osteoarthritis	Nurse Practitioner Healthcare Foundation	0.75
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation & California Association for Nurse Practitioners	2
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation & Gerontological Advanced Practice Nurses Association	2.5
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & Gerontological Advanced Practice Nurses Association	1.5
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation & Horizon CME Advanced Practice Providers Oncology Summit	2
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation & Horizon CME Advanced Practice Providers Oncology Summit	2
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & Iowa Nurse Practitioner Society	1
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation & National	1.5

Course	Source	Hours
	Conference for Nurse Practitioners	
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & National Conference for Nurse Practitioners	1.5
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation & National Nurse Practitioner Symposium	2
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & National Nurse Practitioner Symposium	1.5
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & Nurse Practitioner Associates for Continuing Education	1
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & Nurse Practitioner Associates for Continuing Education	1
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & Nurse Practitioner Associates for Continuing Education	1
Pathways in Pain Management: Osteoarthritis and Chronic Low Back Pain	Nurse Practitioner Healthcare Foundation & Pain Care for Primary Care	1.5
Pain Management and Opioids: Balancing Risks and Benefits	Nurse Practitioner Healthcare Foundation and the Collaborative on REMS (CO*RE) Education	3
Children in Pain	Nurse.com	1
Chronic Pain: How Do We Treat It in an Era of Increasing Prescription Medication Misuse and Abuse?	Nurse.com	1
Complex Regional Pain Syndrome — Type I	Nurse.com	1
Controlled Substance Prescribing for Chronic Pain Management	Nurse.com	1
Controlled Substances Prescribing Practices	Nurse.com	1
Effective Pain Management is More Than Just a Number, Part 1	Nurse.com	0.5
Effective Pain Management is More Than Just a Number, Part 2	Nurse.com	0.5
Evidence-Based Approaches to Pain Control	Nurse.com	2.5
Getting Started in Hospice Care	Nurse.com	6.5
Heroin: The Illegal Opioid	Nurse.com	1.5
Identifying Pain in the Hospice Patient	Nurse.com	1
Interprofessional Guide to Pain Management	Nurse.com	8
Knocking Out Pain Safely with PCA	Nurse.com	1
Medication Reconciliation: Avoiding Dangerous Errors	Nurse.com	1
Meeting the Challenge of Pediatric Pain Management	Nurse.com	2.9
Pain Management and Ethics, Part 1: What's the Right Thing To Do?	Nurse.com	0.5
Pain Management and Ethics, Part 2: What's the Right Thing To Do?	Nurse.com	0.5
Pain Management Basics	Nurse.com	1
Recognizing Signs of the Misuse or Abuse of Controlled Substances	Nurse.com	1
Recognizing, Diagnosing and Managing Emergent Causes of Low Back Pain	Nurse.com	1
Reducing Pain During Minor Procedures for Pediatric Patients	Nurse.com	1
Responsible Opioid Prescribing, Chronic Pain, and Addiction	Nurse.com	1.5

Course	Source	Hours
Responsible Opioid Prescribing: Balancing Effective Chronic Pain Management in an Era of Prescription Medication Misuse and Abuse	Nurse.com	2.5
Opioid Prescribing Practices - PART 1: Managing Opioid Therapy in High-Risk Patients - PART 2: Opioid Epidemic	Oakstone Publishing & Practical Reviews	8.5
Pathways to Safer Opioid Use	Office of Disease Prevention and Health Promotion & American Public Health Association	1
Ohio Pain Management Toolkit	Ohio State Medical Association and the Medical Advantage Group	1
Gettysburg CME Conference: Pain Management and Best Practices	Pennsylvania Academy of Family Physicians	1
Addressing PA's Opioid Crisis: What the Health Care Team Needs to Know (CME)	Pennsylvania Medical Society	5.5
Evidence-Based Complimentary/Integrative Medicine Techniques for Pain Management	Postgraduate Institute for Medicine	1
Knee Pain in the Primary Care Setting: Evaluation, Treatment Options, and When to Refer	Postgraduate Institute for Medicine	1
Mitigating the Risk of Prescription Opioid Misuse in the Management of Acute and Chronic Painful Conditions: Part 1 - Introduction, History, and Shared Guidelines	Postgraduate Institute for Medicine	1
Mitigating the Risk of Prescription Opioid Misuse in the Management of Acute and Chronic Painful Conditions: Part 2 - Wisconsin-Specific Guidelines and Risk Management Tools	Postgraduate Institute for Medicine	1
Safe and Appropriate Opioid Prescribing: A Systems-Based Approach, Part I: Pathophysiology and Assessment of Pain	Postgraduate Institute for Medicine	1
Developing an Effective Treatment Plan: Opioid- and Nonopioid-based Treatment Options for Acute and Chronic Pain Management	Potomac Center for Medical Education	3.5
ON THE FRONT LINE OF A CRISIS: Improving the Care and Education of Patients with Opioid Use Disorder	Potomac Center for Medical Education	1
Tired, Inflamed, and in Pain: Best Practices, Future Therapies and Integrative Medicines	Primary Care Network Inc.	12
How to Perform Urine Drug Testing and Interpret Results Part 2 - Prescription Drug Monitoring in Chronic Opioid Therapy: Employing Urine Drug Testing to Optimize Patient Outcomes	PRI-Med	0.5
Office Rheumatology (Recorded at Pri-Med West)	PRI-Med	1
Optimizing Non-Opioid Pain Management in Primary Care (Recorded at Pri-Med West)	PRI-Med	0.75
Prescription Drug Monitoring in Chronic Opioid Therapy: Employing Urine Drug Testing to Optimize Patient Outcomes	PRI-Med	1
Weaning Off Chronic Opioids (Recorded at Pri-Med East)	PRI-Med	0.75
Opioid Use Disorder: Expanding Access to Treatment	ReachMD	0.25
Opioid Prescribing: Safe Practice, Changing Lives	Southeastern Area Health Education Center	3
Pain Management & Opioids: Balancing the Risks & Benefits	Southern WV Area Health Education Center	3
Tennessee Rx Safety Part 1: Addiction	St. Thomas Health CME	1
Tennessee Rx Safety Part 2: Federal and State Controlled Substance Laws and Guidelines	St. Thomas Health CME	1
An Evidence-Based Approach to the Diagnosis and Management of Migraines in Adults in the Primary Care and General Neurology Setting	Stanford University School of Medicine	1
How to Taper Patients Off of Chronic Opioid Therapy	Stanford University School of Medicine	1.25
Prescription Drug Misuse and Addiction: Compassionate Care for a Complex Problem	Stanford University School of Medicine	2

Course	Source	Hours
Addiction	Tennessee Medical Association	1
Appropriate Prescribing in Tennessee	Tennessee Medical Association	2
Assessment and Medications for Pain	Tennessee Medical Association	1
Examination of a Chronic Pain Patient	Tennessee Medical Association	1
Hot Topics in Addressing Pain	Tennessee Medical Association	1
Medical Decision Making and Weaning of the Pain Patient	Tennessee Medical Association	0.75
Tennessee Pain Laws	Tennessee Medical Association	1
Keynote Address – An Epidemic of Addiction: Responding to the Prescription Opioid and Heroin Crisis	UK Healthcare & CE Central	0.75
Laws and Regulations Applicable to Prescribing Controlled Substances – Kentucky Board of Dentistry	UK Healthcare & CE Central	0.75
Peer Assistance for the Dental Team Member with Opioid Dependency	UK Healthcare & CE Central	0.5
Stoners, Dragon Chasers, Tweakers and Drunks – Not in My Practice…Yeah Right!!!	UK Healthcare & CE Central	1
Buprenorphine for Opioid Use Disorder	University at Buffalo	2
Dispensing Naloxone Via a Non-Patient Specific Prescription Update: The Role of the Community Pharmacist	University at Buffalo	2
Naloxone Pharmacy Continuing Education Program	University at Buffalo	2
Opioid Prescriber Training Program Update Part 1	University at Buffalo	2
Opioid Prescriber Training Program Update Part 2	University at Buffalo	2
Pharmacist's Response to the Opioid Epidemic: Advanced, Opioid-Specific Counseling	University at Buffalo	1.5
Improving Outcomes in Chronic Pain	University of Arizona College of Medicine	1 - 14.5
Introduction to Safe Prescribing of Opioids for Pain Management	University of Arizona College of Medicine	1
Introduction to the Practice of Palliative Medicine	University of Arizona College of Medicine	1
Managing Opioid Misuse Disorder in Pregnancy and Neonatal Care	University of Arizona College of Medicine	1
Opioid Issues in Youth Pain Management for Orthopedic Injuries	University of Arizona College of Medicine	1
Safe and Effective Opioid Prescribing While Managing Acute and Chronic Pain	University of Arizona College of Medicine	3
Palliative Care: It's Not Just Hospice Anymore Specialization: Course 2: Pain Management	University of Colorado Department of Family Medicine	15
Chronic Opiate Analgesic Therapy (COAT) in a Primary Care Outpatient Clinic: Patient Perspective on Quality Improvement	University of Kentucky College of Medicine	0.75
Improving Treatment of Opioid Use Disorder Through Development of Novel Formulations of Buprenorphine	University of Kentucky College of Medicine & Kentucky Office of Drug Control Policy	0.5
Opioid Use Disorder in Pregnancy: Where We Are, What We Know, What We Are Doing at UK	University of Kentucky College of Medicine & Kentucky Office of Drug Control Policy	0.75
Reducing Stigma: The Past, Present and Future of Recovery	University of Kentucky College of Medicine &	0.75

Course	Source	Hours
	Kentucky Office of Drug Control Policy	
Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction	University of Kentucky College of Medicine & Kentucky Office of Drug Control Policy	1.25
Surviving Dreamland and Challenges of Opioids in Front Line Medicine	University of Kentucky College of Medicine & Kentucky Office of Drug Control Policy	0.5
Tips for Prescribing/Dispensing Controlled Substances Within the Law	University of Kentucky College of Medicine & Kentucky Office of Drug Control Policy	0.5
Treating Women with Opioid Use Disorders: A Focus on Pregnant and Parenting Women	University of Kentucky College of Medicine & Kentucky Office of Drug Control Policy	1
An Update on the Kentucky All Schedule Prescription Electronic Reporting System (KASPER)	University of Kentucky College of Medicine & University of Kentucky College of Nursing	1
Best Practice Nursing Care for Patients with Substance Abuse in Acute Care	University of Kentucky College of Nursing	1
Chronic Opiate Analgesic Therapy (COAT) in a Primary Care Outpatient Clinic: Patient Perspective on Quality Improvement	University of Kentucky College of Nursing	1
Laws and Regulations Applicable to APRN Prescribing of Controlled Substances	University of Kentucky College of Nursing	1
Opioid Use in Hospice and Palliative Care Settings	University of North Texas Health Science Center	1
Pain Assessment and Principles of Management	University of North Texas Health Science Center	1
Opioid Prescribing: Pain Management in a New Era	University of Virginia School of Medicine	2
Applying CDC's Guideline for Prescribing Opioids: Module 1: Addressing the Opioid Epidemic: Recommendations from CDC	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 2: Treating Chronic Pain Without Opioids	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 3: Communicating With Patients	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 4: Reducing the Risks of Opioids	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 5: Assessing and Addressing Opioid Use Disorder	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 6: Dosing and Titration of Opioids: How Much, How Long, and How and When to Stop?	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 7: Determining Whether to Initiate Opioids for Chronic Pain	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 8: Implementing CDC’s Opioid Prescribing Guideline into Clinical Practice	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 9: Opioid Use and Pregnancy	US Centers for Disease Control and Prevention	1
Applying CDC's Guideline for Prescribing Opioids: Module 10: Motivational Interviewing	US Centers for Disease Control and Prevention	1

Course	Source	Hours
Applying CDC's Guideline for Prescribing Opioids: Module 11: Fostering Collaborative Patient-Provider Relationships in Pain Management and Opioid Prescribing	US Centers for Disease Control and Prevention	1
Addressing the Opioid Epidemic: A Call to Action to Save Our Communities	USF Health & CME Outfitters	1
Fatal Attraction: Why Are Opioids So Addicting?	USF Health & CME Outfitters	0.25
How PAs are Improving Skill Sets to Approach Opioid Use	USF Health & CME Outfitters	0.25
Managing the Complexity of Chronic Pain in the Primary Care Setting	USF Health & CME Outfitters	0.5
Migraine Milestones: When Translational Research Transforms Patient Care	USF Health & CME Outfitters	1
New Perspectives and Approaches from Orthopedic Surgeons for the Management of Acute Pain	USF Health & CME Outfitters	0.5
Providing the Right Expectations: Understanding the Pathophysiology of Pain	USF Health & CME Outfitters	0.25
Putting Pressure on Opioid Prescribing: Novel Approaches to Pain Management	USF Health & CME Outfitters	1.5
Understanding the Big Picture of Pain and Pain Assessment	USF Health & CME Outfitters	0.25
Chronic Pain Guidelines and Controlled Substance Efforts	Vanderbilt University & Tennessee Department of Health	2.75
Safe Opiate Prescribing	Virginia Commonwealth University Health Continuing Medical Education	2
Appalachian Addiction and Prescription Drug Abuse Conference	West Virginia Medical Professionals Health Program & West Virginia State Medical Association	3
WV PainCare	West Virginia Society of Interventional Pain Physicians	3
Pain and Addiction, Best Practices and Proper Prescribing	West Virginia University Health Sciences Continuing Education	3
The Treatment of Pain and Addiction Utilizing Education and Proper Prescribing the new Paradigm Continued	West Virginia University Office of Continuing Education, West Virginia Medical Professionals Health Program, West Virginia State Medical Association and West Virginia Osteopathic Medical Association	3
Wisconsin Responsible Opioids Prescribing - Live Series	Wisconsin Academy of Family Physicians	2.25

Appendix 26 Legislative and Policy Changes Report

Governmental and Non-Governmental Policies Affecting Opioid Prescribing 2016-2018

July 2019

TABLE OF CONTENTS

LIST OF FIGURES 3
LIST OF ACRONYMS 4
1. INTRODUCTION 5
2. GOVERNMENTAL PRESCRIBING POLICIES 6
2.1 Overview of Governmental Opioid Prescribing Policies 2016-2018 6
2.1.1 Top 20 Issue Areas 7
2.1.2 Major Topics in Prescribing Policies, by Year 7
2.2 Opioid Dosing Threshold and Limit Policies 8
2.3 Extended-Release/Long-Acting Opioid Policies 38
2.4 Pain Specialists and Pain Management Clinics: Referrals, Consultations, and Required Practices 42
2.5 Policies Directly Relevant to FDA 48
2.5.1 Adopted, 2016-2018 48
2.5.2 Proposed, 2019 49
2.6 Policies Directly Referring to CDC Guidelines 49
3. OPIOID POLICIES FROM NON-GOVERNMENTAL SOURCES 55
3.1 Health Insurance Companies 56
3.2 Pharmacy Benefit Management Companies 56
3.3 Healthcare Systems 57
3.4 Chain Pharmacies 58
4. SUMMARY AND RECOMMENDATIONS 59
APPENDIX A: GOVERNMENT OPIOID PRESCRIBING POLICIES 60
APPENDIX B: SAMPLING OF PROPOSED AND PASSED OPIOID POLICIES, 2019 94
APPENDIX C: POLICIES FROM TOP TEN HEALTH INSURERS 106
APPENDIX D: POLICIES FROM TOP FIVE PHARMACY BENEFIT MANAGEMENT COMPANIES 112
APPENDIX E: POLICIES FROM TOP TEN HEALTHCARE SYSTEMS 117
APPENDIX F: POLICIES FROM TOP TEN CHAIN PHARMACIES 124

LIST OF FIGURES

Figure 1: Top 20 Issue Areas, 2016-2018 7

LIST OF ACRONYMS

Following is a list of acronyms used frequently in this document.

CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
DoD	Department of Defense
ER	Extended-Release
ER/LA	Extended-Release/Long-Acting
FDA	United States Food and Drug Administration
HHS	Department of Health and Human Services
LA	Long-Acting
NASEM	National Academies of Sciences, Engineering, and Medicine
OA	Opioid Analgesic
PDMP	Prescription Drug Monitoring Program
REMS	Risk Evaluation and Mitigation Strategy
VA	Department of Veterans Affairs

1. INTRODUCTION

In July 2012, the United States Food and Drug Administration (FDA) approved the initial Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of ER and LA opioid analgesics (OA) used in the outpatient setting outweigh the risks. In September 2018, FDA released their updated Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain.

According to the 2018 update, the *Opioid Analgesic REMS* is intended to support other national efforts underway to address the misuse and abuse of prescription opioid analgesics. To evaluate the effectiveness of the Extended Release/Long-Acting (ER/LA) REMS program, and to better understand the observed changes in opioid analgesic prescribing patterns, the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) Program was mandated by FDA to study opioid-related legislative and policy changes occurring in the last three years. Specifically, FDA's request was as follows:

> "To better understand observed changes in OA prescribing patterns, provide a summary of major legislative and policy changes occurring in the last 3 years at the state, large healthcare system or payer, and federal (CMS) levels related to OA prescribing (e.g., mandatory PDMP [prescription drug monitoring program] checks, initial days' supply or pill limits, maximum dose limits). "

This report responds to FDA's mandate by providing a comprehensive compilation and analysis of all governmental opioid prescribing policies that were adopted from 2016 to 2018—those state and national efforts which are supported by the *Opioid Analgesic REMS*.

Because the 2019 legislative and regulatory season is still underway, no comprehensive report was provided for policies that have been adopted or implemented from January to July 2019. However, numerous opioid policies have been proposed, implemented, and/or adopted during 2019, and a sampling of these policies is included in this report.

2. GOVERNMENTAL PRESCRIBING POLICIES

A review of governmental opioid prescribing policies implemented in 2016 through 2018 reveals that the bulk of the relevant legislation and regulation can be grouped into five categories. Because most new policies fit this scheme, the following review is organized according to those five categories, listed below:

- Opioid Dosing Thresholds and Limits
- Extended-Release/Long-Acting Opioid Policies
- Pain Specialists and Pain Management Clinics: Referrals, Consultations, and Required Practices
- Policies Directly Related to FDA
- Policies Directly Referring to Centers for Disease Control and Prevention (CDC) Guidelines.

Within each category, relevant policies are listed by jurisdiction, with brief descriptions of the key features of each policy.

2.1 Overview of Governmental Opioid Prescribing Policies 2016-2018

Five-hundred twenty-six (526) policies related to opioid prescribing were adopted from 2016-2018. Policies include initiatives from: the President of the United States and numerous Governors; federal statutes; state statutes and regulations; state guidelines from licensing agencies and departments of health; State Medicaid opioid policies; and federal guidelines and policies from the CDC, CMS, the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Department of Health and Human Services (HHS), the National Academies of Sciences, Engineering, and Medicine (NASEM), and the FDA. Professional association guidelines were not included unless a state had officially adopted the guideline, making it a state-adopted standard of care.

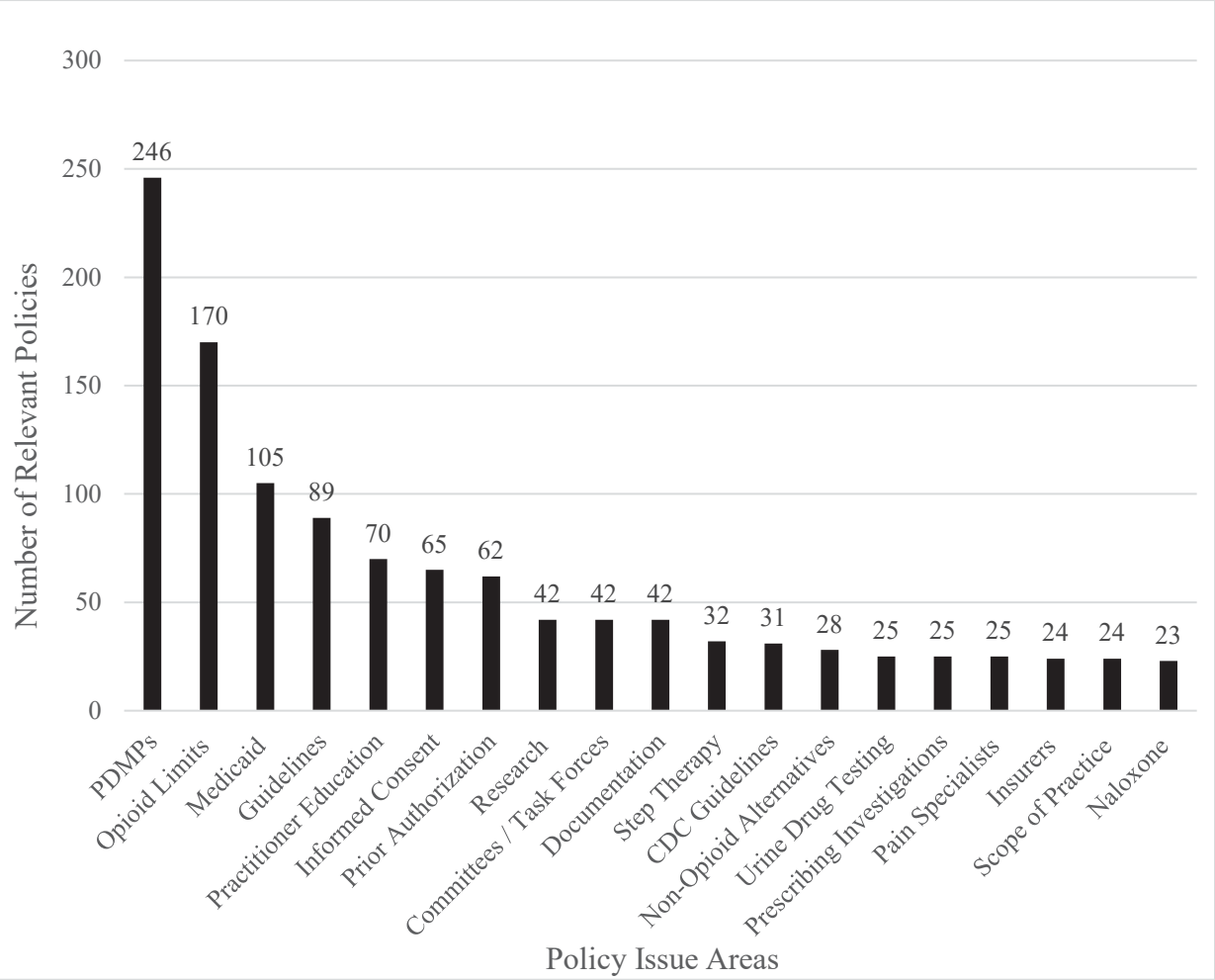
Of the 526 opioid policies that were adopted:

- 246 (47%) contain provisions related to PDMPs.
- 170 (32%) limit opioid prescriptions in some way, with 34 directly limiting opioids in cases of chronic pain, 52 limiting opioids in the acute setting, and 19 limiting initial prescriptions.
- 105 (20%) are Medicaid policies, illustrating that even when states do not directly limit opioids via statute or licensing board rule, they still substantially limit opioids through their Medicaid programs.
- 89 (17%) are either guidelines themselves or are statutes mandating the creation of, or use of, certain guidelines. These guidelines can be helpful in aiding a practitioner to understand the expected standard of care, but they can also be confusing: some claim to be a list of recommendations, others requirements; some explicitly state they *are not* setting a standard of care, others explicitly state that they *are* setting a standard of care; some reflect and carry out existing statutes, others seem to run contrary to existing statutes; some are clear and easy to follow, others make strong recommendations without clearly defining the parameters of those recommendations.
- 70 (13%) regard practitioner/prescriber education about pain, opioids, and/or controlled substances.
- 65 (12%) mandate improved informed consent procedures (a type of patient education) prior to prescribing opioids. Another eight policies relate to patient education that is not specific to informed consent.
- 62 (12%) public policies implemented prior authorization requirements for opioids, and 32 public policies implemented step therapy requirements for opioids, illustrating once again how states are limiting opioid use without directly implementing opioid limits. While some utilization review mechanisms technically apply to dispensing rather than prescribing, they can often affect prescribing patterns as prescribers attempt to avoid onerous approval processes that can delay their patients' treatment. Other utilization review mechanisms directly affect prescribing, as they allow prescribers to use only certain medications.

2.1.1 Top 20 Issue Areas

Figure 1 illustrates the number of policies implemented during 2016-2018, in each of the 20 most commonly occurring categories. PDMPs were subject to the largest number of new policies, followed by limitations on opioid dosing and duration of treatment. A substantial number of policies also addressed opioid therapy in Medicaid programs, prescribing guidelines, education of healthcare providers, informed consent for patients receiving opioid therapy, and prior authorization related to opioid prescribing and dispensing.

Figure 1: Top 20 Issue Areas, 2016-2018



2.1.2 Major Topics in Prescribing Policies, by Year

In 2016, there were 170 new and/or updated prescribing policies, including comprehensive Medicaid updates. The top issues, with number of policies for the year, follow.

- PDMP Utilization, 77
- Opioid Dosage and Duration Limits, 51
- Medicaid Opioid Prescribing Policies, 40
- Prescribing Guidelines, 31
- Practitioner Education, 21

- Prior Authorization, 20
- Pain Committees/Task Forces, 15
- Informed Consent, 14
- Step Therapy, 13
- Scope of Practice, 13
- Endorsing CDC Guidelines, 12

During 2017, the number of new and/or updated prescribing policies, (again including comprehensive Medicaid updates) increased to 200. The top four major topics remained consistent with the previous year.

- PDMP Utilization, 91
- Opioid Dosage and Duration Limits, 75
- Medicaid Opioid Prescribing Policies, 50
- Prescribing Guidelines, 36
- Prior Authorization, 35
- Informed Consent, 26
- Step Therapy, 19
- Pain/Opioid Research, 18
- Practitioner Education, 18
- Endorsing CDC Guidelines, 16

In 2018, there were 155 new and/or updated policies, including limited Medicaid updates. PDMP Utilization, Opioid Dosage and Duration Limits, and Prescribing Guidelines remained in three of the top four issues for the third year in a row.

- PDMP Utilization, 78
- Opioid Dosage and Duration Limits, 44
- Practitioner Education, 31
- Prescribing Guidelines, 27
- Informed Consent, 25
- Documentation in Medical Record, 20
- Nonopioid Alternatives, 16
- Pain/Opioid Research, 15
- Medicaid Opioid Prescribing Policies, 15
- Pain Committees/Task Forces, 13

Other Topics Include: Tapering, Criminal Law, Funding, Unsolicited Reports, Patient Education, Abuse Deterrent Opioids, Public Education, Voluntary Nonopioid Directives, Labeling, Emergency Medical Services, Prescription Forms, Opioid Taxation, Specific Medications (tramadol, carisoprodol, gabapentin, and methadone), Specific Disciplines (Nursing, Naturopathy, Podiatry, Optometry, and Dentistry), Government Agencies (DEA, FDA, and CMS), and Workers' Compensation

2.2 Opioid Dosing Threshold and Limit Policies

According to FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (2018), health care providers should be knowledgeable about: prescribing the appropriate dose based on the expected duration of pain (i.e., the lowest dose of medication necessary to treat pain and for the shortest time), how to determine an initial safe dose, and, special precautions with methadone.

During 2016-2018, 171 governmental policies were implemented in 46 states, the District of Columbia, and at the federal level related to opioid type, quantity, and duration limits for the treatment of both acute and chronic pain. Of those policies: 34 have opioid thresholds and limits specific to chronic pain; 52 apply to acute pain; 19 apply to initial prescriptions, whether for acute or chronic pain; and, 100+ implement general opioid limits, non-specific to chronic or acute pain.

Links follow for pertinent state and federal policies. A succinct summary of how each policy specifically limits the duration and dosage of opioid analgesics is included, though many policies affected additional areas related to opioid prescribing. Additional details for each policy implemented during 2016-2018 can be found in Appendix A. Although FDA specified an evaluation period containing only policies implemented during 2016-2018, a limited sampling of relevant legislation and regulation from the current year may be found in Appendix B.

United States	Kentucky	North Dakota
Alabama	Louisiana	Ohio
Alaska	Maine	Oklahoma
Arizona	Maryland	Oregon
Arkansas	Massachusetts	Pennsylvania
Colorado	Michigan	Rhode Island
Connecticut	Minnesota	South Carolina
Delaware	Missouri	Tennessee
District of Columbia	Montana	Texas
Florida	Nebraska	Utah
Georgia	Nevada	Vermont
Hawaii	New Hampshire	Virginia
Idaho	New Jersey	Washington
Illinois	New Mexico	West Virginia
Indiana	New York	Wisconsin
Iowa	North Carolina	Wyoming

United States

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, Centers for Disease Control and Prevention (2016)

> Chronic Pain: When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. 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 increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

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.

CMCS Informational Bulletin: Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction (2016)

General Limits: A state Medicaid agency or contracted managed care organization may impose quantity limits on medications as a way to promote safe and appropriate use of a medication, ensuring that they are not overprescribed. For example, quantity limits may be useful in verifying that a methadone prescription for pain is prescribed only for a specified duration, so the prescriber can reassess the recipient periodically. A significant percentage of states apply quantity limits to opioid products prescribed for pain.

VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain (2017)

Chronic Pain: If prescribing opioid therapy for patients with chronic pain, recommends a short duration. Consideration of opioid therapy beyond 90 days requires re-evaluation and discussion with patient of risks and benefits.

Acute Pain: Recommends against prescribing long-acting opioids for acute pain, as an as-needed medication, or on initiation of long-term opioid therapy. If take-home opioids are prescribed, recommends that immediate-release opioids are used at the lowest effective dose with opioid therapy reassessment no later than 3-5 days to determine if adjustments or continuing opioid therapy is indicated.

Alabama

Administrative Rule 270-X-2-.23 Risk and Abuse Mitigation Strategies by Prescribing Dentists, Board of Dental Examiners of Alabama (2018)

Acute Pain: Dentists are required to document the use of risk and mitigation strategies under the following circumstances:

- The continuation of controlled substance therapy greater than seven days for any patient.
- Prior to prescribing any controlled substance of more than 50 MME/day.
- For any patient that is prescribed three or more acute pain medicine prescriptions by the dentist in any 90-day period.
- For any patient who gives a history of chronic pain medicines and/or benzodiazepines, so that the dentist may coordinate therapy with the patient's other prescribing medical providers and verify the specifics of the chronic medications. Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, dentists should consider alternative forms of treatment.

Alaska

Recommending Adoption of Washington's Interagency Guidelines on Prescribing Opioids for Pain, Division of Corporations, Business, and Professional Licensing Joint Committee on Prescriptive Guidelines (2016)

Chronic Pain: Recommends adoption of the State of Washington's Interagency Guidelines on Prescribing Opioids for Pain, but with one major change: reducing WA's 120 MME/day dosage threshold to a 90 MME/day dosage threshold.

Opioids; Prescriptions; Database; Licenses, Chapter 2 SSSLA 17 (2017)

Implemented by: Controlled Substance Legislative Update, Alaska's Prescription Drug Monitoring Program (2017)

Initial Prescriptions: Disallows more than a seven-day supply of opioids for an initial prescription. States that it is the intent of the legislature that the seven-day supply limit for an initial opioid prescription (for physicians, dentists, and advanced practice registered nurses) and the four-day supply limit (for optometrists) for an initial opioid prescription under this Act may not be considered as a minimum length of time appropriate for an initial prescription.

Acute Pain: A prescriber may exceed the seven-day and four-day limits in cases of severe acute pain if necessary in the professional judgement of the prescriber.

Chronic Pain: A prescriber may exceed the seven-day and four-day limits in cases of chronic pain if necessary in the professional judgement of the prescriber.

Alaska Opioid Policy Task Force Final Recommendations (2017)

Chronic Pain: The task force appreciates the thoughtful consideration that the Alaska State Medical and Dental Boards, Board of Pharmacy, Board of Nursing, Board of Optometry, and Division of Professional Licensing gave to the issue of establishing prescribing guidelines for Alaska-licensed practitioners. The task force appreciates that, after a thorough public process, these boards have agreed to incorporate the Interagency Guideline on Prescribing Opioids for Pain Developed by the Washington State Agency Medical Directors' Group and stakeholders in 2015 – with the important amendment of a morphine equivalent dose limit of 90 mg/day. Washington's comprehensive guidelines (with the amended morphine equivalent dose of 90mg/day) will address many concerns related to prescribing practices.

Alaska Department of Health and Social Services, Division of Public Assistance (2017)

General Limits: Alaska Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Furthermore, updates were made to opioid quantity limits.

Arizona

Controlled substances; dosage limit, Chapter 243 (2018)

General Limits: Clarifies that the 90 MME/day opioid limit does not apply to patients being treated inside a health care institution, nor does the limit apply for 14 days following a surgical procedure. For cases in which the physician believes more than 90 MME/day of opioid is needed, this bill adds (in addition to consultation with a board-certified pain specialist) an option for the physician to consult with an opioid assistance referral call service.

Pharmacists; controlled substances, Chapter 87 (2018)

Initial Prescriptions: Clarifies that an initial prescription for a Schedule II opioid that is written for more than a 5-day supply (the pre-existing limit for initial prescriptions) is deemed to meet the requirements of an exemption when the prescription is presented to the dispenser. A pharmacist is not required to verify with the prescriber whether the initial prescription complies with law.

Controlled substances; regulation; appropriation, Chapter 1, First Special Session (2018)

Initial Prescriptions: Limits an initial prescription for a Schedule II controlled substance for pain management to a 5-day supply and permits a 14-day supply for initial prescriptions following a surgical procedure, with exceptions.

General Limits: Prohibits a health professional who is authorized to prescribe controlled substances from issuing a new prescription order for a Schedule II controlled substance for pain management that exceeds 90 MMEs, with exceptions. Directs a health professional who believes a patient requires more than 90 MMEs per day to consult with a board-certified pain specialist. Requires that a health professional additionally prescribe naloxone hydrochloride, or another opioid antagonist, to a patient who is prescribed more than 90 MMEs per day.

Optometrists: Specifies that an optometrist may prescribe or administer a controlled substance only if it is an analgesic that was reclassified from Schedule III to Schedule II after January 1, 2014.

Nurses: Directs the Board of Nursing to adopt rules that prohibit registered nurse practitioners and midwives from dispensing Schedule II opioids for pain management, but that permit registered nurse practitioners to dispense Schedule II controlled substances for medication-assisted treatment for substance use disorders.

Arizona Opioid Prescribing Guidelines, Arizona Department of Health Services (2018)

Acute Pain: If opioids are indicated for acute pain, initiate therapy at the lowest effective dose for no longer than a 3-5 day duration; reassess if pain persists beyond the anticipated duration. Do not use long-acting opioids for the treatment of acute pain.

Chronic Pain: If opioids are used to treat chronic pain, prescribe at the lowest possible dose and for the shortest possible time. Reassess the treatment regimen if prescribing doses ≥50 MEDs.

Arkansas

Regulation No. 2, Arkansas Medical Board (2016)

General Limits: The prescribing of excessive amounts of controlled substances to a patient including the writing of an excessive number of prescriptions for an addicting or potentially harmful drug to a patient. “Excessive” is defined as the writing of any prescription in any amount without a detailed medical justification for the prescription documented in the patient record.

