STATES THAT REQUIRE PRESCRIBERS AND/OR DISPENSERS TO ACCESS PMP DATABASE IN CERTAIN CIRCUMSTANCES

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Introduction

A growing number of states are requiring certain practitioners and/or dispensers to access the prescription monitoring program database in certain circumstances, typically before prescribing a Schedule II or III controlled substance; however, the circumstances under which a practitioner is required to access the database vary from state-to-state. Any specific questions regarding whether a practitioner is required to access the database in a particular situation should be directed to the practitioner's licensing entity.

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Colorado

7 CCR 1101-3:17
7 CCR 1101-3:17, Exhibit 6
7 CCR 1101-3:17, Exhibit 7
7 CCR 1101-3:17, Exhibit 9
7 CCR 1101-3:18

West's Colorado Administrative Code (2013)
Title 1100. Department of Labor and Employment
1101. Division of Workers' Compensation
7 CCR 1101-3. Workers' Compensation Rules of Procedure with Treatment Guidelines

1101-3:17 EXHIBIT 5. CUMULATIVE TRAUMA CONDITIONS MEDICAL TREATMENT GUIDELINES

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c. Narcotics: should be primarily reserved for the treatment of severe upper extremity pain. There are circumstances where prolonged use of narcotics is justified based upon specific diagnosis, and in these cases, it should be documented and justified. In mild-to-moderate cases of upper extremity pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a pain scale and assessment of function to rate effectiveness of the narcotic prescribed. Any use beyond the maximum duration should be documented and justified based on the diagnosis and/or invasive procedures.

• Optimal Duration: 3 to 7 days.

• Maximum Duration: 2 weeks. Use beyond two weeks is acceptable in appropriate cases. Refer to the Chronic Pain Guidelines which gives a detailed discussion regarding medication use in chronic pain management. **When prescribing beyond the maximum duration, it is recommended physicians access the Colorado Prescription Drug Monitoring Program (PDMP). This system allows the prescribing physician to see all controlled substances prescribed by other physicians for an individual patient.**

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West's Colorado Administrative Code (2013)
Title 1100. Department of Labor and Employment
1101. Division of Workers' Compensation
7 CCR 1101-3. Workers' Compensation Rules of Procedure with Treatment Guidelines

1101-3:17 EXHIBIT 6. LOWER EXTREMITY INJURY MEDICAL TREATMENT GUIDELINES

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e. Narcotics should be primarily reserved for the treatment of severe lower extremity pain. There are circumstances where prolonged use of narcotics is justified based upon specific diagnosis, and in these cases, it should be documented and justified. In mild-to-moderate cases of lower extremity pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a pain scale and assessment of function to rate effectiveness of the narcotic prescribed. Any use beyond the maximum duration should be documented and justified based on the diagnosis and/or invasive procedures.

Optimal Duration: 3 to 7 days.

Maximum Duration: 2 weeks. Use beyond two weeks is acceptable in appropriate cases. Refer to Chronic Pain Guidelines which gives a detailed discussion regarding medication use in chronic pain management. **When prescribing beyond the maximum duration, it is recommended physicians access the Colorado PDMP (Prescription Drug Monitoring Program). This system allows the prescribing physician to see all controlled substances prescribed by other physicians for an individual patient.**

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West's Colorado Administrative Code (2013)
Title 1100. Department of Labor and Employment
1101. Division of Workers' Compensation
7 CCR 1101-3. Workers' Compensation Rules of Procedure with Treatment Guidelines

1101-3:17 EXHIBIT 7. COMPLEX REGIONAL PAIN SYNDROME/REFLEX SYMPATHETIC DYSTROPHY MEDICAL TREATMENT GUIDELINES

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c. Medical Management History:

i. History of diagnostic tests and results including but not limited to any response to sympathetic nerve blocks, results of general laboratory studies, EMG and nerve conduction studies, radiological examinations, including triple phase bone scan or thermography with autonomic stress testing, and tests of sudomotor functioning such as QSART.

ii. Prior Treatment -- Chronological review of medical records including previous medical evaluations and response to treatment interventions. In other words, what has been tried and what has been helpful?

iii. Prior Surgery -- If the patient has had prior surgery specifically for the pain, he/she may be less likely to have a positive outcome.

iv. History of and current use of medications, including over-the-counter and herbal/dietary supplements to determine drug usage (or abuse) interactions and efficacy of treatment. Drug allergies and other side effects experienced with previous or current medication therapy and adherence to currently prescribed medications should be documented. Ideally, this includes dosing schedules as reported by the patient or patient representative. **Information should be checked against the Colorado Prescription Drug Monitoring Program, offered by the Colorado Pharmacy Board.**

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West's Colorado Administrative Code (2013)
Title 1100. Department of Labor and Employment
1101. Division of Workers' Compensation
7 CCR 1101-3. Workers' Compensation Rules of Procedure with Treatment Guidelines

1101-3:17 EXHIBIT 9. CHRONIC PAIN DISORDER MEDICAL TREATMENT GUIDELINES

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c. Medical Management History:

i. Diagnostic Tests -- All previous radiological and laboratory investigations should be reviewed.

ii. Prior Treatment -- Chronological review of medical records including previous medical evaluations and response to treatment interventions. In other words, what has been tried and which treatments have helped?

iii. Prior Surgery -- If the patient has had prior surgery specifically for the pain, he/she may be less likely to have a positive outcome.

iv. Medications -- History of and current use of medications, including over the counter and herbal/dietary supplements to determine drug usage (or abuse) interactions and efficacy of treatment. Drug allergies and other side effects experienced with previous or current medication therapy and adherence to currently prescribed medications should be documented. Ideally, this includes dosing schedules as reported by the patient or patient representative. **Information should be checked against the Colorado Prescription Drug Monitoring Program (PDMP), offered by the Colorado Pharmacy Board.**

v. Review of Systems Check List -- Determine if there is any interplay between the pain complaint and other medical conditions.

vi. Psychosocial Functioning -- Determine if any of the following are present: current symptoms of depression or anxiety; evidence of stressors in the workplace or at home; and past history of psychological problems. Other confounding psychosocial issues may be present, including the presence of psychiatric disease. Due to the high incidence of co-morbid problems in populations that develop chronic pain, it is recommended that patients diagnosed with chronic pain should be referred for a full psychosocial evaluation.

vii. Pre-existing Conditions -- Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.

viii. Family history pertaining to similar disorders.

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West's Colorado Administrative Code (2013)
Title 1100. Department of Labor and Employment
1101. Division of Workers' Compensation
7 CCR 1101-3. Workers' Compensation Rules of Procedure with Treatment Guidelines

1101-3:18. MEDICAL FEE SCHEDULE

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(5) Chronic Opioid Management Report

(a) When the authorized treating physician prescribes long-term opioid treatment, s/he shall use the Division of Workers' Compensation Chronic Pain Disorder Medical Treatment Guidelines and also review the Colorado State Board of Medical Examiners' Policy # 10-14, "Guidelines for the Use of Controlled Substances for the Treatment of Pain." Urine drug tests for chronic opioid management shall employ testing methodologies that meet or exceed industry standards for sensitivity, specificity and accuracy. The test methodology must be capable of identifying and quantifying the parent compound and relevant metabolites of the opioid prescribed. In-office

screening tests designed to screen for drugs of abuse are not appropriate for chronic opioid compliance monitoring.

(1) Drug testing shall be done prior to the initial long-term drug prescription being implemented and randomly repeated at least annually.

(2) When drug screen tests are ordered, the authorized treating physician shall utilize the Colorado Prescription Drug Monitoring Program (PDMP).

(3) While the injured worker is receiving chronic opioid management, additional drug screens with documented justification may be conducted. Examples of documented justification include the following:

(i) Concern regarding the functional status of the patient

(ii) Abnormal results on previous testing

(iii) Change in management of dosage or pain

(iv) Chronic daily opioid dosage above 150 mg of morphine or equivalent

(4) The opioids prescribed for long-term treatment shall be provided through a pharmacy.

(5) The prescribing authorized treating physician shall review and integrate the screening results, PDMP, and the injured worker's past and current functional status on the prescribed levels of medications. A written report will document the treating physician's assessment of the patient's past and current functional status of work, leisure activities and activities of daily living competencies.

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Delaware

16 § 4798 (eff. until March 1, 2014)
16 § 4798 (eff. March 1, 2014)

West's Delaware Code Annotated (2013)
Title 16. Health and Safety
Part IV. Food and Drugs
Chapter 47. Uniform Controlled Substances Act
Subchapter VII. Miscellaneous

§ 4798. The Delaware Prescription Monitoring Program

<Text of section effective until March 1, 2014>

(a) It is the intent of the General Assembly that the Delaware Prescription Monitoring Act established pursuant to this section serves as a means to promote public health and welfare and to detect the illegal use of controlled substances. The Delaware Prescription Monitoring Act shall have the dual purpose of reducing misuse and diversion of controlled substances in the State while promoting improved professional practice and patient care.

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(e) A prescriber, or other person authorized by the prescriber, shall obtain, before writing a prescription for a controlled substance listed in Schedule II, III, IV or V for a patient, a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Office of Controlled Substances when the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition. The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is necessary.

(f) The Office of Controlled Substances may issue a waiver to a prescriber who is unable to access prescription information by electronic means. A prescriber who is unable to access prescription information by electronic means shall obtain a waiver from the OCS on annual basis until such time they can access the prescription information by electronic means.

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West's Delaware Code Annotated (2013)
Title 16. Health and Safety
Part IV. Food and Drugs
Chapter 47. Uniform Controlled Substances Act
Subchapter VII. Miscellaneous

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(e) When a dispenser has a reasonable belief that a patient may be seeking a controlled substance listed in Schedule II, III, IV or V for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the Prescription Monitoring Program before dispensing the prescription.

(f) A prescriber, or other person authorized by the prescriber, shall obtain, before writing a prescription for a controlled substance listed in Schedule II, III, IV or V for a patient, a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Office of Controlled Substances when the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition. The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is necessary.

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Kentucky
§ 218A.172
201 KAR 9:260

Baldwin's Kentucky Revised Statutes Annotated (2013)
Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 218A.172 Protocols preceding initial prescribing or dispensing of Schedule II controlled substance or Schedule III controlled substance containing hydrocodone; continuing course of treatment; recordkeeping; exemptions

(1) Administrative regulations promulgated under subsection (3) of Section 4 of this Act shall require that, prior to the initial prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a practitioner shall:

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query the electronic monitoring system established in KRS 218A.202 for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(2)(a) Administrative regulations promulgated under subsection (3) of Section 4 of this Act shall require that a practitioner prescribing or dispensing additional amounts of Schedule II controlled substances or Schedule III controlled substances containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;

2. Provide to the patient any new information about the treatment; and

3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the administrative regulations shall also require that the practitioner:

1. Query the electronic monitoring system established in KRS 218A.202 no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and

2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

(3) Administrative regulations promulgated under subsection (3) of Section 4 of this Act shall require that, for each patient for whom a practitioner prescribes any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the practitioner shall keep accurate, readily accessible, and complete medical records which include, as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

(g) Medications, including date, type, dosage, and quantity prescribed or dispensed;

(h) Instructions and agreements; and

(i) Periodic reviews of the patient's file.

(4) Administrative regulations promulgated under subsection (3) of Section 4 of this Act may exempt, in whole or in part, compliance with the mandatory diagnostic, treatment, review, and other protocols and standards established in this section for:

(a) A licensee prescribing or administering a controlled substance immediately prior to, during, or within fourteen (14) days following an operative or invasive procedure or a delivery if the

prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;

(b) A licensee prescribing or administering a controlled substance necessary to treat a patient in an emergency situation;

(c) A licensed pharmacist or other person licensed by the Kentucky Board of Pharmacy to dispense drugs or a licensed pharmacy;

(d) A licensee prescribing or dispensing a controlled substance:

1. For administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a practitioner in those hospitals or facilities where no institutional account exists, queries the electronic monitoring system established in Section 3 of this Act for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

5. Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing or dispensing;

b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

6. Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another practitioner in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or

7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United State Department of Health and Human Services, Office for Human Research Protections where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health;

(e) The prescribing of a Schedule III, IV, or V controlled substance by a licensed optometrist to a patient in accordance with the provisions of KRS 320.240; or

(f) The prescribing of a three (3) day supply of a Schedule III controlled substance following the performance of oral surgery by a dentist licensed pursuant to KRS Chapter 313.

(5)(a) A state licensing board promulgating administrative regulations under subsection (3) of Section 4 of this Act may promulgate an administrative regulation authorizing exemptions supplemental or in addition to those specified in subsection (4) of this section. Prior to exercising this authority, the board shall:

1. Notify the Kentucky Office of Drug Control Policy that it is considering a proposal to promulgate an administrative regulation authorizing exemptions supplemental or in addition to those specified in subsection (4) of this section and invite the office to participate in the board meeting at which the proposal will be considered;

2. Make a factual finding based on expert testimony as well as evidence or research submitted to the board that the exemption demonstrates a low risk of diversion or abuse and is supported by the dictates of good medical practice; and

3. Submit a report to the Governor and the Legislative Research Commission of its actions, including a detailed explanation of the factual and policy basis underlying the board's action. A copy of this report shall be provided to the regulations compiler.

(b) Within one (1) working day of promulgating an administrative regulation authorizing an exemption under this section, the promulgating board shall email to the Kentucky Office of Drug Control Policy:

1. A copy of the administrative regulation as filed, and all attachments required by KRS 13A.230(1) and

2. A request from the board that the office review the administrative regulation in the same manner as would the Commission on Small Business Advocacy under KRS 11.202(1)(e), and submit its report or comments in accordance with the deadline established in KRS 13A.270 (1)(c). A copy of the report or comments shall be filed with the regulations compiler.

Kentucky Administrative Regulations (2013)
Title 201. General Government Cabinet
Chapter 9. Board of Medical Licensure

201 KAR 9:260. Professional standards for prescribing and dispensing controlled substances

Section 1. Applicability. (1) A physician who is authorized to prescribe or dispense a controlled substance shall comply with the standards of acceptable and prevailing medical practice for prescribing and dispensing a controlled substance established in this administrative regulation.

(2) The professional standards established in this administrative regulation shall not apply to a physician prescribing or dispensing a controlled substance:

(a) To a patient as part of the patient's hospice or end-of-life treatment;

(b) To a patient admitted to a licensed hospital as an inpatient, outpatient, or observation patient, during and as part of a normal and expected part of the patient's course of care at that hospital;

(c) To a patient for the treatment of pain associated with cancer or with the treatment of cancer;

(d) To a patient who is a registered resident of a long-term-care facility as defined in KRS 216.510;

(e) During the effective period of any period of disaster or mass casualties which has a direct impact upon the physician's practice;

(f) In a single dose prescribed or dispensed to relieve the anxiety, pain, or discomfort experienced by that patient submitting to a diagnostic test or procedure; or

(g) That has been classified as a Schedule V controlled substance.

Section 2. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes and Monitoring. (1) Each physician prescribing or dispensing a controlled substance shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the physician is conforming to professional standards for prescribing or dispensing controlled substances and other relevant professional standards.

(2) If a physician is unable to conform to professional standards for prescribing or dispensing controlled substances due to circumstances beyond the physician's control, or the physician makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the physician shall document those circumstances in the patient's record and only prescribe or dispense a controlled substance to the patient if the patient record appropriately justifies the prescribing or dispensing of a controlled substance under the circumstances.

Section 3. Professional Standards for the Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the same primary medical complaint, the first physician prescribing or dispensing a controlled substance shall:

(1) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

(a) If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

(b) If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(2) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(3) After examining the benefits and risks of prescribing or dispensing a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified;

(4) Not prescribe or dispense a long-acting or controlled-release opioid (e.g. OxyContin, fentanyl patches, or methadone) for acute pain that is not directly related to and close in time to a specific surgical procedure;

(5) Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of the controlled substance when the condition requiring the controlled substance use has resolved; and

(6) Explain to the patient how to safely use and properly dispose of any unused controlled substance.

Section 4. Professional Standards for Commencing Long Term Use of Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) Before a physician commences to prescribe or dispense any controlled substance to a patient sixteen (16) years or older for pain or other symptoms associated with the same primary medical complaint for a total period of longer than three (3) months, the physician shall comply with the mandatory professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the prescribing physician if:

(a) Each practitioner involved has lawful access to the patient's medical record;

(b) There is compliance with all applicable standards; and

(c) Each practitioner performing an action to meet the required standards is acting within the practitioner's legal scope of practice.

(2)(a) The physician shall obtain the following information from the patient and record all relevant information in the patient's medical record:

1. History of present illness;

2. Past medical history;

3. History of substance use and any prior treatment for that use by the patient, and history of substance abuse by first degree relatives of the patient;

4. Past family history of relevant illnesses and treatment; and

5. Psychosocial history.

(b) The physician shall conduct an appropriate physical examination of the patient sufficient to support the medical indications for prescribing or dispensing a controlled substance on a long-term basis.