Chronic Pain: For chronic pain, even with a documented justification, “excessive” means anything above 50 MME/day of opioids unless certain requirements are met related to diagnosis, documentation, PDMP checks, objective findings, and more.

Acute Pain: For acute pain, “excessive” means any prescription written for more than 7 days.

Arkansas Medicaid (2016)

General Limits: Arkansas Medicaid has adopted the CDC Guidelines for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Further, updates were made related to opioid quantity limits.

Arkansas Medicaid (2017)

General Limits: Arkansas Medicaid expressed that they planned to update their Fee-for-Service program in 2017 related to opioid quantity limits.

Mandate Prescribers to check the Prescription Monitoring Program, Arkansas State Board of Dental Examiners (2018)

Dentists: Limits prescriptions for Schedule II or III opiates to the total maximum manufacturer's recommended daily dose for a total of 7 days administration.

Regulation No. 2, Arkansas Medical Board (2018)

General Limits: Requires documented medical justification for "excessive" opioid prescriptions that exceed 50 MME/day.

Colorado

Opioid Policy Change FAQs for Providers, Health First Colorado (Medicaid) and Department of Health Care Policy and Financing (2017)

General Limits: The maximum daily quantity of short-acting opioids is 8 dosage forms per day (56 pills for a 7-day supply) for opioid naïve patients. All long-acting opioids will require a prior authorization for opioid naïve patients.

Clinical Practice for Opioid Prescribing, SB 22 (2018)

Initial Prescriptions: Restricts the number of opioid pills that a health care practitioner, including physicians, physician assistants, advanced practice nurses, dentists, optometrists, podiatrists, and veterinarians, may prescribe for an initial prescription to a seven-day supply and allows each health care practitioner to exercise discretion to include a second fill for a seven-day supply, with exceptions.

Health First Colorado Benefits and Services, Health First Colorado (Medicaid), Department of Health Care Policy and Financing (2018)

General Limits: Beginning November 15, 2018, the total daily limit of MME will be decreasing from 250 MME per day, to 200 MME per day. If a prescription puts a member above 200 MME per day, further approvals will be required to allow time for the prescriber to work with the member to safely taper opioid doses down to 200 MME, while making sure the member has adequate pain control. In some circumstances, a consultation with the Department's pain management physician may be required.

Dentists: In dental settings, the opioid policy will allow members to receive three, four-day prescription fills and a fourth refill request will require further approvals. In each fill, the quantity limit for dental opioids will be 24 pills. Members undergoing more complex dental procedures such as major orofacial surgery, may be approved for up to a seven-day supply and up to 56 pills per fill.

Connecticut

An Act Concerning Opioids and Access to Overdose Reversal Drugs, Public Act No. 16-43 (2016)

Initial Prescriptions: Limits opioid prescriptions to seven days for new patient in the outpatient setting.

General Limits: Limits opioid prescriptions for minors to seven-day supplies. Creates exceptions based on professional medical judgment.

An Act Concerning the Legislative Commissioner's Recommendations for Technical Changes to the Public Statutes, Public Act No. 17-188 (2017)

General Limits: Makes only technical changes to existing law related to opioid limits.

Husky Health (Medicaid) (2017)

General Limits: Connecticut Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Further, updates were made related to opioid quantity limits.

Delaware

An Act to Amend Title 24 of the Delaware Code Relating to Profession and Occupation of Optometry, Delaware Code, Title 24, Chapter 21 (2016)

Optometrists: Allows optometrists to prescribe controlled substances, but with a limitation of a 72-hour supply for Schedule II controlled substances containing hydrocodone and for all Schedule III, IV, and V controlled substances.

9.0 Safe Prescribing of Opioid Analgesics, Department of State, Division of Professional Regulation (2017)

Acute Pain: When issuing a prescription for an opioid analgesic to an adult patient for outpatient use for the first time, for an Acute Pain Episode, a practitioner may not issue a prescription for more than a seven-day supply.

General Limits: A practitioner may not issue a prescription for an opioid analgesic to a minor for more than a seven-day supply at any time, unless, in the professional medical judgment of the practitioner, more than a seven-day supply is required to treat the acute medical condition.

Delaware Prescription Opioid Guidelines for Health Care Providers, Delaware Health and Social Services, Division of Public Health (2017)

Acute Pain: Reiterates existing regulations (9.0 Safe Prescribing of Opioid Analgesics, above) which limit prescriptions for acute pain to no more than 7 days.

Delaware Health and Social Services, Medicaid and Medical Assistance (Medicaid) (2017)

General Limits: Delaware Medicaid made updates related to opioid quantity limits and opioid clinical criteria.

District of Columbia

DC Medicaid (2017)

General Limits: DC Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Further, they planned to require that Managed Care Organizations adopt the guideline. They also implemented new opioid quantity limits.

Florida

Controlled Substances, Chapter No. 2018-13 (2018)

Acute Pain: Prescriptions for Schedule II opioids prescribed for acute pain are limited to no more than a three-day supply (with exceptions for specified conditions), or up to a seven-day supply may be issued if it is determined to be medically necessary and the prescriber records the acute medical condition and lack of alternative treatment options that justify deviation from the three-day supply limit, and indicates “acute pain exception” on the prescription. Dispensing

practitioners are limited from dispensing a supply of a Schedule II opioid to three days, or up to a seven-day supply if the practitioner determines it is medically necessary, and follows the same specified procedures listed for prescribing Schedule II opioids for acute pain. All regulatory boards within the Department of Health are required to adopt rules establishing guidelines for the prescribing of controlled substances to treat acute pain.

Implementation for Dentists: Rule: 64B5-17.0045 Standards for the Prescribing of Controlled Substances for the Treatment of Acute Pain, Board of Dentistry (2018)

Georgia

Georgia Medicaid (2016)

General Limits: Georgia Medicaid made updates related to opioid quantity limits in their Fee-for-Service program in 2016.

Georgia Medicaid (2017)

General Limits: Georgia Medicaid made updates related to opioid quantity limits in their Fee-for-Service program in 2017.

Hawaii

Relating to the Uniform Controlled Substances Act, Act 218 (2016)

General Limits: Prohibits all Schedule II narcotic controlled substances from being prescribed or dispensed for more than a 30-day supply.

Relating to Workers' Compensation, Act 155 (2018)

Initial Prescriptions: Initial concurrent prescriptions for opioids and benzodiazepines shall not be for longer than seven consecutive days.

Chronic Pain: An exception for "chronic pain" is available to the above restriction related to initial prescriptions.

Idaho

Idaho Department of Health and Welfare (Medicaid) (2016)

General Limits: Idaho Medicaid has adopted the CDC Guidelines for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Further, updates were made to opioid quantity limits in 2016.

Idaho Department of Health and Welfare (Medicaid) (2017)

General Limits: Idaho Medicaid made updates to opioid quantity limits in 2017.

Illinois

Methadone Prescribed for Pain, Illinois Department of Healthcare and Family Services (Medicaid) (2016)

General Limits: Due to safety concerns, HFS is removing methadone products for the treatment of pain from the Illinois HFS Preferred Drug List (PDL) effective April 5, 2016.

Illinois Department of Healthcare and Family Services (Medicaid) (2017)

General Limits: Illinois Medicaid updated opioid quantity limits and opioid clinical criteria in their Fee-for-Service program.

Indiana

An Act to amend the Indiana Code Concerning Human Services, Public Law 37 (2016)

> General Limits: Prohibits Medicaid reimbursement for Subutex™, Suboxone™, or a similar trade name or generic of the drug if the drug was prescribed for the treatment of pain or pain management and the drug is only indicated for addiction treatment.

844 IAC 5-6-3 Triggers for imposition of requirements; exemptions, Medical Licensing Board of Indiana (2016)

> Chronic Pain: Establishes requirements concerning the use of opioids for chronic pain management for patients, with exemptions. Under certain circumstances, disallows: more than 60 opioid-containing pills/month for more than three consecutive months; a morphine equivalent dose of more than 15 MME/day for more than three consecutive months; a transdermal opioid patch for more than three consecutive months; tramadol in excess of 60 MME/day for more than three months; or, an extended release opioid that is not in an abuse-deterrent form for which there is an FDA-approved abuse deterrent form available.

Indiana Medicaid (2016)

> General Limits: Indiana Medicaid updated requirements related to opioid quantity limits in their Fee-for-Service program.

Prescribing and Dispensing of Opioids, Public Law 82 (2017)

> Initial Prescriptions: Limits the amount of an opioid prescription a prescriber may issue for an adult who is being prescribed an opioid for the first time to no more than a seven-day supply, with exceptions.
>
> General Limits: Limits the amount of an opioid prescription a prescriber may issue to a child less than 18 years of age to no more than a seven-day supply, with exceptions. Requires the medical licensing board, in consultation with specified persons, to adopt emergency rules and rules concerning conditions that will be exempt from the prescription limitations.

Indiana Medicaid (2017)

> General Limits: Indiana Medicaid updated requirements related to opioid quantity limits in their Fee-for-Service program.

Indiana Guidelines for the Management of Acute Pain, Indiana State Department of Health (2018)

> Acute Pain: The lowest effective dose should be prescribed with no greater quantity than needed for the expected duration of pain severe enough to require opioids. For patients with unresolved acute pain after 6 weeks, providers should repeat an assessment and determine whether treatment should be adjusted. Referral to the Indiana Chronic Pain Management Prescribing Rule may be helpful at this point.

Iowa

Iowa Medicaid (2016)

> General Limits: Iowa Medicaid made updates to opioid quantity limits in their fee-for-service program in 2016.

657-10.24(124,126,155A) Prescription Requirements, Pharmacy Board, Iowa Administrative Code (2017)

General Limits: Schedule 2 and Schedule 2N drugs require a properly executed, manually signed prescription or a prescription electronically prepared, signed, and transmitted pursuant to DEA requirements for electronic prescribing of controlled substances. No refills are permitted on these orders.

Kentucky

Kentucky Medicaid (2016)

General Limits: Kentucky Medicaid made updates related to opioid quantity limits in their Fee-for-Service program in 2016.

An Act Relating to Controlled Substances, Acts, Chapter 168 (2017)

Acute Pain: Requires state licensing boards to promulgate regulations limiting prescriptions for Schedule II controlled substances for acute pain to a three-day supply, with certain exceptions.

Louisiana

Louisiana Medicaid (2016)

General Limits: Louisiana Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016.

DRUGS/CONTROLLED: Provides for limitations on the prescribing of opioids, Act 82 (2017)

Acute Pain: When issuing a first-time opioid prescription for outpatient use to an adult patient with an acute condition, a medical practitioner shall not issue a prescription for more than a seven-day supply.

General Limits: A medical practitioner shall not issue a prescription for an opioid to a minor for more than a seven-day supply at any time (with exceptions) and shall discuss with a parent, tutor, or guardian of the minor the risks associated with opioid use and the reasons why the prescription is necessary.

2017-23: Opioid Prescription Policy Update, Louisiana Department of Health (Medicaid) (2017)

General Limits: Effective July 10, 2017, LDH will implement seven-day quantity limits for short-acting (SA) opioids for opioid naïve recipients enrolled in Healthy Louisiana Managed Care Organizations (MCO) and Fee for Service (FFS). MCOs, including Louisiana Healthcare Connections, are directed to implement opioid quantity limits at the Point of Sale (POS) on July 10, 2017, for opioid naïve recipients (no opioids in the most current 90-day period). Prior Authorization override provisions will be implemented to allow for medically necessary quantities above limits.

2017-38: Opioid Prescription Policy Update, Louisiana Department of Health (Medicaid) (2017)

General Limits: Effective September 12, 2017, the Louisiana Department of Health (LDH) will implement updated short-acting opioid quantity limits for Medicaid pharmacy claims for opioid naïve (no opioids in the most current 90-day period). Opioid prescriptions for naïve recipients will be decreased to a Morphine Equivalent Dosing (MED) limit of 90 mg per day. Prescriptions and cumulative MEDs above 90 mg per day should deny at the Point of Sale. Recipients with a diagnosis of cancer and palliative care are exempt from the MED requirements.

Chronic Pain: Opioid prescriptions for chronic recipients will be decreased to a Morphine Equivalent Dosing (MED) limit of 90 mg per day.

Louisiana Medicaid Opioid Prescription Policy, Louisiana Department of Health (Medicaid) (2017)

Acute Pain: For patients with acute pain, limits Medicaid opioid quantity to: 15 days for fee for service patients; 15 days for opioid-naïve managed care organization patients; no more than 120 MME/day.

Chronic Pain: For patients with chronic pain, limits Medicaid opioid quantity to: 15 days for fee for service patients; no more than 120 MME/day by July 10, 2017; no more than 90 MME/day by September 12, 2017.

HEALTH/ACC INSURANCE: Prohibits a health insurance issuer from denying a nonopioid prescription in favor of an opioid prescription, Act 372 (2018)

General Limits: When an opioid is deemed necessary and prescribed, the insurer may not substitute an alternative that would require: an increased number of pills per prescription; a higher DEA schedule medication than the one prescribed; or, an extended release medication that does not have abuse deterrent properties for a prescription that was intended to be abuse deterrent.

Maine

An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program, SP 671 (2016)

General Limits: Prohibits opioid prescriptions in excess of 100 morphine milligram equivalents per day to any one patient.

Chronic Pain: Prohibits opioid prescriptions of more than 15 days at a time when treating chronic pain.

Acute Pain: Prohibits opioid prescriptions of more than 3 days when treating acute pain.

An Act to Clarify the Opioid Medication Prescribing Limit Law, Chapter 213 (2017)

General Limits: Clarifies that dispensing in connection with surgical procedures is exempt from the 100 morphine milligram equivalents limitation on opioids. Clarifies that an opioid product that is labeled by the federal Food and Drug Administration to be dispensed only in a stock bottle that exceeds a 7-day supply may be prescribed as long as the amount dispensed does not exceed a 14-day supply.

Resolve, Regarding Legislative Review of Portions of Chapter 11: Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications, a Late-filed Major Substantive Rule of the Department of Health and Human Services, Chapter 16 (2017)

General Limits: Amends exemptions related to opioid limits.

14-118 C.M.R. Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications, Department of Health and Human Services, MaineCare Services (2017)

General Limits: Requires prescribers include a designation on the prescription as to whether the prescription is for the treatment of acute or chronic pain (to aid pharmacists in determining whether a 100 MME/day and/or 7-day supply limit apply). Defines exemptions to limits on opioid medication prescribing.

§3300-F. Requirements regarding prescription of opioid medication, Chapter 48: Board of Licensure in Medicine (2017)

General Limits: Limits opioid prescriptions to no more than 100 MME/day. For patients already receiving in excess of 100 MME/day, they may immediately receive no more than 300 MME/day; on or after July 1, 2017, they may not receive more than 100 MME/day. No more than a 7-day supply of opioids may be dispensed in most cases.

Acute Pain: Allows no more than a 14-day supply of opioids for acute pain.

Maryland

The Prescriber Limits Act of 2017, Chapter 570 (2017)

General Limits: Requiring health care providers to prescribe the lowest effective dose of an opioid and in a quantity no greater than the quantity needed for the expected duration of specified pain unless the opioid is prescribed to treat a specified disorder or specified pain; requiring the dosage, quantity, and duration of specified prescribed opioids to be based on an evidence-based clinical guideline for prescribing controlled dangerous substances.

Implemented by: Limits on Prescribing Opioids, MD Health Occ Code § 1-223 (2017)

Opioid Prior Authorization Indications, Maryland Medicaid (2017)

General Limits: All pill forms of all opioids have a 30-day quantity limit of 180 or less. Prior authorization is required if: (1) exceeding a 30-day quantity limit; (2) exceeding daily dose of 90 MME (cumulative of all opioids prescribed); or (3) any prescription for fentanyl, methadone (for pain), or any long-acting opioids. Individual types of opioids have a variety of daily quantity limits and 30-day quantity limits (see policy for details).

Massachusetts

An Act Relative to Substance Use, Treatment, Education, and Prevention, Chapter 52 (2016)

Initial Prescriptions: When issuing a prescription for an opiate to an adult patient for outpatient use for the first time, a practitioner shall not issue a prescription for more than a 7-day supply.

General Limits: A practitioner shall not issue an opiate prescription to a minor for more than a 7-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opiate use and the reasons why the prescription is necessary.

Opioid/Controlled Substance Protocol, Department of Industrial Accidents (2016)

Acute Pain: Disallows initiating treatment of acute pain with long acting or extended release opioids.

Initial Prescriptions: Initial prescriptions for opioids are limited to no more than 7 days.

General Limits: Adopts CDC dosage recommendations.

Michigan

Michigan Medicaid (2016)

General Limits: Michigan Medicaid updated the opioid quantity limits in their Fee-for-Service program in 2016.

Health; controlled substances; prescription for opioids; limit for acute pain and allow for the partial filling of certain controlled substance prescriptions if consistent with federal law. Public Act 251 (2017)

Acute Pain: Beginning July 1, 2018, if a prescriber is treating a patient for acute pain, the prescriber shall not prescribe the patient more than a 7-day supply of an opioid within a 7-day period.

Michigan Medicaid (2017)

General Limits: Michigan Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Further, updates were made to opioid quantity limits.

Minnesota

Minnesota Medicaid (2016)

General Limits: Minnesota Medicaid updated the opioid quantity limits in their Fee-for-Service program in 2016.

Limit on quantity of opiates prescribed for acute dental and ophthalmic pain, SF No. 2 (1st Special Session), Chapter 6 (2017)

Dentists: When used for the treatment of acute dental pain, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV shall not exceed a four-day supply.

Optometrists: When used for the treatment of acute pain associated with refractive surgery, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV shall not exceed a four-day supply.

Minnesota Opioid Prescribing Guidelines, Minnesota Department of Human Services, Minnesota Department of Health (2018)

Acute Pain: Avoid prescribing more than 100 MME of low-dose, short-acting opioids. Limit the entire prescription to 100 MME (not 100 MME/day). Limit the initial acute prescription to no more than 200 MME, unless circumstances clearly warrant additional opioid therapy.

Dentists: Avoid prescribing more than 100 MME total supply of low-dose, short-acting opioids following a dental procedure.

Post-Acute Pain: Prescribe opioids in multiples of 7 days, with no more than 200 MME per 7 day period and no more dispensed than the number of doses needed. Avoid prescribing in excess of 700 MME (cumulative) in order to reduce the risk of chronic opioid use and other opioid-related harms.

Chronic Pain: Use caution when prescribing opioids at any dosage and make every effort to keep daily dosage under 50 MME/day. Re-evaluate the patient's individual risks and benefit of continued treatment when increasing dosage. Avoid increasing daily dosage to equal to, or greater than, 90 MME/day. Clinicians who decide to increase the daily dosage to, or beyond, this point must carefully document that the risks and benefits were weighted and benefits warrant the risk. Limit the duration of the prescription to one month and prescribe so that the prescription does not end during a weekend or on a holiday.

Missouri

MO HealthNet (Medicaid) (2017)

General Limits: MO HealthNet made updates to opioid quantity limits for their fee-for-service programs in 2017.

Modifies provisions relating to health care, Sections 195.010 and 195.080 (2018)

Acute Pain: Limits certain initial prescriptions of opioid controlled substances to no more than a 7-day supply for the treatment of acute pain. Prior to prescribing the opioid, a practitioner shall consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity, as well as inform the patient of the risks associated with the prescribed opioid. If, in the practitioner's medical judgment, more than a 7-day supply is required to treat the patient, the practitioner may issue a prescription for the quantity needed after noting in the patient's medical record the condition triggering the necessity for a greater quantity and that a nonopioid was not appropriate. Contains exceptions.

Implemented by: Controlled Substance Guidelines for Missouri Practitioners, Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs (2018). The Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) are publishing this guideline as a ready reference and review of the most common controlled substance laws. This guide does not address every single statute and regulation but it addresses the most common requirements and questions from practitioners. The guideline covers subjects related to pain and Schedule II medications such as: documentation, storage, inventory, packaging, labeling, supervision, disposal, written and verbal prescriptions, electronic prescribing, multiple prescriptions, initial opiate prescriptions for acute pain, prescribing authority for mid-level practitioners, and more.

Montana

Montana Medicaid (2016)

General Limits: Montana Medicaid updated their opioid quantity limits in their Fee-for-Service program in 2016.

Montana Medicaid (2017)

General Limits: Montana Medicaid updated their opioid quantity limits in their Fee-for-Service program in 2017.

Chronic Pain Disorder: Montana Utilization and Treatment Guidelines, Department of Labor and Industry, Employment Relations Division (2018)

General Limits: It is highly recommended that prescribers of opioids, among other things, prescribe the lowest possible effective dose. Doses of opioids in excess of 120 mg morphine equivalent have been observed to be associated with increased duration of disability, even when adjusted for injury severity in injured workers with acute low back pain and thus any use above 120 mg should be very closely monitored. Doses in excess of 200 mg should be avoided.

Nebraska

Nebraska Pain Management Guidance Document, Department of Health and Human Services (2017)

Acute Pain: For most injuries and minor procedures (e.g., dental extraction, sports injuries), prescribe no more than a three-day supply or 10 doses of a short-acting opioid. For more severe injuries (e.g., fractures), prescribe no more than a seven-day supply of a short-acting opioid. Do not prescribe extended-release opioids for acute pain.

Acute Pain Flares of Chronic Conditions: Do not use opioids for acute flares of non-specific musculoskeletal pain, headaches, or fibromyalgia. For acute flares of other chronic conditions

(e.g., osteoarthritis, sickle cell anemia), limit prescribing to a three-day supply of a short-acting opioid. In rare instances, up to a seven-day supply may be appropriate.

Chronic Pain: Do not prescribe chronic opioids for non-specific musculoskeletal pain, headache or fibromyalgia. Do not combine opioids with benzodiazepines, muscle relaxants, or sedative hypnotics. Avoid exceeding 90 mg/day MED. For patients with one or more risk factors (e.g., history of substance-use disorder, tobacco users, mental health disorders, cannabis-use disorder), do not prescribe more than 50 mg/day MME.

Department of Health and Human Services, Division of Medicaid and Long-Term Care (2017)

General Limits: Nebraska Medicaid expressed that they planned to require that Managed Care Organizations adopt the CDC Guideline for Prescribing Opioids for Chronic Pain.

Provide requirements for opiate and controlled substance prescriptions, Section 28-401.01 (2018)

Initial Prescriptions: Initial opiate prescriptions for children should not exceed seven days for most situations, and two or three days of opiates will often be sufficient.

General Limits: If a patient needs medication beyond three days, the prescriber should reevaluate the patient prior to issuing another prescription for opiates. A practitioner who is prescribing an opiate for a patient younger than eighteen years of age for outpatient use for an acute condition shall not prescribe more than a seven-day supply except as otherwise provided. If, in the professional medical judgment of the practitioner, more than a seven-day supply of an opiate is required to treat such patient's medical condition or is necessary for the treatment of pain associated with a cancer diagnosis or for palliative care, the practitioner may issue a prescription for the quantity needed to treat such patient's medical condition or pain. The practitioner shall document the medical condition triggering the prescription of more than a seven-day supply of an opiate in the patient's medical record and shall indicate that a nonopiate alternative was not appropriate to address the medical condition.

Implemented by: Opiates; legislative findings; limitation on certain prescriptions; practitioner; duties, NRS 28-474 (2018)

Preferred Drug List with Prior Authorization Criteria, Nebraska Medicaid (2018)

General Limits: Short-acting opioid analgesics are limited to a maximum quantity limit of 150 tablets/capsules per 30 days.

Initial Prescriptions: Opiate limits for opiate naïve patients will be limited to no more than a 7-day supply no more than 50 MME/day, with exceptions.

Nebraska Medicaid (2018)

Chronic Pain: An initial limit of 300 MME daily will be put in place in December of 2018 for Nebraska Medicaid patients with chronic pain, unless being treated for active cancer, enrolled in hospice, or receiving end of life care. Claims for total daily doses of more than 300 MME will reject beginning December 6, 2018 unless a prior authorization is on file. Nebraska Medicaid plans to lower the maximum MME to:

- 250 MME in June 2019
- 200 MME in December 2019
- 150 MME in June 2020
- 120 MME in December 2020

- 90 MME in June 2021

Nevada

Medicaid Services Manual, Division of Health Care Financing and Policy (2016)

Initial Prescriptions: Opioids are covered without prior authorization for initial prescriptions of 7 days or less.

General Limits: Opioids are only covered without prior authorization for a total of 13 7-day prescriptions in any rolling 12-month period, and for prescriptions of less than 60 MME/day.

Chronic Pain: To exceed the general quantity limits, the patient must have chronic pain that cannot be controlled through use of non-opioids, the lowest effective dose must be used, and a pain contract must be on file.

Division of Health Care Financing and Policy (Medicaid) (2017)

General Limits: Nevada Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2017.

New Hampshire

Relative to rulemaking for prescribing controlled drugs, Chapter 213 (2016)

General Limits: Requires the board of medicine, the board of dental examiners, the board of nursing, the board of registration in optometry, the board of podiatry, the naturopathic board of examiners, and the board of veterinary medicine to adopt rules for prescribing controlled drugs. Contains mandatory standards for such rules, including requiring the lowest effective dosage for the fewest number of days.

Med 502 Opioid Prescribing, Board of Medicine (2016)

Acute Pain: In an emergency department, urgent care setting, or walk-in clinic, a prescriber shall prescribe more than the minimum amount of opioids medically necessary to treat the patient's medical condition. In most cases, an opioid prescription of 3 or fewer days is sufficient, but a licensee shall not prescribe for more than 7 days. If prescribing an opioid for acute pain that exceeds a board-approved limit, document the medical condition and appropriate clinical rationale in the patient's medical record. If opioids are indicated and appropriate for persistent, unresolved acute pain that extends beyond a period of 30 days, the licensee shall conduct an in-office follow-up with the patient prior to issuing a new opioid prescription.

Chronic Pain: Document the consideration of a consultation with an appropriate specialist when the patient receives a 100 mg morphine equivalent dose daily for longer than 90 days.

Nur 502 Opioid Prescribing, Board of Nursing (2016)

Acute Pain: In an emergency department, urgent care setting, or walk-in clinic, a prescriber shall prescribe more than the minimum amount of opioids medically necessary to treat the patient's medical condition. In most cases, an opioid prescription of 3 or fewer days is sufficient, but a licensee shall not prescribe for more than 7 days. If prescribing an opioid for acute pain that exceeds a board-approved limit, document the medical condition and appropriate clinical rationale in the patient's medical record. If opioids are indicated and appropriate for persistent, unresolved acute pain that extends beyond a period of 30 days, the licensee shall conduct an in-office follow-up with the patient prior to issuing a new opioid prescription.

Chronic Pain: Document the consideration of a consultation with an appropriate specialist when the patient receives a 100 mg morphine equivalent dose daily for longer than 90 days.

New Jersey

New Jersey Medicaid (2016)

General Limits: New Jersey Medicaid updated opioid quantity limits in their Fee-for-Service program in 2016.

Requires health insurance coverage for treatment of substance use disorders; places certain restrictions on the prescription of opioid and certain other drugs; concerns continuing education related thereto, P.L.2017, Chapter 28 (2017)

Initial Prescriptions: Limits initial opioid prescriptions to five days.

Implemented by: 13:35-7.6 Limitations on Prescribing, Administering, or Dispensing of Controlled Substances; Special Requirements for Management of Acute and Chronic Pain, Division of Consumer Affairs (2017)

New Jersey Medicaid (2017)

General Limits: New Jersey Medicaid updated opioid quantity limits in their Fee-for-Service program in 2017.

New Mexico

2016 Recommendations, Governor's Prescription Drug Misuse and Overdose Prevention and Pain Management Advisory Council (2016)

General Limits: Practitioners should adhere to the summary of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain. Providers should not use the Guideline to override a provider's judgement regarding a specific patient, but rather to guide skillful and appropriate pain management. The medical provider licensing boards should not use the CDC Guideline to set strict policy or to enforce practice standards.

Acute Pain: Licensing entities should promulgate rules requiring practitioners to limit an initial opioid prescription for acute pain to no more than a 10-day supply for a single prescription.

New York

Pain Management Drugs: Subscriber Training, Chapter 71 (2016)

Acute Pain: Restricts initial opioid prescriptions for acute pain to seven days.

Scheduled substances administering and dispensing by practitioners, N.Y. Pub. Health § 3331(5) (2016)

Acute Pain: A practitioner may not prescribe more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for the opioid or any other drug.

Department of Health (Medicaid) (2016)

Acute Pain: Effective July 22, 2016, initial opioid prescribing for acute pain is limited to a seven (7) day supply per New York State Public Health Law Section 3331 (see above). The Department of Health will communicate a date in the near future when this will be systematically enforced by

the Medicaid Fee-for-Service Program. Until such time that the Department is able to implement an automated solution to exempt copayments for such subsequent opioid prescriptions: If a prescriber initiates a subsequent prescription for the same pain medication within 30 days of the initial 7-day supply, and the pharmacist is notified and/or confirms this upon reviewing the patient's prescription history or utilizing ProDUR editing, the following may be used to exempt the copayment for the subsequent prescription: In NCPDP field 461-EU, enter a value "04" (Exempt Copay and/or Coinsurance). Although pharmacists should continue to use all of the tools at their disposal when dispensing opioid prescriptions, pharmacists are not required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with the above-referenced statutory requirements. Pharmacists may continue to dispense opioids as prescribed, consistent with current laws, regulations, and Medicaid policies.

Amd Various Law, generally (Budget), Chapter 57 (2018)

General Limits: No opioids shall be prescribed to a patient initiating or being maintained on opioid treatment for pain which has lasted more than three months or past the time of normal tissue healing, unless the medical record contains a written treatment plan that follows generally accepted national professional or governmental guidelines. Exceptions apply in the case of patients who are being treated for cancer that is not in remission, who are in hospice or other end-of-life care, or whose pain is being treated as part of palliative care practices.

North Carolina

Strengthen Opioid Misuse Prevention (STOP) Act, SL 217-74 (2017)

Initial Prescriptions: Limits initial prescriptions of all controlled substances in Schedules II through V to no more than a five-day supply if the prescription is for pain, with exceptions.

Policy for the use of opioids for the treatment of pain, North Carolina Medical Board (2017)

General Limits: In order to provide its licensees with guidance that reflects the most current medical and scientific research and recommended practices, the Board has decided to adopt and endorse the CDC Guideline for Prescribing Opioids for Chronic Pain written and maintained by the Centers for Disease Control and Prevention ("CDC").

NC Medicaid and Health Choice (2017)

General Limits: North Carolina Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Updates were also made to opioid quantity limits.

North Dakota

North Dakota Medicaid (2016)

General Limits: North Dakota Medicaid updated opioid quantity limits in their Fee-for-Service program in 2016.

North Dakota Tri-Regulator Position Statement on Opioid Prescribing/Dispensing, Boards of Medicine, Nursing and Pharmacy (2018)

General Limits: In order to balance the risk of potential misuse with legitimate pain control, all healthcare professionals should, as their scope of practice allows, uphold their professional obligation to pursue educational opportunities to further their knowledge on standards of care and

evidence-based approaches to pain management including, but not limited to, the CDC opioid prescribing guidelines (2016).

Ohio

Ohio Department of Medicaid (2017)

General Limits: Ohio Medicaid updated opioid quantity limits, opioid clinical criteria, and opioid step therapy requirements in their Fee-for-Service program in 2017.

Chapter 4731-11 Controlled Substances, State Medical Board (2018)

Chronic Pain: Starting December 23, 2018 Ohio prescribers will need to follow new regulations when prescribing opioids for the treatment of long-term pain (lasting 12 weeks or more) and subacute pain (lasting between six and 12 weeks). Physicians are required to engage in conversations with patients before starting on long-term medication treatment to ensure opioids are improving function and the patient is offered non-opioid treatments when appropriate. Sets requirements that prescribers must follow at 50 MME/day, 80 MME/day, and 120 MME/day. Limits opioids in excess of 120 MME/day without a recommendation from a board-certified pain specialist.

Oklahoma

SoonerCare (Oklahoma Medicaid) (2016)

General Limits: Oklahoma Medicaid updated opioid quantity limits in their Fee-for-Service program in 2016.

Oklahoma Opioid Prescribing Guidelines, Department of Health (2017)

Acute Pain: When opioids are started, providers should prescribe the lowest possible effective dose. Prescribe no more than a short course; most patients require opioids for no more than three days. Long-acting or extended-release opioids should not be prescribed for acute pain.

Chronic Pain: Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. The trial should begin with a short-acting opioid medication.

Regulation of opioid drugs; providing limitations on quantities of certain prescriptions, SB 1446 (2018)

Initial Prescriptions: The measure restricts initial prescriptions for opioids to a seven-day supply.

General Limits: The measure requires the Insurance Department to evaluate the effect of the limits on prescriptions of opioid medication on claims paid by health insurance carriers.

Oregon

Opioid Prescribing for Conditions of the Back and Spine, Health Evidence Review Commission, Oregon Health Authority (Medicaid) (2016)

Acute Pain: For acute pain (first 6 weeks), opioid treatment is only available when the prescription is 7 days or less, for short-acting opioids only, when one or more non-opioids have been tried and found ineffective or contraindicated, and when prescribed with a plan to keep active and with consideration of additional non-pharmacological therapies. There can be no documented history or opioid misuse or abuse.

Subacute Pain: For pain after 6 weeks and up to 90 days, treatment with opioids requires: documented evidence of improved function of at least 30% compared to baseline; co-prescription of non-pharmacological treatments (acupuncture, physical therapy, etc.); and, each prescription is for no more than 7 days and for short-acting opioids only. After 90 days, opioids may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery.

Chronic Pain: For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long-term opioids for diagnoses on these lines.

Opioid Prescribing Guidelines for Dentists, Oregon Health Authority, Public Health Division (2017)

Dentists: Recommends not exceeding a 3-day or 10-tablet supply.

Oregon Opioid Prescribing Guidelines: Recommendations for the Safe Use of Opioid Medications, Oregon Health Authority, Public Health Division (2017)

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.

Chronic Pain: When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. 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 increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

Oregon Chronic Opioid Prescribing Guidelines (2017-2018), Oregon Health Authority, Public Health Division (2017)

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.

Chronic Pain: When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. 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 increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

Oregon Medicaid, Oregon Health Authority, Public Health Division (2017)

General Limits: Oregon Medicaid expressed that they planned to adopt the CDC Guidelines for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Further, they

planned to require that Managed Care Organizations adopt the guideline. Updates were also made related to opioid quantity limits.

Oregon Acute Opioid Prescribing Guidelines, Oregon Health Authority (Medicaid) (2018)

Acute Pain: Prescribers are urged to, "Prescribe the lowest effective dose of short-acting opioids usually for a duration of less than 3 days; in cases of more severe acute pain limit initial prescription to less than 7 days."