(c) The physician shall perform appropriate baseline assessments to establish beginning values to assist in establishing and periodically evaluating the functional goals of any treatment plan.

(d) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall only continue the use of a controlled substance after determining that continued use of the controlled substance is safe and medically appropriate in the absence of that information.

(e) If the physician determines that the patient has previously received medical treatment for the presenting medical complaint or related symptoms and that review of the prior treatment records is necessary to justify long-term prescribing of a controlled substance, the physician shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient.

(f)1. Based upon consideration of all information available, the physician shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms without simply describing or listing the related symptoms.

2. If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician shall consider the usefulness of additional information, such as a specialized evaluation or assessment, referral to an appropriate specialist, and the usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis.

3. If the physician is unable to formulate a working diagnosis, despite the use of an appropriate specialized evaluation or assessment, the physician shall only prescribe long term use of a controlled substance after establishing that its use at a specific level is medically indicated and appropriate.

(g)1. To the extent that functional improvement is medically expected based upon the patient's condition, the physician shall formulate an appropriate treatment plan.

2. The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations.

(h)1. The physician shall utilize appropriate screening tools to screen each patient to determine if the patient:

a. Is presently suffering from another medical condition which may impact the prescribing or dispensing of a controlled substance; or

b. Presents a significant risk for illegal diversion of a controlled substance.

2. If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, or a psychiatric or psychological condition, the physician shall take the necessary actions to facilitate a referral to an appropriate treatment program or provider. The physician shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient.

3. If, after screening, the physician determines that there is a risk that the patient may illegally divert a controlled substance, but determines to continue long term prescribing of the controlled substance, the physician shall use a prescribing agreement that meets professional standards. The prescribing agreement and informed consent document may be combined into one (1) document.

4. The physician shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled substance prescribed to the patient will be used or is likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall not prescribe any controlled substance to that patient.

(i) After explaining the risks and benefits of long-term use of a controlled substance, the physician shall obtain the written informed consent of the patient in a manner that meets professional standards.

(j) The physician shall initially attempt, to the extent possible, or establish and document a previous attempt by another physician, of a trial of noncontrolled modalities and lower doses of a controlled substance in increasing order to treat the pain and related symptoms associated with the primary medical complaint, before continuing with long term prescribing of a controlled substance at a given level.

Section 5. Professional Standards for Continuing Long Term Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) If a physician continues to prescribe or dispense a controlled substance beyond three (3) months to a patient sixteen (16) years or older for pain and related symptoms associated with the primary medical complaint, the physician shall comply with the professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the prescribing physician as established in Section 4(1) of this administrative regulation.

(2)(a)1. The physician shall ensure that the patient is seen at least once a month initially for evaluation and review of progress. The physician may determine that the patient is to be evaluated less frequently, on a schedule determined by the physician's professional judgment after the physician has determined:

a. The controlled substance prescribed or dispensed has been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

b. The controlled substance prescribed or dispensed is not causing unacceptable side effects; and

c. There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled substance in an improper or inappropriate manner or divert it for an improper or inappropriate use.

(b) At appropriate intervals, the physician shall:

1. Ensure that a current history is obtained from the patient;

2. Ensure that a focused physical examination is considered, and performed, if appropriate; and

3. Perform appropriate measurable examinations as indicated in the treatment plan.

(c) At appropriate intervals, the physician shall evaluate the working diagnosis and treatment plan based upon the information gained to determine whether there has been functional improvement or any change in baseline measures. The physician shall modify the diagnosis, treatment plan, or controlled substance therapy, as appropriate.

(d) If the physician determines that the patient presents a significant risk of diversion or improper use of a controlled substance, the physician shall discontinue the use of the controlled substance or justify its continued use in the patient record.

(e) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with a controlled substance, and if improvement is medically expected, the physician shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions to be addressed in order to resolve the medical complaint.

(f) For a patient exhibiting symptoms suggestive of a mood, anxiety, or psychotic disorder, the physician shall obtain a psychiatric or psychological consultation for intervention if appropriate.

(g) If a patient reports experiencing episodes of breakthrough pain, the physician shall:

1. Attempt to identify the trigger or triggers for each episode;

2. Determine whether the breakthrough pain may be adequately treated through noncontrolled treatment; and

3. If the physician determines that the nonmedication treatments do not adequately address the triggers, and after considering the risks and benefits, determines to add an as-needed controlled substance to the regimen, take appropriate steps to minimize the improper or illegal use of the additional controlled substance.

(h) At least once a year, the physician shall perform or shall ensure that the patient's primary treating physician performs a preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition.

(i)1. At least once every three (3) months, the physician shall obtain and review a current KASPER report, for the twelve (12) month period immediately preceding the request, and appropriately use that information in the evaluation and treatment of the patient.

2. If the physician obtains or receives specific information that the patient is not taking the controlled substance as directed, is diverting a controlled substance, or is engaged in any improper or illegal use of a controlled substance, the physician shall immediately obtain and review a KASPER report and appropriately use the information in the evaluation and treatment of the patient.

3. If a KASPER report discloses that the patient is obtaining a controlled substance from another practitioner without the physician's knowledge and approval, in a manner that raises suspicion of illegal diversion, the physician shall promptly notify the other practitioner of the relevant information from the KASPER review.

4. The physician shall obtain consultative assistance from a specialist if appropriate.

(j) If appropriate, the physician shall conduct random pill counts and appropriately use that information in the evaluation and treatment of the patient.

(k)1. During the course of long-term prescribing or dispensing of a controlled substance, the physician shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times. If the drug screen or other information available to the physician indicates that the patient is noncompliant, the physician shall:

a. Do a controlled taper;

b. Stop prescribing or dispensing the controlled substance immediately; or

c. Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program, depending upon the circumstances.

2. The physician shall discontinue controlled substance treatment or refer the patient to addiction management if:

a. There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected;

b. Controlled substance therapy has produced significant adverse effects; or

c. The patient exhibits inappropriate drug-seeking behavior or diversion.

Section 6. Professional Standards for the Prescribing and Dispensing of Controlled Substances in an Emergency Department. In addition to complying with the standards for the initial prescribing or dispensing of a controlled substance as established in Sections 3 and 7 of this administrative regulation, a physician prescribing or dispensing a controlled substance for a specific medical complaint and related symptoms to a patient in an emergency department shall not routinely:

(1) Administer an intravenous controlled substance for the relief of acute exacerbations of chronic pain, unless intravenous administration is the only medically appropriate means of delivery;

(2) Provide a replacement prescription for a controlled substance that was lost, destroyed, or stolen;

(3) Provide a replacement dose of methadone, suboxone, or subutex for a patient in a treatment program;

(4) Prescribe a long-acting or controlled-release controlled substance, such as OxyContin, fentanyl patches, or methadone or a replacement dose of that medication;

(5) Administer Meperidine to the patient; or

(6) Prescribe or dispense more than the minimum amount medically necessary to treat the patient's medical condition until the patient can be seen by the primary treating physician or another physician, with no refills. If the controlled substance prescription exceeds seven (7) days in length, the patient record shall justify the amount of the controlled substance prescribed.

Section 7. Professional Standards for the Prescribing and Dispensing of Controlled Substances for the Treatment of Other Conditions. (1) Before initially prescribing or

dispensing a controlled substance to a patient for a condition other than pain, the physician shall:

(a) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

1. If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

2. If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(b) Obtain and review a KASPER report for that patient, for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(c) After examining the benefits and risks of prescribing or dispensing a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified;

(d) Avoid providing more controlled substances than necessary by prescribing or dispensing only the amount of a controlled substance needed to treat the specific medical complaint;

(e) Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of a controlled substance when the condition requiring the controlled substance use has resolved; and

(f) Explain to the patient how to safely use and properly dispose of any unused controlled substance.

(2) If the physician continues to prescribe or dispense a controlled substance to a patient for the same medical complaint and related symptoms, the physician shall fully conform to the standards of acceptable and prevailing practice for treatment of that medical complaint and for the use of the controlled substance.