Pennsylvania

Safe Emergency Prescribing Act, Act 122 (2016)

General Limits: A health care practitioner may not prescribe an opioid drug product to an individual seeking treatment in an emergency department or urgent care center, or who is in observation status in a hospital, in a quantity sufficient to treat that individual for more than seven days. If, in the professional medical judgment of a health care practitioner, more than a seven-day supply of an opioid drug product is required to treat a patient's acute medical condition or is necessary for the treatment of pain associated with a cancer diagnosis or for palliative care, then the health care practitioner may issue a prescription for the quantity needed to treat such acute medical condition or pain associated with a cancer diagnosis or for palliative care. The condition triggering prescription of the opioid drug product under this paragraph shall be documented in the patient's medical record, and the health care practitioner must indicate that a non-opioid drug product alternative was not appropriate to treat the medical condition. A health care practitioner in an emergency department or urgent care center, or who is caring for a patient in observation status, may not write a prescription refill for an opioid drug product.

Prescribing Opioids to Minors, Act 125 (2016)

General Limits: A prescriber may not prescribe to a minor more than a seven-day supply of a controlled substance containing an opioid. If, in the professional medical judgment of the prescriber, more than a seven-day supply of a controlled substance containing an opioid is required to stabilize the minor's acute medical condition, the prescriber must: document the acute medical condition in the minor's record with the prescriber; and, indicate the reason why a non-opioid alternative is not appropriate to address the acute medical condition. The prescription must be for: management of pain associated with cancer; use in palliative or hospice care; or, management of chronic pain not associated with cancer.

Geriatric Pain, Opioid Use and Safe Prescribing, Department of Health (2016)

General Limits: Guidelines related to opioid use in geriatric patients, covering subjects including, among other things, avoiding use of long-acting opioids in older adults, situations in which low-dose opioids may be indicated, and initiating lower doses than typically used in adult populations.

Pennsylvania Medical Assistance (Medicaid) (2016)

General Limits: Pennsylvania Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016.

Safe Prescribing of Opioids in Pediatric and Adolescent Populations, Department of Health (2017)

General Limits: Opioid analgesics should be reserved for those children and adolescents with moderate to severe pain. The opioids of choice when treating children for moderate to severe pain are morphine or oxycodone. Short-acting opioids should be used first. Longer-acting opioids

should be avoided, as they pose greater safety and misuse risks and are rarely needed. Codeine and tramadol should not be used. The smallest effective dose should be prescribed when an opioid is selected for use. Prescribers should anticipate how long the patient is likely to have moderate to severe pain requiring opioid treatment and dispense only enough opioid medication to be used during the expected period of pain. Reiterates Pennsylvania law which limits the prescriptions of opioids to minors (see above).

The Safe Prescribing of Opioids in Orthopedics and Sports Medicine, Department of Health (2017)

General Limits: Reiterates Pennsylvania law which limits the prescriptions of opioids to minors (see above).

Pennsylvania Medical Assistance (Medicaid) (2017)

General Limits: Pennsylvania Medicaid updated opioid quantity limits in their Fee-for-Service program in 2017.

Treatment of Pain in an Emergent Setting, Department of Health (2018)

General Limits: Opioids should be used in the lowest effective dose for the shortest duration possible, as both dose and duration of therapy are associated with increased risk of harm. Hydrocodone acetaminophen offers the lowest potency of all commonly available formulations. Long-acting or controlled-release opioids (such as extended-release oxycodone, fentanyl patches, extended-release morphine, and methadone) should not be prescribed from the emergency department.

Chronic Pain: Chronic opioid therapy should be provided by a provider, who has the clinical expertise to provide appropriate monitoring. Consideration should be given for referral to a specialist as indicated by the patient's clinical needs, who may assist the prescribing physician in proper administration of opioids.

Rhode Island

Uniform Controlled Substances Act--regulation Of Manufacturing, Distributing, Prescribing, Administering, And Dispensing Controlled Substances, Chapter 199 (2016)

Acute Pain: Provides limits on amounts of opioids to be prescribed, allowing no more than 30 MME/day for a maximum of 20 total doses for acute pain.

Uniform Controlled Substances Act--regulation Of Manufacturing, Distributing, Prescribing, Administering, And Dispensing Controlled Substances, Chapter 180 (2016)

Acute Pain: Provides limits on amounts of opioids to be prescribed, allowing no more than 30 MME/day for a maximum of 20 total doses for acute pain.

Rhode Island Medicaid (2016)

General Limits: Rhode Island Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016.

Rhode Island Medicaid (2017)

General Limits: Rhode Island Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2017.

South Carolina

Revised Joint Pain Management Guidelines, Boards of Dentistry, Medical Examiners, Nursing and Pharmacy (2017)

> General Limits: Adopts the CDC Guidelines (2016) to the extent the recommendations do not conflict with state law.

Opioid prescriptions, limits, prescription report cards, Act No. 201 (2018)

> Acute Pain: Initial opioid prescriptions for acute pain management or postoperative pain management must not exceed a seven-day supply, except when clinically indicated for cancer pain, chronic pain, hospice care, palliative care, major trauma, major surgery, treatment of sickle cell disease, treatment of neonatal abstinence syndrome, or medication-assisted treatment for substance use disorder. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new opioid prescription.

Opioid Prescribing Limits, South Carolina Department of Health and Human Services, Healthy Connections Medicaid (2018)

> Acute Pain: Prescribers must limit the initial prescribing of opioid medications for the treatment of acute or post-operative pain to the lowest effective dose and for a quantity no more than necessary for the expected duration of pain. Providers must not exceed a five-day supply or 90 morphine milligram equivalents (MMEs) daily.
>
> Chronic Pain: Providers must not exceed a five-day supply or 90 morphine milligram equivalents (MMEs) daily, except in the cases of chronic pain, cancer pain, pain related to sickle cell disease, hospice care, palliative care or medication-assisted treatment for substance use disorder. If, in a prescriber's clinical judgement, an initial supply of more than five days or 90 MMEs is medically necessary, the prescriber must document that need in the patient's medical record.

Tennessee

Relative to Dispensing Opioids or Benzodiazepines, Pub. Ch. 973 (2016)

> General Limits: Disallows (with certain exceptions) prescribers of opioids and benzodiazepines from dispensing opioids and benzodiazepines.

TennCare (Medicaid) (2016)

> General Limits: TennCare made updates related to opioid quantity limits in their Fee-for-Service program in 2016.

TennCare will begin implementation of a Morphine Milligram Equivalent (MME) edit, TennCare (Medicaid) (2017)

> General Limits: Effective September 5, 2017, TennCare will begin implementation of a Morphine Milligram Equivalent (MME) edit for all agents in the Short-Acting Narcotic and Long-Acting Narcotic Classes of the PDL. The edit will accumulate MME for all short-acting narcotics and long-acting narcotics a patient is currently receiving and will deny claims for patients prescribed a cumulative daily MME of greater than 200 MME. Prior authorization will be required for patients exceeding the daily MME limit.

As enacted, makes various changes to the requirements for prescribing, dispensing, and reporting of opioids, Public Chapter 1039 (2018)

General Limits: As with prior to the passage of Public Chapter 1039, a healthcare practitioner can treat a patient with a three-day supply of an opioid at a total dosage of 180 morphine milligram equivalent (MME) total dosage without any new requirements. A healthcare practitioner may treat a patient with more than a three-day supply of an opioid if the healthcare practitioner treats the patient with no more than one (1) prescription for an opioid per encounter and meets certain evaluation and documentation requirements. If a healthcare practitioner treats a patient with more than a three-day supply of an opioid, the healthcare practitioner may treat the patient with no more than a ten-day supply and with a dosage that does not exceed a total of a five hundred (500) morphine milligram equivalent dose. In rare cases, a healthcare practitioner may treat a patient with up to a twenty-day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose. Includes exemptions.

As enacted, requires a prescriber to provide certain information prior to prescribing more than a three-day supply of an opioid or an opioid dosage that exceeds a total of a 180 morphine milligram equivalent dose to a woman of childbearing age, Public Chapter 901 (2018)

General Limits: If a health care prescriber prescribes more than a five (5) day supply of opioids to a non-pregnant fertile woman, the prescriber shall inform the patient of the risk of fetal injury and neonatal abstinence syndrome in the event of pregnancy while on therapy.

Changes to Prior Authorization Criteria and quantity limits for the Preferred Drug List (PDL), TennCare (Medicaid) (2018)

Acute Pain: Effective January 16, 2018, TennCare has implemented an edit on agents in the short-acting and long-acting narcotics classes of the PDL that will impact all first-time and non-chronic opioid users. Members can receive opioid coverage up to 15 days in a 180 period at the maximum dosage of 60 MME/day. All first-fill scripts in a 180 day period will be limited to a 5 day supply of a short-acting opioid at a maximum dose of 60 MME/day. After the first fill, members can receive an additional 10 days at a maximum of 60 MME/day. Limited use exceptions are available for treatment of pain due to severe burn or corrosion, sickle cell disorder, or those residing in a Medicaid-certified nursing facility; when an exception applies, patients can receive up to 45 days with a maximum dose of 60 MME/day. All long-acting narcotics require prior authorization.

Texas

§170.3 Minimum Requirements for the Treatment of Chronic Pain, Texas Medical Board (2016)

General Limits: Revised pain management rules related to, among other things, limitations on who may prescribe to patients being treated for pain and the limitation of only one pharmacy for a patient being treated for pain.

Texas Medicaid (2016)

General Limits: Texas Medicaid updated opioid quantity limits in their Fee-for-Service program in 2016.

Texas Medicaid (2017)

General Limits: Texas Medicaid updated opioid quantity limits in their Fee-for-Service program in 2017.

Morphine Equivalent Dose Limitations for Traditional Medicaid to Decrease, Texas Medicaid Vendor Drug Program (2018)

General Limits: Beginning Jan. 9, 2018, Texas HHS will limit the daily morphine equivalent dose that people enrolled in traditional Medicaid may receive. The initial limit will be set at 300 morphine milligram equivalents (MME)/day, and will apply to all opioid prescriptions with exceptions for those people diagnosed with cancer or those receiving palliative or hospice care. The maximum allowable limit will decrease over time according to the following tentative schedule: January 2018, 300 MME/day; May 2018, 240 MME/day; September 2018, 160 MME/day; January 2019, 90 MME/day. Claims that exceed the 300 MME/day limit will reject during pharmacy claims processing. Prescribing providers requesting an override for claims exceeding the maximum allowable limit must contact the Texas Prior Authorization Call Center at 1-877-PA-TEXAS.

Utah

Opioid Prescribing Regulations, Session Law Chapter 237 (2017)

Acute Pain: A prescription for a Schedule II or III opioid that is issued for an acute condition shall be completely or partially filled in a quantity not to exceed a 7-day supply as directed on the daily dosage rate of the prescription, with exceptions.

Insurance Opioid Regulation, Session Law Chapter 53 (2017)

General Limits: This bill authorizes commercial insurers, the state Medicaid program, workers' compensation insurers, and public employee insurers to implement policies to minimize the risk of prescribing opioids.

Implemented by:

- Utah Medicaid (2017)
  General Limits: Utah Medicaid updated the opioid quantity limits for their Fee-for-Service program in 2017.
- Utah Medicaid Provider Manual, Drugs with Quantity Limits (2018)
  General Limits: In addition to drug-specific limits (found within the Provider Manual), cumulative limits for any combination of short-acting opioids and/or opioid/APAP combination products is 180 tablets per 30 days (independent of long-acting opioid accumulation). In addition to the drug-specific limits, cumulative limits for any combination of long-acting opioids is 90 tablets per 30 days (independent of short-acting and/or opioid/APAP combination product accumulation). The cumulative limit may be overridden if the prescriber writes a valid ICD code for cancer on the face of the prescription. Fentanyl is mutually exclusive with methadone and all other long acting opioids. Methadone is mutually exclusive with fentanyl and all other long acting opioids. All other opioids are not mutually exclusive with each other.
  Initial Prescriptions: Initial prescriptions for over a 7-day supply require prior authorization.
- Initial Prescriptions of Short Acting Opiates Prescribed by Dentists, Utah Medicaid (2018)
  Dentists: Effective July 1, 2018, Utah Medicaid will restrict the initial fill of short acting opiates to no more than a 3-day supply when prescribed by a dentist. When a claim for a short acting opiate is submitted to Utah Medicaid, the pharmacy claims processing system will determine whether the member has had a prescription for the same medication in the previous 60 days. If the member has not had a claim for the same medication in the previous 60 days, the system will treat the claim as an initial fill and allow no more than a

3-day supply. If a claim has been filled for the member for the same medication in the previous 60 days, then the claims processing system will allow the claim to process for up to a 30-day supply; however, the claim will be subject to all limitations and restrictions including, but not limited to, early refills and quantity limits.

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, Utah Department of Health and Utah Medical Association (2018)

Acute Pain: When opioids are indicated for the treatment of acute pain, prescribe immediate-release/short-acting (IR/SA) opioids. Extended-release/long-acting (ER/LA) opioids, including methadone, should rarely, if ever, be prescribed for acute pain, including post-operative pain. When opioid medications are prescribed for treatment of acute pain, prescribers should prescribe the lowest effective dose and no more than the number needed for the usual duration of pain associated with that condition, usually 3-5 days and rarely more than seven days. Utah law states, "an opiate…issued for an acute condition shall be completely or partially filled in a quantity not to exceed a seven-day supply as directed on the daily dosage rate of prescription."

Chronic Pain: An opioid trial should begin with immediate-release/short-acting (IR/SA) opioid medication. ER/LA opioids should be reserved for severe continuous pain and should be considered only for patients who have received IR/SA opioids daily for at least one week. Initial treatment should not use methadone, fentanyl, or the combination of opioids and benzodiazepines. When opioids are prescribed for the treatment of chronic pain, prescribers should prescribe the lowest effective dose. Prescribers should use caution when prescribing opioids at any dosage, should carefully re-assess evidence of individual benefits and risks when increasing dosage to > 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to > 90 or carefully justify a decision to titrate dosage to > 90 MME/day.

Vermont

An Act relating to Combating Opioid Abuse in Vermont, Act 173 (2016)

General Limits: Directs the Commissioner of Health to adopt rules on prescribing opioids after consulting with the Council, which may include number and time limits on pills prescribed, including a maximum number of pills to be prescribed following minor medical procedures.

Implemented by: Rules Governing the Prescribing of Opioids for Pain, Department of Health (2017).

- Initial Prescriptions: The prescription limits for acute pain only apply to the first prescription written for a given course of treatment, and do not apply to renewals or refills.
- General Limits: Establishes various--extremely specific and detailed--limits for opioids when used to treat minor pain, moderate pain, severe pain, and extreme pain.

Vermont Medicaid (2017)

General Limits: Vermont Medicaid updated the opioid quantity limits for their Fee-for-Service program in 2017.

Virginia

Virginia Department of Medical Assistance Services (Medicaid) (2016)

General Limits: Virginia Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Updates were also made to opioid quantity limits.

Regulations Governing Prescribing of Opioids and Buprenorphine, Department of Health Professions (2017)

Acute Pain: Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply, with exceptions. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days, with exceptions. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

Chronic Pain: In initiating and treating with an opioid, the practitioner shall, among other things:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;
2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.
3. Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

Virginia Department of Medical Assistance Services (Medicaid) (2017)

General Limits: Virginia Medicaid made updates related to opioid quantity limits in their Fee-for-Service program in 2017.

Washington

Concerning opioid treatment programs, Chapter 297 (2017)

General Limits: Requires the various licensing boards and commissions to adopt rules establishing requirements for prescribing opioid drugs. Such rules may contain exemptions based on the amount of opioids prescribed (among other things). In developing the rules, the commission must consider the agency medical directors' group and centers for disease control guideline.

Implemented by:

WSR 18-20-085, Podiatric Medical Board (2018)

WSR 18-20-086, Nursing Care Quality Assurance Commission (2018)

WSR 18-20-087, Board of Osteopathic Medicine and Surgery (2018)

WSR 19-02-043, Dental Quality Assurance Commission (2018)

Acute Pain: If the prescriber prescribes opioids for effective pain control for acute nonoperative pain, such prescription must not be in a greater quantity than needed for the expected duration of pain severe enough to require opioids. A three-day supply or less will often be sufficient; more than a seven-day supply will rarely be needed. The prescriber shall not prescribe beyond a seven-day supply without clinical documentation in the patient record to justify the need for such a quantity.

If the prescriber prescribes opioids for effective pain control for acute perioperative pain, such prescription must not be in a greater quantity than needed for the expected duration of pain severe

enough to require opioids. A three-day supply or less will often be sufficient; more than a seven-day supply will rarely be needed. The prescriber shall not prescribe beyond a fourteen-day supply from the time of discharge without clinical documentation in the patient record to justify the need for such a quantity. For more specific best practices, the prescriber may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative.

Subacute Pain: If the prescriber prescribes opioids for effective pain control, such prescription shall be in no greater quantity than needed for the expected duration of pain severe enough to require opioids. During the subacute phase, the prescriber shall not prescribe beyond a fourteen-day supply of opioids without clinical documentation to justify the need for such a quantity.

Chronic Pain: The mandatory consultation threshold is one hundred twenty milligrams MED per day. Unless the consultation is exempt under WAC 246-922-740 or 246-922-745, a podiatric physician who prescribes a dosage amount at or above the mandatory consultation threshold must comply with the pain management specialist consultation requirements described in WAC 246-922-750.

HCA to implement opioid clinical policy for Apple Health (Medicaid) on Nov. 1, Washington State Health Care Authority (Medicaid, Public Employees) (2017)

Acute Pain: Limits the quantity of opioids that can be prescribed to opiate naïve patients for noncancer pain. The limits for new opioid prescriptions will be: No more than 18 doses (approximately a 3-day supply) for patients age 20 or younger; and, No more than 42 doses (approximately a 7-day supply) for patients age 21 or older. Prescribers can override these limits if they feel it is medically necessary, by typing “Exempt” in the text of the prescription.

Chronic Pain: At the point of transition from acute to chronic opioid treatment, defined as six weeks of therapy, the policy requires prescribers to attest they are following best practices for opioid prescribing. Pharmacies should not turn away patients with prescriptions above the quantity limits. Prescriptions that reject for being over the allowed limit for acute use, can be dispensed as a partial fill up to that limit. Alternatively, pharmacies can call prescribers to see if an exemption or other override is appropriate. Long-acting opioids are only approved when one of these situations exists: The patient is grandfathered (already on chronic opioids before November 1, 2017); The patient is undergoing active cancer treatment; The patient is in hospice, palliative care, or end-of-life care; Prescriber has followed the EXEMPT process; Prescriber has obtained prior authorization following 42 days of therapy.

Dental Guideline on Prescribing Opioids for Acute Pain Management, Agency Medical Directors’ Group, Dr. Robert Bree Collaborative (2017)

Dentists: Sets various opioid limits depending upon the type of procedure and expected recovery time. For expected rapid recovery, if opioids are necessary, prescribe ≤3 days (e.g., 8 to 12 pills) of short-acting opioids in combination with an NSAID or acetaminophen for severe pain. Prescribe the lowest effective dose strength. For expected medium term recovery, if opioids are necessary, prescribe ≤7 days (e.g., up to 42 pills) of short-acting opioids for severe pain, and prescribe the lowest effective dose strength. For expected longer term recovery, if opioids are necessary, prescribe ≤14 days of short-acting opioids for severe pain. Prescribe the lowest effective dose strength. Patients should be re-evaluated before refilling opioids and tapered off opioids within 6 weeks after surgery.

Washington Emergency Department Opioid Prescribing Guidelines, Department of Health, Emergency Department Opioid Abuse Work Group (2018)

> Acute Pain: Prescriptions for opioid pain medication from the ED for acute injuries, such as fractured bones, in most cases should not exceed 30 pills.
>
> Chronic Pain: Prescribing pain medicine for chronic pain from the ED should be limited to only the immediate treatment of acute exacerbations of pain associated with objective findings of uncontrolled pain. Discourages use of intravenous and intramuscular opioids for exacerbations of chronic pain. ED providers should not provide replacements for lost controlled substance prescriptions. Methadone and long-acting opioids should not be used in the ED. EDs are encouraged to use the Emergency Department Information Exchange. Physicians should send patient pain agreements to the local EDs and work to include a plan for pain treatment in the ED. Prescriptions for controlled substances from the ED should state that the patient is required to provide government issued photo identification. For exacerbations of chronic pain, the emergency medical provider should contact the patient's primary opioid prescriber or pharmacy. Emergency medical providers should only prescribe enough pills to last until the office of the patient's primary opioid prescriber opens.

Prescribing Opioids for Postoperative Pain – Supplemental Guidance, Agency Medical Directors' Group, Dr. Robert Bree Collaborative (2018)

> Initial Prescriptions: Initial prescriptions shall not exceed two weeks.

West Virginia

West Virginia Medicaid (2016)

> General Limits: West Virginia Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016.

Clarifying that optometrists may continue to exercise the same prescriptive authority which they possessed prior to hydrocodone being reclassified, Chapter 183 (2016)

> Optometrists: Optometrists may not use Schedule II controlled substances. However, an oral pharmaceutical certified licensee may prescribe hydrocodone and hydrocodone containing drugs for a duration of no more than three days.

West Virginia Medicaid (2017)

> General Limits: West Virginia Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2017.

Opioid Reduction Act, Chapter 46 (2018)

> General Limits: When issuing a prescription for an opioid to an adult patient seeking treatment in an emergency room for outpatient use, a health care practitioner may not issue a prescription for more than a four-day supply. When issuing a prescription for an opioid to an adult patient seeking treatment in an urgent care facility setting for outpatient use, a health care practitioner may not issue a prescription for more than a four-day supply: Provided, that an additional dosing for up to no more than a seven-day supply may be permitted, but only if the medical rational for more than a four-day supply is documented in the medical record. A health care practitioner may not issue an opioid prescription to a minor for more than a three-day supply and shall discuss with the parent or guardian of the minor the risks associated with opioid use and the reasons why the prescription is

necessary. No medication listed as a Schedule II controlled substance may be prescribed by a practitioner for greater than a 30-day supply; however, two additional prescriptions, each for a 30-day period for a total of a 90-day supply, may be prescribed if the practitioner accesses the West Virginia Controlled Substances Monitoring Program Database as required.

Initial Prescriptions: A practitioner may not issue an initial opioid prescription for more than a seven-day supply. The prescription shall be for the lowest effective dose which in the medical judgement of the practitioner would be the best course of treatment for this patient and his or her condition.

Dentists: Dentists may not issue opioid prescriptions for more than a three-day supply at any time.

Optometrists: An optometrist may not issue an opioid prescription for more than a three-day supply at any time.

Wisconsin

Wisconsin Medicaid (2017)

General Limits: Wisconsin Medicaid updated their requirements related to opioid quantity limits in their Fee-for-Service program in 2017.

Opioid Prescribing Guideline, Wisconsin Medical Examining Board (2018)

General Limits: When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

Acute Pain: In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 5 days' worth. When prescribing opioids, physicians should consider writing two separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Initial dose titration for both acute and chronic pain should be with short-acting opioids.

Chronic Pain: Evidence for opioids is poor. There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior. The use of oxycodone is discouraged. The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long- acting agents for a majority of the daily dose. Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented. Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and appropriate documentation to support such dosing should be present on the chart.

Wyoming

Wyoming Medicaid (2016)

General Limits: Wyoming Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016.

Treatment Guidelines – Chronic Non-Malignant Pain, Department of Workforce Services, Division of Workers' Compensation (2017)

Chronic Pain: The Division has approved oxycodone/APAP, hydrocodone/APAP, Butrans™ patch, oxycodone APAP, OxyContin™, morphine, oxymorphone, Kadian™, and the analgesic tramadol for the treatment of chronic pain. All transmucosal and transdermal immediate release Duragesic™ (fentanyl) agents, Suboxone/Subutex, and Demerol™ will be denied for chronic nonmalignant pain relief. Transcutaneous opioid analgesics will be considered only if there is documentation that the disorder prevents adequate oral dosing. Recommends consulting with a pain specialist if a dose is in excess of 120 MME/day, for patients who have not improved after 6 months, for those with a history of chemical dependency, etc.

Wyoming Medicaid (2017)

General Limits: Wyoming Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2017.

2.3 Extended-Release/Long-Acting Opioid Policies

In 2012, the FDA approved the initial ER and LA Opioid Analgesics Risk Evaluation and Mitigation Strategy, most recently updated in 2018. The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications.

From 2016-2018, 28 policies in 17 states and agencies in the U.S. government have implemented policies specifically related to the use of ER/LA opioid analgesics.

United States	Maryland	Pennsylvania
Arizona	Massachusetts	Tennessee
Colorado	Nebraska	Utah
Illinois	New Hampshire	Virginia
Indiana	Oklahoma	Washington
Louisiana	Oregon	Wisconsin

United States

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, Centers for Disease Control and Prevention (2016)

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

VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain (2017)

Relevance to ER/LA Opioids: Recommends against prescribing long-acting opioids for acute pain, as an as-needed medication, or on initiation of long-term opioid therapy. If take-home opioids are prescribed, recommends that immediate-release opioids are used at the lowest effective dose with opioid therapy reassessment no later than 3-5 days to determine if adjustments or continuing opioid therapy is indicated.

Arizona

Arizona Opioid Prescribing Guidelines, Arizona Department of Health Services (2018)

Relevance to ER/LA Opioids: Do not use long-acting opioids for the treatment of acute pain.

Colorado

Opioid Policy Change FAQs for Prescribers, Health First Colorado (Medicaid), Department of Health Care Policy and Financing (2017)

Relevance to ER/LA Opioids: All long-acting opioids will require a prior authorization for opioid naïve patients.

Illinois

Fentanyl products non-preferred in Illinois Medicaid, Illinois Department of Healthcare and Family Services (2016)

Relevance to ER/LA Opioids: As a result of safety concerns, effective August 15, 2016, fentanyl transdermal patches will require prior approval for all fee-for-service HFS participants. Long-acting opioid therapy options on the Preferred Drug List are extended-release morphine oral tablets and Embeda™ capsules.

Indiana

844 IAC 5-6-3 Triggers for imposition of requirements; exemptions, Medical Licensing Board of Indiana (2016)

Relevance to ER/LA Opioids: Under certain circumstances, disallows an extended release opioid that is not in an abuse-deterrent form for which there is an FDA-approved abuse deterrent form available.

Louisiana

HEALTH/ACC INSURANCE: Prohibits a health insurance issuer from denying a nonopioid prescription in favor of an opioid prescription, Act 372 (2018)

Relevance to ER/LA Opioids: When an opioid is deemed necessary and prescribed, an insurer may not substitute an alternative that would require an extended release medication that does not have abuse deterrent properties for a prescription that was intended to be abuse deterrent.

Maryland

Opioid Prescribing Guidance and Policy, Maryland Medicaid (2017)

Relevance to ER/LA Opioids: Requires prior authorization every six months for long acting opioids.

Massachusetts

An Act Relative to Substance Use, Treatment, Education, and Prevention, Chapter 52 (2016)

Relevance to ER/LA Opioids: Prior to issuing an extended-release long-acting opioid in a non-abuse deterrent form for outpatient use for the first time, a practitioner shall (i) evaluate the patient's current condition, risk factors, history of substance abuse, if any, and current medications; and (ii) inform the patient and note in the patient's medical record that the prescribed medication, in the prescriber's medical opinion, is an appropriate course of treatment based on the medical need of the patient. In the event that an ER/LA opioid is used during the course of long-term pain management, the practitioner shall enter into a written pain management treatment agreement with the patient.

Opioid/Controlled Substance Protocol, Department of Industrial Accidents (2016)

Relevance to ER/LA Opioids: Disallows initiating treatment of acute pain with long acting or extended release opioids.

Nebraska

Nebraska Pain Management Guidance Document, Department of Health and Human Services (2017)

Relevance to ER/LA Opioids: For most injuries and minor procedures (e.g., dental extraction, sports injuries), prescribe no more than a three-day supply or 10 doses of a short-acting opioid. For more severe injuries (e.g., fractures), prescribe no more than a seven-day supply of a short-acting opioid. Do not prescribe extended-release opioids for acute pain.

New Hampshire

NH Fee-for-Service (FFS) Medicaid Preferred Drug List (PDL)/Clinical Prior Authorization Updates/ Web Portal Information/E-mail Notifications, New Hampshire Medicaid (2018)

Relevance to ER/LA Opioids: Effective December 1, 2018, revisions were made to the clinical prior authorization rules applying to long acting opioid analgesics.

Oklahoma

Oklahoma Opioid Prescribing Guidelines, Department of Health (2017)

Relevance to ER/LA Opioids: Long-acting or extended-release opioids should not be prescribed for acute pain. For chronic pain, long-acting or extended-release opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.

Oregon

Opioid Prescribing for Conditions of the Back and Spine, Health Evidence Review Commission, Oregon Health Authority (Medicaid) (2016)

Relevance to ER/LA Opioids: For acute pain (first 6 weeks) and for pain after 6 weeks and up to 90 days, opioid treatment is available with short-acting opioids only. ER/LA opioids are not covered by Oregon Medicaid for patients with back and spine conditions.

Oregon Chronic Opioid Prescribing Guidelines (2017-2018), Oregon Health Authority, Public Health Division (2017)

Relevance to ER/LA Opioids: Recommends the use of immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

Oregon Acute Opioid Prescribing Guidelines, Oregon Health Authority (Medicaid) (2018)

Relevance to ER/LA Opioids: Recommends the use of short-acting opioids instead of extended-release/long-acting (ER/LA) opioids.

Pennsylvania

Geriatric Pain, Opioid Use and Safe Prescribing, Department of Health (2016)

Relevance to ER/LA Opioids: Guidelines recommend avoiding the use of long-acting opioids in older adults.

Safe Prescribing of Opioids in Pediatric and Adolescent Populations, Department of Health (2017)

Relevance to ER/LA Opioids: Short-acting opioids should be used first. Longer-acting opioids should be avoided, as they pose greater safety and misuse risks and are rarely needed.

Treatment of Pain in an Emergent Setting, Department of Health (2018)

Relevance to ER/LA Opioids: Long-acting or controlled-release opioids (such as extended-release oxycodone, fentanyl patches, extended-release morphine, and methadone) should not be prescribed from the emergency department.

Tennessee

TennCare will begin implementation of a Morphine Milligram Equivalent (MME) edit, TennCare (Medicaid) (2017)

Relevance to ER/LA Opioids: Effective September 5, 2017, TennCare will begin implementation of a Morphine Milligram Equivalent (MME) edit for all agents in the Short-Acting Narcotic and Long-Acting Narcotic Classes of the PDL. The edit will accumulate MME for all short-acting narcotics and long-acting narcotics a patient is currently receiving and will deny claims for patients prescribed a cumulative daily MME of greater than 200 MME. Prior authorization will be required for patients exceeding the daily MME limit.

Changes to Prior Authorization Criteria and quantity limits for the Preferred Drug List (PDL), TennCare (Medicaid) (2018)

Relevance to ER/LA Opioids: All long-acting narcotics require prior authorization.

Utah

Utah Medicaid Provider Manual, Drugs with Quantity Limits (2018)

Relevance to ER/LA Opioids: In addition to the drug-specific limits (found within the provider manual), cumulative limits for any combination of long-acting opioids is 90 tablets per 30 days (independent of short-acting and/or opioid/APAP combination product accumulation). The cumulative limit may be overridden if the prescriber writes a valid ICD code for cancer on the face of the prescription. Initial prescriptions for over a 7-day supply require prior authorization. Fentanyl is mutually exclusive with methadone and all other long acting opioids. Methadone is mutually exclusive with fentanyl and all other long acting opioids. All other opioids are not mutually exclusive with each other.

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, Utah Department of Health (2018)

Relevance to ER/LA Opioids: Recommends the use of short acting opioids rather than long acting opioids. ER/LA opioids should be reserved for severe continuous pain and should be considered

only for patients who have received IR/SA opioids daily for at least one week. Initial treatment should not use methadone, fentanyl, or the combination of opioids and benzodiazepines.

Virginia

Regulations Governing Prescribing of Opioids and Buprenorphine, Department of Health Professions (2017)

Relevance to ER/LA Opioids: For the treatment of acute pain, allows for only a 7-day supply or less (for up to only 14 days total) of short-acting opioids. Long-acting opioids are disallowed for treatment of acute pain.

Washington

Dental Guideline on Prescribing Opioids for Acute Pain Management, Agency Medical Directors' Group, Dr. Robert Bree Collaborative (2017)

Relevance to ER/LA Opioids: If opioids are necessary, only recommends short-acting opioids.

HCA to implement opioid clinical policy for Apple Health (Medicaid) on Nov. 1, Washington State Health Care Authority (Medicaid, Public Employees) (2017)

Relevance to ER/LA Opioids: Long-acting opioids are only approved when one of these situations exists: The patient is grandfathered (already on chronic opioids before November 1, 2017); The patient is undergoing active cancer treatment; The patient is in hospice, palliative care, or end-of-life care; Prescriber has followed the EXEMPT process; Prescriber has obtained prior authorization following 42 days of therapy.

Washington Emergency Department Opioid Prescribing Guidelines, Department of Health, Emergency Department Opioids Abuse Work Group (2018)

Relevance to ER/LA Opioids: Long-acting opioids should not be used in the emergency department.

Wisconsin

Opioid Prescribing Guideline, Wisconsin Medical Examining Board (2018)

Relevance to ER/LA Opioids: Initial dose titration for both acute and chronic pain should be with short-acting opioids. Recommends avoiding the use of long-acting opioids for patients being treated for acute or chronic pain who are not in active cancer treatment, palliative care, or end-of-life care. For chronic therapy, it would be appropriate once an effective dose is established to consider long- acting agents for a majority of the daily dose.

2.4 Pain Specialists and Pain Management Clinics: Referrals, Consultations, and Required Practices

According to FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain, health care providers should be knowledgeable about when referral to a pain management specialist is indicated.

From 2016-2018, 28 policies in 18 states and from the CDC have implemented policies related to: 1) the qualifications related to medical directors of pain clinics and/or requirements for those clinics; and/or 2) required or recommended referrals to, and consultations with, pain specialists.

United States
Alabama
Arizona
Arkansas
Colorado
Florida
Georgia
Kansas
Nevada
New Hampshire
North Dakota
Ohio
Pennsylvania
Tennessee
Vermont
Washington
West Virginia
Wisconsin
Wyoming

United States

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, Centers for Disease Control and Prevention (2016)

> Relevance to Pain Specialists: Clinicians should avoid increasing opioid dosages to ≥90 MME/day or should carefully justify a decision to increase dosage to ≥90 MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at ≥90 MME/day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management with the patient, consider working with patients to taper opioids to a lower dosage or to taper and discontinue opioids, and consider consulting a pain specialist. Clinicians should maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate and consider consulting a pain specialist as needed to assist with pain management.

Alabama

540-x-19-.05 Training Requirements; Medical Director; Other Requirements, Alabama Board of Medical Examiners (2016)

> Relevance to Pain Specialists: Revises training/education/qualification requirements related to medical directors of pain management clinics.

Arizona

Controlled substances; dosage limit, Chapter 243 (2018)

> Relevance to Pain Specialists: For cases in which the physician believes more than 90 MME/day of opioid is needed, this bill adds (in addition to consultation with a board-certified pain specialist) an option for the physician to consult with an opioid assistance referral call service. Permits the Arizona Poison Control System to provide opioid assistance and referral call services. Allows a registered nurse practitioner who has advanced pain certification to serve as the medical director of a pain management clinic.

Controlled substances; regulation; appropriation, Chapter 1, First Special Session (2018)

Relevance to Pain Specialists: Directs a health professional who believes a patient requires more than 90 MMEs per day to consult with a board-certified pain specialist.

Arkansas

Regulation No. 19, Pain Management Programs, Arkansas Medical Board (2016)

Relevance to Pain Specialists: Establishes requirements for physicians operating pain management programs. Sets rules related to education and qualifications for physicians managing Chronic Pain Management Programs.

Colorado

Health First Colorado Benefits and Services, Health First Colorado (Medicaid), Department of Health Care Policy and Financing (2018)

Relevance to Pain Specialists: Beginning November 15, 2018, the total daily limit of MME will be decreasing from 250 MME per day, to 200 MME per day. If a prescription puts a member above 200 MME per day, further approvals will be required to allow time for the prescriber to work with the member to safely taper opioid doses down to 200 MME, while making sure the member has adequate pain control. In some circumstances, a consultation with the Department's pain management physician may be required.

Florida

Access to Health Care Services, Chapter No. 2016-224 (2016)

Relevance to Pain Specialists: Adds physicians who are board-eligible or board-certified with the American Board of Interventional Pain Physicians and the American Association of Physician Specialties to the list of those who are exempted from referring their patients with signs of substance use disorder to a specialist.

Behavioral Health Workforce, Chapter No. 2016-231 (2016)

Relevance to Pain Specialists: Adds physicians who are board-eligible or board-certified with the American Board of Interventional Pain Physicians and the American Association of Physician Specialties to the list of those who are exempted from referring their patients with signs of substance use disorder to a specialist.

Rule: 64B5-17.0045 Standards for the Prescribing of Controlled Substances for the Treatment of Acute Pain, Board of Dentistry (2018)

Relevance to Pain Specialists: The dentist shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Georgia

Pain Management Clinics; health care professionals who must be on-site; revise a provision, Act 237 (2017)

Relevance to Pain Specialists: Revises a provision relating to the health care professionals who must be on-site at a pain management clinic in order for the clinic to provide medical treatment or services.

Kansas

Joint Policy Statement from the Kansas Boards of Healing Arts, Nursing and Pharmacy on the Use of Controlled Substances for the Treatment of Chronic Pain (2016)

> Relevance to Pain Specialists: The health care provider should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with co-morbid psychiatric disorders and those who are at risk for misuse or diversion of their medications. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder can be challenging, and extra care, monitoring, documentation, and consultation with or referral to an expert(s) in the management of such patients may be appropriate. In addition, many patients with chronic pain may benefit from referral to providers with other areas of expertise, to develop a multimodality approach to pain control.

Nevada

Medicaid Services Manual, Division of Health Care Financing and Policy (2016)

> Relevance to Pain Specialists: Opioids are subject to prior authorization, step therapy, clinical criteria, and quantity limits. Opioids are only covered without prior authorization for initial prescriptions of 7 days or less, for a total of 13 7-day prescriptions in any rolling 12-month period, and for prescriptions for less than 60 MME/day. To exceed the quantity limits, the patient must have chronic pain that cannot be controlled through use of non-opioids, the lowest effective dose must be used, and a pain contract must be on file. Exceptions to the limits exist for cancer-related pain, post-surgical pain, palliative and long-term care, those with HIV/AIDS, and prescriptions written by or in consultation with a pain specialist.

New Hampshire

Med 502 Opioid Prescribing, Board of Medicine (2016)

> Relevance to Pain Specialists: A prescriber of opioids must document the consideration of a consultation with an appropriate specialist when the patient receives a 100 MME/day dose for longer than 90 days.

Nur 502 Opioid Prescribing, Board of Nursing (2016)

> Relevance to Pain Specialists: A prescriber of opioids must document the consideration of a consultation with an appropriate specialist when the patient receives a 100 MME/day dose for longer than 90 days.

North Dakota

North Dakota Tri-Regulator Position Statement on Opioid Prescribing/Dispensing, Boards of Medicine, Nursing and Pharmacy (2018)

> Relevance to Pain Specialists: In order to balance the risk of potential misuse with legitimate pain control, all healthcare professionals should, as their scope of practice allows, uphold their professional obligation to pursue educational opportunities to further their knowledge on standards of care and evidence-based approaches to pain management including, but not limited to, the CDC opioid prescribing guidelines (2016). They should also refer patients to other providers, such as treatment specialists, when appropriate.

Ohio

Chapter 4731-11 Controlled Substances, State Medical Board (2018)

> Relevance to Pain Specialists: Limits opioids in excess of 120 MME/day without a recommendation from a board-certified pain specialist.

Pennsylvania

Geriatric Pain, Opioid Use and Safe Prescribing, Department of Health (2016)

> Relevance to Pain Specialists: Rarely are doses of oral morphine sulfate equivalents of 60 mg a day or more necessary. If dosages of oral morphine sulfate equivalents reach 100 mg daily, then tapering or referral to a pain specialist should be considered.

Tennessee

Relative to Qualifications for a Pain Management Specialist, Pub. Ch. 829 (2016)

> Relevance to Pain Specialists: Specifies that, on and after July 1, 2016, a new applicant may only qualify as a pain management specialist through board certification by the American board of interventional pain physicians (ABIPP) by passing parts 1 and 2 of its examination, and holding an unencumbered Tennessee license, and maintaining the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status.

Physicians and Surgeons - As enacted, revises certain requirements governing pain management clinics and pain management specialists, Pub. Ch. 210 (2017)

> Relevance to Pain Specialists: Substitutes existing language that read "pain medicine" with "pain medicine or pain management." Amends qualifications related to who may practice interventional pain management.

As enacted, makes various changes to the requirements for prescribing, dispensing, and reporting of opioids, Pub. Ch. 1039 (2018)

> Relevance to Pain Specialists: As with prior to the passage of Public Chapter 1039, a healthcare practitioner can treat a patient with a three-day supply of an opioid at a total dosage of 180 morphine milligram equivalent (MME) total dosage without any new requirements. A healthcare practitioner may treat a patient with more than a three-day supply of an opioid if the healthcare practitioner treats the patient with no more than one (1) prescription for an opioid per encounter and meets certain evaluation and documentation requirements. If a healthcare practitioner treats a patient with more than a three-day supply of an opioid, the healthcare practitioner may treat the patient with no more than a ten-day supply and with a dosage that does not exceed a total of a five hundred (500) morphine milligram equivalent dose. In rare cases, a healthcare practitioner may treat a patient with up to a twenty-day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose. Includes exemptions, including exemptions specific to pain specialists.

Vermont

Rule Governing the Prescribing of Opioids for Pain, Department of Health (2017)

> Relevance to Pain Specialists: Requires consultation with, or referral to, a pain specialist at certain times during treatment.

Washington

WSR 18-20-085, Podiatric Medical Board (2018)

Relevance to Pain Specialists: The mandatory consultation threshold is one hundred twenty milligrams MED per day. Unless the consultation is exempt under WAC 246-922-740 or 246-922-745, a podiatric physician who prescribes a dosage amount at or above the mandatory consultation threshold must comply with the pain management specialist consultation requirements described in WAC 246-922-750.

WSR 18-20-086, Nursing Care Quality Assurance Commission (2018)

Relevance to Pain Specialists: The mandatory consultation threshold is one hundred twenty milligrams MED per day. Unless the consultation is exempt under WAC 246-922-740 or 246-922-745, a podiatric physician who prescribes a dosage amount at or above the mandatory consultation threshold must comply with the pain management specialist consultation requirements described in WAC 246-922-750.

WSR 18-20-087, Board of Osteopathic Medicine and Surgery (2018)

Relevance to Pain Specialists: The mandatory consultation threshold is one hundred twenty milligrams MED per day. Unless the consultation is exempt under WAC 246-922-740 or 246-922-745, a podiatric physician who prescribes a dosage amount at or above the mandatory consultation threshold must comply with the pain management specialist consultation requirements described in WAC 246-922-750.

WSR 19-02-043, Dental Quality Assurance Commission (2018)

Relevance to Pain Specialists: The mandatory consultation threshold is one hundred twenty milligrams MED per day. Unless the consultation is exempt under WAC 246-922-740 or 246-922-745, a podiatric physician who prescribes a dosage amount at or above the mandatory consultation threshold must comply with the pain management specialist consultation requirements described in WAC 246-922-750.

West Virginia

Opioid Reduction Act, Chapter 46 (2018)

Relevance to Pain Specialists: Defines “pain specialist” to mean a practitioner who is board certified in pain management or a related field. At the time of the issuance of the third prescription opioid, the practitioner shall consider referring the patient to a pain clinic or a pain specialist. The practitioner shall discuss the benefits of seeking treatment through a pain clinic or a pain specialist and provide him or her with an understanding of any risks associated by choosing not to pursue that as an option. If the patient declines to seek treatment from a pain clinic or a pain specialist and opts to remain a patient of the practitioner, the practitioner must follow certain statutory requirements regarding patient evaluation and documentation. Contains exceptions.

Wisconsin

Pain clinic certification and requirements, granting rule-making authority, and providing a penalty, Act 265 (2016)

Relevance to Pain Specialists: Defines “Pain Clinic” and sets requirements for the operation of such clinics. Adopts requirements related to medical directors, payment methods, direct dispensing, and multiple locations.

Wyoming

Treatment Guidelines - Chronic Non-Malignant Pain, Department of Workforce Services, Division of Workers' Compensation (2017)

> Relevance to Pain Specialists: Recommends consulting with a pain specialist if a dose is in excess of 120 MME/day, for patients who have not improved after 6 months, for those with a history of chemical dependency, etc.

2.5 Policies Directly Relevant to FDA

2.5.1 Adopted, 2016-2018

Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Public Law 114-145 (2016)

> Relevance to FDA: Requires FDA, SAMHSA, AHRQ, and CDC, in coordination with DEA, to report to Congress on: obstacles to legitimate patient access to controlled substances; diversion of controlled substances; how agency and pharmaceutical manufacturer collaboration can address these issues; enhancements to PDMPs; the availability of and gaps in medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing; and, improvements to prescription opioid reporting requirements to that the Public and Congress have more information re: opioids prescribed annually, dispensing, outliers and trends.

Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use, National Academies of Sciences, Engineering, and Medicine (NASEM), Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse (2017)

> Relevance to FDA: This report is a result of the U.S. Food and Drug Administration (FDA) asking the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic. The resulting report states that a sustained, coordinated effort is necessary to stem the still-escalating prevalence of opioid-related harms, including a culture change in prescribing for chronic noncancer pain, aggressive regulation of opioids by the FDA, and multi-pronged policies by state and local governments. However, the committee also counsels against arbitrary restrictions on access to opioids by suffering patients whose health care providers have prescribed these drugs responsibly. Major points relate to: restricting the lawful supply of opioids, influencing prescribing practices (use of alternatives, use of PDMP), reducing demand, and reducing harm.

Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act, Public Law 115-271 (2018)

> Relevance to FDA: Requires the Food and Drug Administration (FDA) to develop guidance regarding alternative methods for collecting data on opioid sparing (i.e., the use of drugs that reduce pain while also allowing reduced use or avoidance of oral opioids) and using such information in product labels.

FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain, Food and Drug Administration (2018)

> Relevance to FDA: Revised FDA REMS related to opioids. Issued a number of updated/new strategies, including modifications to REMS programs that require, for example: training on non-opioid pain alternatives; training for prescribing related to immediate-release formulations of opioid drugs; and, broader training that covers more health care providers who help manage patients with pain. Additionally, there is a plan to leverage nutrition and diet as ways to reduce morbidity and

mortality from disease; FDA has identified dietary factors as one contributor to patients' pain experience.

2.5.2 Proposed, 2019

Changing the Culture of the FDA Act, S 417 (2019)

Relevance to FDA: The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall amend the mission statement of the Food and Drug Administration to include the following statement: "The FDA is also responsible for protecting the public health by strongly considering the danger of addiction and overdose death associated with prescription opioid medications when approving these medications and when regulating the manufacturing, marketing, and distribution of opioid medications."

FDA Accountability for Public Safety Act, S 418 (2019)

Relevance to FDA: A bill to establish procedures regarding the approval of opioid drugs by the Food and Drug Administration. Before approving any opioid against the recommendation of the advisory committee, the FDA must report to Congress on (1) medical and scientific evidence regarding patient safety that clearly supports the Commissioner's decision to approve the opioid drug against the recommendation of the advisory committee, and (2) a disclosure of any potential conflicts of interest that may exist regarding any official of the Food and Drug Administration who was involved in the decision to approve the drug prior to the Commissioner's final decision under subsection. Such drug shall not be introduced or delivered for introduction into interstate commerce until such report has been submitted.

Protecting Americans from Dangerous Opioids Act, S 419 (2019)

Relevance to FDA: To require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved.

2.6 Policies Directly Referring to CDC Guidelines

Since the FDA released the initial ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) in 2012, the CDC released the CDC Guideline for Prescribing Opioids for Chronic Pain (2016). The most recently updated version of the Opioid Analgesic REMS (2018) acknowledges this, stating that health care providers will gain a greater understanding of safe opioid practices by reviewing the CDC guidelines.

The CDC Guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses: 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. The guideline is intended to improve communication between clinicians 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, overdose, and death.

Since the release of the CDC Guideline for Prescribing Opioids for Chronic Pain, 35 policies in 25 states and the District of Columbia (adopted 2016-2019) have directly referred to and/or incorporated the CDC Guideline by reference.

This list does not include policies that merely adopted policies *similar to* the CDC Guideline; the policy had to directly refer to the CDC Guideline to be included.

Alaska	Connecticut	Idaho
Arkansas	District of Columbia	Iowa

Maine	New Mexico	Tennessee
Massachusetts	New York	Utah
Michigan	North Carolina	Vermont
Mississippi	North Dakota	Virginia
Nebraska	Oregon	Washington
New Hampshire	Rhode Island	
New Jersey	South Carolina	

Alaska

Policies and Procedures, Prescribing Controlled Substances, Alaska State Medical Board (2016)

Relevance to CDC Guideline: Updated a previously existing guideline to include the CDC Guideline as an available tool for risk mitigation.

Alaska Department of Health and Social Services, Division of Public Assistance (Medicaid) (2017)

Relevance to CDC Guideline: Alaska Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Arkansas

Arkansas Medicaid (2016)

Relevance to CDC Guideline: Arkansas Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

Connecticut

Husky Health (Medicaid) (2017)

Relevance to CDC Guideline: Connecticut Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

District of Columbia

DC Medicaid (2017)

Relevance to CDC Guideline: DC Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Idaho

Idaho Department of Health and Welfare (Medicaid) (2016)

Relevance to CDC Guideline: Idaho Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

Iowa

Iowa Department of Human Services (Medicaid) (2017)

Relevance to CDC Guideline: Iowa Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Maine

Department of Health and Human Services, MaineCare Services (Medicaid) (2017)

Relevance to CDC Guideline: MaineCare Services expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Massachusetts

Opioid/Controlled Substance Protocol, Department of Industrial Accidents (2016)

Relevance to CDC Guideline: Adopts CDC dosage recommendations that: suggest avoiding increasing the total daily dose of opioids above 90 MME/day; and, offering naloxone when a patient is on doses of over 50 MME/day.

MassHealth (Medicaid) (2016)

Relevance to CDC Guideline: MassHealth has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

Michigan

Michigan Medicaid (2017)

Relevance to CDC Guideline: Michigan Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Mississippi

Mississippi Division of Medicaid (2017)

Relevance to CDC Guideline: Mississippi Division of Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Nebraska

Nebraska Department of Health and Human Services (Medicaid) (2016)

Relevance to CDC Guideline: Nebraska Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

Department of Health and Human Services, Division of Medicaid and Long-Term Care (2017)

Relevance to CDC Guideline: Nebraska Medicaid expressed that they planned to require that Managed Care Organizations adopt the CDC Guideline for Prescribing Opioids for Chronic Pain.

New Hampshire

New Hampshire Medicaid (2017)

Relevance to CDC Guideline: New Hampshire Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Further, they planned to require that Managed Care Organizations adopt the guideline.

New Jersey

Assembly Resolution 157 (2017)

Relevance to CDC Guideline: Urges State Board of Medical Examiners to adopt CDC guideline for prescribing opioids for chronic pain.

New Mexico

2016 Recommendations, Governor's Prescription Drug Misuse and Overdose Prevention and Pain Management Council (2016)

> Relevance to CDC Guideline: Practitioners should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible. Practitioners should adhere to the summary of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline), published in the New England Journal of Medicine, and the complete CDC Guideline, in addition to the one-page summary document. Providers should not use the Guideline to override a provider's judgement regarding a specific patient, but rather to guide skillful and appropriate pain management. The medical provider licensing boards should not use the CDC Guideline to set strict policy or to enforce practice standards.

New York

Department of Health (Medicaid) (2016)

> Relevance to CDC Guideline: New York Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

North Carolina

Policy for the use of opioids for the treatment of pain, North Carolina Medical Board (2017)

> Relevance to CDC Guideline: In order to provide its licensees with guidance that reflects the most current medical and scientific research and recommended practices, the Board has decided to adopt and endorse the CDC Guideline for Prescribing Opioids for Chronic Pain written and maintained by the Centers for Disease Control and Prevention ("CDC").

NC Medicaid and Health Choice (2017)

> Relevance to CDC Guideline: North Carolina Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

North Dakota

North Dakota Tri-Regulator Position Statement on Opioid Prescribing/Dispensing, Boards of Medicine, Nursing and Pharmacy (2018)

> Relevance to CDC Guideline: In order to balance the risk of potential misuse with legitimate pain control, all healthcare professionals should, as their scope of practice allows, uphold their professional obligation to pursue educational opportunities to further their knowledge on standards of care and evidence-based approaches to pain management including, but not limited to, the CDC opioid prescribing guidelines (2016).

Oregon

Oregon Chronic Opioid Prescribing Guidelines (2017-2018), Oregon Health Authority, Public Health Division (2017)

> Relevance to CDC Guideline: Relevance to CDC Guideline: Adopts CDC dosage recommendations that: suggest avoiding increasing the total daily dose of opioids above 90 MME/day; and, offering naloxone when a patient is on doses of over 50 MME/day.

Rhode Island

Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island (216-RICR-20-20-4), Department of Health (2018)

> Relevance to CDC Guideline: Lowers the threshold dosage triggering a naloxone co-prescription threshold from ninety (90) morphine milligram equivalents (MMEs) to more than or equal to fifty (50) MMEs, in line with the Centers for Disease Control and Prevention's recommendations on such prescriptions.

South Carolina

Revised Joint Pain Management Guidelines, Boards of Dentistry, Medical Examiners, Nursing and Pharmacy (2017)

> Relevance to CDC Guideline: Adopts the CDC Guidelines (2016) to the extent the recommendations do not conflict with state law.

Tennessee

TennCare (Medicaid) (2017)

> Relevance to CDC Guideline: TennCare expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017.

Utah

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, Utah Department of Health and Utah Medical Association (2018)

> Relevance to CDC Guideline: When opioids are prescribed for the treatment of chronic pain, prescribers should prescribe the lowest effective dose. Prescribers should use caution when prescribing opioids at any dosage, should carefully re-assess evidence of individual benefits and risks when increasing dosage to > 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to > 90 or carefully justify a decision to titrate dosage to > 90 MME/day. The CDC states that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages below 50 MME/day would likely reduce risk among most patients who would experience fatal overdose at higher prescribed dosages. Utilization of any dose should be based on incremental functional gains.

Concurrent Prescriptions for Benzodiazepines and Opioids, Utah Medicaid (2019)

> Relevance to CDC Guideline: Utah Medicaid is implementing a multi-stage effort to identify and limit the concurrent filling of benzodiazepine and opioid medications. This initiative aims to support CDC guidelines that recommend against combined use, which is associated with risk of fatal overdose. Currently, an automated process monitors and reports when an individual is co-prescribed opioids and benzodiazepines. The peer to peer team will conduct outreach to identified prescribers to alert them of patients receiving concurrent therapy, provide education around concurrent use avoidance, and encourage prescription drug monitoring program (PDMP) use before prescribing a Schedule II controlled substance, in accordance with the Federal HR 6 (2018).

Opioid Policy Changes, Utah Medicaid (2019)

> Relevance to CDC Guideline: Effective July 1, 2019, the higher cumulative daily morphine equivalent dose (MED) threshold for “opioid experienced” individuals will be reduced to 150 MED. This will support ongoing efforts to achieve one common MED standard for all Utah Medicaid members over

time. On January 1, 2019, Utah Medicaid adopted morphine milligram equivalent (MME) and MED methodology for adjudication of all opioid claims for the treatment of non-cancer pain. This initiative was added to existing opioid quantity limits and days' supply limitations to support CDC safety guidance and best practice standards. At that time, two sets of daily MED thresholds were established, a threshold of 90 MED for "opioid naïve" individuals who have not had a claim for an opioid in the last 90 days, and 180 MED for "opioid experienced" individuals who have had a claim for an opioid in the last 90 days.

Vermont

Vermont Medicaid (2016)

Relevance to CDC Guideline: Vermont Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

Virginia

Virginia Department of Medical Assistance Services (Medicaid) (2016)

Relevance to CDC Guideline: Virginia Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program.

Washington

Addressing the Opioid Use Public Health Crisis, Executive Order (2016)

Relevance to CDC Guideline: The state Agency Medical Directors Group (AMDG) shall work with the Bree Collaborative (a health care improvement partnership), Tribal governments, boards and commissions, professional associations, health care systems, insurers, teaching institutions, and others to consider amendments to the state pain guidelines and other training and policy materials, consistent with the 2015 AMDG and the 2016 CDC opioid guidelines, to reduce unnecessary prescribing for acute pain conditions for the general population, especially adolescents.

Concerning opioid treatment programs, Chapter 297 (2017)

Relevance to CDC Guideline: Requires the various licensing boards and commissions to adopt rules establishing requirements for prescribing opioid drugs. Such rules may contain exemptions based on the amount of opioids prescribed (among other things). In developing the rules, the commission must consider the agency medical directors' group and centers for disease control guideline.

Washington State Health Care Authority (Medicaid, Public Employees) (2017)

Relevance to CDC Guideline: Washington Medicaid expressed that they planned to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program in 2017. Further, they planned to require that Managed Care Organizations adopt the guideline.

WSR 18-20-085, Podiatric Medical Board (2018)

Relevance to CDC Guideline: If the podiatric physician prescribes opioids for effective pain control for perioperative pain, such prescription must not be in a greater quantity than needed for the expected duration of pain severe enough to require opioids. A three-day supply or less will often be sufficient; more than a seven-day supply will rarely be needed. The podiatric physician shall not prescribe beyond a seven-day supply without clinical documentation in the patient record to justify the need for such a quantity. For more specific best practices, the podiatric physician may refer to clinical practice guidelines including, but not limited to, those produced by the agency medical directors' group, the Centers for Disease Control and Prevention, or the Bree Collaborative.

Similar Statements re: CDC in:

WSR 18-20-086, Nursing Care Quality Assurance Commission (2018)

WSR 18-20-087, Board of Osteopathic Medicine and Surgery (2018)

WSR 19-02-043, Dental Quality Assurance Commission (2018)

3. OPIOID POLICIES FROM NON-GOVERNMENTAL SOURCES

In its communication, FDA requested:

> *"…a summary of major…policy changes occurring in the last 3 years at the…large healthcare system or payer…level related to OA prescribing (e.g., mandatory PDMP checks, initial days' supply or pill limits, maximum dose limits)."*

In responding to this request, the decision was made to gather information not only from healthcare systems and payers (i.e., health insurers), but also from pharmacy benefit managers (PBMs), who work with health insurers to impose policies regarding coverage of prescription medications, and large chain pharmacies, which also have established policies limiting dispensing of opioid analgesic prescriptions.

After consultation with the contractor, it was decided to seek the requested information from the ten largest health insurers, healthcare systems, and chain pharmacies, and from the five largest PBMs. An internet search was conducted to identify the constituents of each of these groups. In the case of healthcare systems, slightly different lists were generated when measuring by annual revenue and by number of facilities, so the two lists were combined into a larger list of 13 systems.

Obtaining information from these entities proved to be very challenging.

- Each identified entity was contacted through points of contact identified on its website. In most cases, these points of contact were the media relations office, while in a few cases, contact was made through webforms directed to various entities within the companies.
- Additionally, attempts were made to identify the chief medical officers or company officials in substantially similar capacities. LinkedIn profiles were identified for these individuals at 32 of the 40 designated non-governmental entities.
- For each company, media relations personnel email addresses, webforms, or LinkedIn profiles were used to send emails describing the project and requesting that the appropriate individuals respond to discuss the request and provide the information if possible.
- Only a handful of responses to these requests was received. Two of those responses were cooperative and led to conversations with individuals within the companies who provided the requested information. Several respondents indicated that, if FDA requires this information, FDA will need to contact the company to request it. One company official with whom the contractor spoke indicated that it would be extremely unlikely that the requested policy information would be provided, as the companies keep it confidential out of concern about possible law enforcement action related to those policies.
- Additionally, telephone calls were placed to the ten health insurers, requesting to speak with someone in the chief medical officer's office who could provide the requested information. In no case was the contractor able to proceed past the initial point of telephone contact within the company. Given the complete lack of success in pursuing this route of contact, it was abandoned.

In light of the contractor's inability to obtain the requested information directly from the designated companies, it was decided to conduct extensive internet searches to glean whatever information was available

regarding the companies' policies related to opioid prescribing. The information uncovered is summarized below, with specific content of web pages included in the related Appendices. While this method is unlikely to have captured all of the content and nuance of these companies' policies, it nonetheless revealed some consistent themes, summarized below.

3.1 Health Insurance Companies

The ten largest health insurance companies in the United States, surveyed for this report, include the following:

- United Health
- Anthem
- Aetna
- Cigna
- Humana
- Centene
- Molina
- WellCare
- Health Net
- Magellan

Key findings from the survey of health insurance company websites are found in Appendix C. Consistencies across companies included the following:

- Of the nine companies for which meaningful information was available, two specifically mentioned that their policies are intended to be consistent with the CDC guideline
- Three of the nine companies serve primarily Medicaid programs, thus have taken state-specific approaches, although those given as examples are generally consistent with system-wide actions taken by most other health insurers
- Seven of the nine specifically had policies (either generally, or for some states' Medicaid programs) limiting days' supply of short-acting opioids for treatment of acute pain in opioid-naïve patients
- Eight of the nine had prior authorization programs in place for some aspects of opioid prescribing
    - Three specifically listed prior authorization programs for initiation of extended-release opioids, with the requirement that patients use short-acting opioids prior to receiving an extended-release opioid
    - One established a prior authorization program requiring approval for opioid doses exceeding 250 MME per day
- Three mentioned developing educational programs regarding safe opioid prescribing for providers
- One insurer reported having a special program for dentists, with lower dose and days' supply limits for dental patients younger than 19 years of age

Most of these ten insurers appear to be establishing policies generally consistent with the recommendations in the CDC guideline—at least those recommendations involving days' supply of opioids used to treat acute pain and those involving daily dose thresholds. Other CDC guideline recommendations, such as periodic urine drug testing, use of non-pharmacological treatments, and checking PDMP reports, received scant attention.

3.2 Pharmacy Benefit Management Companies

The five largest PBMs in the country have all established policies intended to limit days' supply and/or daily dose of opioids. These companies, surveyed for this report, include the following:

- CVS Health (Caremark)
- Express Scripts
- OptumRX
- Humana
- MedImpact

Key findings from the survey of PBM websites are found in Appendix D. These are among the consistent findings for the five largest PBMs:

- Two of the five specifically mention following the CDC guideline, with one other listing policies that mirror those found in the CDC guideline
- Three limit initial prescriptions for opioid-naïve patients with acute pain to a 7-day supply; the same three also have daily dose limits that can be exceeded only with a prior authorization, and one additional PBM has instituted soft edits based on daily dose and duration of therapy
- Three of the five flag patients meeting certain dose and duration criteria at the pharmacy when the prescription is entered for dispensing
- One also flags patients whose records indicate they have obtained prescriptions from multiple prescribers and/or pharmacies in the previous six months
- One specifically lists different days' supply limits for pediatric patients, while the others are silent on this subject

Overall, there appears to be a high degree of consistency of practice among the PBMs, with variations only in the specific doses and days' supply criteria used to flag a patient or to trigger a hard or soft edit at the pharmacy.

3.3 Healthcare Systems

Efforts to identify the ten largest healthcare systems uncovered differing lists, based on the criteria used. It was decided to include in this analysis all systems found in the top ten lists based on annual revenue and number of facilities. This combined list identified the following 13 systems:

- HCA
- Ascension Health
- Catholic Health Initiatives
- Trinity Health
- Providence St. Joseph Health
- Tenet Healthcare
- Community Health Systems
- University of California Health
- Dignity Health
- Universal Health Services
- Kaiser Permanente
- UPMC Health System
- Carolinas Healthcare System/Atrium Health

Policies established by the largest healthcare systems, as found on their websites, are summarized in Appendix E. Compared to health insurers and PBMs, healthcare systems appear to vary more in their responses to opioid concerns. Below are themes that appeared more than once among the 13 selected companies:

- Six have undertaken educational efforts to inform healthcare providers about safe opioid use and appropriate pain management. Some of these are comprehensive education programs, while others consist of order sets and flags in the electronic health record.
- Two mentioned the use of Enhanced Recovery After Surgery (ERAS) protocols
- Three reported efforts to require and facilitate PDMP checks when prescribing opioids
- Two mentioned efforts to educate patients with respect to pain management expectations in the post-surgery period
- Only two imposed a 7-day supply limit on prescriptions for acute pain in opioid-naïve patients; for one of those, it was unenforceable on a system level, so was regarded as a recommendation
- Three reported efforts to screen prescribing patterns on a system level, to identify practice areas and/or prescribers who are most prolific in their prescribing
- Three of the healthcare systems did not have any information on their websites regarding opioid initiatives

In sum, although most of the largest healthcare systems have opioid stewardship initiatives underway, there is little consistency with regard to the specific practices that are chosen to comprise those initiatives.

3.4 Chain Pharmacies

Following is a list of the ten largest chain pharmacies in the United States. This list formed the basis for surveys conducted and reported below.

- CVS
- Walgreens
- Walmart
- Rite Aid
- Kroger
- Albertsons
- Publix
- Ahold Delhaize
- H-E-B
- Costco

Information regarding opioid policies adopted by these chain pharmacies is found in Appendix F. As is true of PBM policies, there is a fair degree of consistency across the policies adopted by these pharmacies. Commonalities include:

- Five of the ten state on their websites that they are imposing a 7-day limit on prescriptions for acute pain in opioid-naïve patients
- Two report that they are following the CDC guideline, although the policies of an additional three clearly reflect the recommendations found in that guideline
- Three have developed a list of "red flags" that must be cleared before a pharmacist dispenses an opioid prescription to a patient
- Two have a dose limit for prescriptions, and one additional chain requires a prior authorization before proceeding to a dose above an unspecified threshold
- Two have a step therapy protocol in place, requiring use of a short-acting opioid before a patient can receive an extended-release opioid

Taken together with the PBM policies outlined above, it is apparent that a large portion of the pharmacy landscape is characterized by the presence of policies mimicking the CDC guideline recommendations, with a

days' supply limit for opioid naïve patients with acute pain and significant efforts to restrict total daily dose, if not an outright cap on that dose.

4. SUMMARY AND RECOMMENDATIONS

The reviews outlined above, and details contained in the related appendices, indicate that there are many efforts by non-governmental entities underway that limit opioid prescribing in several ways. While state governments in 31 states (as of October 2018, according to the National Council of State Legislatures) have approved legislation or regulations limiting opioid dosing, policies put into place by insurers, PBMs, chain pharmacies, and healthcare systems all can substantially affect prescribing in the remaining 19 states and the District of Columbia. Any evaluation of the impact of the opioid REMS program on opioid prescribing must, therefore, include timely and accurate information about policies established by these non-governmental agencies.