(3) If a physician receives a request from an established patient to prescribe or dispense a limited amount of a controlled substance to assist the patient in responding to the anxiety or depression resulting from a nonrecurring single episode or event, the physician shall:

(a) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient request and appropriately utilize the information obtained in the evaluation and treatment of the patient;

(b) Make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified, with or without requiring a personal encounter with the patient to obtain a more detailed history or to conduct a physical examination; and

(c) If the decision is made that it is medically appropriate to prescribe or dispense the controlled substance, prescribe or dispense the minimum amount of the controlled substance to appropriately treat the situational anxiety or depression.

Section 8. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) A physician prescribing or dispensing a controlled substance shall take appropriate steps to educate a patient receiving a controlled substance.

(2) Educational materials relating to these subjects may be found on the board's Web site, www.kbml.ky.gov.

Section 9. Additional Standards for Prescribing or Dispensing Schedule II Controlled Substances or Schedule III Controlled Substances Containing Hydrocodone. (1) In addition to the other standards established in this administrative regulation, prior to the initial prescribing or dispensing of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a physician shall:

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(2)(a) In addition to the other standards established in this administrative regulation, a physician prescribing or dispensing additional amounts of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;

2. Provide to the patient any new information about the treatment; and

3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the physician shall:

1. Query KASPER no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and

2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

(3) To the extent not already required by the standards established in this administrative regulation, for each patient for whom a physician prescribes or dispenses a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the physician shall keep accurate, readily accessible, and complete medical records which include, as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

(g) Medications, including date, type, dosage, and quantity prescribed or dispensed;

(h) Instructions and agreements, and

(i) Periodic reviews of the patient's file.

(4) The additional standards for prescribing or dispensing a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone established in this section shall not apply to:

(a) A physician prescribing or administering that controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive

procedure or delivery and the medication usage does not extend beyond the fourteen (14) days; or

(b) A physician prescribing or dispensing that controlled substance:

1. For administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a physician in those hospitals or facilities if no institutional account exists, queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query, within twelve (12) hours of the patient's or resident's admission, and places a copy of the query in the patient's or resident's medical records for use during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

5. Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing or dispensing;

b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

6. Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another physician in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or

7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department for Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.

Section 10. Violations. (1) Any violation of the professional standards established in this administrative regulation shall constitute a violation of KRS 311.595(12) and (9), which may result in the imposition of disciplinary sanctions by the board, pursuant to KRS 311.595.

(2) Each violation of the professional standards established in this administrative regulation shall be established by expert testimony by one (1) or more physicians retained by the board,

following a review of the licensee's patient records and other available information including KASPER reports.

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Louisiana

ADC Title 48, Part I, § 7831

Louisiana Administrative Code (2013)
Title 48. Public Health general
Part I. General Administration
Subpart 3. Licensing
Chapter 78. Pain Management Clinics
Subchapter C. Clinic Administration

§ 7831. Medical Director

A. Each clinic shall be under the direction of a medical director who shall be a physician who:

1. possesses a current, unrestricted license from the board to practice medicine in Louisiana;

2. during the course of his practice, has not been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled dangerous substance; and

3. during the course of his practice has not had any board action taken against his medical license as a result of dependency on drugs or alcohol.

B. The medical director shall be a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties, except for the following exemption.

1. A clinic which has been verified as being in operation on or before June 15, 2005, is required to have a medical director, but is exempt from having a medical director who is certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

C. Responsibilities. The medical director is responsible for the day-to-day operation of a clinic and shall be on-site 50 percent of the time during the operational hours of the clinic. In the event the medical director is not on-site during the hours of operation, then the medical director shall be available by telecommunications and shall be able to be on-site within 30 minutes.

1. The medical director shall oversee all medical services provided at the clinic.

2. The medical director shall ensure that all qualified personnel perform the treatments or procedures for which each is assigned. The clinic shall retain documentation of proficiency and training.

3. The medical director, or his designee, is responsible for ensuring a medical referral is made to an addiction facility, when it has been determined that a patient or staff member has been diverting drugs or participating in the illegal use of drugs.

4. The medical director is responsible for ensuring a urine drug screen of each patient is obtained as part of the initial medical evaluation and intermittently, no less than quarterly, during the course of treatment for chronic pain.

5. The medical director shall ensure that patients are informed of after-hours contact and treatment procedure.

6. The medical director is responsible for applying to access and query the Louisiana Prescription Monitoring Program (PMP).

a. The PMP is to be utilized by the medical director and the pain specialist as part of a clinics' quality assurance program to ensure adherence to the treatment agreement signed by the patient.

i. The treatment agreement states that the patient has been informed that he shall only obtain and receive narcotic prescriptions from the clinic where he is being treated for chronic pain.

(a). The patient shall be subject to periodic unannounced drug screens and shall not participate in diversion of any controlled dangerous substance.

b. Compliance to this agreement is to be determined and evaluated at each subsequent visit to a clinic when the patient receives a prescription for a controlled dangerous substance.

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Massachusetts
94C § 24A

Massachusetts General Laws Annotated (2013)
Part I. Administration of the Government (Ch. 1-182)
Title XV. Regulation of Trade (Ch. 93-110H)
Chapter 94C. Controlled Substances Act

§ 24A. Electronic monitoring of the prescribing and dispensing of controlled substances and certain additional drugs

(a)(1) The department shall establish and maintain an electronic system to monitor the prescribing and dispensing of all schedule II to V, inclusive, controlled substances and certain additional drugs by all professionals licensed to prescribe or dispense such substances. For the purposes of this section, "additional drugs" shall mean substances determined by the department to carry a bona fide potential for abuse.

(2) The department shall enter into reciprocal agreements with other states that have compatible prescription drug monitoring programs to share prescription drug monitoring information among the states.

(b) The requirements of this section shall not apply to the dispensing of controlled substances to inpatients in a hospital.

(c) For the purposes of monitoring the prescribing and dispensing of all schedule II to V, inclusive, controlled substances and additional drugs, as authorized in subsection (a), the department shall promulgate regulations including, but not limited to, (1) a requirement that each pharmacy that delivers a schedule II to V, inclusive, controlled substance or a substance classified as an additional drug by the department to the ultimate user shall submit to the department, by electronic means, information regarding each prescription dispensed for a drug included under subsection (a); and (2) a requirement that each pharmacy collects and reports, for each prescription dispensed for a drug under subsection (a), a customer identification number and other information associated with the customer identification number, as specified by the department. Each pharmacy shall submit the information in accordance with transmission methods and frequency requirements promulgated by the department; provided, however, that the information shall be submitted at least once every 7 days. The department may issue a waiver to a pharmacy that is unable to submit prescription information by electronic means. The waiver shall permit the pharmacy to submit prescription information by other means promulgated by the department; provided, however, that all information required in this section is submitted in this alternative format.

<[Paragraph in subsection (c) added by 2012, 244, Sec. 8 effective January 1, 2013. See 2012, 244, Sec. 29.]>

The department, in consultation with all relevant licensing authorities, shall promulgate regulations that require participants to utilize the prescription monitoring program prior to seeing a new patient, including circumstances where participants would not be required to utilize the prescription monitoring program prior to seeing a new patient; a requirement that pharmacists be trained in the use of the prescription monitoring program as part of the continuing education requirements mandated for licensure by the board of registration in pharmacy, under section 24A of chapter 112 and a requirement that allows authorized support staff to use the prescription monitoring program on behalf of a registered participant.

(d) Prescription information submitted to the department under this section shall be confidential and exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4 and chapter 66. The department shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except as provided for in this chapter.

(e) The department shall review the prescription and dispensing monitoring information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the department shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity and provide prescription information required for an investigation.

(f) The department shall, upon request, provide data from the prescription monitoring program to the following:--

(1) persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients;

(2) individuals who request their own prescription monitoring information in accordance with procedures established under chapter 66A;

(3) persons authorized to act on behalf of state boards and regulatory agencies that supervise or regulate a profession that may prescribe controlled substances; provided, however, that the data request is in connection with a bona fide specific controlled substance or additional drug-related investigation;

(4) local, state and federal law enforcement or prosecutorial officials working with the executive office of public safety engaged in the administration, investigation or enforcement of the laws governing prescription drugs; provided, however, that the data request is in connection with a bona fide specific controlled substance or additional drug-related investigation;

(5) personnel of the executive office of health and human services regarding Medicaid program recipients; provided, however that the data request is in connection with a bona fide specific controlled substance or additional drug-related investigation; or

(6) personnel of the United States attorney, office of the attorney general or a district attorney; provided, however, that the data request is in connection with a bona fide specific controlled substance or additional drug related investigation.

(g) The department may, at its initiative, provide data from the prescription monitoring program to practitioners in accordance with section 24.

(h) The department may provide de-identified, aggregate information to a public or private entity for statistical research or educational purposes.

(i) The department may contract with another agency or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. A contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in this section.

(j) The department shall promulgate rules and regulations setting forth the procedures and methods for implementing this section.

(k) The department shall submit an annual report on the effectiveness of the prescription monitoring program with the clerks of the house and senate, the chairs of the joint committee on public health, the chairs of the joint committee on health care financing and the chairs of the joint committee on public safety and homeland security.

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Minnesota
§ 245A.192

Minnesota Statutes Annotated (2013)
Public Welfare and Related Activities (Ch. 245-267)
Chapter 245A. Human Services Licensing

§ 245A.192. Providers licensed to provide treatment of opioid addiction.

Subdivision 1. Scope. (a) This section applies to services licensed under this chapter to provide treatment for opioid addiction. In addition to the requirements under Minnesota Rules, parts 9530.6405 to 9530.6505, a program licensed to provide treatment of opioid addiction must meet the requirements of this section.

(b) Where a standard in this section differs from a standard in an otherwise applicable administrative rule, the standards of this section apply.

(c) When federal guidance or interpretations have been issued on federal standards or requirements also required under this section, the federal guidance or interpretations shall apply.

Subd. 2. Definitions. (a) For purposes of this section, the terms defined in this subdivision have the meanings given them.

(b) "Diversion" means the use of a medication for the treatment of opioid addiction being diverted from its intended use.

(c) "Guest dose or dosing" means the practice of administering medication used for the treatment of opioid addiction to a person who is not a client of the program that is administering or dispensing the medication.

(d) "Medical director" means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision.

(e) "Medication used for the treatment of opioid addiction" means a medication approved by the Food and Drug Administration for the treatment of opioid addiction.

(f) "Opioid treatment program" has the meaning given in Code of Federal Regulations, title 42, section 8.12, and includes programs licensed under Minnesota Rules, part 9530.6500.

(g) "Program" means an entity that is licensed under Minnesota Rules, part 9530.6500.

(h) "Unsupervised use" means the use of a medication for the treatment of opioid addiction dispensed for use by a client outside of the program setting. This is also referred to as a "take-home" dose.

(i) "Placing authority" has the meaning given in Minnesota Rules, part 9530.6605, subpart 21a.

(j) "Minnesota health care programs" has the meaning given in section 256B.0636, clause (3).

Subd. 3. Medication orders. Prior to the program administering or dispensing a medication used for the treatment of opioid addiction:

(1) a client-specific order must be received from an appropriately credentialed physician;

(2) the signed order must be documented in the client's record; and

(3) if the order is not directly issued by the physician, such as a verbal order, the physician that issued the order must review the documentation and sign the order in the client's record within 72 hours of the medication being administered or dispensed. The physician must document whether the medication was administered or dispensed as ordered. The license holder must report to the commissioner any medication error that endangers a patient's health, as determined by the medical director.

Subd. 4. Drug testing. Each client enrolled in the program must receive a minimum of eight random drug abuse tests per 12 months of treatment. These tests must be reasonably disbursed over the 12-month period. A license holder may elect to conduct more drug abuse tests.

Subd. 5. Criteria for unsupervised use. (a) To limit the potential for diversion of medication used for the treatment of opioid addiction to the illicit market, any such medications dispensed to patients for unsupervised use shall be subject to the following requirements:

(1) any patient in an opioid treatment program may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and state and federal holidays; and

(2) treatment program decisions on dispensing medications used to treat opioid addiction to patients for unsupervised use beyond that set forth in paragraph (a), clause (1), shall be determined by the medical director.

(b) The medical director must consider the criteria in paragraph (a) in determining whether a client may be permitted unsupervised or take-home use of such medications. The criteria must also be considered when determining whether dispensing medication for a client's unsupervised use is appropriate to increase or extend the amount of time between visits to the program. The criteria includes:

(1) absence of recent abuse of drugs including but not limited to opioids, nonnarcotics, and alcohol;

(2) regularity of program attendance;

(3) absence of serious behavioral problems at the program;

(4) absence of known recent criminal activity such as drug dealing;

(5) stability of the client's home environment and social relationships;

(6) length of time in comprehensive maintenance treatment;

(7) reasonable assurance that take-home medication will be safely stored within the client's home; and

(8) whether the rehabilitative benefit the client derived from decreasing the frequency of program attendance outweighs the potential risks of diversion or unsupervised use.

(c) The determination, including the basis of the determination, must be consistent with the criteria in paragraph (a), clause (2), and must be documented in the client's medical record.

Subd. 6. Restrictions for unsupervised or take-home use of methadone hydrochloride. (a) In cases where it is determined that a client meets the criteria in subdivision 5, paragraph (a), clause (2), and may be dispensed a medication used for the treatment of opioid addiction, the restrictions in paragraphs (b) to (g) must be followed when the medication to be dispensed is methadone hydrochloride.

(b) During the first 90 days of treatment, the take-home supply must be limited to a maximum of a single dose each week and the client shall ingest all other doses under direct supervision.

(c) In the second 90 days of treatment, the take-home supply must be limited to two doses per week.

(d) In the third 90 days of treatment, the take-home supply must not exceed three doses per week.

(e) In the remaining months of the first year, a client may be given a maximum six-day supply of take-home medication.

(f) After one year of continuous treatment, a client may be given a maximum two-week supply of take-home medication.

(g) After two years of continuous treatment, a client may be given a maximum one-month supply of take-home medication, but must make monthly visits.

Subd. 7. Restriction exceptions. When a license holder has reason to accelerate the number of unsupervised or take-home doses of methadone hydrochloride, the license holder must comply

with the requirements of Code of Federal Regulations, title 42, chapter 1, subchapter A, part 8, section 8.12, the criteria for unsupervised use in subdivision 5, and must use the exception process provided by the federal Center for Substance Abuse Treatment Division of Pharmacologic Therapies. For the purposes of enforcement of this subdivision, the commissioner has the authority to monitor for compliance with these federal regulations and may issue licensing actions according to sections 245A.05, 245A.06, and 245A.07 based on the commissioner's determination of noncompliance.

Subd. 8. Guest dosing. In order to receive a guest dose, the client must be enrolled in an opioid treatment program elsewhere in the state or country and be receiving the medication on a temporary basis because the client is not able to receive the medication at the program in which the client is enrolled. Such arrangements shall not exceed 30 consecutive days in any one program and must not be for the convenience or benefit of either program. Guest dosing may also occur when the client's primary clinic is not open and the client is not receiving take-home doses.

Subd. 9. Data and reporting. The license holder must submit data concerning medication used for the treatment of opioid addiction to a central registry. The data must be submitted in a method determined by the commissioner and must be submitted for each client at the time of admission and discharge. The program must document the date the information was submitted. This requirement is effective upon implementation of changes to the Drug and Alcohol Abuse Normative Evaluation System (DAANES) or development of an electronic system by which to submit the data.

Subd. 10. Nonmedication treatment services; documentation. (a) The program must offer at least 50 consecutive minutes of individual or group therapy treatment services as defined in Minnesota Rules, part 9530.6430, subpart 1, item A, subitem (1), per week, for the first ten weeks following admission, and at least 50 consecutive minutes per month thereafter. As clinically appropriate, the program may offer these services cumulatively and not consecutively in increments of no less than 15 minutes over the required time period, and for a total of 60 minutes of treatment services over the time period, and must document the reason for providing services cumulatively in the client's record. The program may offer additional levels of service when deemed clinically necessary.

(b) Notwithstanding the requirements of individual treatment plans set forth in Minnesota Rules, part 9530.6425:

(1) treatment plan contents for maintenance clients are not required to include goals the client must reach to complete treatment and have services terminated;

(2) treatment plans for clients in a taper or detox status must include goals the client must reach to complete treatment and have services terminated;

(3) for the initial ten weeks after admission for all new admissions, readmissions, and transfers, progress notes must be entered in a client's file at least weekly and be recorded in each of the six

dimensions upon the development of the treatment plan and thereafter. Subsequently, the counselor must document progress no less than one time monthly, recorded in the six dimensions or when clinical need warrants more frequent notations; and

(4) upon the development of the treatment plan and thereafter, treatment plan reviews must occur weekly, or after each treatment service, whichever is less frequent, for the first ten weeks of treatment for all new admissions, readmissions, and transfers. Following the first ten weeks of treatment, treatment plan reviews may occur monthly, unless the client has needs that warrant more frequent revisions or documentation.