Appendix A: Government Opioid Prescribing Policies

Government Opioid Prescribing Policies

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
United States	Public Law 114-255	HR 34	21st Century Cures Act	Established an account within the Treasury known as the "Account for the State Response to the Opioid Abuse Crisis." Directed the transfer of funds from the general account into this new account in the amounts of $500M/year in 2017 and 2018. Creates the Opioid Grant Program for States addressing substance abuse prevention and treatment, including: improving prescription monitoring programs; implementing prevention activities; training healthcare practitioners in best practices for prescribing opioids and treating pain; supporting access to healthcare services; and, other activities.
United States	Public Law 114-145	S 483	Ensuring Patient Access and Effective Drug Enforcement Act of 2016	Revised and expanded the required elements of an order to show cause issued by the DEA before it denies, revokes, or suspends a registration for a Controlled Substances Act violation. An order to show cause must specifically state the legal basis for the action and notify the registrant of the opportunity to submit a corrective action plan. Further, requires FDA, SAMHSA, AHRQ, and CDC, in coordination with DEA, to report to Congress on: obstacles to legitimate patient access to controlled substances; diversion of controlled substances; how agency and pharmaceutical manufacturer collaboration can address these issues; enhancements to PDMPs; the availability of and gaps in medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing; and, improvements to prescription opioid reporting requirements to that the Public and Congress have more information re: opioids prescribed annually, dispensing, outliers and trends.
United States	Public Law 114-198	S 524	Comprehensive Addiction and Recovery Act of 2016	Expands prevention and educational efforts—particularly aimed at teens, parents and other caretakers, and aging populations—to prevent the abuse of methamphetamines, opioids and heroin, and to promote treatment and recovery. Expand disposal sites for unwanted prescription medications to keep them out of the hands of our children and adolescents. Launch an evidence-based opioid and heroin treatment and intervention program to expand best practices throughout the country. Strengthen prescription drug monitoring programs to help states monitor and track prescription drug diversion and to help at-risk individuals access services. Allows for the partial filling of Schedule II controlled substances (would require DEA to update regulations).
United States	Centers for Disease Control and Prevention	n/a	CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016	Provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. The guideline is intended to improve communication between clinicians 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

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html) with additional tools to guide clinicians in implementing the recommendations.
United States	Centers for Medicare and Medicaid Services	n/a	Opioid Misuse Strategy 2016	CMS effort includes four priority areas: 1) Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion; 2) Expand naloxone use, distribution, and access, when clinically appropriate; 3) Expand screening, diagnosis, and treatment of opioid use disorders, with emphasis on increasing access to medication-assisted treatment; and 4) Increase use of evidence-based practices for acute and chronic pain management.
United States	Centers for Medicare and Medicaid Services	n/a	CMCS Informational Bulletin: Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction	The purpose of this Bulletin is to highlight emerging Medicaid strategies for preventing opioid-related harms. Strategies included relate to: provider education, preferred drug list, clinical criteria, step therapy, prior authorization, quantity limits, drug utilization review, use of PDMPs, patient review and restriction programs, use of naloxone, and coverage for SUD treatment,
United States	Department of Veterans Affairs	n/a	Pain Management Opioid Taper Decision Tool, A VA Clinician's Guide	The Opioid Taper Decision Tool is designed to assist Primary Care providers in determining if an opioid taper is necessary for a specific patient, in performing the taper, and in providing follow-up and support during the taper.
Alabama	Alabama Board of Medical Examiners	n/a	540-x-19-.05 Training Requirements; Medical Director; Other Requirements	Revises training/education/qualification requirements related to medical directors of pain management clinics.
Alaska	CHAPTER 25 SLA 16	SB 74	Medicaid Reform; Telemedicine; Drug Database	Contains a directive to the licensing boards (Medical, Dental, Nursing, Optometry, Pharmacy) to jointly prepare a report that describes recommended guidelines for the prescription of Schedule II controlled substances. Requires licensed prescribers with DEA numbers to register with the PDMP.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Alaska	Division of Corporations, Business, and Professional Licensing Joint Committee on Prescriptive Guidelines	Implementing SB 74 (2016)	Recommending Adoption of Washington's Interagency Guidelines on Prescribing Opioids for Pain	Recommends adoption of the State of Washington's Interagency Guidelines on Prescribing Opioids for Pain, but with one major change: reducing WA's 120 MME/day dosage threshold to a 90 MME/day dosage threshold.
Alaska	Alaska State Medical Board	n/a	Policies and Procedures, Prescribing Controlled Substances	Updated a previously existing guideline to include the CDC guideline as an available tool for risk mitigation.
Arizona	Chapter 211	SB 1283	Controlled Substances Prescription Monitoring Program	Requires PDMP check, at least once per quarter, prior to issuing an opioid analgesic or benzodiazepine listed in Schedule II, III, or IV. Creates exceptions. Promotes PDMP/EHR integration. Requires report from AZ Board of Pharmacy re: the usability, efficiency, and clinical use of the PDMP.
Arizona	Governor, Declaration of Emergency	n/a	Opioid Overdose Epidemic	Directs the Director of the Arizona Department of Health Services to initiate emergency rulemaking with the Arizona Attorney General's Office in order to develop rules for opioid prescribing and treatment within health care institutions, to develop guidelines to educate healthcare providers on responsible prescribing practices; and other related items.
Arkansas	Arkansas Medical Board	n/a	Regulation No. 2	Includes within the definition of “Malpractice”: The prescribing of excessive amounts of controlled substances to a patient including the writing of an excessive number of prescriptions for an addicting or potentially harmful drug to a patient. “Excessive” is defined as the writing of any prescription in any amount without a detailed medical justification for the prescription documented in the patient record. For chronic pain, even with a documented justification, “excessive” means anything above 50 MME/day of opioids unless certain requirements are met related to diagnosis, documentation, PDMP checks, objective findings, and more. For acute pain, “excessive” means any prescription written for more than 7 days.
Arkansas	Arkansas Medical Board	n/a	Regulation No. 19, Pain Management Programs	Establishes requirements for physicians operating pain management programs. Sets rules related to written treatment plans, coordinated care, education and qualifications for physicians managing Chronic Pain Management Programs, PDMP checks, etc.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Arkansas	Arkansas Medicaid	n/a	n/a	Arkansas Medicaid has adopted the CDC Guidelines for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Further, updates were made related to opioid quantity limits and opioid clinical criteria. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
California	Chapter 708	SB 482	Controlled Substances: CURES Database	Require a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance to consult the CURES database to review a patient's controlled substance history no earlier than 24 hours, or the previous business day, before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every 4 months thereafter if the substance remains part of the treatment of the patient. Contains exemptions.
Colorado	Colorado Revised Statutes, 12-36-106	SB 158	Physician Duties Delegated To Physician Assistant	Each prescription for a controlled substance issued by a physician assistant shall be imprinted with the name of the physician assistant's supervising physician. For all other prescriptions issued by a physician assistant, the name and address of the health facility and, if the health facility is a multi-specialty organization, the name and address of the specialty clinic within the health facility where the physician assistant is practicing must be imprinted on the prescription.
Colorado	Health First Colorado (Medicaid)	n/a	n/a	Colorado Medicaid made updates to their fee-for-service program related to prior authorization for opioids, opioid step therapy requirements, and opioid clinical criteria for FY 2016. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Connecticut	Public Act No. 16-43	HB 5053	An Act Concerning Opioids and Access to Overdose Reversal Drugs	Amends the definition of "Practice of alcohol and drug counseling" to include SUD screening, risk stratification, treatment and referral options for patients taking drugs for pain. Limits opioid prescriptions to seven days for new patient in the outpatient setting. Limits opioid prescriptions for minors to seven-day supplies. Creates exceptions based on professional medical judgment. Changes PDMP reporting requirements from "24 hours" to "next business day." Requires PDMP checks at least annually for Schedule V medications. Allows for delegates to check the PDMP on behalf of the prescribing practitioner.
Connecticut	Special Act No. 16-3	HB 5534	An Act Concerning a Committee on the Practice of Naturopathy	Creates a committee to consider (1) the education and examination requirements and other qualifications necessary to allow persons licensed to practice naturopathy to prescribe, dispense and administer prescription drugs consistent with their scope of practice, and (2) the development of a naturopathic formulary of prescription drugs for persons licensed to practice naturopathy who meet specified educational and examination requirements or other qualifications to prescribe, dispense or administer.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Delaware	Delaware Code, Title 16, Chapter 47	HB 239	An Act to Amend Title 16 of the Delaware Code Relating to the Distribution or Delivery of a Controlled Substance Causing Death (Brock Cerklefskie's Law)	A person is guilty of drug dealing resulting in death when the person delivers a Schedule I or II controlled substance in Tier 1 or greater quantity to another person in violation of this chapter, and said controlled substance thereafter causes the death of another person who uses or consumes it. It is not a defense to a prosecution under this section that the defendant did not directly deliver the controlled substance to the decedent.
Delaware	Delaware Code, Title 16, Chapter 47	SB 8	An Act To Amend Title 16 Of The Delaware Code Relating To Uniform Controlled Substances	Senate Bill 119, passed during 2015's 147th General Assembly, inadvertently omitted the exception for veterinarians and methadone clinics (in addition to pharmacies) from dispensing more than 72 hours of a controlled substance. This bill corrected that error.
Delaware	Delaware Code, Title 24, Chapter 21	SB 143	An Act To Amend Title 24 Of The Delaware Code Relating To Profession And Occupation Of Optometry	Allows optometrists to prescribe controlled substances, but with a limitation of a 72-hour supply for Schedule II controlled substances containing hydrocodone and for all Schedule III, IV, and V controlled substances. Requires optometrists to register with the Drug Enforcement Agency. Requires optometrists to provide proof of graduate level coursework that includes general and ocular pharmacology.
Delaware	Delaware Code, Title 16, Subchapter VIII	SB 174	An Act To Amend Titles 16 And 29 Of The Delaware Code With Respect To Drug Overdose Fatalities	Established a Commission to investigate and review the facts and circumstances of all overdose deaths involving opiates, fentanyl or heroin which occur in Delaware. The Commission shall make recommendations to the Governor and General Assembly, at least annually, regarding those practices or conditions which impact the frequency of overdose deaths involving opiates, fentanyl or heroin, and steps that can be taken to reduce the frequency of such overdose deaths.
Delaware (DE)	DE Health and Social Services, Medicaid and Medical Assistance	n/a	n/a	Delaware Medicaid made updates to their Fee-for-Service program in 2016 related to opioid clinical criteria. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
District of Columbia	District of Columbia Municipal Regulations	n/a	Chapter 103, Prescription Drug Monitoring Program	Establishes the District of Columbia Prescription Drug Monitoring Program. Outlines reporting requirements, covered substances, standards and formats for reporting, prescriber and dispenser access to PDMP data, disclosure of data to law enforcement and regulatory agencies, interstate data sharing, the PDMP Advisory Committee, etc.
Florida	Chapter No. 2016-224	HB 423	Access to Health Care Services	Allows advanced practice nurse practitioners to prescribe, dispense, administer, or order controlled substances under certain circumstances. Establishes a committee to recommend a formulary of controlled substances that an advanced registered nurse practitioner may not prescribe or may prescribe only for specific uses or in limited quantities. Mandates continuing education on safe and effective prescription of controlled substances. Adds physicians who are board-eligible or board-certified with the American Board of Interventional Pain Physicians and the American Association of Physician Specialties to the list of those who are exempted from referring their patients with signs of substance use disorder to a specialist.
Florida	Chapter No. 2016-231	HB 977	Behavioral Health Workforce	Makes technical changes to existing laws related to pain to improve clarity. Adds physicians who are board-eligible or board-certified with the American Board of Interventional Pain Physicians and the American Association of Physician Specialties to the list of those who are exempted from referring their patients with signs of substance use disorder to a specialist.
Florida	Chapter No. 2016-145	HB 1241	Ordering of Medication	Makes technical changes to existing laws related to prescription requirements. Allows practitioners who supervise licensed physician assistants or advanced registered nurse practitioners to authorize those practitioners to order controlled substances under certain circumstances.
Florida	Chapter No. 2016-112	SB 422	Health Insurance Coverage for Opioids	Provides that a health insurance policy that covers abuse-deterrent opioid analgesic drug products may impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the insurer imposes the same requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim. Prohibits such health insurance policy from requiring use of an opioid analgesic drug product without an abuse-deterrence labeling claim before authorizing the use of an abuse-deterrent opioid analgesic drug product.
Florida	Chapter No. 2016-177	SB 964	Prescription Drug Monitoring Program	Exempts rehabilitative hospitals, assisted living facilities, and nursing homes from the reporting requirements of the PDMP. Allows designees of prescribers and dispensers to access the PDMP.
Georgia	Act 354	HB 900	Crimes and offenses; electronic data base of	Authorizes the retention of prescription monitoring program information for two years. Provides for delegates of prescribers and dispensers to access PDMP data. Revises language relating to subpoenas and search warrants for PDMP data. Provides for

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			prescription information; authorize the retention of data base information for 2 years; provisions	accessing PDMP data for purposes of investigation of potential abuse. Allows for the release of de-identified PDMP data for instructional, drug abuse prevention, and research purposes.
Georgia	Georgia Medicaid	n/a	n/a	Georgia Medicaid made updates related to opioid quantity limits, opioid clinical criteria, and opioid step therapy requirements in their Fee-for-Service program in 2016. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Hawaii	Act 183	SB 2672	Relating to Advanced Practice Registered Nurses	Amends various statutes to clarify the role of advanced practice registered nurses with regards to their authority and participation in the health care system, including granting APRNs the authority to prescribe controlled substances.
Hawaii	Act 92	SB 2861	Relating to the Joint Formulary Advisory Committee	Eliminates the Joint Formulary Advisory Committee, and instead allows the Board of Nursing to solely determine the exclusionary formulary for qualified advanced practice registered nurses (APRNs) with prescriptive authority.
Hawaii	Act 218	SB 2915	Relating to the Uniform Controlled Substances Act	Prohibits all Schedule II narcotic controlled substances from being prescribed or dispensed for more than a 30-day supply. Mandates that as a part of the controlled substance registration process, all practitioners and pharmacies shall be registered to utilize the electronic prescription accountability system. Expands the class of persons to whom PDMP data may be disclosed.
Idaho	Session Law Chapter 72	HB 337	Relating to Prescriptions	Amends existing law to provide that medical examiners or coroners may access information in the prescriptions database.
Idaho	Session Law Chapter 82	HB 374	Relating to the Controlled Substances Prescription Database	Authorizes certain supervised individuals (delegates) to access the prescription monitoring program database. Limits the number of delegates to be supervised. Requires Board of Pharmacy registration by each delegate.
Idaho	Idaho Department of Health and Welfare (Medicaid)	n/a	n/a	Idaho Medicaid has adopted the CDC Guidelines for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Further, updates were made to opioid quantity limits, prior authorization for opioids, and opioid clinical criteria. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Illinois	Illinois Department of Healthcare and Family Services (Medicaid)	n/a	Fentanyl products non-preferred in Illinois Medicaid	As a result of safety concerns, effective August 15, 2016, fentanyl transdermal patches will require prior approval for all fee-for-service HFS participants. Long-acting opioid therapy options on the Preferred Drug List are extended-release morphine oral tablets and Embeda capsules.
Illinois	Illinois Department of Healthcare and Family Services (Medicaid)	n/a	Methadone Prescribed for Pain	Due to safety concerns, HFS is removing methadone products for the treatment of pain from the Illinois HFS Preferred Drug List (PDL) effective April 5, 2016.
Illinois	Illinois Department of Healthcare and Family Services (Medicaid)	n/a	n/a	Illinois Medicaid updated requirements related to prior authorization for opioids in their Fee-for-Service program. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Indiana	Public Law 82	HB 1278	An Act to amend the Indiana Code Concerning Professions and Occupations	Allows prescribers to include an INSPECT (PDMP) report in a patient's medical file. Allows a patient to access any PDMP report in their medical file. Allows coroners and prescriber delegates to access the PDMP. Requires boards that regulate health care providers that prescribe or dispense prescription drugs to establish by December 1, 2016, prescribing norms and dispensing guidelines that, if exceeded, justify the unsolicited dissemination of exception reports.
Indiana	Public Law 31	SB 174	An Act to amend the Indiana Code Concerning Criminal Law and Procedure	Creates the offense of dealing in a controlled substance by a practitioner and enhances the offense if the offense causes the death of another person.
Indiana	Public Law 37	SB 214	An Act to amend the Indiana Code Concerning Human Services	Prohibits Medicaid reimbursement for Subutex, Suboxone, or a similar trade name or generic of the drug if the drug was prescribed for the treatment of pain or pain management and the drug is only indicated for addiction treatment.
Indiana	Medical Licensing	n/a	844 IAC 5-6-3 Triggers for	Establishes requirements concerning the use of opioids for chronic pain management for patients, with exemptions. Under certain circumstances, disallows: more than 60 opioid-

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
	Board of Indiana		imposition of requirements; exemptions	containing pills/month for more than three consecutive months; a morphine equivalent dose of more than 15 MME/day for more than three consecutive months; a transdermal opioid patch for more than three consecutive months; tramadol in excess of 60 MME/day for more than three months; or, an extended release opioid that is not in an abuse-deterrent form for which there is an FDA-approved abuse deterrent form available.
Indiana	Medical Licensing Board of Indiana	n/a	844 IAC 5-6-5 Physician discussion with patient; treatment agreement	Requires the physician to discuss with the patient the risks and benefits of opioid treatment for chronic pain, as well as expectations related to prescription requests and proper medication use.
Indiana	Medical Licensing Board of Indiana	n/a	844 IAC 5-6-8 Drug monitoring testing	Establishes rules related to drug testing while treating a patient with opioids.
Indiana	Indiana Medicaid	n/a	n/a	Indiana Medicaid updated requirements related to opioid quantity limits, prior authorization for opioids, opioid clinical criteria, and opioid step therapy requirements in their Fee-for-Service program. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Iowa	Chapter 1052	SF 2102	Drug Prescribing and Dispensing - Information Program - Access	Directs the Board of Pharmacy to implement improvements to facilitate secure access to the prescription monitoring program through electronic health and pharmacy information systems. The board is authorized to provide PDMP information to an institutional user to facilitate secure access by prescribing practitioners or pharmacists to program information through electronic health and pharmacy information systems. Authorizes the release of PDMP information for statistical, public research, public policy, or educational purposes, if all the personal identifying information is first removed.
Iowa	Iowa Admin. Code § 653-13.2 (2016)	n/a	Standards of practice -- appropriate pain management.	This rule establishes standards of practice for the management of acute and chronic pain. Encourages the use of non-opioid therapies. Clarifies that the undertreatment of pain is a departure from the acceptable standard of practice in Iowa. Requires documentation related to the treatment of acute and chronic pain. Urges use of a thorough patient evaluation, a comprehensive treatment plan, documented informed consent, periodic review, consideration of consultation or referral, written pain management treatment agreements, use of urine drug testing, and use of the prescription monitoring program.
Iowa	Iowa Medicaid	n/a	n/a	Iowa Medicaid began requiring use of the prescription monitoring program in their Fee-for-Service program in 2016. Updates were also made to opioid quantity limits, prior authorization for opioids, opioid step therapy requirements, and opioid clinical criteria.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				(According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Kansas	Kansas Boards of Healing Arts, Nursing, and Pharmacy	n/a	Joint Policy Statement from Kansas Boards of Healing Arts, Nursing and Pharmacy on Use of Controlled Substances for Treatment of Chronic Pain	Makes recommendations regarding assessment of the patient, treatment plan, informed consent and treatment agreement, periodic review, consultation, documentation in the medical record, and compliance with controlled substances laws and regulations.
Kentucky	Department of Medicaid Services	n/a	n/a	Kentucky Medicaid made updates related to opioid quantity limits, prior authorization for opioids, opioid step therapy requirements, and opioid clinical criteria in their Fee-for-Service program in 2016. Use of the PDMP was required. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Louisiana	HCR 113	HCR 113	A Concurrent Resolution	To establish the Louisiana Commission on Preventing Opioid Abuse to study and make recommendations regarding both short-term and long-term measures that can be taken to tackle prescription opioid and heroin abuse and addiction in Louisiana, by using the best practices and evidence-based strategies for its prevention, treatment, and enforcement.
Louisiana	Act No. 189	SB 56	Relative to the State Prescription Monitoring Program	Directs the Board to establish standards, by rulemaking, for the retention, archiving, and destruction of prescription monitoring information.
Louisiana	Louisiana Department of Health (Medicaid)	n/a	n/a	Louisiana Medicaid began requiring use of the prescription monitoring program in their Fee-for-Service program in 2016. Updates were also made to opioid quantity limits and opioid clinical criteria. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Maine	SP 671	LD 1646	An Act To Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program	Requires prescribers to check the PDMP upon an initial prescription for an opioid or benzodiazepine and again every 90 days. Requires dispensers to check the PDMP prior to dispensing opioids or benzodiazepines, and the dispenser shall notify the program and withhold a prescription until the dispenser is able to reach the prescriber if the dispenser has reason to believe the prescription is fraudulent or duplicative. Requires prescribers of opioids to complete a training course on the prescription of opioid pain medication that has been approved by the Department of Health and Human Services. Prohibits opioid prescriptions in excess of 100 morphine milligram equivalents per day to any one patient. Prohibits opioid prescriptions of more than 15 days at a time when treating chronic pain.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				Prohibits opioid prescriptions of more than 3 days when treating acute pain. Requires all opioid prescriptions to be transmitted electronically. Creates fines for prescribers and dispensers who knowingly violate these sections.
Maryland	Chapter 147	HB 437	Department of Health and Mental Hygiene - Prescription Drug Monitoring Program - Modifications	Requires providers who prescribe controlled dangerous substances listed in Schedule II through Schedule V to register with the Prescription Drug Monitoring Program before obtaining a new or renewal registration. Authorizes prescriber and pharmacist delegates to access the PDMP. Authorizes the publication of a list of monitored prescription drugs that have a low potential for abuse by individuals. Requires dispensers to submit information to the PDMP once every 24 hours. Requires prescribers and pharmacists to complete a course of instruction and training developed by the department regarding the effective use of the PDMP. Requires prescribers to request at least 4 months of PDMP data prior to initiating a course of treatment that includes opioids or benzodiazepines, and then again every 90 days. Requires that prescribers document their use of the PDMP in the patient medical record. Exempts prescribers from checking the PDMP if the prescription is (1) for 3 days or less, (2) for the treatment of cancer-related pain in the inpatient setting, (3) for a patient with a terminal illness, (4) for patients in assisted living or long-term care, or (5) for acute pain for no more than 14 days related to surgery, fractures, significant trauma, or childbirth. Creates additional exemptions.
Maryland	Chapter 116	HB 752	Physicians - Prescriptions Written by Physician Assistants or Nurse Practitioners - Preparing and Dispensing	Providing that specified provisions of law do not prohibit a licensed physician who complies with specified requirements from personally preparing and dispensing a prescription written by a physician assistant in accordance with a specified delegation agreement or a nurse practitioner who is authorized to practice under a specified provision of law and is working with the physician in the same office setting.
Maryland	Chapter 700	SB 806	State Board of Physicians - Naturopathic Doctors - Establishment of Naturopathic Doctors Formulary Council and Naturopathic Formulary	Establishes a Naturopathic Doctors Formulary Council within the State Board of Physicians. Requires the Council to develop formulary recommendations for the Board. The Board will then adopt a specified formulary. Specifies that “naturopathic medicine” includes prescribing, dispensing, or administering nonprescription and prescription drugs, but specifically prohibits the naturopathic formulary from including controlled substances.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Maryland	Lawrence J. Hogan, Jr., Governor	Executive Order 01.01.2017.01	Inter-Agency Heroin and Opioid Coordinating Council	Establishes the Opioid Operational Command Center. The Center shall develop operational strategies to continue implementing the recommendations of the Heroin and Opioid Emergency Task Force.
Massachusetts	Chapter 46	H 3650	An Act making appropriations for the fiscal year 2016	Section 191 provides for an examination of the prescribing and treatment history, including court ordered treatment or treatment within the criminal justice system, of persons in the commonwealth who suffered fatal opiate overdoses in calendar year 2014, and directs the creation of a report in an aggregate and de-identified form on trends discovered through the examination.
Massachusetts	Chapter 52	HB 4056	An Act Relative to Substance Use, Treatment, Education, and Prevention	A registered pharmacist filling a prescription for an opioid substance in schedule II may dispense the prescribed substance in a lesser quantity than the recommended full quantity indicated on the prescription if requested by the patient. The remaining quantity in excess of the quantity requested by the patient shall be void. Practitioners who prescribe controlled substances, except veterinarians, shall be required, as a prerequisite to obtaining or renewing their professional licenses, to complete appropriate training relative to: (i) effective pain management; (ii) the risks of abuse and addiction associated with opioid medication; (iii) identification of patients at risk for substance use disorders; (iv) counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications; (v) appropriate prescription quantities for prescription medications that have an increased risk of abuse; and (vi) opioid antagonists, overdose prevention treatments and instances in which a patient may be advised on both the use of and ways to access opioid antagonists and overdose prevention treatments. The boards of registration for each professional license that requires this training shall develop the standards for appropriate training programs. Establishes rules related to prescriptions for extended-release long-acting opioids. Allows patients to file voluntary non-opiate directives. When issuing a prescription for an opiate to an adult patient for outpatient use for the first time, a practitioner shall not issue a prescription for more than a 7-day supply. A practitioner shall not issue an opiate prescription to a minor for more than a 7-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opiate use and the reasons why the prescription is necessary. Requires PDMP use.
Massachusetts	Department of Industrial Accidents	n/a	Opioid/Controlled Substance Protocol	This Protocol is intended to: Promote the delivery of safe, quality health care to injured workers; Ensure patient pain relief and functional improvement; Be used in conjunction with other treatment guidelines, not in lieu of other recommended treatment; Prevent and reduce the number of complications caused by prescription medication, including addiction; and Recommend opioid prescribing practices that promote functional restoration. Requires, in part, risk assessment, PDMP checks, urine drug testing,

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				treatment agreement, starting with the lowest possible effective dose, documentation in the medical record, informed consent, review of job requirements and guidance regarding safely performing those duties while medicated. Disallows initiating treatment of acute pain with long acting or extended release opioids. Initial prescriptions for opioids are limited to no more than 7 days. Adopts CDC dosage recommendations. States that patients should not be abandoned, but rather, need to be tapered off of opioid medications (at pain resolution, lack of functional improvement, etc.).
Massachusetts	MassHealth (Medicaid)	n/a	n/a	MassHealth has adopted the CDC Guidelines for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Further, they adopted the guideline as a requirement for Managed Care Organizations to adopt. They also updated their requirements related to prior authorization for opioids. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Michigan	Public Act No. 499	HB 5400	Health occupations; advanced practice registered nurses; licensure of advanced practice registered nurses (APRNs); provide for and provide other general amendments.	Establishes parameters under which APRN's may prescribe controlled substances.
Michigan	Public Act No. 379	HB 5533	Health occupations; physician's assistants; regulation and oversight of physician's assistants; modify.	Establishes parameters under which physician assistants may prescribe controlled substances.
Michigan	Michigan Medicaid	n/a	n/a	Michigan Medicaid updated the opioid quantity limits, prior authorization requirements for opioids, opioid clinical criteria, and opioid step therapy requirements in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Minnesota	Chapter 124	SF 1425	An act relating to health; adding provisions to the definition of the	Allows pharmacies to collect legend drugs from patients for the purpose of disposing the legend drug as pharmaceutical waste. Special rules apply to the collection of controlled substances.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			"practice of pharmacy"; making changes concerning the collection and disposal of legend drugs as pharmaceutical waste; etc.	
Minnesota	Chapter 185	SF 1440	An act relating to health; making changes to the Minnesota prescription monitoring program; etc.	Sets time frames regarding the retention and disposal of de-identified PDMP information. Expands the class of persons/entities who may access the PDMP. Requires all prescribers licensed to prescribe controlled substances within the state to register and maintain a user account with the PDMP.
Minnesota	Minnesota Statutes		256B.0638 Opioid prescribing improvement program; annual report to legislature	By September 15, 2016, and annually thereafter, the commissioner of human services shall report to the legislature on the implementation of the opioid prescribing improvement program in the Minnesota health care programs. The report must include data on the utilization of opioids within the Minnesota health care programs.
Minnesota	Minnesota Medicaid	n/a	n/a	Minnesota Medicaid updated the opioid quantity limits in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Mississippi	Mississippi Division of Medicaid	n/a	n/a	Mississippi Medicaid updated the opioid clinical criteria in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Montana	Montana Medicaid	n/a	n/a	Montana Medicaid updated their opioid quantity limits, prior authorization requirements for opioids, opioid clinical criteria, and opioid step therapy requirements in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Nebraska	Section 71-2454, Section 84-712.05	LB 471	Change prescription drug monitoring provisions and create the Veterinary Prescription	Requires all dispensed prescriptions of controlled substances to be reported to the PDMP daily. Allows dispensers and prescribers to authorize designees for purposes of submitting information to, or accessing, the PDMP.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			Monitoring Program Task Force	
Nebraska	Nebraska Department of Health and Human Services (Medicaid)	n/a	n/a	Nebraska Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Nevada	Division of Health Care Financing and Policy (Medicaid)	n/a	Medicaid Services Manual	Opioids are subject to prior authorization, step therapy, clinical criteria, and quantity limits. Opioids are only covered without prior authorization for initial prescriptions of 7 days or less, for a total of 13 7-day prescriptions in any rolling 12-month period, and for prescriptions for less than 60 MME/day. To exceed the quantity limits, the patient must have chronic pain that cannot be controlled through use of non-opioids, the lowest effective dose must be used, and a pain contract must be on file. Exceptions to the limits exist for cancer-related pain, post-surgical pain, palliative and long-term care, those with HIV/AIDS, and prescriptions written by or in consultation with a pain specialist.
New Hampshire	Chapter 221	HB 1210	Relative to prescriptions for controlled drugs by telemedicine and relative to rulemaking authority and enforcement concerning prices for filling certain prescriptions.	Clarifies when it is appropriate for practitioners to adjust or prescribe controlled drugs to patients by telemedicine.
New Hampshire	Chapter 213	HB 1423	Relative to rulemaking for prescribing controlled drugs.	Requires board of medicine, board of dental examiners, board of nursing, board of registration in optometry, board of podiatry, naturopathic board of examiners, and board of veterinary medicine to adopt rules for prescribing controlled drugs. Contains mandatory standards for such rules, such as mandatory risk assessments, establishment of treatment plans, PDMP checks, informed consent, and requiring the lowest effective dosage for the fewest number of days.
New Hampshire	Chapter 329	SB 522	Making an appropriation to the office of	Appropriates $130,000 for the purposes of technology upgrades for the controlled drug prescription health and safety program (PDMP).

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			professional licensure and certification for technology upgrades for the controlled drug prescription health and safety program and relative to the forfeiture of property.	
New Hampshire	Chapter 309	SB 523	Relative to the controlled drug prescription health and safety program and establishing a commission to study requiring controlled drugs and controlled drug analogs to be provided in abuse-deterrent formulation.	Adds naturopaths to the definition of practitioner for the purposes of the controlled drug prescription health and safety program (PDMP). Establishes a commission to study requiring controlled drugs and controlled drug analogs to be provided in abuse-deterrent formulation.
New Hampshire	Chapter 330	SB 533	Relative to the governor's commission on alcohol and drug abuse prevention, treatment, and recovery and making supplemental appropriations to the commission, the New Hampshire housing finance authority, and the department of health and human services,	Makes changes in the membership, organization, duties, meetings, and reports of the governor's commission on alcohol and drug abuse prevention, treatment, and recovery, and establishes that the commission serves in an advisory capacity to both the governor and the general court. Makes supplemental appropriations to the commission, the New Hampshire housing finance authority, and the department of health and human services. Authorizes the department of justice to accept gifts, grants, and donations for the purpose of funding an assistant attorney general dedicated to prosecuting drug cases.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			bureau of drug and alcohol services.	
New Hampshire	Chapter 2	SB 576	Relative to the penalty for possession and use of fentanyl-class drugs, insurance coverage for substance use disorders, the funding of the controlled drug prescription health and safety program, the membership of the board of medicine, and prescribers of controlled drugs.	Adds possession and use of fentanyl-class drugs for the purposes of the penalty under the controlled drug act. Clarifies the funding of the controlled drug prescription health and safety program (PDMP). Clarifies access to the PDMP. Requires prescribers of controlled drugs to query the PDMP prior to prescribing controlled substances and to take 3 hours of continuing education or an online examination. Adds 2 physician members to the medical review subcommittee.
New Hampshire	Board of Medicine	Implementing HB 1423	Med 502 Opioid Prescribing	Rules regarding acute pain, chronic pain, lowest effective dose for limited duration, documentation, informed consent, safe disposal, compliance with rules, risk assessment, opioid limits, consultation with a pain specialist, urine drug testing, treatment agreements, PDMP, etc.
New Hampshire	Board of Nursing	Implementing HB 1423	Nur 502 Opioid Prescribing	Rules for nurses regarding acute pain, chronic pain, lowest effective dose for limited duration, documentation, informed consent, safe disposal, compliance with rules, risk assessment, opioid limits, consultation with a pain specialist, urine drug testing, treatment agreements, PDMP, etc.
New Hampshire	NH Medicaid	n/a	n/a	New Hampshire Medicaid began requiring of the prescription monitoring program in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
New Hampshire	NH Rev Stat § 318-B:39 (2016)		Prescribers Required to Query the Program Prior to Prescribing Controlled Substances.	Prescribers shall query the PDMP for a patient's initial prescription when prescribing schedule II, III, and IV opioids for the management or treatment of pain and then periodically and at least twice per year, with exceptions.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
New Jersey	Chapter 8	S 2156	Requires prescribers to discuss addiction risk associated with certain drugs prior to issuing prescription to minor patient.	Requires prescribers to discuss addiction risk associated with Schedule II controlled substances prior to issuing prescription to minor patient. Requires the documentation of this discussion in the patient's medical record.
New Jersey	New Jersey Medicaid	n/a	n/a	New Jersey Medicaid updated opioid quantity limits, prior authorization requirements for opioids, and opioid clinical criteria in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
New Mexico	Chapter 46	SB 263	Opioid Prescription Monitoring	Requires practitioners to obtain and review PDMP reports prior to prescribing or dispensing an opioid for the first time to a patient, and then again every three months. Requires the practitioner to document the receipt and review of the PDMP report in the patient's medical record.
New Mexico	Governor's Prescription Drug Misuse and Overdose Prevention and Pain Management Advisory Council	Implementing revisions to the Pain Relief Act	2016 Recommendations	Practitioners should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible. Practitioners should adhere to the summary of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline), published in the New England Journal of Medicine, and the complete CDC Guideline, in addition to the one-page summary document. Providers should not use the Guideline to override a provider's judgement regarding a specific patient, but rather to guide skillful and appropriate pain management. The medical provider licensing boards should not use the CDC Guideline to set strict policy or to enforce practice standards. Licensing entities should promulgate rules requiring practitioners to limit an initial opioid prescription for acute pain to no more than a 10-day supply for a single prescription.
New York	Chapter 71	A 10727 / SB 8139	Pain Management Drugs: Subscriber Training	Requires prescribers of pain medications to undergo three hours of continuing education every three years on pain management and palliative care. Restricts to seven days an initial opioid prescription for acute pain, and it limits the copay if additional medication is needed for the same underlying issue. Pharmacists also must provide educational materials to consumers upon dispensing of a controlled substance.
New York	Chapter 66	SB 6516	To amend the public health law, in relation to reporting of opioid overdose data; and providing	Requires all statewide overdose information, not just fatal overdose data, to be included in the Department of Health's (DOH) report that will be posted annually on DOH's website no later than the first day of October. The report's information will identify by each of the state's regions where the dispensing of opioid antagonists is occurring in order to better identify the areas that are experiencing high rates of overdoses.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			for the repeal of certain provisions upon expiration thereof	
New York	Chapter 167	SB 8106	To amend the public health law, in relation to including a Lyme disease and tick-borne infection awareness and prevention program within the health care and wellness education and outreach program.	Adds a Lyme and tick-borne disease awareness and prevention initiative to the state's Health Care and Wellness Education Program.
New York	N.Y. Pub. Health § 3331(5) (2016)	n/a	Scheduled substances administering and dispensing by practitioners	Disallows prescribing or dispensing Schedule II - V controlled substances to "addicts" or "habitual users", unless an exception applies. Establishes rules for the labeling of controlled substances. No more than a 30 day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time. A practitioner may not prescribe more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for the opioid or any other drug.
New York	Department of Health (Medicaid)	n/a	n/a	Effective July 22, 2016, initial opioid prescribing for acute pain is limited to a seven (7) day supply per New York State Public Health Law Section 3331 (see above). The Department of Health will communicate a date in the near future when this will be systematically enforced by the Medicaid Fee-for-Service Program. The following procedure is being put in place until such time that the Department is able to implement an automated solution to exempt copayments for such subsequent opioid prescriptions. Procedure: If a prescriber initiates a subsequent prescription for the same pain medication within 30 days of the initial 7-day supply, and the pharmacist is notified and/or confirms this upon reviewing the patient's prescription history or utilizing ProDUR editing, the following may be used to exempt the copayment for the subsequent prescription: In NCPDP field 461-EU, enter a value "04" (Exempt Copay and/or Coinsurance). Although

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				pharmacists should continue to use all of the tools at their disposal when dispensing opioid prescriptions, pharmacists are not required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with the above-referenced statutory requirements. Pharmacists may continue to dispense opioids as prescribed, consistent with current laws, regulations, and Medicaid policies.
New York	Department of Health (Medicaid)	n/a	n/a	New York Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Further, they adopted the guideline as a requirement for Managed Care Organizations to adopt. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
North Carolina	NC Medicaid and Health Choice	n/a	n/a	North Carolina Medicaid updated opioid step therapy requirements in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
North Dakota	North Dakota Medicaid	n/a	n/a	North Dakota Medicaid updated opioid quantity limits, prior authorization for opioids, opioid clinical criteria, opioid step therapy requirements, and requirements related to required use of the prescription monitoring program in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Ohio	HCR 16	HCR 16	Urges revision of patient pain management survey	To encourage the federal Centers for Medicare and Medicaid Services to revise survey measures included in the Hospital Consumer Assessment of Healthcare Providers and Systems that relate to patient pain management.
Ohio	Governor's Cabinet Opiate Action Team (GCOAT) and the workgroup on Opioids and Other Controlled Substances.	n/a	Ohio Guideline for the Management of Acute Pain Outside of Emergency Departments	This guideline provides a general approach to the outpatient management of acute pain. It is not intended to take the place of clinician judgement. Discusses assessment and diagnosis of pain, development of a treatment plan, use of non-pharmacologics and non-opioids, different types of pain, opioid pharmacologic treatment, pain reevaluation, etc.
Oklahoma	SoonerCare (Oklahoma Medicaid)	n/a	n/a	Oklahoma Medicaid updated opioid quantity limits, prior authorization requirements for opioids, opioid step therapy requirements, and required use of the prescription monitoring program in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Oregon	Chapter 100	HB 4124	Relating to prescription drugs; and declaring an emergency.	Requires Oregon Health Authority to disclose prescription monitoring information to practitioner or pharmacist or member of practitioner's or pharmacist's staff for use in certain health information technology systems.
Oregon	Health Evidence Review Commission, Oregon Health Authority (Medicaid)	n/a	State of Oregon Evidence-based Clinical Guidelines Project: Evaluation and Management of Low Back Pain	Retired on January 14, 2016, this was a clinical practice guideline based on the Joint Practice Guideline of the American College of Physicians and the American Pain Society. Contained recommendations related to patient evaluation, routine imaging, imaging for suspected conditions, advanced imaging, pharmacologic therapy (including opioids and non-opioids), and non-pharmacologic therapy.
Oregon	Health Evidence Review Commission, Oregon Health Authority (Medicaid)	n/a	Opioid Prescribing for Conditions of the Back and Spine	Strictly limits opioids for all on Medicaid. For acute pain (first 6 weeks), opioid treatment is only available when the prescription is 7 days or less, for short-acting opioids only, when one or more non-opioids have been tried and found ineffective or contraindicated, and when prescribed with a plan to keep active and with consideration of additional non-pharmacological therapies. There can be no documented history or opioid misuse or abuse. For pain after 6 weeks and up to 90 days, treatment with opioids requires: documented evidence of improved function of at least 30% compared to baseline; co-prescription of non-pharmacological treatments (acupuncture, physical therapy, etc.); and, each prescription is for no more than 7 days and for short-acting opioids only. After 90 days, opioids may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long-term opioids for diagnoses on these lines. Updates were made regarding the required use of the prescription monitoring program.
Pennsylvania	Act 122	HB 1699	Safe Emergency Prescribing Act	A health care practitioner may not prescribe an opioid drug product to an individual seeking treatment in an emergency department or urgent care center, or who is in observation status in a hospital, in a quantity sufficient to treat that individual for more than seven days. If, in the professional medical judgment of a health care practitioner, more than a seven-day supply of an opioid drug product is required to treat a patient's acute medical condition or is necessary for the treatment of pain associated with a cancer diagnosis or for palliative care, then the health care practitioner may issue a prescription for the quantity needed to treat such acute medical condition or pain associated with a cancer diagnosis or for palliative care. The condition triggering prescription of the opioid drug product under this paragraph shall be documented in the patient's medical record,

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				and the health care practitioner must indicate that a non-opioid drug product alternative was not appropriate to treat the medical condition. A health care practitioner in an emergency department or urgent care center, or who is caring for a patient in observation status, may not write a prescription refill for an opioid drug product. Requires referral to treatment under certain circumstances. Requires the prescribing health care practitioner to query the PDMP, but this does not apply to any medication provided to a patient in the course of treatment while undergoing care in an emergency department.
Pennsylvania	Act 124	SB 1202	Achieving Better Care By Monitoring All Prescriptions Program (ABC-MAP) Act - Omnibus Amendments	A dispenser shall query the PDMP before dispensing an opioid drug product or a benzodiazepine prescribed to a patient if: the patient is a new patient of the dispenser; the patient pays cash when they have insurance; the patient requests a refill early; or, the patient is getting opioid drug products or benzodiazepines from more than one prescriber. A new patient does not include an individual going to the same pharmacy, or a different physical location of that pharmacy, if the patient's record is available to the dispenser. A prescriber shall check the PDMP each time a patient is prescribed an opioid drug product or benzodiazepine by the prescriber. Requires prescribers and dispensers to complete at least two hours of education in pain management or identification of addiction and at least two hours of education in the practices of prescribing or dispensing of opioids.
Pennsylvania	Act 125	SB 1367	Prescribing Opioids to Minors	Establishes strict rules regarding opioid prescriptions to minors. Contains a 7-day limit with exceptions, informed consent mandates, documentation in the medical record, parental consent rules, etc.
Pennsylvania	Act 126	SB 1368	Safe Opioid Prescription	Implements a Patient Voluntary Nonopioid Directive. Further Beginning August 1, 2017, the licensing boards shall, by joint regulation, implement a safe prescription of a controlled substance containing an opioid curriculum. The curriculum may be offered in colleges or by providers approved by the licensing boards and shall include all of the following: (1) Current, age-appropriate information relating to pain management, (2) Multimodal treatments for chronic pain that minimize the use of a controlled substance containing an opioid, (3) If a controlled substance containing an opioid is indicated, instruction on safe methods of prescribing a controlled substance containing an opioid that follow guideline-based care, (4) Identification of patients who have risk factors for developing problems with prescription of a controlled substance containing an opioid, (5) Training on managing substance use disorders as a chronic disease.
Pennsylvania	Department of Health	n/a	Geriatric Pain, Opioid Use and Safe Prescribing	Guidelines related to opioid use in geriatric patients, covering subjects such as: avoiding use of long-acting opioids in older adults, situations in which low-dose opioids may be indicated, informed consent, treatment plans, opioids' effect on cognitive function, use of daily pill box organizers, initiating lower doses than typically used in adult populations, use of pain specialists for high dosages, etc.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Pennsylvania	Department of Health	n/a	Opioid Dispensing Guidelines	Guidelines related to dispensing opioids, covering topics such as: appropriate monitoring for safety and efficacy; weaning schedules, coordination of care, recognizing opioid equivalencies, verifying the legitimacy of the patient, provider, and prescription, drug interactions, safe dosages, patient education, communication with prescribers, etc.
Pennsylvania	Pennsylvania Medical Assistance (Medicaid)	n/a	n/a	Pennsylvania Medicaid made updates to opioid quantity limits, prior authorization for opioids, and opioid clinical criteria in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Rhode Island	Chapter 194	H 7847	Uniformed Controlled Substance Act	Authorizes any vendor, agent, contractor, or designee who operates an electronic medical health record (EMR) or clinical management system to have access to the prescription drug monitoring program (PDMP).
Rhode Island	Chapter 199	H 8224	Uniform Controlled Substances Act--regulation Of Manufacturing, Distributing, Prescribing, Administering, And Dispensing Controlled Substances	Requires pharmacies to transmit prescription information to the PDMP within 24 hours of dispensing an opioid. Provides limits on amounts of opioids to be prescribed, allowing no more than 30 MME/day for a maximum of 20 total doses for acute pain. Directs the Director of Health to develop regulations for appropriate training in best prescribing practices needed for license renewal. Makes registration with the PDMP a condition of license renewal. The PDMP shall be reviewed by prescribers or their designees prior to initiating opioid therapy, and then at least every three months.
Rhode Island	Chapter 200	H 8326	Uniform Controlled Substances Act	Improves the usefulness and value of the prescription drug monitoring database program by adding analytical functions, requiring program updates at least weekly, and incorporating data from similar programs in other states.
Rhode Island	Chapter 180	S 2823	Uniform Controlled Substances Act--regulation Of Manufacturing, Distributing, Prescribing, Administering, And Dispensing Controlled Substances	Requires pharmacies to transmit prescription information to the PDMP within 24 hours of dispensing an opioid. Provides limits on amounts of opioids to be prescribed, allowing no more than 30 MME/day for a maximum of 20 total doses for acute pain. Directs the Director of Health to develop regulations for appropriate training in best prescribing practices needed for license renewal. Makes registration with the PDMP a condition of license renewal. The PDMP shall be reviewed by prescribers or their designees prior to initiating opioid therapy, and then at least every three months.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Rhode Island	Chapter 464	S 2897	Uniformed Controlled Substance Act	Authorizes any vendor, agent, contractor, or designee who operates an electronic medical health record (EMR) or clinical management system to have access to the prescription drug monitoring program (PDMP).
Rhode Island	Chapter 351	S 2946	Uniform Controlled Substances Act	Improves the usefulness and value of the prescription drug monitoring database program by adding analytical functions, requiring program updates at least weekly, and incorporating data from similar programs in other states.
Rhode Island	Rhode Island Medicaid	n/a	n/a	Rhode Island Medicaid made updates to opioid quantity limits and opioid clinical criteria in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
South Carolina	South Carolina Healthy Connections Medicaid	n/a	n/a	South Carolina Medicaid began requiring use of the prescription monitoring program in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Tennessee	Pub. Ch. 656	HB 1768	Relative to Dispensing of Prescription Medication	Allows pharmacists to exercise professional judgment to dispense varying quantities of medication per fill up to the total number of dosage units prescribed, but expressly states that this section does not apply to controlled substances or any medications for which a report to the PDMP is required.
Tennessee	Pub. Ch. 1033	SB 1466	Hospitals and Health Care Facilities - As enacted, imposes licensure and other requirements on pain management clinics. - Amends TCA Title 63 and Title 68.	Amends existing requirements for the operation of a pain management clinic, including adding a licensure requirement and a requirement that a pain management clinic obtain a certificate of need.
Tennessee	Pub. Ch. 546	SB 1513	Relative to the Controlled Substance Database Advisory Committee	Requires representatives of the Controlled Substance Database Advisory Committee to appear before legislative committees to update them on the committee's findings.
Tennessee	Pub. Ch. 959	SB 1850	Relative to Review of Prescribers Association with	Authorizes the commissioner of health to obtain records maintained by any healthcare facility in order to facilitate investigations and inquiries concerning opioid drug abuse, opioid drug overdoses, and opioid overdose deaths.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			Overdoses of Prescription Opiates	
Tennessee	Pub. Ch. 829	SB 2057	Relative to Qualifications for a Pain Management Specialist	Specifies that, on and after July 1, 2016, a new applicant may only qualify as a pain management specialist through board certification by the American board of interventional pain physicians (ABIPP) by passing parts 1 and 2 of its examination, and holding an unencumbered Tennessee license, and maintaining the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status.
Tennessee	Pub. Ch. 973	SB 2060	Relative to Dispensing Opioids or Benzodiazepines	Sets requirements that prescribers must meet in order to dispense opioids or benzodiazepines.
Tennessee	Pub. Ch. 1002	SB 2552	Tennessee Prescription Safety Act of 2016	Deletes and replaces pre-existing provisions related to the controlled substance database committee. Directs the committee to examine PDMP data to identify unusual patterns of prescribing and dispensing and refer those practitioners to the chief board of pharmacy investigator. Establishes new PDMP reporting requirements. Requires all prescribers and dispensers of controlled substances to register with the PDMP. Establishes the persons and entities that may access PDMP data.
Tennessee	TennCare (Tennessee Medicaid)	n/a	n/a	TennCare made updates related to opioid quantity limits, prior authorization for opioids, opioid clinical criteria, opioid step therapy requirements, and required use of the prescription monitoring program in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Texas	Texas Medical Board	n/a	§170.3 Minimum Requirements for the Treatment of Chronic Pain	Revised pain management rules related to: evaluation of the patient; documentation; treatment plans; informed consent; treatment agreements; urine drug testing; limitations on who may prescribe to patients being treated for pain; limitation of only one pharmacy for a patient being treated for pain; discontinuation/tapering; consultation and referral; etc.
Texas	Texas Medical Board	n/a	§195.2 Certification of Pain Management Clinics	Makes updates to the rules pertaining to Certification of Pain Management Clinics.
Texas	Texas State Board of Pharmacy	n/a	§315 Controlled Substances	Amends the Controlled Substances chapter relating to: definitions; official prescription forms; pharmacy responsibility; electronic reporting; emergency prescriptions; modification of prescriptions; Out-of-State prescribers; release of prescription data; Schedule III-V prescription forms; access requirements; etc.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Texas	Texas Medicaid	n/a	n/a	Texas Medicaid updated opioid quantity limits in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Utah	Session Law Chapter 99	HB 114	Controlled Substance Reporting	Amends the requirement for a general acute hospital to report to the Division of Occupational and Professional Licensing admissions for poisoning or overdose involving a prescribed controlled substance. Requires courts to report to the division certain violations of the Utah Controlled Substances Act. Amends the purposes of the division's controlled substance database. Requires the division to enter into the database information it receives in reports by hospitals concerning persons admitted for poisoning involving a prescribed controlled substance. Requires the division to enter into the database information it receives in reports by courts concerning persons convicted for driving under the influence of a prescribed controlled substance.
Utah	Session Law Chapter 104	HB 149	Regarding Controlled Substances	Requires the medical examiner to provide a report to the Division of Occupational and Professional Licensing (DOPL) when the medical examiner determines that a death resulted from poisoning or overdose involving a prescribed controlled substance. Requires that, when DOPL receives a report described in the preceding paragraph, DOPL shall notify each practitioner who may have written a prescription for the controlled substance involved in the poisoning or overdose. Allows probation and parole officers to obtain information in the controlled substance database without a warrant. Allows the division to provide information to law enforcement officers engaged in specified types of investigations.
Utah	Session Law Chapter 197	HB 150	Controlled Substance Prescription Notification	Amends the Controlled Substance Database Act to allow a person for whom a controlled substance is prescribed to designate a third party who is to be notified when a controlled substance prescription is dispensed to the person. Allows the person to direct the division to discontinue providing the information. Requires that the division advise the person that if the person discontinues the notification, the third party will be advised of the discontinuance. Requires that the division comply with the direction and also notify the third party of the discontinuation. Authorizes the division to make administrative rules to facilitate implementation of this provision.
Utah	Session Law Chapter 112	HB 239	Access to Opioid Prescription Information via Practitioner Data Management Systems	Requires the Division of Occupational and Professional Licensing within the Department of Commerce to make opioid prescription data information in its controlled substance database accessible to an opioid prescriber or pharmacist via the prescriber's or pharmacist's electronic data system. Limits access to and use of the information by an electronic data system, a prescriber, or a pharmacist in accordance with rules established by the division. Requires rulemaking by the division. Requires the division to

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				periodically audit use of the information. Amends Controlled Substance Database Act penalty provisions.
Utah	Session Law Chapter 275	HB 375	Prescription Drug Abuse Amendments	Mandates that a prescriber or dispenser of an opioid for individual outpatient usage shall access and review the PDMP as necessary in the prescriber's or dispenser's professional judgment. If the dispenser's access and review suggest that the individual seeking an opioid may be obtaining opioids in quantities or frequencies inconsistent with generally recognized standards, the dispenser shall reasonably attempt to contact the prescriber to obtain the prescriber's informed, current, and professional decision regarding whether the prescribed opioid is medically justified, notwithstanding the results of the PDMP search.
Utah	Session Law Chapter 127	SB 58	Nurse Practitioner Amendments	Allows an advanced practice registered nurse to prescribe a Schedule II controlled substance without a consultation and referral plan under certain circumstances. Requirements include 2 years or 2,000 hours of experience, ongoing PDMP checks, and adherence to appropriate guidelines.
Utah	Session Law Chapter 005	SB 3001 (Special Session 3)	Controlled Substance Database Modifications	Describes the circumstances under which probation and parole officers may access information from the controlled substance database without a warrant.
Utah	Division of Occupational and Professional Licensing	Implementing HB 239 (2016)	58-37f-303. Access to opioid prescription information via an electronic data system.	Clarifies who may be a user of the PDMP. Sets forth rules regarding the availability of PDMP data and electronic data systems. Specifies that the Division shall make rules specifying: (i) an electronic data system's: (A) allowable access to and use of opioid prescription information in the database; and, (B) minimum actions that must be taken to ensure that opioid prescription information accessed from the database is protected from inappropriate disclosure or use; and, (ii) an EDS user's: (A) allowable access to opioid prescription information in the database via an electronic data system; and, (B) allowable use of the information.
Vermont	Act 173	S 243	An Act relating to Combating Opioid Abuse in Vermont	This act adds the appropriate prescription of controlled substances to treat acute pain to the topics on which professional licensing authorities must develop evidence-based standards and requires the licensing authorities to submit their standards to the Commissioner of Health to review the PDMP and increases the frequency with which dispensers must report to the PDMP from at least once a week to daily. The act creates the 35-member Controlled Substances and Pain Management Advisory Council as the successor to the Unified Pain Management System Advisory Council and other advisory groups. It directs the Commissioner of Health to adopt rules on prescribing opioids after consulting with the Council, which may include number and time limits on pills prescribed, including a maximum number of pills to be prescribed following minor medical procedures. Requires health care professionals who have a federal Drug Enforcement Agency number or who dispense controlled substances to complete a total

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				of at least two hours of continuing education for each licensing period on topics related to preventing opioid abuse, misuse, and diversion. Requires the Commissioner of Health to convene medical educators to develop curricular materials to ensure that students in medical education programs learn safe prescribing practices and screening, prevention, and intervention for cases of prescription drug misuse and abuse and directs the Department of Health to establish a community grant program to support local opioid prevention strategies. The act increases a fee imposed on pharmaceutical manufacturers whose drugs are paid for by DVHA from 0.5 percent to 1.5 percent of annual DVHA drug spending and adds to the permissible uses of the Evidence-Based Education and Advertising Fund. The act requires the Department of Health to establish and maintain a statewide unused prescription drug disposal program and directs BlueCross BlueShield of Vermont to evaluate the evidence supporting the use of acupuncture to treat pain and whether its plans should provide coverage for acupuncture services. It also creates a pilot project to offer acupuncture services to Medicaid-eligible Vermonters with a diagnosis of chronic pain.
Vermont	Vermont Medicaid	n/a	n/a	Vermont Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Virginia	Chapter 406	HB 293 / SB 513	Prescription Monitoring Program; Requirements of Prescribers of Opioids	Requires a prescriber to check the PDMP upon initiating a new course of treatment that includes opioids when that treatment is expected to last more than 14 days. Eliminates the requirement to check the PDMP when prescribing a benzodiazepine. Allows prescribers to have delegates access the PDMP on their behalf.
Virginia	Chapter 86	HB 498	TPA-certified Optometrists; Prescription of Certain Schedule II Controlled Substances	Provides that a TPA-certified optometrist who is authorized to prescribe controlled substances may issue prescriptions for or provide manufacturer's samples of analgesics included on Schedule II consisting of hydrocodone in combination with acetaminophen to his patients.
Virginia	Chapter 98	HB 657	Prescription Monitoring Program; indicators of misuse, disclosure of information.	Directs the Director of the Department of Health Professions to develop, in consultation with an advisory panel that shall include representatives of the Boards of Medicine and Pharmacy, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers. Authorizes the Director to disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Virginia	Chapter 447	HB 829	Prescribers of covered substances; continuing education.	Authorizes the Director of the Department of Health Professions to disclose information to the Board of Medicine about prescribers who meet a certain threshold for prescribing covered substances for the purpose of requiring relevant continuing education. Directs the Board of Medicine to require prescribers identified by the Director of the Department of Health Professions to complete two hours of continuing education in each biennium on topics related to pain management, the responsible prescribing of covered substances, and the diagnosis and management of addiction.
Virginia	Chapter 410	HB 1044 / S 491	Prescription Monitoring Program; disclosure of certain information.	Provides that the Director of the Department of Health Professions may disclose information in the possession of the PDMP about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist licensed in the Commonwealth and employed by the Virginia Medicaid managed care program to determine eligibility for and to manage the care of the specific recipient in a Patient Utilization Management Safety or similar program. Requires the PDMP advisory committee to provide guidance to the Director regarding such disclosures.
Virginia	Chapter 309	SB 287	Prescription Monitoring Program; reports by dispensers shall be made within 24 hours or next day.	Reports by dispensers to the PDMP shall be made within 24 hours or the dispenser's next business day, whichever comes later. Outlines the persons and entities to whom the Director of the Department of Health Professions may disclose PDMP data.
Virginia	Virginia Department of Medical Assistance Services (Medicaid)	n/a	n/a	Virginia Medicaid has adopted the CDC Guideline for Prescribing Opioids for Chronic Pain in their Fee-for-Service program. Updates were also made to opioid quantity limits, prior authorization for opioids, opioid clinical criteria, opioid step therapy requirements, and required use of the prescription monitoring program. (According to a survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Washington	Chapter 104	HB 2730	Prescription Monitoring Program - Data Access Eligibility	Allows PDMP data to be provided to a health care facility or entity for the purpose of providing medical or pharmaceutical care to the patients of the facility, subject to certain requirements.
Washington	Chapter 148	SB 6203	Practice of Pharmacy - Long-Term Care Settings	In part, makes amendments to the law relating to controlled substance prescriptions in long-term care settings.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
Washington	Executive Order	n/a	Addressing the Opioid Use Public Health Crisis	The state Agency Medical Directors Group (AMDG) shall work with the Bree Collaborative (a health care improvement partnership), Tribal governments, boards and commissions, professional associations, health care systems, insurers, teaching institutions, and others to consider amendments to the state pain guidelines and other training and policy materials, consistent with the 2015 AMDG and the 2016 CDC opioid guidelines, to reduce unnecessary prescribing for acute pain conditions for the general population, especially adolescents. (Includes other provisions related to substance use disorder, education of youth, morbidity and mortality data, etc.)
Washington	Washington State Health Care Authority (Medicaid, Public Employees)	n/a	n/a	Washington Medicaid updated requirements related to the prior authorization of opioids in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
West Virginia	Chapter 134	HB 4146	Providing insurance cover abuse-deterrent opioid analgesic drugs	Provides for insurance coverage of abuse-deterrent opioid analgesic drugs.
West Virginia	Chapter 175	HB 4334	Clarifying the requirements for a license to practice as an advanced practice registered nurse and expanding prescriptive authority	Directs the promulgation of governing the eligibility and extent to which an advanced practice registered nurse may prescribe drugs. Such rules shall provide, at a minimum, a state formulary classifying those categories of drugs which shall not be prescribed by advanced practice registered nurse including, but not limited to, Schedules I and II of the Uniform Controlled Substances Act, anti-neoplastics, radiopharmaceuticals and general anesthetics. Drugs listed under Schedule III shall be limited to a thirty-day supply without refill.
West Virginia	Chapter 183	HB 4428	Clarifying that optometrists may continue to exercise the same prescriptive authority which they possessed prior to hydrocodone being reclassified	Optometrists may not use Schedule II controlled substances. However, an oral pharmaceutical certified licensee may prescribe hydrocodone and hydrocodone containing drugs for a duration of no more than three days.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
West Virginia	Chapter 201	HB 4537	Chronic Pain Clinic Licensing Act	Amends and reenacts the Chronic Pain Clinic Licensing Act, relating to the regulation of chronic pain clinics, updating definitions, deleting an exemption for affiliation with a medical school, and clarifying due process concerns regarding the process for hearing notices upon appeal.
West Virginia	Chapter 149	SB 195	Authorizing DHHR to promulgate legislative rules	In relevant part, authorizes the Department of Health and Human Resources to promulgate a legislative rule regarding chronic pain management licensure which exempts terminal patients from portions of the rules. Further amends existing rules to require that a pain clinic shall not offer a bounty, monetary or equipment or merchandise reward, or free services for individuals in exchange for recruitment of new patients into the clinic. Further, a pain clinic shall not recruit new patients for the purpose of attempting to circumvent the licensure requirements of this rule.
West Virginia	Office of the Attorney General, Consumer Protection and Antitrust Division	n/a	Best Practices for Prescribing Opioids in West Virginia	Guidelines/best practices intended for (1) utilizing West Virginia's Controlled Substance Monitoring Program, (2) reducing risk of opioid misuse, (3) ensuring that the prescription medication, dose, and quantity is safe and appropriate, and (4) incorporating naloxone into opioid treatment discussions.
West Virginia	West Virginia Medicaid	n/a	n/a	West Virginia Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)
Wisconsin	Act 266	AB 364	Reporting, disclosure, and practitioner review requirements under the prescription drug monitoring program; providing an exemption from emergency rule procedures; and granting rule-making authority.	Dispensers must report to the PDMP by the next business day. Specifies the persons to whom PDMP records may be disclosed, including to relevant law enforcement agencies.
Wisconsin	Act 268	AB 365	Duty of law enforcement officers to report to the	Requires law enforcement officers to report controlled substance violations, opioid-related drug overdoses or deaths, and reports of stolen prescription drugs to the PDMP.

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
			Prescription Drug Monitoring Program controlled-substance violations, opioid-related drug overdoses or deaths, and reports of stolen prescription drugs.	
Wisconsin	Act 265	AB 366	Pain clinic certification and requirements, granting rule-making authority, and providing a penalty.	Defines “Pain Clinic” and sets requirements for the operation of such clinics. Adopts requirements related to medical directors, payment methods, direct dispensing, and multiple locations.
Wisconsin	Act 262	AB 367	Reporting by treatment programs using methadone and requiring review of prescription drug monitoring database.	Adopts reporting requirements by treatment programs using methadone, including the program's plan for tapering individuals off methadone, staffing requirements, and more.
Wisconsin	Act 269	AB 660	Guidelines for prescribing controlled substances and the examination authority of the Medical Examining Board.	Allows the medical examining board, the podiatry affiliated credentialing board, the board of nursing, the dentistry examining board, and the optometry board to issue guidelines regarding best practices in prescribing controlled substances.
Wisconsin	Act 267	AB 766	Review and reporting requirements for the Prescription Drug Monitoring Program.	Requires the Board to conduct a review of the PDMP to evaluate the actual outcomes of the program compared with projected outcomes, including an evaluation of (1) the satisfaction with the program of pharmacists, pharmacies, practitioners, and other users, and (2) the program's impact on referrals of dispensers and prescribers to licensing boards for discipline and to law enforcement for investigation/prosecution. Requires a separate report regarding the trends and changes in use of monitored prescription drugs within the state; the number of participating practitioners; the number of individuals

Jurisdiction	Enacted As or By	Bill Number	Title	How Policy Affects Opioid Prescribing
				receiving prescription orders from 5 or more practitioners and/or pharmacies within any 90-day period; etc.
Wisconsin	Chapter 961.385	n/a	Prescription Drug Monitoring Program	The board shall conduct a quarterly review of the PDMP to evaluate the actual outcomes of the program compared with projected outcomes. The board's review shall include an evaluation of all of the following: (1) The satisfaction with the program of pharmacists, pharmacies, practitioners, and other users of the program; and, (2) The program's impact on referrals of pharmacists, pharmacies, and practitioners to licensing or regulatory boards for discipline and to law enforcement agencies for investigation and possible prosecution. The board shall provide a report to the department of safety and professional services that includes all of the following: (a) The results of the board's review under sub. (5). This paragraph does not apply after October 30, 2020; (b) An assessment of the trends and changes in the use of monitored prescription drugs in this state; (c) The number of practitioners, by profession, and pharmacies submitting records to the board under the program in the previous quarter; (d) A description of the number, frequency, and nature of submissions by law enforcement agencies under s. 961.37 (3) (a) in the previous quarter; (e) A description of the number, frequency, and nature of requests made in the previous quarter for disclosure of records generated under the program; (f) The number of individuals receiving prescription orders from 5 or more practitioners or having monitored prescription drugs dispensed by 5 or more pharmacies within the same 90-day period at any time over the course of the program; (g) The number of individuals receiving daily morphine milligram equivalents of 1 to 19 milligrams, 20 to 49 milligrams, 50 to 99 milligrams, and 100 or more milligrams in the previous quarter; and, (h) The number of individuals to whom both opioids and benzodiazepines were dispensed within the same 90-day period at any time over the course of the program.
Wyoming	Wyoming Medicaid	n/a	n/a	Wyoming Medicaid made updates to opioid quantity limits in their Fee-for-Service program in 2016. (According to a 2016 survey administered by the Henry J Kaiser Family Foundation to the State Medicaid Programs)

Appendix B: Sampling of Proposed and Passed Opioid Policies, 2019

Sampling of Proposed and Passed Opioid Policies, 2019

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
United States	HR 1614/ S 724	John S. McCain Opioid Addiction Prevention Act	House - 04/12/2019 Referred to the Subcommittee on Crime, Terrorism, and Homeland Security	A bill to amend the Controlled Substances Act to establish additional registration requirements for prescribers of opioids, and for other purposes. Limits opioid prescriptions for the initial treatment of acute pain to no more than 7 days.
United States	S 417	Changing the Culture of the FDA Act	Senate - 02/07/2019 Read twice; referred to the Committee on Health, Education, Labor, and Pensions	The Secretary of HHS, acting through the Commissioner of Food and Drugs, shall amend the mission statement of the FDA to include the following statement: “The FDA is also responsible for protecting the public health by strongly considering the danger of addiction and overdose death associated with prescription opioid medications when approving these medications and when regulating the manufacturing, marketing, and distribution of opioid medications.”.
United States	S 418	FDA Accountability for Public Safety Act	Senate - 02/07/2019 Read twice and referred to the Committee on Health, Education, Labor, and Pensions	To establish procedures regarding the approval of opioid drugs by the FDA. Before approving any opioid against the recommendation of the advisory committee, the FDA must report to Congress on (1) medical and scientific evidence regarding patient safety that clearly supports the Commissioner's decision to approve the opioid drug against the recommendation of the advisory committee, and (2) a disclosure of any potential conflicts of interest that may exist regarding any official of the Food and Drug Administration who was involved in the decision to approve the drug prior to the Commissioner's final decision under subsection. Such drug shall not be introduced or delivered for introduction into interstate commerce until such report has been submitted.
United States	S 419	Protecting Americans from Dangerous Opioids Act	Senate - 02/07/2019 Read twice, referred to Committee on Health, Education, Labor, and Pensions	To require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved.
United States	S 424	DEA Enforcement and Authority Act of 2019	Senate - 02/07/2019 Read twice and referred to the Committee on the Judiciary	This bill modifies enforcement authorities of the DEA. It modifies the required elements of an order to show cause issued by the DEA before it denies, revokes, or suspends a registration for a CSA violation. Specifically, the bill eliminates the requirement for an order to show cause to notify the registrant of the opportunity to submit a corrective action plan. Additionally, the bill modifies the standard of review for an immediate suspension order. Currently, the DEA may immediately suspend the registration of a controlled substances manufacturer, distributor, or dispenser to prevent imminent danger to public health and safety. This bill lowers the standard for determining imminent danger to the