Subd. 11. Prescription monitoring program. (a) Upon admission to a methadone clinic outpatient treatment program, clients shall be notified that the Department of Human Services and the medical director will monitor the prescription monitoring program to review the prescribed controlled drugs the clients have received. **The medical director or the medical director's delegate must review data from the Minnesota Board of Pharmacy, prescription monitoring program (PMP) established under section 152.126 prior to the client being ordered any controlled substance as defined under section 152.126, subdivision 1, paragraph (b), including medications used for the treatment of opioid addiction. The subsequent reviews of the PMP data must occur quarterly and be documented in the client's individual file. When the PMP data shows a recent history of multiple prescribers or multiple prescriptions for controlled substances, then subsequent reviews of the PMP data must occur monthly and be documented in the client's individual file.** If, at any time, the medical director believes the use of the controlled substances places the client at risk of harm, the program must seek consent to discuss the client's opioid treatment with other prescribers and must seek consent for the other prescriber to disclose to the opioid treatment programs' medical director the client's condition that formed the basis of the other prescriptions. Additionally, any findings from the PMP data that are relevant to the medical director's course of treatment for the client must be documented in the client's individual file. **A review of the PMP is not required for every medication dose adjustment.**

(b) The commissioner shall collaborate with the Minnesota Board of Pharmacy to develop and implement an electronic system through which the commissioner shall routinely access the data from the Minnesota Board of Pharmacy prescription monitoring program established under section 152.126 for the purpose of determining whether any client enrolled in an opioid addiction treatment program licensed according to this section has also been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid addiction treatment program. When the commissioner determines there have been multiple prescribers or multiple prescriptions of controlled substances, the commissioner shall:

(1) inform the medical director of the opioid treatment program only that the commissioner determined the existence of multiple prescribers or multiple prescriptions of controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, review the effect of the multiple prescribers or multiple prescriptions, and document the review.

(c) If determined necessary, the commissioner shall seek a federal waiver of, or exception to, any applicable provision of Code of Federal Regulations, title 42, part 2.34, item (c), prior to implementing this paragraph.

Subd. 12. Policies and procedures. (a) License holders must develop and maintain the policies and procedures required in this subdivision. Where a standard in this section differs from a standard in otherwise applicable administrative rule, the standards of this subdivision apply.

(b) For programs that are not open every day of the year, the license holder must maintain a policy and procedure that permits clients to receive a single unsupervised use of medication used for the treatment of opioid addiction for days that the program is closed for business, including, but not limited to, Sundays and state and federal holidays as required under subdivision 5, paragraph (a), clause (1).

(c) The license holder must maintain a policy and procedure that includes specific measures to reduce the possibility of medication used for the treatment of opioid addiction being diverted from its intended treatment use. The policy and procedure must:

(1) specifically identify and define the responsibilities of the medical and administrative staff for carrying out diversion control measures; and

(2) include a process for contacting no less than five percent of clients who have unsupervised use of medication for the treatment of opioid addiction, excluding those approved solely under subdivision 5, paragraph (a), clause (1), to require them to physically return to the program each month. The system must require clients to return to the program within a stipulated time frame and turn in all unused medication containers related to opioid addiction treatment. The license holder must document all related contacts on a central log and the outcome of the contact for each client in the individual client's record.

(d) Medications used for the treatment of opioid addiction must be ordered, administered, and dispensed according to applicable state and federal regulations and the standards set by applicable accreditation entities. In addition, when an order requires assessment by the person administering or dispensing the medication to determine the amount to be administered or dispensed, the assessment must be completed by an individual whose professional scope of practice permits such assessment. For the purposes of enforcement of this paragraph, the commissioner has the authority to monitor for compliance with these state and federal regulations and the relevant standards of the license holder's accreditation agency and may issue licensing actions according to sections 245A.05, 245A.06, and 245A.07 based on the commissioner's determination of noncompliance.

Subd. 13. Quality improvement plan. The license holder must develop and maintain a quality improvement process and plan. The plan must:

(1) include evaluation of the services provided to clients with the goal of identifying issues that may improve service delivery and client outcomes;

(2) include goals for the program to accomplish based on the evaluation;

(3) be reviewed annually by the management of the program to determine whether the goals were met and if not, whether additional action is required;

(4) be updated at least annually to include new or continued goals based on an updated evaluation of services; and
(5) identify two specific goal areas, in addition to others identified by the program including:

(i) a goal concerning oversight and monitoring of the premises around and near the exterior of the program to reduce the possibility of medication used for the treatment of opioid addiction being inappropriately used by clients, including but not limited to the sale or transfer of the medication to others; and

(ii) a goal concerning community outreach, including but not limited to communications with local law enforcement and county human services agencies with the goal of increasing coordination of services and identification of areas of concern to be addressed in the plan.

Subd. 14. Placing authorities. Programs must provide certain notification and client-specific updates to placing authorities for clients who are enrolled in Minnesota health care programs. At the request of the placing authority, the program must provide client-specific updates, including but not limited to informing the placing authority of positive drug screenings and changes in medications used for the treatment of opioid addiction ordered for the client.

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Nevada
§ 639.23507

West's Nevada Revised Statutes (2013)
Title 54. Professions, Occupations and Businesses
Chapter 639. Pharmacists and Pharmacy
Prescriptions

§ 639.23507. Patient utilization report required before writing prescription for controlled substance

A practitioner shall, before writing a prescription for a controlled substance listed in schedule II, III or IV for a patient, obtain a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Board and the Investigation Division of the Department of Public Safety pursuant to NRS 453.1545 if the practitioner has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:

1. The patient is a new patient of the practitioner; or

2. The patient has not received any prescription for a controlled substance from the practitioner in the preceding 12 months.

The practitioner shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

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New Mexico
ADC 16.10.14
ADC 16.12.9
ADC 16.19.4

Code of New Mexico Rules (2013)
Title 16. Occupational and Professional Licensing
Chapter 10. Medicine and Surgery Practitioners
Part 14. Management of Chronic Pain with Controlled Substances

16.10.14. MANAGEMENT OF PAIN WITH CONTROLLED SUBSTANCES

16.10.14.1 ISSUING AGENCY: New Mexico Medical Board, hereafter called the board.

[16.10.14.1 NMAC - N, 1/20/03; A, 4/3/05]

16.10.14.2 SCOPE: This part applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration.

[16.10.14.2 NMAC - N, 1/20/03; A, 9/28/12]

16.10.14.3 STATUTORY AUTHORITY: These rules are promulgated pursuant to and in accordance with the Medical Practice Act, Sections 61-6-1 through 61-6-35 NMSA 1978 and the Pain Relief Act, Sections 24-2D-1 NMSA through 24-2D-6.

[16.10.14.3 NMAC - N, 1/20/03; A, 9/28/12]

16.10.14.4 DURATION: Permanent

[16.10.14.4 NMAC - N, 1/20/03]

16.10.14.5 EFFECTIVE DATE: January 20, 2003, unless a later date is cited at the end of a section.

[16.10.14.5 NMAC - N, 1/20/03]

16.10.14.6 OBJECTIVE: It is the position of the board that practitioners have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed for that purpose. When such medicines and drugs are used, they should be prescribed in adequate doses and for appropriate lengths of time after a thorough medical evaluation has been completed.

[16.10.14.6 NMAC - N, 1/20/03; A, 4/3/05]

16.10.14.7 DEFINITIONS:

A. “Addiction” is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and, craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

B. “Acute pain” means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and is generally time-limited.

C. “Chronic pain” means pain that persists after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. “Chronic pain” does not, for purpose of the Pain Relief Act requirements, include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

D. “Clinical expert” means a person who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

E. “Drug abuser” means a person who takes a drug or drugs for other than legitimate medical purposes.

F. “Pain” means acute or chronic pain or both.

G. “Physical dependence” means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

H. “Prescription monitoring program” means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.

I. “Therapeutic purpose” means the use of pharmaceutical and non-pharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

J. “Tolerance” means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

[16.10.14.7 NMAC - N, 1/20/03; A, 9/28/12]

16.10.14.8 The following regulations shall be used by the board to determine whether a health care practitioner's prescriptive practices are consistent with the appropriate treatment of pain.

A. The treatment of pain with various medicines or controlled substances is a legitimate medical practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

B. The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substance abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A practitioner shall be familiar with and employ screening tools as appropriate, as well as the spectrum of available modalities, in the evaluation and management of pain. The practitioner shall consider an integrative approach to pain management.