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
				public health and safety from substantial likelihood of an immediate threat of harm to probable cause that harm will occur.
United States	S 425	Budgeting for Opioid Addiction Treatment Act	Senate - 02/07/2019 Read twice and referred to the Committee on Finance	Imposes a one cent/milligram fee on the sale of active opioids by the manufacturer, producer, or importer. Fee excludes prescription drugs used exclusively for treatment of opioid addiction as part of a medically assisted treatment effort. HHS must establish a program to provide rebates or discounts to cancer and hospice patients to ensure they do not pay the fee. Any increase in federal revenues from the fee after rebates and discounts are subtracted must be distributed to states under the Substance Abuse Prevention and Treatment Block Grant program. The states must use the funds exclusively for substance abuse (including opioid abuse) efforts in the states, including (1) specified treatment programs, and (2) the recruitment and training of substance use disorder professionals to work in rural and medically underserved communities. HHS must report to Congress on the impact of this bill on the retail cost of opioids and patient access to opioid medication, the effectiveness of the discount or rebate for cancer and hospice patients, how the funds are being used to improve substance abuse treatment efforts, and suggestions for improving access to opioids for cancer and hospice patients and substance abuse treatment efforts.
United States	S 724	John S. McCain Opioid Addiction Prevention Act	Senate - 03/07/2019 Read twice; referred to the Committee on the Judiciary	A bill to amend the Controlled Substances Act to establish additional registration requirements for prescribers of opioids, and for other purposes. Limits opioid prescriptions for the initial treatment of acute pain to no more than 7 days.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
United States	n/a	A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019	Centers for Medicare and Medicaid Services; implemented	Implements safety alerts at the pharmacy for Part D beneficiaries who are filling their initial opioid prescription or who are receiving high doses of prescription opioids. Medicare drug plans will perform additional safety checks by sending pharmacies an alert to review certain opioid prescriptions before they are filled. Safety alerts may cover: (1) Possible unsafe amounts of opioids. The pharmacist or Medicare drug plan may need to perform a closer safety review of the prescription with the prescribing doctor if a Part D beneficiary receives opioid prescription(s) that exceed a certain amount; (2) First prescription fills for opioids. Part D beneficiaries may be limited to a 7-day supply or less for acute pain if they haven't recently taken opioids (such as within the past 60 days). The limit is based on medical best practices that show that the risk of developing an opioid use disorder increases after 7 days of use. This policy is not intended for current users of prescription opioids; or, (3) Use of opioids and benzodiazepines at the same time. These medications can be dangerous when taken in combination. If the prescription can't be filled as written, including the full amount on the prescription, the pharmacist will give the beneficiary a notice explaining how they or their doctor can contact the plan to ask for a "coverage determination" (a decision about whether or not the plan will cover the drug). The beneficiary or their doctor may also ask the Part D plan for an exception to its rules before the beneficiary goes to the pharmacy, so they know in advance whether the prescription is covered.
Alabama	n/a	540-x-19-.03 Pain Management Registration Required	Implemented: Alabama Board of Medical Examiners	Revises registration requirements related to pain management clinics.
Alaska	n/a	Medication Prior Authorization, Analgesics, opioid and reversal agents	Implemented: Alaska Department of Health and Social Services, Division of Health Care Services	Contains clinical criteria and forms for prior authorization for opioid drugs covered by Alaska Medicaid.
Alaska	n/a	Medication Prior Authorization, Maximum Units Medication List (eff. Through 6-9-2019)	Implemented: Alaska Department of Health and Social Services, Division of Health Care Services	Contains information regarding Max units/30 days and MME/day, and prior authorization information, for opioid drugs covered by Alaska Medicaid.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
Alaska	n/a	Medication Prior Authorization, Maximum Units Medication List (eff. 6-10-2019)	Implemented: Alaska Department of Health and Social Services, Division of Health Care Services	Contains information regarding Max units/30 days and MME/day, and prior authorization information, for opioid drugs covered by Alaska Medicaid.
Arizona	HB 2075	Electronic Prescribing of Controlled Substances	Signed by Governor, Chapter 4	Extends the electronic prescription order deadline for all counties until January 1, 2020. Requires the use of electronic prescriptions for Schedule II controlled substances, including opioids, with exceptions.
Arizona	n/a	n/a	Implemented: Arizona Department of Health Services, effective July 1, 2019	Requires an administrator of a health care institution where opioids are prescribed or ordered as part of treatment shall establish, document, and implement policies and procedures for prescribing or ordering an opioid as part of treatment that includes how, when, and by whom a patient's profile in the PDMP is reviewed and, if applicable, include documenting a dispensed opioid in the PDMP.
California	AB 149	Controlled substances: prescriptions.	Signed by Governor, Chapter 4	Previously existing law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the department, and further requires those prescription forms to be printed with specified features, including a uniquely serialized number. This bill delays the requirement for those prescription forms to include a uniquely serialized number until a date determined by the Department of Justice that is no later than January 1, 2020. The bill requires, among other things, the serialized number to be utilizable as a barcode that may be scanned by dispensers. The bill additionally makes any prescription written on a prescription form that was otherwise valid prior to January 1, 2019, but that does not include a uniquely serialized number, or any prescription written on a form approved by the Department of Justice as of January 1, 2019, a valid prescription that may be filled, compounded, or dispensed until January 1, 2021. The bill authorizes the Department of Justice to extend this time period for a period no longer than an additional 6 months, if there is an inadequate availability of compliant prescription forms.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
California	AB 528	Controlled substances: CURES database.	Active Bill - 6/19/19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read 2nd time, amended, re-referred to Committee on Business, Professions and Economic Development	As amended on 6/19/2019: Adds a section that states: "It is the intent of the Legislature that state laws regarding the operation and use of prescription drug monitoring programs continue to empower health care-oriented technology solutions to the opioid crisis." Would require a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed. Would require all controlled substance prescriptions to be reported to the PDMP, including Schedule IV and V. Requires the adoption of new regulations to address the conditions under which an insurer providing workers' compensation coverage may access information in CURES for purposes of reviewing a workers' compensation claim, which shall at a minimum prohibit an insurer from using information obtained from the CURES database as the sole factor in evaluating a claim for approval or denial.
California	AB 888	Opioid prescriptions: information: nonpharmacological treatments for pain.	Active Bill - 07/01/19 In Senate Business, Professions and Economic Development Committee, Hearing Date 07/01/2019	Existing law requires a prescriber, with certain exceptions, before directly dispensing or issuing for a minor the first prescription for a controlled substance containing an opioid in a single course of treatment, to discuss specified information with the minor, the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment. This bill would extend that requirement for the prescriber by applying it to any patient, not only a minor, under those circumstances. The bill would also require the prescriber to discuss the availability of nonpharmacological treatments for pain, as defined. Existing law makes an exception to the requirement for the prescriber in the case of a patient who is being treated for a diagnosis of chronic intractable pain, as specified. This bill would remove that exception and would instead make an exception in the case of a patient who is currently receiving hospice care. The bill would require the prescriber, after discussing the information, to offer, as deemed appropriate by the prescriber, a referral for a provider of nonpharmacological treatments for pain, and to obtain informed written consent from the patient, a minor patient's parent or guardian, or another authorized adult, as specified. Existing federal law (PPACA), requires a health benefit plan to ensure that coverage includes the essential health benefits package, as defined. This bill would make legislative findings and declarations relating to addiction associated with overreliance on prescription medication for pain management, and providing that nonpharmacological treatments for pain should be considered during the next update to the state's essential health benefits benchmark plan.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
California	AB 1468	Opioid Prevention and Rehabilitation Act.	Active Bill - In Floor Process - Assembly 3rd Reading File, Assembly Bills	This bill would, commencing with the 2021–22 fiscal year, require a manufacturer or wholesaler, as defined, that sells or distributes opioid drugs in this state to submit to the department a report, including specified information, that details all opioid drugs sold or distributed in this state during the preceding fiscal year. The bill would, commencing with the 2021–22 fiscal year, require the department, in consultation with the board, to calculate the ratable share of a manufacturer or wholesaler, which is the individual portion of the collective sum of $50,000,000 or a lesser amount, as specified, to be paid by the manufacturers and wholesalers, based on the information reported, without double-counting the opioid drug if both a manufacturer and a wholesaler sold or distributed the drug in this state. The bill would subject the manufacturer and wholesaler to specified civil penalties for failing to comply with the reporting or payment requirements. The bill would require the deposit of the payments and penalties, less refunds and the department's administrative costs, into the continuously appropriated Opioid Prevention and Rehabilitation Program Fund, which the bill would create, thereby making an appropriation. The bill would require the department to distribute moneys in the fund to counties or local nonprofit community-based organizations for purposes of opioid prevention and rehabilitation programs. The bill would base the distribution of moneys on county needs, using only specified information relating to opioid overdose in the counties.
Colorado	Implementing SB 22 (2018)	Guidelines for the Safe Prescribing and Dispensing Opioids	Implemented: Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Optometry, Colorado Podiatry Board, State Board of Pharmacy, and endorsed by the State Board of Veterinary Medicine	On March 14, 2019, the revised Guidelines for Prescribing and Dispensing Opioids were adopted by all six of Colorado's prescribing and dispensing Boards. Revisions were necessary due to the new requirements in Senate Bill 18-22 Clinical Practice for Opioid Prescribing. This new state law went into effect on May 21, 2018, immediately upon the Governor's signature. The law sets forth prescribing requirements, such as the number of opioids to be prescribed and required Prescription Drug Monitoring Program checks in certain clinical situations. The law also provides specific exemptions to these requirements. The Boards will continue to evaluate the Policy, incorporating new legislation and collaborating with other state agencies, researchers, practitioners, patients, the Colorado Consortium for Prescription Drug Abuse Prevention, and other stakeholders to identify and evaluate outcomes. The Boards remain committed to this Policy as a living document, reflective of the evolving science, technology, policy and law in their ongoing efforts to address Colorado's opioid crisis.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
Iowa		Rule making related to controlled substances	Implemented: Pharmacy Board, Iowa Administrative Code	Requires prescribing practitioners to register with PDMP at the same time they apply for controlled substance registration. Allows Board to assess a surcharge of up to 25% of a registration fee to be deposited into PDMP fund. Require PDMP checks for butalbital (exempted under previous law). Allows disposal of controlled substances of a hospice patient by employees of a qualified hospice program, pursuant to 2018-enacted federal SUPPORT Act.
Minnesota	HF 400	Opioid Omnibus	Signed by Governor, Session Law Chapter 63	Contains articles related to: opioid product stewardship; health plan company requirements; prevention and education initiatives to address opioid addiction; intervention, treatment, and recovery initiatives to address opioid addiction; and appropriations for opioid initiatives. Establishes the Opioid Addiction Advisory Council and the opioid stewardship fund. Requires drug manufacturers and wholesale drug distributors that sell or distribute opioids in Minnesota to pay an opiate product registration fee. Requires health plans to cover acupuncture services for the treatment of pain and ongoing pain management. Allows persons to include in health care directives instructions to prohibit the use of opioids, provides alternative methods of drug disposal for county sheriffs, expands photo identification requirements for the purchase of controlled substances, places time limits on filling opioid prescriptions, establishes opioid quantity limits for treating acute pain associated with a major trauma or surgical procedure, and requires continuing education on prescribing opioids and other controlled substances, including nonpharmacological alternatives for pain treatment and management.
Montana	HB 86	Generally revise prescription drug laws	Signed by Governor, Chapter 89	Providing for the positive identification of potential recipients of controlled substances; restricting prescriptions for opioid-naive patients to a 7-day supply and providing exceptions; requiring certain professionals who prescribe or dispense prescription drugs to register to use the prescription drug registry; requiring a prescriber or authorized agent to review the prescription drug registry before prescribing an opioid or a benzodiazepine to a patient and providing exceptions; providing penalties; providing rulemaking authority; etc.
Montana	HB 654	Generally revise laws for funding of treatment courts	Signed by Governor, Chapter 413	Any person engaging in the initial sale of opioids in the state shall first obtain a license from the department and pay the annual license fee of $500. A retail pharmacy is not required to obtain the license. The department shall maintain on its website a current list of approved licensed opioid sellers eligible to sell opioids in the state. The annual license fee revenue must be deposited in the treatment court support account.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
New Hampshire	n/a	Morphine Milligram Equivalent Criteria	Implemented: New Hampshire Medicaid Fee-for-Service Program, approved April 5, 2019	If more than 100 MME/day of an opioid is requested: the patient must be at least 18 years of age, have a diagnosis of chronic pain, and have documented failure or adequate trial of opioids at a lower dose; the PDMP must be reviewed within the past 60 days; the prescription must be written by a pain specialist or in consultation with a pain specialist; a written treatment agreement must be in use; and, the patient must be prescribed concurrent naloxone. Hospice, cancer, end-of-life, and sickle cell are exempt from prior authorization.
North Carolina	n/a	Joint Statement on Medication Management of Pain in End-of-Life Care	Implemented: Board of Nursing, Medical Board, Board of Pharmacy	Outlines the legal scope of practice for each type of prescriber (physician, nurse, pharmacist), professional collaboration and communication among health professionals providing palliative care, and a standard of care that assures ongoing pain assessment, a therapeutic plan for pain management interventions, and evidence of adequate symptom management for the dying patient.
Ohio	n/a	For Prescribers - New Limits on Prescription Opioids for Acute Pain	Implemented: Board of Pharmacy	No more than seven days of opioids can be prescribed for adults, with exceptions. No more than five days of opioids can be prescribed for minors and only after the written consent of the parent or guardian is obtained. Health care providers may prescribe opioids in excess of the day supply limits only if they provide a specific reason in the patient's medical record. Except as provided for in the rules, the total morphine equivalent dose (MED) of a prescription for acute pain cannot exceed an average of 30 MED per day. All prescribers are required to include the first four alphanumeric characters of the diagnosis code (ICD-10) or the full procedure code (Current Dental Terminology - CDT) on all controlled substance prescriptions, which will then be entered by the pharmacy into Ohio's prescription monitoring program.
Oregon	n/a	n/a	Implemented: Health Evidence Review Commission, Oregon Health Authority	Effective October 1, 2019, Oregon Medicaid patients with back and neck pain will no longer be required to taper off opioids, as had been required under existing policy.
Pennsylvania	n/a	Opioids in the Dental Practice	Implemented: Department of Health	Guidelines covering topics such as: acute and post-operative pain, non-opioid options, avoiding long-acting and/or extended-release formulations, drug interactions, informed consent, PDMP checks, etc.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
Rhode Island	n/a	Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island (216-RICR-20-20-4)	Department of Health, Proposed Amendment to Rule, Public Comment Ends 6/17/2019	The Rhode Island Department of Health (RIDOH) is proposing rulemaking to create requirements for e-prescriptions, implement grammatical corrections and revise the use of several terms including MME and PDMP, eliminate definitions that are not utilized in the regulations or that are being replaced with updated terms, create definitions for electronic prescription, standing order, and substance use disorder, clarify mandatory PDMP review, clarify requirements for documentation of patient education regarding opioids, clarify requirements for ICD10 code equivalents as determined by RIDOH, revise/remove section titles, and correct references to other RIDOH regulations.
Tennessee	n/a	Tennessee Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain	Implemented: Department of Health	Guidelines intended to define the appropriate treatment of chronic pain, covering topics such as: prior to initiating opioid therapy; initiating opioid therapy; ongoing opioid therapy; pain medicine specialists; the PDMP; urine drug testing; tapering; morphine milligram equivalent dose; naloxone; safe disposal; workers compensation; issues specific to women; non-opioid therapies; acute and surgical pain; pediatric pain, and more.
Utah	HB 186	Opioid Prescription Regulation Amendments	Signed by Governor, Session Law Chapter 128	Permits the Division of Occupational and Professional Licensing to consult with prescribers and health care systems to assist the prescriber or health care system in following evidence-based guidelines regarding the prescribing of controlled substances. Amends provisions relating to steps that the division must take after it receives a report from a medical examiner relating to an overdose involving a controlled substance.
Utah	HB 191	Controlled Substance Abuse Amendments	Signed by Governor, Session Law Chapter 130	Requires a prescriber to discuss the risks of using an opiate with a patient or the patient's guardian before issuing an initial opiate prescription.
Utah	Implementing HB 186 (2019)	58-37f-304. Database utilization.	Implemented: Division of Occupational and Professional Licensing	Permits the Division of Occupational and Professional Licensing to consult with prescribers and health care systems to assist the prescriber or health care system in following evidence-based guidelines regarding the prescribing of controlled substances. Amends provisions relating to steps that the division must take after it receives a report from a medical examiner relating to an overdose involving a controlled substance.
Utah	Implementing HB 191 (2019)	58-37-19. Opiate prescription consultation.	Implemented: Division of Occupational and Professional Licensing	Requires a prescriber to discuss the risks of using an opiate with a patient or the patient's guardian before issuing an initial opiate prescription.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
Utah	n/a	Concurrent Prescriptions for Benzodiazepines and Opioids	Utah Medicaid, effective April 2019	Utah Medicaid is implementing a multi-stage effort to identify and limit the concurrent filling of benzodiazepine and opioid medications. This initiative aims to support CDC guidelines that recommends against combined use, which is associated with risk of fatal overdose. Currently, an automated process monitors and reports when an individual is co-prescribed opioids and benzodiazepines. The peer to peer team will conduct outreach to identified prescribers to alert them of patients receiving concurrent therapy, provide education around concurrent use avoidance, and encourage prescription drug monitoring program (PDMP) use before prescribing a Schedule II controlled substance, in accordance with the Federal HR 6 (2018).
Utah	n/a	Opioid Policy Changes	Utah Medicaid, effective January and July 2019	Effective July 1, 2019, the higher cumulative daily morphine equivalent dose (MED) threshold for "opioid experienced" individuals will be reduced to 150 MED. This will support ongoing efforts to achieve one common MED standard for all Utah Medicaid members over time. On January 1, 2019, Utah Medicaid adopted morphine milligram equivalent (MME) and MED methodology for adjudication of all opioid claims for the treatment of non-cancer pain. This initiative was added to existing opioid quantity limits and days' supply limitations to support CDC safety guidance and best practice standards. At that time, two sets of daily MED thresholds were established, a threshold of 90 MED for "opioid naïve" individuals who have not had a claim for an opioid in the last 90 days, and 180 MED for "opioid experienced" individuals who have had a claim for an opioid in the last 90 days.
Vermont	Implementing Act 75 (2013) and Act 173 (2016)	Rule Governing the Prescribing of Opioids for Pain	Implemented: Department of Health	Updates the 2017 rules. Provides legal requirements for the appropriate use of opioids in treating pain. The prescription limits for acute pain only apply to the first prescription written for a given course of treatment, and do not apply to renewals or refills. This rule only applies to Schedule II, III, or IV Controlled Substances. Requires: consideration of the use of non-opioids and non-pharmacological treatments; documentation; use of the PDMP; patient education; informed consent; consultation or referral to a pain specialist at certain times during treatment; co-prescriptions of naloxone for certain patients. Establishes various--extremely specific and detailed--limits for opioids when used to treat minor pain, moderate pain, severe pain, and extreme pain.

Jurisdiction	Bill Number	Title	Status	How Policy Affects Opioid Prescribing
Washington	SB 5380	Concerning Opioid Use Disorder Treatment, Prevention, and Related Services	Signed by Governor; effective July 28, 2019	Requires prescribers of opioids to inform patients of their right to refuse an opioid prescription for any reason. If a patient indicates such a refusal, it must be documented in the medical record to prevent the prescription of opioids to the patient, until such time that the patient revokes the request. Allows pharmacists to partially fill a prescription for a Schedule II controlled substance if requested by the patient or prescribing practitioner. Establishes exemptions from required PDMP checks. Establishes requirements for electronic prescriptions. Requires informed consent, consideration of non-opioids, and the distribution of written warning language for patient education. Allows PDMP data about dispensers and prescribers (that includes indirect patient identifiers) to be used by various entities for research purposes. Allows prescriber feedback reports to aid in quality improvement.

Appendix C: Policies from Top Ten Health Insurers

Policies from Top Ten Health Insurers

	Notes	Source
United Health		https://www.uhc.com/
	1. Prevent misuse and addiction. Ensure adherence to CDC guidelines for use, dosing and length of opioid therapy in treatment of chronic and acute pain; sharing information on outliers with providers; supply limits on prescriptions; prior authorization programs; real-time medication checks to identify unsafe combinations; educating health professionals on best practices. 2. Treating addiction. Connecting members with MAT, decreasing opioid prescriptions to pregnant women referred to MAT or case management; promoting naloxone and offering personalized treatment with evidence-based methods. 3. Supporting long-term recovery. Use of certified peer support specialists; identifying those at risk ahead of time; UnitedHealth Opioid Community Partnership.	https://newsroom.uhc.com/opioids/opioid-epidemic.html
	Provides more detail regarding programming, such as working with dentist on wisdom tooth pain management.	https://newsroom.uhc.com/opioids/uhc-opioids-overview.html
	A prescription drug policy that limits all first-time opioid prescriptions written by dental health professionals for people age 19 and under to no more than three days and fewer than 50 morphine milligram equivalents per day, as recommended by the CDC guideline.	https://newsroom.uhc.com/opioids/dental-opioids.html
Anthem		https://www.anthem.com/
	Limits days' supply for acute pain; prior authorization for long-acting opioid therapy initiation; can lock patients into one pharmacy/prescriber; electronic notices to prescribers about patients at risk; notice to prescribers about additional concerns	https://www.bcbs.com/news/press-releases/anthem-blue-cross-and-blue-shield-helps-reduce-opioid-use-connecticut-17
Aetna		https://aetna.com
	identify and promote in-network high-value treatment facilities for opioid use disorder through Institutes of Quality program	https://news.aetna.com/2018/09/aetna-making-progress-in-its-fight-against-opioid-misuse-abuse/
	Controlled Substance Use Program monitors for potential at-risk prescribing and alerts members and their prescribing doctors.	https://news.aetna.com/wpcontent/uploads/2017/06/OpioidAbuse_OnePager_July2018_FINAL.pdf
	Story about activities in DeKalb County, Georgia	https://news.aetna.com/2018/08/aetna-joins-local-leaders-in-dekalb-county-georgia-to-combat-opioid-crisis/
	Guardian Angel program--substance abuse counselors call patients identified as recently experienced an opioid overdose	https://news.aetna.com/2019/06/a-lifeline-for-members-who-recently-survived-an-overdose/

	Notes	Source
	Academic detailing program aims to educate prescribers about safe opioid prescribing	https://news.aetna.com/2019/03/aetna-empowering-physicians-to-fight-opioid-crisis-via-best-practices/
	Infographic highlighting Aetna's response to the opioid crisis	https://news.aetna.com/2019/03/innovative-meaningful-solutions-to-the-national-opioid-epidemic/
Cigna		https://www.cigna.com
	Behavioral health management plans for OUD	https://www.cigna.com/assets/docs/about-cigna/opioid-%20faq.pdf
	Immediate release opioids without prior authorization for longer than 7 days only: if the prescriber attests it is medically necessary for acute pain; or, attests that the pain is chronic.	https://cignaforhcp.com/public/content/pdf/coveragePolicies/pharmacy/ph_1704_coveragepositioncriteria_Opioid_Therapy.pdf
	Multiple criteria all need to be met to cover extended-released opioids: o Diagnosis of pain severe enough to require daily, around-the-clock, long-term opioid treatment o Failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for a minimum one week trial of immediate-release opioids o Opioid therapy management agreement signed by BOTH the individual and prescribing clinician for therapy longer than 7 days	https://cignaforhcp.com/public/content/pdf/coveragePolicies/pharmacy/ph_1704_coveragepositioncriteria_Opioid_Therapy.pdf
Humana		https://www.humana.com/
	Humana Pharmacy Solutions: 1/1/2018 enhancements to the opioid utilization program point-of-sale edits based on the opioid threshold (cancer and hospice patients will not get flagged). A. Upper opioid threshold/multiple providers – prior authorization will be required • Opioid doses greater than 250mg MMED or • Multiple providers AND pharmacies are used to obtain the same or similar opioid medications - error message Opioid threshold exceeded. B. Lower opioid threshold – Pharmacy professional service codes allowed • Opioid doses between 100 mg and 250mg MMED - Cumulative morphine equivalent dose exceeds limits	http://apps.humana.com/marketing/documents.asp?file=3307317
	Page 22 of 2018 Humana Corporate Social Responsibility Report describes initiatives addressing opioids.	http://apps.humana.com/marketing/documents.asp?file=3307317
Centene		https://www.centene.com
	OpiEnd™: OpiEnd uses proprietary business intelligence tools to identify at-risk members for potential opioid misuse; OpiEnd Pharmacy Advisory Group established a pharmacy opioid policy designed to prevent opioid misuse by restricting the daily dosage and maximum days of use prescribed for members;	https://www.centene.com/news/addressing-opioid-epidemic.html

	Notes	Source
	KS prior authorization information for KanCare (Medicaid) Short-Term/Acute Pain Opioid User (patients who have received opioid prescription(s) for < 90 days in a look back period of 4 months): – An initial fill limit of 7-day supply of IR opioid – Limit of fills up to14-day supply total is allowed within a 60-day look-back period (must be no more than a 7-day supply per prescription) – Daily dosing limit cannot exceed 90 MME or FDA maximum-approve dose – Prior authorization required for • all ER opioid prescriptions • any IR opioid prescriptions exceeding the limits above	https://www.sunflowerhealthplan.com/content/dam/centene/sunflower/pdfs/KS-Opioid-PA-Presentation.pdf
	Clinical Policy for IlliniCare (Medicaid) has stipulations for the prescribers: Provider must submit documentation (including such items as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Lists criteria that must be met for different therapy levels in both the initial stages for: --Short-term therapy, --Cancer, sickle cell, or palliative care --Transitioning from short-term to long-term therapy; and for continued cancer, sickle cell or palliative care and long-term therapy New criteria added in 2019 refer to, for an abuse-deterrent formulation (ADF), medical justification supporting inability to use a generic non-abuse-deterrent formulation of the same active ingredient as the requested opioid	https://www.illinicare.com/content/dam/centene/policies/pharmacy-policies/CP.PMN.97%20Opioid%20Analgesics.pdf
	Centene Corporation's provider education efforts include an informative webinar called Pharmacy Buzz for both prescribers and pharmacists about concurrent use of opioids and benzodiazepines; distributed mailings and newsletters to instruct providers on how to enroll in the Controlled Substances Prescription Monitoring Program (PDMP); Data mining and data analytics drive provider accountability efforts, as Centene reviews the PDMP and e-prescribing, and then flags for review the outlying prescribers, pharmacies, and members who are dispensing or using high volumes of opioids.	https://downloads.cms.gov/files/hfpp/hfpp-opioid-white-paper.pdf
Molina		https://www.molinahealthcare.com/
	Ohio Medicaid provider information through Molina asks for provider help: "We request you support us in our efforts to impact the opioid epidemic by: --Sending member referrals for CSP (Coordinated Services Process) if you suspect a dangerous mishandling of controlled substance prescriptions. --Agree to be the primary lock in prescriber for CSP members. --Agree to limit the member's ability to access controlled medications from multiple sources."	https://www.molinahealthcare.com/providers/oh/medicaid/drug/PDF/opioid.pdf

	Notes	Source
	In a letter to the Senate Finance Committee - "Provider education is a barrier to non-pharmaceutical therapy for chronic pain that Molina is working hard to overcome." Launched a Pain Safety Initiative that encourages providers to utilize the CDC's Guideline for Prescribing Opioids for Chronic Pain; offering and supporting provider education in areas such as: opioid and naloxone prescribing; pain management; and the development of taper plans for patients on high opioid doses or combinations. Many of the resources allow for earning CME (continuing medical education) and include video webinars, online self-paced courses, and even mobile applications that providers can access on their phones or tablets to use at the point of care.	https://www.finance.senate.gov/imo/media/doc/2.16.18%20-%20Molina%20Healthcare%20-%20Senate%20Finance%20Opioid%20Response%20-%20Updated.pdf
	Washington State implemented an opioid policy for Medicaid, so Molina issued a Q&A document - one of the questions from a provider and its answer follows: Q: What is the window of time that the 42 doses applies to? Is that 42 doses in a 90-day period or 120 days? When does this reset? A: 42 doses per script can be given to adult patient for multiple scripts, until the patient has had opioids for 6 weeks (42 days) in a 90-day period. At that time, the attestation form for chronic use is required prior to continuing on opioid therapy.	https://www.molinahealthcare.com/providers/wa/medicaid/forms/PDF/opioid-webinar-questions.pdf
	Because the company works with Medicaid, they have multiple state-instituted rules to address - in Washington state: short-acting opioids approved for acute use; (people not treated for cancer, sickle-cell or palliative care) Limits apply as follows: a) For short acting opioids only: i) A quantity limit of 18 dosages per prescription for children (≤20 years of age); [Note: Prescriber indicating EXEMPT overrides quantity limit] OR ii) A quantity limit of 42 dosages per prescription for adults (≥21 years of age); [Note: Prescriber indicating EXEMPT overrides the quantity]; AND b) For both long and short acting opioids: i) No more than 42 calendar days of opioid use within a rolling 90-day period. Use of any opioid for more than 42 days within a 90-day period is considered chronic use of opioids and requires prior authorization; and there are exemptions and expedited claims for chronic users.	https://www.hca.wa.gov/assets/billers-and-providers/opioid-policy.pdf
WellCare		https://www.wellcare.com/
	WellCare provider newsletter for MOCare recommends the CDC guidelines, such as non-opioid therapy, lowest effective dose and prescription monitoring	https://www.wellcare.com/~/media/PDFs/Newsletters/Missouri/Providers/PDFs/2018/MO_CAID_PR
	2/11/18 Opioid Task Force - from 2015-17 intervention for patients with 120 mg MED; In Kentucky at-risk members were connected to one pharmacy, one healthcare provider and a care manager specialized in substance abuse treatment	https://blog.wellcare.com/2018/02/11/how-wellcare-is-addressing-the-opioid-epidemic/
Health Net		https://www.healthnet.com/

	Notes	Source
	Most searches just have memos from Centene; the clinical policy for the extended release Levorphanol refers to chronic pain and FDA guidelines for administration thereof	https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/7377.pdf
Magellan		https://www.magellanhealth.com/
	In November 2017, Magellan Rx Management (the PBM) implemented a standard formulary and utilization management approach consistent with the CDC guidelines -limit the daily dosage of opioids dispensed based on the strength of the opioid; require the use of IR formulations before ER opioid formulations-starting in the first quarter of 2018 it began 7 day limits for naïve patients for certain acute prescriptions; enroll all of our clients utilizing our standard approach in all of these measures unless the client directs us to implement an alternative approach; even for those clients (whether it be state Medicaid programs, commercial health plans, or employers) choosing to develop an alternative, our practice is to consult with and recommend best practices – such as the CDC's 2016 Guideline – so our clients can make fully-informed decisions.	https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Srivastava-Opioid%20Crisis%20Medicare%20Medicaid%20Hearing-041218.pdf

Appendix D: Policies from Top Five Pharmacy Benefit Management Companies

Policies from Top Five Pharmacy Benefit Management Companies

	Notes	Source
CVS Health (Caremark)		https://www.caremark.com
	Summary of efforts with opioids	https://www.managedhealthcareexecutive.com/mhe-articles/four-pbm-programs-poised-rein-opioid-epidemic/page/0/3
	Following the CDC Guideline, updated standards for CVS Caremark members, unless prior authorization is given, include: 1) Seven-day supply limits for acute pain where appropriate; 2) Morphine milligram equivalent (MME) quantity limits (unspecified); 3) Immediate release (IR) before extended release (ER) step therapy.	https://www.cvshealth.com/thought-leadership/cvs-health-enterprise-response-opioid-epidemic/cvs-health-responds-to-nations-opioid-crisis
	Making electronic prescribing easy to increase its use and leveraging its access to the entire patient record for PDMP.	https://payorsolutions.cvshealth.com/insights/helping-to-solve-the-epidemic-of-prescription-drug-abuse
	Wellmark Blue Cross Blue Shield: managed by Caremark. Opioids requested will be covered with prior authorization when the following criteria are met: • The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care; OR • The patient can safely take the requested dose based on their history of opioid use; AND • The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder; AND The requested drug is being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate. [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]; AND o The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety; OR o The patient requires extended treatment beyond 7 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate. Coverage is provided without prior authorization (for patients not identified as potential first fills) for 30-day or 90-day supply of immediate-release opioids for a quantity that corresponds to ≤ 90 MME/day. Coverage for quantities that correspond to ≤ 200 MME/day for a 30-day or 90-day supply is provided through prior authorization when criteria for approval are met.	https://www.wellmark.com/Provider/MedicalDentalPharm/Pharmacy/docs/Opioids_IR_Acute_Pain_Duration_Limit_with_MME_Limit_and_Post_Limit_Policy.pdf
Express Scripts		https://www.express-scripts.com/

	Notes	Source
	Initial fill for adults initiating opioid therapy is limited to a 7-days' supply for members' first 4 fills, requiring a prior authorization to exceed 28-days' supply in a 60-day period; limiting the morphine equivalent dosing to 90 morphine milligram equivalent (MME) for patients starting on opioids; Existing users are limited to 200 MME, unless they receive a prior authorization for a higher dosage; pediatric patients are limited to a 3-days' supply for each of their first 4 fills, requiring a prior authorization to exceed 12-days' supply in a 60-day period.	https://lab.express-scripts.com/lab/insights/drug-safety-and-abuse/our-focus-opioid-recovery-and-abuse-prevention
	Advanced Opioid Management - at the pharmacy: - First-time users of short-acting opioids are restricted to an initial fill of seven days' supply (unless patients have a history of chronic pain requiring opioid therapy, have cancer or receive palliative care) - Enhanced Prior Authorization encourages safe-starts for all long-acting opioids - Morphine Milligram Equivalent Dose (MMED) edit gives pharmacy visibility to high doses of morphine equivalent dosing, alerting the pharmacy at doses of 90 MMED and 200 MMED; prior authorization required for members accumulating quantities of opioid medication exceeding 200 mg MMED -concurrent drug utilization review (CDUR) ensures opioid prescriptions are appropriate, medically necessary and unlikely to result in adverse medical consequences; CDUR provides real-time alerts to dispensing pharmacists to prevent adverse events.	https://lab.express-scripts.com/lab/insights/drug-safety-and-abuse/changing-the-way-we-fight-the-opioid-epidemic
	Summary of efforts	https://www.managedhealthcareexecutive.com/mhe-articles/four-pbm-programs-poised-rein-opioid-epidemic/page/0/2
OptumRx		https://optumrx.com
	Document describing the need to better manage opioid prescribing	https://www.optum.com/resources/library/deflecting-the-curve.html?s=rxopioid
	Document describing the need to better manage pain	https://www.optum.com/resources/library/the-problem-of-pain.html?s=rxopioid
	OptumRx Opioid Risk Management Strategies 1. Prevention & education 2. Minimizing early exposure 3. Reducing inappropriate supply 4. Treating the at-risk, high-risk 5. Supporting chronic populations and those in recovery.	https://www.optum.com/resources/library/managing-opioid-costs-managing-risks.html?s=rxopioid
	Edits flag people's first uses of opioids following CDC guideline: algorithms calculate, at point of claims processing, the exact MMED for every opioid on the market. Instituted expanded concurrent drug utilization review (CDUR) edits and plan design edits at the point of service: when a prescription is issued for an opioid that is inappropriate for any reason – too many pills, dose too strong, a patient who is already on benzodiazepines, a patient on prenatal vitamins (to prevent neonatal abstinence syndrome), a patient actively in MAT for OUD. They have put in place monitoring systems that prevent OUD patients in	https://www.optum.com/resources/library/managing-opioid-costs-managing-risks.html?s=rxopioid

	Notes	Source
	MAT programs from getting other opiate prescriptions; they also alert providers when outpatients stop adhering to MAT, and leverage point-of-sale programs to look for members who might relapse after one of these programs. CDUR screens incoming claims through a member claims profile for opioid use after a person has completed MAT.	
	Members with no opioid in their most recent 120-day claims history will be limited to a maximum of 49 MMED and two 7-day supplies within a 60-day timeframe. Members who are not new to opioids will be limited to a maximum of 90 MMED and to 2 fills within a 60-day timeframe.	https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/Quantity%20Limit%20Changes%20on%20Short%20Acting%20Opioids_Provider%20Portal_v20170613_vf.pdf
	Article listing PBM efforts	https://www.managedhealthcareexecutive.com/mhe-articles/four-pbm-programs-poised-rein-opioid-epidemic
Medimpact		https://www.medimpact.com/
	12-page document summarizing their efforts and laying out a goal to reduce opioid "overutilization" by 36%	https://pbm.medimpact.com/documents/10180/73930/Managing+Opioid+Overutilization+Challenges.pdf/e222c73d-81a4-4af6-ad60-9162da1e4d89
	Program applies point-of-sale messaging directly to the pharmacy. This is based on MMED thresholds that are calculated for a specific drug and dose. Soft edits may be overridden by pharmacists or via a clinical review; hard edits reject claims meeting or exceeding the highest threshold and can only be overridden after clinical review.	https://pbm.medimpact.com/documents/10180/422130/MedImpactCaseStudy_on_Combating_the_OpioidCrisis.pdf/c6ff7d2c-5b54-4d61-bd7b-4cd8292e851b
	Sample of a prior authorization form	https://mp.medimpact.com/brandcontentprovider/OGB/MP/MedImpact%20Standard%20MRF_with%20OGB%20logo.pdf
	Patient information on opioid edits: SummaCare™ has implemented the following opioid edits: Enhanced Opioid Cumulative Dosing: This limit is based on MMED. An opioid prescription will be denied at the pharmacy if the total MMED is greater than 80. This means that members will need to get approval from SummaCare to fill these opioid prescription(s). Days' Supply Limit Edit: If the course of opioid treatment continues for more than 90 days, the opioid prescription will be denied at the pharmacy. If a member needs more than 90 days of therapy, approval will be required from SummaCare to fill the opioid prescription.	https://www.summacare.com/-/media/project/summacare/website/document-library/formulary-documents/2019-rx-formulary-marketplace.pdf
Prime Therapeutics		https://www.primetherapeutics.com/

	Notes	Source
	Prime uses a controlled substance (CS) score that flags people likely to abuse; alerts go to pharmacies and prescribers in order to notify them of potential problems.	https://www.primetherapeutics.com/content/dam/corporate/Documents/Newsroom/Pressreleases/2017/release-opioid-epidemic-071717.pdf
	Prime published its algorithm to determine CS score.	https://www.jmcp.org/doi/full/10.18553/jmcp.2016.22.12.1403
	An outlier has an average MMED of 90 mg or higher; or, they receive opioids from more than three prescribers and more than three pharmacies; or, they might get their opioids from more than five prescribers regardless of number of pharmacies over a six-month period.	https://www.primetherapeutics.com/en/news/prime-insights/2018-insights/insights-opioidoutliers.html
	Article summarizing efforts	https://www.managedhealthcareexecutive.com/mhe-articles/four-pbm-programs-poised-rein-opioid-epidemic/page/0/1