(3) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan shall include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(4) The practitioner shall discuss the risks and benefits of using controlled substances with the patient or surrogate or guardian, and shall document this discussion in the record.

(5) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized shall be recorded. Prescriptions for opioids shall include indications for use. For chronic pain patients treated with controlled substance analgesic(s), the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. As part of a written agreement, chronic pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.

(6) The management of patients needing chronic pain control requires monitoring by the attending or the consulting practitioner. The practitioner shall periodically review the course of treatment for chronic pain, the patient's state of health, and any new information about the etiology of the chronic pain at least every six months. In addition, a practitioner shall consult, when indicated by the patient's condition, with health care professionals who are experienced (by

the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control.

(7) If, in a practitioner's medical opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

C. Pain management for patients with substance use disorders shall include:

(1) a contractual agreement;

(2) appropriate consultation;

(3) drug screening when other factors suggest an elevated risk of misuse or diversion; and

(4) a schedule for re-evaluation at appropriate time intervals at least every six months.

D. The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medical indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

E. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection.

F. A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Medical Practice Act or board rules.

[16.10.14.8 NMAC - N, 1/20/03; A, 4/3/05; A, 9/28/12]

16.10.14.9 PHYSICIAN, PHYSICIAN ASSISTANTS AND ANESTHESIOLOGIST ASSISTANTS TREATED WITH OPIATES: Physicians, physician assistants or anesthesiologist assistants who have chronic pain and are being treated with opiates shall be evaluated by a pain clinic or, by an M.D. or D.O. pain specialist, and must have a complete, independent neuropsychological evaluation, as well as clearance from their physician, before returning to or continuing in practice. In addition, they must remain under the care of a physician for as long as they remain on opiates while continuing to practice.

[16.10.14.9 NMAC - N, 4/3/05; A, 9/28/12]

16.10.14.10 PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS: The intent of the New Mexico medical board in requiring participation in the PMP is to assist practitioners in balancing the promotion of the safe use of controlled substances for the provision of medical care and services with the need to impede illegal and harmful activities involving these pharmaceuticals.

A. A health care practitioner who holds a federal drug enforcement administration registration and a New Mexico controlled substance registration shall register with the board of pharmacy to become a regular participant in PMP inquiry and reporting.

B. A health care practitioner shall, before prescribing, ordering, administering or dispensing a controlled substance listed in Schedule II, III or IV, obtain a patient PMP report for the preceding 12 months when one of the following situations exists:

(1) the patient is a new patient of the practitioner, except in the setting of urgent or emergent care, in which situation a patient PMP report for the previous 12 months shall only be required when Schedules II, III, and IV drugs are prescribed for a period greater than 10 days; and

(2) during the continuous use of opioids by established patients a PMP shall be requested and reviewed a minimum of once every six months.

[16.10.14.10 NMAC - N, 9/28/12]

16.10.14.11 PAIN MANAGEMENT CONTINUING EDUCATION: This section applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids. Pursuant to the Pain Relief Act, in order to ensure that all such health care practitioners safely prescribe for pain management and harm reduction, the following rules shall apply.

A. Immediate requirements effective November 1, 2012.Between November 1, 2012 and no later than June 30, 2014, all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids, shall complete no less than five continuing medical education hours in appropriate courses that may include a review of this rule (16.10.14 NMAC) for treatment of pain. Courses shall include 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. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. Practitioners who have taken continuing medical education hours in these educational elements between July 1, 2011 and November 1, 2012, may apply those hours toward the required five continuing medical education hours described in this subsection.

B. Triennial requirements for physicians. Beginning with the July 1, 2014 triennial renewal date, as part of the 75 continuing medical education hours required during each triennial renewal

cycle, all New Mexico medical board physician licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit five continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the three-year period immediately preceding the triennial renewal date. The five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of the required continuing medical education hours in pain management in either the triennial cycle in which these hours are completed, or the triennial cycle immediately thereafter.

C. Biennial requirements for physician assistants. Beginning with the July 1, 2014 biennial renewal date, in addition to the NCCPA certification required during each biennial renewal cycle pursuant to 16.10.15.16 NMAC, all New Mexico medical board physician assistant licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit three continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the two-year period immediately preceding the renewal date. Three of the five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of these required three continuing medical education hours in pain management in either the biennial cycle in which these hours are completed, or the biennial cycle immediately thereafter. These three hours may also be applied to satisfy NCCPA requirements for certification.

D. Biennial requirements for anesthesiologist assistants. Beginning with the July 1, 2014 biennial renewal date, all New Mexico medical board anesthesiologist assistant licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit three continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the two-year period immediately preceding the renewal date. Three of the five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of these required three continuing medical education hours in pain management in either the biennial cycle in which these hours are completed, or the biennial cycle immediately thereafter.

E. Requirements for new licensees. All New Mexico medical board licensees, whether or not the New Mexico license is their first license, who hold a federal drug enforcement administration registration and license to prescribe opioids, shall complete five continuing medical education hours in pain management during the first year of licensure. These five continuing medical education hours completed prior to the first renewal may be included as part of the hours required in Subsections B, C or D, above.

F. The continuing medical education requirements of this section are included in the total continuing medical education requirements set forth at 16.10.4.8 NMAC, 16.10.15.16 NMAC and 16.10.19.15 NMAC.

[16.10.14.11 NMAC - N, 9/28/12]

16.10.14.12 NOTIFICATION: In addition to the notice of procedures set forth in the State Rules Act, Section 14-4-1 et seq NMSA 1978, the board shall separately notify the following persons of the Pain Relief Act and Part 14 of the New Mexico medical board rule, 16.10.14 NMAC:

A. health care practitioners under its jurisdiction; and

B. a health care practitioner being investigated by the board in relation to the practitioner's pain management services.

[16.10.14.12 NMAC - N, 9/28/12]

HISTORY OF 16.10.14 NMAC: [RESERVED]

Code of New Mexico Rules (2013)
Title 16. Occupational and Professional Licensing
Chapter 12. Nursing and Health Care Related Providers
Part 9. Management of Chronic Pain with Controlled Substances

16.12.9. MANAGEMENT OF CHRONIC PAIN WITH CONTROLLED SUBSTANCES

16.12.9.1 ISSUING AGENCY: New Mexico Board of Nursing.

[16.12.9.1 NMAC - N, 02-17-06]

16.12.9.2 SCOPE: This rule applies to all advanced practice nurses, including certified nurse practitioners, certified registered nurse anesthetists, and clinical nurse specialists with prescriptive authority.

[16.12.9.2 NMAC - N, 02-17-06; A, 11-20-12]

16.12.9.3 STATUTORY AUTHORITY: Section 61-3-1 et seq., authorized the board of nursing to regulate the practice of nursing in the state and the Pain Relief Act, sections 24-2D-1 through 24-2D-6.

[16.12.9.3 NMAC - N, 02-17-06, A, 11-20-12]

16.12.9.4 DURATION: Permanent

[16.12.9.4 NMAC - N, 02-17-06]

16.12.9.5 EFFECTIVE DATE: February 17, 2006, unless a later date is cited at the end of a section.

[16.12.9.5 NMAC - N, 02-17-06]

16.12.9.6 OBJECTIVE: It is the position of the board that certified nurse practitioners, certified registered nurse anesthetists and clinical nurse specialists with prescriptive authority have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed after a thorough evaluation has been completed.

[16.12.9.6 NMAC - N, 02-17-06; A, 11-20-12]

16.12.9.7 DEFINITIONS:

A. “Acute Pain” means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and generally time limited.

B. “Addiction” is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

C. “Chronic pain” means pain that persists after reasonable efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. “Chronic pain” does not, for the purpose of the Pain Relief Act requirements, include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

D. “Clinical expert” means a person who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

E. “Drug abuser” means a person who takes a drug or drugs for other then legitimate medical purposes.

F. “Pain” means an unpleasant sensory and emotional experience associated with inflammation or with actual or potential tissue damage, or described in terms of such inflammation and damage, which could include acute, persistent or chronic pain.

G. “Physical dependence” means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

H. “Prescription monitoring program (PMP)” means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.

I. “Therapeutic purpose” means the use of pharmaceutical and non-pharmaceutical treatments and the spectrum of available modalities that conforms substantially to accepted guidelines for pain management.

J. “Tolerance” means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

[16.12.9.7 NMAC - N, 02-17-06; A, 11-20-12]

16.12.9.8 RULES: The following rules shall be used by the board to determine whether a health care practitioner's prescriptive practices are consistent with the appropriate treatment of pain.