Appendix E: Policies from Top Ten Healthcare Systems

Policies from Top Ten Healthcare Systems

	Notes	Source
HCA		https://hcahealthcare.com/
	Enhanced Surgical Recovery (ESR) is a multi-modal approach to pain management using pre-, intra-, and post-operative interventions to optimize outcomes; Emergency Department – Alternative to Opioids (ALTO) program is a multi-modal approach to pain control, promoting non-opioid treatment as first-line therapy and patient education about opioid addiction.	https://nam.edu/wp-content/uploads/2019/04/HCA-Healthcare-Commitment-Statement.pdf
	Summary of efforts by HCA, from a conference presentation	https://365.himss.org/sites/himss365/files/365/handouts/552572000/handout-104.pdf
	Pre-surgery protocol to help manage patient expectations of pain. Under the new protocol, physicians will tell patients they "will treat the pain, but you should expect that you're going to have some pain. And you should also understand that taking a narcotic so that you have no pain really puts you at risk of becoming addicted to that narcotic" --Michael Schlosser, MD, CMO for HCA	https://www.beckershospitalreview.com/opioids/hca-warns-patients-they-will-feel-pain-in-effort-to-curb-opioid-use-4-things-to-know.html
	As described by Michael Schlosser, M.D., MBA, FAANS, chief medical officer (CMO), HCA National Group and vice president, Clinical Excellence and Surgical Services at HCA, the conversation quickly shifted to "ways to change the pervasive and damaging culture of reflexive prescribing for pain management that exists among many providers across the country."	https://healthtrustpg.com/clinical-performance/members-in-action/
Ascension Health		https://ascension.org/
	Pain Management Initiative - deliver safe, compassionate evidence-based pain management in accordance with national guidelines. Pain Management Goals - standardize evidence-based pain assessment tools for all patients; increase awareness and use of integrative therapies for pain management; recommend evidence-based practice solutions (in alignment with national guidelines) for acute, chronic and hospital-based order sets across the continuum of care. Pain Management Minimum Standards - document pain assessment using the appropriate assessment tool for the patient; access local prescription drug monitoring program prior to prescribing opioids; assess opioid risk prior to prescribing opioids; all inpatients must have documented pain assessment score and acceptable level of pain within 24 hours of admission and once a day after the initial assessment; do not order X-ray, MRI and CT for acute low back pain without positive differentiation factors; order a scheduled non-opioid drug(s) if there are no contraindications when opioids are prescribed; offer patients integrative therapy solutions for pain management; prescribe no more than 7-14 days of opioids when indicated for acute pain; educate patients on how to dispose of unused	https://www.ndhi.org/files/6415/2640/7161/Inroads_Against_Addiction_-_print_quality.pdf

	Notes	Source
	medication; ensure baseline and annual urine drug screen on chronic patients with an opioid patient agreement/contract.	
CommonSpirit Health (Merger of Catholic Health Initiatives and Dignity Health)		https://commonspirit.org/ https://www.catholichealthinitiatives.org/ https://www.dignityhealth.org/
	CHI internet search showed a couple of programs for OUD. A Dignity program in NV for prenatal treatment was mentioned in its overview of statutes. CommonSpirit Health is new merger.	https://oig.hhs.gov/oas/reports/region9/91801004_Factsheet.pdf
	Initiatives at CHI Franciscan Health have been geared toward limiting the amount of opioids prescribed overall. “Through education, guidelines, and by sharing best practices, we’ve helped to standardize the number of pills given to a single person, thus limiting abuse. We’ve set up a database to determine where the most pills are being prescribed so we can also assess how to reduce those numbers.”	https://www.catholichealthinitiatives.org/en/who-we-are/blogs/relieving-pain-reliever-crisis.html
Trinity Health		https://www.tenethealth.com/
	Trinity chartered its opioid stewardship program in late 2016. It was partly spurred by a bad patient outcome related to failure to identify patient risk. There is a steering group for the system-wide effort, plus partners at each hospital. They produce a monthly newsletter and have monthly meetings.	Interview with Christopher Manthey, VP Chief Pharmacy Informatics Officer
	The home office makes recommendations for programs to hospitals in the system, but there is very little ability to systematically implement those programs or track their outcomes due to having multiple EHR systems in place. Epic will be rolling out system-wide in a couple of years.	Interview with Christopher Manthey, VP Chief Pharmacy Informatics Officer
	Officially, their stance is that they will provide no more than a 7-day supply of opioids to opioid-naïve patients with acute pain, unless state law has shorter limits. They recommend the use of the PDMP and have hard-wired it into some of their hospitals' EHRs. There are system-level reports on individual provider prescribing for those hospitals using Cerner systems. They would like to build alerts in the EHR for OUD diagnosis and a risk evaluation for discharge scripts of controlled substances.	Interview with Christopher Manthey, VP Chief Pharmacy Informatics Officer
Providence St. Joseph Health		https://www.psjhealth.org/

	Notes	Source
	Marino - chief medical informatics officer (CMIO) discussed access to patient information, multiple-state policies and guidelines and use of multiple electronic medical records (EMR). Regarding managing patients' expectations about pain post-surgery, he stated, "The problem is, you have to really tightly manage it. Within the EMR, we built what are called 'multimodal pain sets.' What that means is, when you're first in severe pain, you should do this, but then we should rapidly wean you to something else. So maybe it starts with narcotics, then long-acting NSAIDs, and then something as simple as Tylenol or ibuprofen."	https://healthsystemcio.com/2019/02/05/marino-cmio-provst-joseph-chapter-1/
	Link to plan to use one EMR - they were using three different Epic systems for patient records.	https://www.psjhealth.org/initiatives/nursing-institute/news/2018/08/epic-upgrade-alignment-optimization
Tenet Healthcare		https://www.tenethealth.com
	"High-alert" medication policy - mentions opioids, but not specific to them. Mostly just about double-checking when administering.	https://www.tenethealth.com/docs/default-source/meeting-quality-standards/co-2-024-independent-double-check-high-alert-medications.pdf?sfvrsn=c4362db7_4
Community Health Systems		http://www.chs.net/
	From the searches it looks like they only manage hospitals, but the website is out-of-date. It has links to locations, but they do not work - see next cell.	https://www.chs.net/serving-communities/locations/
	This speaks of affiliates. Did not link to any, but it also spoke of Quorum, whose website does link to individual hospitals. Does not seem to have an explicit, public policy on opioids.	https://www.chs.net/company-overview/
University of California Health		https://www.ucop.edu/uc-health/
	1. Provide better guidance for primary care providers. UC Davis updated policies to follow CDC guidelines. 2. Minimize opioid prescriptions. UC San Diego Health's pain management team has re-written the pain order sets to emphasize non-opioid and multimodal pain management options. 3. Ensure prescribers check the "doctor shopping" database. All California health care providers are required to first check the Controlled Substance Utilization Review and	https://health.ucsd.edu/news/features/Pages/2019-01-07-otc-Six-Ways-UC-San-Diego-Health-is-Combatting-the-Opioid-Crisis.aspx

	Notes	Source
	Evaluation System (CURES) site, a database maintained by the California Department of Justice. 4. Arm patients with more information. 5. Provide a place for secure opioid disposal. MedSafe™ — a collection bin for the disposal of unused, unneeded prescription opioids. 6. Improve access to medication-assisted addiction treatment. UC San Diego Health is expanding its addiction clinic to help primary care providers, women's health care providers, internal medicine physicians and other specialists identify patients with opioid use disorders.	
	UC San Diego gets access to the Bridge Program MAT treatment	https://health.ucsd.edu/news/releases/Pages/2019-02-20-program-gives-uc-san-diego-health-new-resources-to-combat-opioid-epidemic.aspx
	UC Davis program being expanded to other hospitals - the Substance Abuse Navigator (SUN) program trains physicians on best practices on prescribing buprenorphine, a unique schedule III opioid that blocks the euphoric effects of heroin, reducing dope-sickness and craving as patients pursue long-term recovery.	https://health.ucdavis.edu/publish/news/newsroom/13713
	OptumRx prior authorization policies from UCOP links	https://www.ucop.edu/ucship/_files/all-campus-files/pharmacy/optumrx-premium-exclusion-list-july-18.pdf
	A universal policy for opioids for the whole of UC Health system was not found.	
Universal Health Services		https://www.uhsinc.com/
	Information was not found online.	
Kaiser Permanente		https://healthy.kaiserpermanente.org
	Kaiser Permanente's focus on prescribing the lowest effective dose	https://about.kaiserpermanente.org/our-story/our-care/safer-appropriate-opioid-prescribing-kaiser-permanentes-comprehe
	Opioid Medication Agreement	https://thrive.kaiserpermanente.org/care-near-you/northern-california/napasolano/wp-content/uploads/sites/8/2019/05/Opioid-Agreement-ada.pdf

	Notes	Source
	Through the electronic health record, physicians can access the Chronic Opioid Therapy Management Smart Set, decision-support technology, that can be used as a best-practice guide for treating acute and chronic pain, can help flag high-risk patients. The Empathic Pain Conversations program provides physicians with help and support on how to speak about pain and opioids with their patients.	https://about.kaiserpermanente.org/our-story/news/in-the-news/managing-pain-opioids-epidemic
	Enhanced Recovery After Surgery (ERAS) was rolled out in 2014 for patients undergoing colon and hip fracture surgery; now it's used in all inpatient surgeries.	https://about.kaiserpermanente.org/our-story/health-research/news/helping-surgical-patients-avoid-long-term-use-of-opioids
UPMC Health System		https://www.upmc.com
	Three UPMC physicians researched solutions to help patients manage their lower back pain while also decreasing the risk of addiction and maximizing the role of non-opioid therapies.	https://inside.upmc.com/data-prevent-better-treat-pain-addiction/
	Jessica S. Merlin, M.D., a visiting associate professor of medicine at the University of Pittsburgh School of Medicine, pinpointed the common concerning behaviors of chronic-use opioid pain patients, identified management strategies, and established areas of consensus on the importance of each strategy.	https://www.upmc.com/media/news/merlin-jgim
	Research and education are the topics of discussion - UPMC and Pitt take a multidisciplinary approach, bringing together researchers, addiction specialists, pain medicine clinicians, public health practitioners, emergency doctors, pharmacists and others to better understand the problem and seek solutions.	https://www.upmc.com/media/media-kit/opioid-epidemic
Carolinas Healthcare System Atrium Health		https://atriumhealth.org/
	Four-page overview of the opioid problem and the health system's response to it.	https://atriumhealth.org/-/media/chs/images/medical-services/prevention-and-wellness/opioids/opioid-crisis-in-the-carolinas.pdf
	PRIMUM$_{TM}$ - Prescription Reporting with Immediate Medication Utilization Mapping "Our goal was to provide actionable information at the moment it is needed most - before writing a prescription. PRIMUM removes physicians' implicit biases for what an opioid use disorder looks like." - Rachel Seymour, PhD, Vice Chair of Research, Atrium Health Musculoskeletal Institute.	https://atriumhealth.org/medical-services/prevention-wellness/opioid-crisis

	Notes	Source
	Using Atrium's centralized electronic health records to develop an innovative "opioid dashboard," allows medical directors to identify trends in prescribing habits across different locations and specialties.	https://atriumhealth.org/medical-services/prevention-wellness/opioid-crisis/primum
	Opioid task force successfully implemented protocols involving the following modalities to help patients manage their pain beyond opioids: Cryotherapy, Aromatherapy, Guided imagery, Massage and Reiki therapy, Multimodal pain pathways. Added educational intranet page in 2017 - to keep providers up to date on Atrium Health's pain management recommendations as well as public policy impacting prescribing practices.	https://atriumhealth.org/medical-services/prevention-wellness/opioid-crisis/quality-and-safety

Appendix F: Policies from Top Ten Chain Pharmacies

Policies from Top Ten Chain Pharmacies

	Notes	Source
CVS		https://www.cvs.com/
	7-Day Acute Limit: A new prescription for an acute condition is limited to a 7-day supply for a patient with no opioid prescriptions in the prior 90 days.	CVS Caremark Opioid Quantity Limits: Pharmacy Reference Guide https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf
	IR/ER Step Therapy: Use of an IR opioid is required prior to receiving an ER opioid due to increased patient risk. Prior authorization is needed if there is no history of an IR or ER opioid in the previous 90 days.	
	Max Dose Limits: Limit the dose of opioids prescribed to a 90 MME/day. Prescribers may request a prior authorization for higher doses up to 200 MME/day.	
	"When max quantity limits are exceeded…Pharmacists should reach out to prescribers by phone to communicate the rejection and understand whether the quantity can be reduced within limits."	
	Via link to Aetna: "By providing coverage for EXPAREL™ for wisdom tooth extractions, members have access to a safe and effective pain treatment option that can provide relief for the first few days following a procedure. As part of this strategy, Aetna has enhanced its online provider search tool, DocFind, to help members search for providers who offer opioid alternatives like EXPAREL."	
	Via link to Aetna: "Aetna's strategic programs focus on prevention… including 'super-prescriber' interventions to physicians, surgeons, and dentists with outlying opioid prescribing habits."	
	Via link to Aetna: "By providing coverage for EXPAREL for wisdom tooth extractions, members have access to a safe and effective pain treatment option that can provide relief for the first few days following a procedure. As part of this strategy, Aetna has enhanced its online provider search tool, DocFind, to help members search for providers who offer opioid alternatives like EXPAREL."	https://news.aetna.com/2018/09/aetna-making-progress-in-its-fight-against-opioid-misuse-abuse/
	Via link to Aetna: "Aetna's strategic programs focus on prevention… including 'super-prescriber' interventions to physicians, surgeons, and dentists with outlying opioid prescribing habits."	https://news.aetna.com/2016/08/opioid-super-prescribers/
Walgreens		https://www.walgreens.com/
	7-day limit for Rx treating acute pain. No dose limit for ongoing Rx. Pharmacists have a red flag list they use to evaluate the appropriateness of a Rx.	Telephone interview with Tasha Polster, VP, Pharmacy Quality, Compliance, and Patient Safety (she could not provide information in writing but approved being cited as the information source).

	Notes	Source
	Red flag list includes: seek additional info from patient and physicians if Rx for any drug containing oxycodone, hydromorphone, methadone, morphine, fentanyl, or Opana™; copy photo ID; run PDMP; inform Pt may take longer to fill Rx; Call physician if "in your professional judgment a call to a prescriber is warranted"; ask doctor to verify writing Rx, patient diagnosis, expected length of treatment, date of last office visit. Red flag list includes: Rx not previously filled at Walgreens, new doctor writing Rx for same pain med, doctor who is not close geographically to the pharmacy, patient paying in cash, patient seeking early refill, patient seeking excessive number of pills, patient taking same pain med more than 6 months.	http://nationalpainreport.com/walgreens-secret-checklist-pain-meds-8821775.html
	Asked about Walgreen's pressure on prescribers to follow the CDC guidelines, company spokesperson Phil Caruso told Fox News, "As a key patient touchpoint in the nation's healthcare delivery system, we regularly communicate with prescribers to help ensure the safe and effective dispensing of medications in the best interest of our customers."	https://www.foxnews.com/health/doctors-abandon-opioid-prescribing-as-state-and-federal-authorities-step-up-enforcement
	"The heart of this policy is Title 21 of the Code of Federal Regulations, Section 1306.4 which explains that a pharmacist has a corresponding responsibility to ensure that any prescription for a controlled substance that is dispensed is done so for a legitimate medical purpose."	http://paindr.com/is-walgreens-opiate-policy-deceptive/
	"Walgreens responded by tightening its preexisting 'Good Faith Dispensing' policy, requiring pharmacists to take a series of steps when presented with a controlled substance prescription, steps that might include calling the prescriber to confirm information about the patient and the patient's diagnosis and treatment plan, and about the prescriber."	https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21243
	Outlier is "…one who has an average daily morphine milligram equivalent (MME) of 90mg or higher; receives opioids from more than three prescribers and more than three pharmacies; or they might get their opioids from more than five prescribers regardless of number of pharmacies over a six-month period."	
Walmart		https://www.walmart.com/cp/pharmacy/5431
	Restricts initial acute opioid prescriptions to no more than a seven-day supply, with up to a 50 MME maximum per day in alignment with CDC guidelines. If a state law for fills on new acute opioid prescriptions is less than seven days, the company will follow state law. Pharmacists provide patients with counseling using CDC guidelines, focusing on using the lowest effective dose for pain management for the shortest time possible.	https://corporate.walmart.com/media-library/document/opioid-fact-sheet/_proxyDocument?id=00000163-3abc-ded8-ab7f-3ffe314e0000
	By January 1, 2020, e-prescriptions will be required for controlled substances.	https://news.walmart.com/2018/05/07/walmart-introduces-additional-measures-to-help-curb-opioid-abuse-and-misuse
	Walmart's policies also apply to Sam's Club Pharmacies.	

	Notes	Source
Rite Aid		https://www.riteaid.com/
	Participating in prescription drug monitoring programs, including a "red flag" process for pharmacists to regularly review prescriptions for patients not known by the pharmacy or where there may be concerns or suspicions of misuse.	https://www.riteaid.com/corporate/news/-/pressreleases/news-room/2018/rite-aid-applauds-new-law-signed-by-president-trump-to-help-fight-opioid-abuse
	Rite Aid's PBM has a program, EnvisionCare Pain Management, with 7-day limit on prescriptions for patients who have not used an opioid analgesic in the past 3 months, step therapy for extended-release opioid analgesics, and prior authorization for extremely high dosages, greater than 200 MMEs. Drug utilization reviews at the pharmacy promote proper dispensing and point-of-sale alerts for high dosages or unsafe interactions between medications.	https://www.pharmacist.com/article/rite-aids-envisionrx-takes-steps-minimize-opioid-addiction-risk
	Supplemental reviews to identify patients who may be filling high dosage opioids and/or receiving prescriptions from multiple prescribers and dispensers. Shortened refill window to exhausted 85% of supply before refill dispensed.	https://www.drugstorenews.com/pharmacy/rite-aids-envisionrx-takes-steps-to-minimize-opioid-addiction-risk/
Kroger		https://www.kroger.com/
	Appriss PMP Gateway through the National Association of Boards of Pharmacy PMP Interconnect (PMPI) Hub.	https://www.healthit.gov/sites/default/files/2019-01/InteroperabilityOpioidsPDMPs.pdf
	"Implementation of a prescription drug monitoring program (PDMP) report review in workflow with NARxCHECK™" "Kroger was first major pharmacy chain to integrate a PDMP report review with workflow...in those states where the feature is enabled..."	https://www.cdcfoundation.org/businesspulse/opioid-overdose-epidemic-Q-A-menkhaus
	"In January, North Carolina's Controlled Substances Reporting System (CSRS) joined the National Association of Boards of Pharmacy's data sharing network, PMP InterConnect, to help reduce prescription drug misuse. This network allows doctors and other clinicians to obtain multi-state information about their patients' opioid prescriptions. The 45-state prescription monitoring network processes more than 15 million transactions of prescription data per month. Kroger and Harris Teeter utilize this in more than 1,300 stores across 18 states. They are the first pharmacy chains to implement this into their regular workflow, a step that occurs before dispensing to reduce the potential to dispense unwarranted controlled substance prescriptions."	https://apprisshealth.com/press-release/kroger-harris-teeter-pharmacies-join-dhhs-fight-prescription-drug-misuse/
	"The NARxCHECK risk detection algorithms and Kroger's system configuration settings for required review are proprietary information, thus not available for this report."	https://webcache.googleusercontent.com/search?q=cache:RyyxOQxFf_8J:https://www.pdmpassist.org/pdf/NFF_Kroger_20161208.pdf+&cd=9&hl=en&ct=clnk&gl=us&client=firefox-b-1-d
	"The Kroger system automatically requests and receives a PDMP report for all controlled substance prescriptions submitted for the patient, using data from all enabled neighboring states linked to the host state's PDMP The reports are available using the analytical tool, accessible via the "PDMP" button in the pharmacists' dispensing software, so no separate	

	Notes	Source
	PDMP login is necessary Should the patient's prescription data meet or exceed specific risk thresholds, the system is configured to alert the pharmacist that the report must be reviewed prior to dispensing...The credentials of the reviewing pharmacists are captured and stored."	
	"Should a review be required, prompts appear that notify the pharmacist that PDMP data must be consulted; attempts to bypass a forced review automatically block the promotion of the prescription to the next workflow step."	
	"Guidance on how to use the system and interpret PDMP data, such as detecting red flags, is available from links within the application; it includes FAQS, training materials, and a detailed manual."	
	States include AK, AR, AZ, CO, ID, IN, KS, LA, MS, NM, NV, OH, SC, TX, VA, WV.	
	Menkhaus: "Pharmacies can decline to fill CS Rxs when a legitimate need exists".	Presentation https://www.slideshare.net/OPUNITE/rx16-pharma-wed11151ryle2menkhaus3mcginley
Albertsons		https://www.albertsons.com
	Unable to find online information	
Publix		
	The Opioid Management program applies to all members and consists of daily quantity limits specific to each covered opioid drug and prior authorization requirements for certain prescribing situations.	https://member.myhealthtoolkitfl.com/web/nonsecure/publix/Member+Home/Education+Center/Enrollment+Tools/Drug+Lists/Drug+Lists
	In line with CDC prescribing guidelines	
	Link to 7-page document explaining their policy. Document includes 4 pages of medications with specific limits based on drug, drug strength, and if the med is IR, ER, or combination. Certain drugs are disallowed. Monthly quantity limits are detailed in the charts but the verbiage for the public says that there are daily quantity limits specific to each opioid and prior authorization is required for certain prescribing situations.	https://member.myhealthtoolkitfl.com/web/nonsecure/publix/Member+Home/Education+Center/Enrollment+Tools/Drug+Lists/Drug+Lists
	Doctor can request medications to be dispensed over amount in policy, but requests go to CVS Caremark or patient's health plan for review.	
	Program does NOT apply to patients with cancer or sickle cell disease, or those on hospice. These will be pre-authorized.	
	If one's Rx is more than the limit, the pharmacist can reduce to the quantity the plan covers, the patient can pay full price for all or the part that exceeds the limit, or the pharmacist can ask the prescriber for a quantity override, if available.	

	Notes	Source
	CVS Caremark is the PBM for Publix.	
	Pharmacy benefit managers (CVS Caremark) "are better placed than others in the pharmacy supply chain to put this approach to the CDC Guideline into practice," as opposed to medication wholesalers or retail pharmacists.	https://www.statnews.com/2017/09/21/cvs-opioid-prescription-limits/
	CVS Caremark: opioid naïve patients have a 7-day limit, daily dosage limits, and required IR before ER; doctor can ask for exemptions and employers and insurers can opt out.	
Ahold Delhaize		https://www.aholddelhaize.com/en/home/
	Ahold Delhaize brands have WellDyneRx pharmacies	
	"WellDyneRx is an independent PBM: We integrate claims from multiple pharmacies, including retail, mail order, and specialty service pharmacies each time a member uses the benefit. More importantly, each claim passes through more than 200 edits for member eligibility, plan design, pricing, clinical appropriateness and more."	
	"The Well-Managed-Opioids program, launched in 2014 to address the opioid crisis, leverages Morphine Equivalent Dose (MED) checks at the point-of-sale (prior to pharmacy dispensing) to ensure high dosage patients are being carefully monitored by their providers and receiving appropriate prescriptions. These MED checks take into account all of the pain medications a patient is prescribed and combine their dosing totals instead of looking only at the dosage levels of each drug individually. Using advanced pharmacy technology, patients who are prescribed potentially inappropriate concomitant medications with opioids, such as benzodiazepines or muscle relaxers, are identified and actionable reports are created for both prescriber and patient outreach."	https://www.welldynerx.com/solutions/clinical-expertise/
	"Our Well-Managed-Opioids Program takes a comprehensive approach to addressing this growing problem." Real time point of service (POS) cumulative MED edits, Prior Authorization for targeted high-risk meds, proprietary risk stratification evaluation, physician communication on at-risk members, cancer, end-of-life care, or hospice patients are excluded.	https://www.welldynerx.com/listening-client-faqs/
H-E-B		https://www.heb.com/
	"H-E-B RxTRA Advantage offers you a fresh approach to Pharmacy Benefit Management services by delivering complete transparency and full disclosure. We guarantee 100% pass-through pricing. In addition, we don't believe in a one-size-fits-all approach. Instead we work with you to customize a plan that meets the needs of your business and your employees."	https://www.heb.com/static-page/article-template/heb-rxtra-advantage
	Offer compounding for pain management.	https://www.heb.com/

	Notes	Source
	Accepts ECPS.	
	Mr. Wiesner (Sr. Dir. of Gov't Affairs, Privacy, and Pharmacy for H-E-B) says H-E-B, which installed EPCS software in its 240 Texas pharmacies more than a year ago, trains its pharmacists to look for red flags. He says the red flags apply to electronic and paper prescriptions and include: Questionable drug combinations and quantities; the physical distance between the prescribing physician's office and the pharmacy, distance between the prescribing physician and the patient's home address, and distance between the patient and the pharmacy; and cash payment. (July 2014 article)	https://www.texmed.org/NecessaryPain/
	"When pharmacists encounter one of these red flags, they can call the prescribing physician to confirm the medication or search the patient's DPS profile to look for signs of drug abuse."	
	"We trust pharmacists to use professional judgment," he said. "I think our folks tend to err on the side of the patient when they can."	
	Mr. Wiesner says "when a physician sends an EPCS to H-E-B, the prescription must pass through Surescripts, an intermediary that looks at multiple data, including the drug in question. Surescripts also checks to see if the prescribing physician's EPCS software is DEA-certified. If it is, the prescription is sent to an H-E-B pharmacy for processing."	
		http://www.texaspharmacycongress.org/images/TFDS_Report_to_The_Pharmacy_Congress_02.20.2018.pdf
Costco		https://www.costco.com/Pharmacy/
	Unable to find online information	

Appendix 29 Evaluation of the Impact of REMS-Compliant Accredited CE White Paper Addendum

Addendum to:
Options for Evaluating the Impact of REMS-Compliant Continuing Education on Opioid Prescribing Practices, Patient Management and Patient Outcomes

Reflecting New RPC Reports on Efforts to Contain Opioid Prescribing and Improve the Care of Patients Receiving Opioids in the United States

Prepared for the Opioid Analgesic REMS Program Companies

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CONTENTS

1. SUMMARY 3
2. BACKGROUND 4
3. IMPLICATIONS 5
4. A PATH FORWARD 7
5. REFERENCES 8

1. SUMMARY

As detailed in reports commissioned and recently received by the REMS Program Companies (RPC), there has been an extraordinary increase in legislation and policy to manage the prescription of opioid products across the United States. Prescribers who go through continuing education (CE) programs on opioids are simultaneously receiving information from the health care organizations that employ them, as well as from insurers, states, the Federal government and state medical boards. Many of these organizations also seek to influence opioid prescribing practices through restrictions on practice. The consequent changes may affect the feasibility of population-level assessments of the impact of CE programs.

Usual methods for direct assessment of the impact of CE on prescriber behavior may have become ineffective in the current US environment. First, there may not be informative concurrent comparison groups. The current requirements for opioid-specific CE from state medical boards remove the possibility of comparing persons who undergo REMS-compliant CE against an untrained control group. Such untrained prescribers as do remain in the active medical population may be so unrepresentative as to say nothing about the counterfactual: "What would have been the performance of the recipients of training, had they not received training?"

The second usual comparison technique is an examination of practice before and after training. This approach is heavily influenced by concurrent trends in practice, which can masquerade as a before-after effect of CE. If the trends are sufficiently stable, and if their drivers are well-understood, statistical adjustment may be able to remove their effects. In the present setting of hundreds of new laws and policies, differing across the nation, an assumption that the resulting trends can be accurately modeled is aspirational at best, and may be foolhardy.

There are extraordinary resources for monitoring drug prescription in the US as a whole and patient care for large segments of the population.

The best current strategy may be to aggressively monitor prescription patterns against CDC guidelines, state-by-state and year-by-year. The monitoring will permit stakeholders to assess the net impact of the forces that are changing opioid practice in the US. Important regional and secular effects, properly linked to information on population level, may also prove instructive for the creation of better laws and policies.

The considerations arising from the newly received reports on the landscape of opioid prescription control in the US do not invalidate the analysis or recommendations of our July 2019 report. They do however point to the wisdom of focusing first on characterizing the regional and secular trends, as recommended there. The apparent magnitude of the environmental factors that are driving possible changes may however mean that direct assessment of behaviors induced by individual CE programs will be infeasible.

2. BACKGROUND

On July 18, 2019, WHISCON submitted to the RPC a White Paper on the evaluation of REMS-compliant CE programs.[1] The key messages were:

1. Data for evaluating opioid prescribing and patient management exist for large segments of the US population.
2. The CDC has provided guidelines for suitable population-level endpoints to assess both the quality of opioid prescribing and the management of patients who receive opioid products.[2]
3. A straightforward conceptual framework provides the basis for a statistical model that can link CDC-endpoints to static and time-varying facts about prescribers, patients and the prescribing environment.
4. Evaluation of CE requires the integration of CE completion data for individual prescribers into the existing data systems.

The recommendation of the White Paper was to use a proposed conceptual framework for the determinants of opioid prescribing that incorporates prescriber, patient and environmental factors (including past history for each) as the basis for statistical modeling of opioid prescription and patient management practices over time. The next step was to superimpose on that model individual data on completion of REMS-compliant CE, so as to assess the marginal effect of REMS-compliant CE on prescribing and patient management.

In July 2019, the RPC received a draft report on the landscape of CE related to opioid prescribing and patient management in the US.[3] The report enumerates every state medical board's CE requirements for doctors of medicine and osteopathy, physician assistants. podiatrists, naturopaths, nurses, dentists, optometrists and pharmacists. The report identifies and provides information on 273 currently active CE programs related to opioids. Finally, it provides information on substantial CE requirement by health systems including the US Department of Defense, Veterans Administration, Indian Health Services and 13 large non-governmental health systems.

Additionally, the RPC received a final report on "Governmental and Non-Governmental Policies Affecting Opioid Prescribing: 2016-2019" on July 12, 2019.[4] The following excerpt from the report's Overview provides the flavor of the documentation:

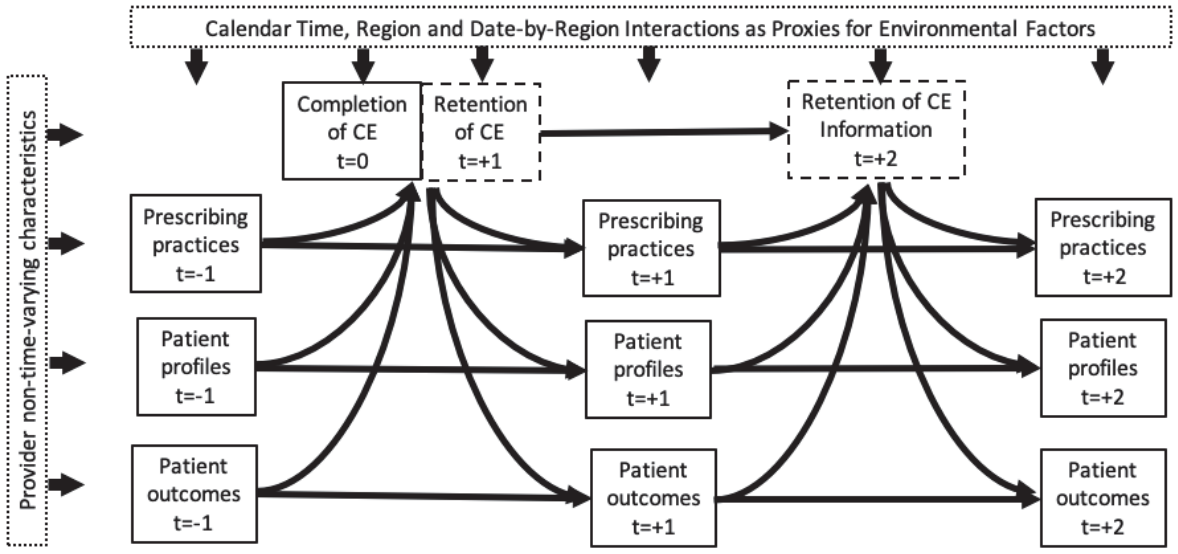
> "Five-hundred twenty-six (526) policies related to opioid prescribing were adopted from 2016–2018. Policies include federal statutes, state statutes and regulations, state guidelines from licensing agencies and departments of health, federal guidelines and policies from CDC, CMS, VA, HHS, NASEM, and FDA, State Medicaid opioid policies, and initiatives from the President of the United States and numerous Governors."

All of the policies are summarized in the report, with links to the full texts.

3. IMPLICATIONS

The analyses of CE proposed in the WHISCON White Paper arose from a conceptual framework that recognized that prescriber behaviors could be conditioned by a wide range of current and historical factors whose relations were sketched in the White Paper's Figure 2, reproduced below.

Figure 2. Possible causal pathways for the evaluation of continuing education interventions.



Completion date REMS-compliant CE is known for each caregiver. This determines t=0
Prescribing practices, patient profiles, and patient outcomes are all measurable at t=-1, 0, +1 .
Calendar time (date), region and date-by-region interactions are proxies for environmental factors.
Provider non-time-varying characteristics are known by the proxies of specialty, age, sex.
Boxes with solid outlines refer to observables. Dotted lines enclose factors that are not observed directly.

The White Paper noted that there were data available in the US to characterize prescribing behavior essentially across the nation, and that there were large bodies of information from health insurers and medical care organizations that could be brought to the analysis of patient management. Taking the known data elements from these sources, and recommendation from the US Centers for Disease Control for population monitoring of opioid prescribing and patient management, and placing these within a statistical structure based on the conceptual framework of Figure 2, the White Paper proposed overall approach that consisted first in estimating the dynamics of the system of Figure 2 absent CE, and then adding a representation of the immediate and subse uent effects of CE training for individual prescribers whose time of REMS-compliant CE was known and linkable to other available information.

The statistical models proposed in the White Paper subsumed the two usual methods for direct assessment of CE. The first was the assumption of informative concurrent comparison groups of active prescribers who had not attended opioid-specific CE programs, or whose non-REMS-compliant CE failed to meet the standards of the FDA Blueprint.[5] The effect of CE versus absence of REMS-compliant CE was to be modeled with a series of indicator terms, with control for all the other determinants of CDC-proposed outcomes.

An assumption of the modeling proposed in the White Paper was that REMS-compliant CE was special, if not uni ue , in the completeness of information offered to participants. This assumption permitted other CE programs to be either ignored or treated in effect as an environmental factor. The newly available detailed on the components of these programs suggests that many, if audited, would be found to meet the same criteria of the FDA Blueprint as the RPC-sponsored programs. Against a background of 273 existing CE programs on

opioids, the assumption that the effects of alternative programs could be ignored in evaluating the 14 RPC-sponsored, REMS-compliant CE programs seems implausible.

Such untrained prescribers as may remain in the active medical population will be so unrepresentative as to say nothing about the counterfactual of what would have been the performance of the recipients of training, had they not received training.

The second usual comparison technique is an examination of practice before and after training. This approach is heavily influenced by concurrent trends in practice, which can masquerade as a before-after effect of CE. If these trends are sufficiently stable and well-understood, statistical adjustment may be able to remove their effects. In the present setting of literally hundreds of new laws and policies, differing across the nation, an assumption that these can be accurately modeled going forward is aspirational at best, and may be foolhardy.

The White Paper did not provide detail on the nature of the environmental factors of Figure 2. It suggested instead that the initial modeling should allow for arbitrary secular effects that might vary within states. There was an assumption that this level of detail would be a sufficient accounting for the effects external to the CE programs. It is unlikely that such modeling could correct for the evolving temporal effects of the 526 identified policies in sufficient detail to permit attribution of residual temporal changes in prescriber behavior to their particular CE programs.

4. A PATH FORWARD

The RPC are proposing to conduct ongoing monitoring of prescription practices in the US. We concur with that idea, specifying that the analyses recognize that the determinants of prescription practice are likely to have strong regional and temporal variations. REMS-compliant CE is likely to be a part of the regional and temporal determinants of practice and patient management, but there appears to be little opportunity to sort out the behavior effects of the sponsored programs.

5. REFERENCES

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