A. The treatment of pain with various medicines or controlled substances is a legitimate nursing practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

B. Pain management for patients with substance use disorders should include a contractual agreement, the use of drug screens prior to treatment with opiates and during the course of treatment to identify actual drugs being consumed and to compare with patients self reports. If concerns about misuse are identified, the patient will be referred for appropriate consultation, and scheduled for re-evaluation at appropriate time intervals.

C. The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a history and physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substances abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A practitioner shall be familiar with and employ screening tools, as well as the spectrum of available modalities for therapeutic purposes, in the evaluation and management of pain. They shall consider an integrative approach to pain management specialists including but not limited

to an acupuncturist, chiropractor, doctor of oriental medicine, exercise physiologist, massage therapist, pharmacist, physical therapist, psychiatrist, psychologist or other advanced practice registered nurse.

(3) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan should include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(4) The practitioner shall provide education and discuss the risks and benefits of using controlled substances with the patient or surrogate or guardian, and shall document this in the record.

(5) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized should be recorded. Prescriptions for opioids shall include indications for use. For chronic noncancer pain patients treated with controlled substance analgesic(s), the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. As part of a written agreement, chronic noncancer pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.

(6) The management of patients needing chronic pain control requires monitoring by the attending or the consulting practitioner. The practitioner shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the chronic noncancer pain at least every six months. In addition, a practitioner should consult, when indicated by the patient's condition, with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control. Consultation should occur early in the course of long-term treatment, and at reasonable intervals during continued long-term treatment for assessment of benefit and need, at least every six months. Drug screening is recommended and should be conducted when other factors suggest an elevated risk of misuse or diversion.

(7) If, in a practitioner's opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

D. The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medial indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while

effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

E. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection as a guiding principle.

F. A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Nursing Practice Act, board rules and Pain Relief Act (24-2 D, 1 to 24-2 D, 6 NMSA 1978).

[16.12.9.8 NMAC - N, 02-17-06, A, 11-20-12]

16.12.9.9 PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS: The intent of the NM board of nursing in requiring participation in the PMP is to assist practitioners in balancing the promotion of the safe use of controlled substances for the provision of nursing care and services with the need to impede illegal and harmful activities involving these pharmaceuticals.

A. A health care provider who holds a federal drug enforcement administration registration and licensure to prescribe opioids shall register with the board of pharmacy to become a regular participant in PMP inquiry and reporting.

B. Upon prescribing, ordering, administering or dispensing a controlled substance, the practitioner shall obtain and review a prescription monitoring report covering at least a one year time period or another state's report, where applicable and available. The practitioner shall be aware of a person currently:

(1) receiving opiates from multiple prescribers;

(2) receiving opiates for more than twelve consecutive weeks;

(3) receiving more than one controlled substance analgesic;

(4) receiving a new prescription for any long-acting controlled substance analgesic formulation, including oral dosage forms and transdermal (e.g. fentanyl) or methadone;

(5) exhibiting potential for abuse or misuse of opiates (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presentation, or an unfamiliar patient requesting an opiate by specific name, street name, color, or identifying marks, or paying cash when the patient has prescription insurance).

C. Upon recognizing any of the above, the practitioner, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing additional controlled substance prescription monitoring reports

or another state's report if applicable and available, or consulting with a pain management specialist or addiction treatment specialist or counseling the patient, which may include termination of treatment. The practitioner shall document steps taken to resolve the potential problem, which may include termination from treatment.

D. After obtaining an initial prescription monitoring report on a patient, the practitioner shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further prescription monitoring reports or other state's report on that patient. Prescription monitoring reports shall be requested and reviewed a minimum of once every six months during the continuous use of opioids for each established patient. The practitioner shall document the review of these reports.

[16.12.9.9 NMAC - N, 11-20-12]

16.12.9.10 NON-CANCER PAIN MANAGEMENT CONTINUING EDUCATION: Any health care provider with a DEA registration and licensure that permits prescribing opioids, shall obtain continuing education on the management of non-cancer pain. These practitioners shall be required to obtain five CE of the 15 CE currently required every two years in pharmacology to include a review of these rules (16.12.9 NMAC) for management of non-cancer 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.

[16.12.9.10 NMAC - N, 11-20-12]

16.12.9.11 NOTIFICATION: The board shall notify the following persons of the Pain Relief Act and Part 9 of the New Mexico nursing board rule: 16.12.9 NMAC. The board shall notify the following persons of the Pain Relief Act and rules:

(1) health care providers under its jurisdiction; and

(2) a health care provider being investigated by the board in relation to the provider's pain management services.

[16.12.9.11 NMAC - N, 11-20-12]

16.12.9.12 ADVANCED PRACTICE NURSES, REGISTERED NURSES, AND LICENSED PRACTICAL NURSES TREATED WITH OPIATES: Advanced practice nurses, registered nurses, licensed practical nurses who have chronic pain and are being treated with opiates shall be evaluated by a pain clinic or, by a physician, CRNA, CNP, CNS pain specialist and must have a complete, independent neuropsychological evaluation, as well as clearance from their practitioner, before returning to or continuing in practice. In addition, they must remain under the care of a physician, CRNA, CNP or CNS for as long as they remain on opiates while continuing to practice.

Code of New Mexico Rules (2013)
Title 16. Occupational and Professional Licensing
Chapter 19. Pharmacists
Part 4. Pharmacist

16.19.4. PHARMACIST

16.19.4.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM.

[02-15-96; 16.19.4.1 NMAC - Rn, 16 NMAC 19.4.1, 03-30-02; A, 12-15-02; A, 08-16-10]

16.19.4.2 SCOPE: All designations of pharmacists subject to licensure and regulation by the Board of Pharmacy.

[02-15-96; 16.19.4.2 NMAC - Rn, 16 NMAC 19.4.2, 03-30-02]

16.19.4.3 STATUTORY AUTHORITY: Section 61-11-6.A.(1) authorizes the Board of Pharmacy to adopt, regularly review and revise rules and regulations necessary to carry out the provisions of the Pharmacy Act, Sections 61-11-1, 61-11-2, 61-11-4 to 61-11-28 NMSA 1978. Those provisions include the authority to (i) deny or take disciplinary action with respect to any certificate of registration or license held or applied for under the Pharmacy Act, Sections 61-11-20 NMSA 1978; (ii) require and establish criteria for continuing education as a condition of renewal of a pharmacist license, Sections 61-11-6.A.(4) NMSA 1978; (iii) issue permits or licenses, as defined and limited by Board regulation, to nursing homes, industrial and public health clinics and home care services, Sections 61-11-6.A.(6), 61-11-14 NMSA 1978; (iv) provide for the annual renewal of licenses for pharmacists, Sections 61-11-6.A.(3), 61-11-13 NMSA 1978; (v) provide for the registration of pharmacist interns, their certification, annual renewal of certification, training, supervision, and discipline, Sections 61-11-6.A.(5) NMSA 1978; and (vi) adopt rules and regulations that establish patient counseling requirements, 61-11-6.A.(18) NMSA 1978. Under the Pharmacist Prescriptive Authority Act, Sections 61-11B-1 to 61-11B-3 NMSA 1978, the Board is required to establish regulations governing certification as a pharmacist clinician. The Impaired Pharmacists Act, Sections 61-11A-1 to 61-11A-8 NMSA 1978, requires the establishment by the Board of a plan for treatment and rehabilitation of impaired pharmacists.

[03-14-98; 16.19.4.3 NMAC - Rn, 16 NMAC 19.4.3, 03-30-02]

16.19.4.4 DURATION: Permanent

[02-15-96; 16.19.4.4 NMAC - Rn, 16 NMAC 19.4.4, 03-30-02]

16.19.4.5 EFFECTIVE DATE: February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.

[03-14-98; 16.19.4.5 NMAC - Rn, 16 NMAC 19.4.5, 03-30-02]

16.19.4.6 OBJECTIVE: The objective of Part 4 of Chapter 19 is to promote the delivery of quality pharmaceutical services by establishing comprehensive regulations governing pharmacists, conduct, continuing education and requirements, criteria for specialized certification, and duties and responsibilities.

[02-15-96; 16.19.4.6 NMAC - Rn, 16 NMAC 19.4.6, 03-30-02]

. . .

16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

A. The following responsibilities require the use of professional judgement and therefore shall be performed only by a pharmacist or pharmacist intern:

(1) receipt of all new verbal prescription orders and reduction to writing;

(2) initial identification, evaluation and interpretation of the prescription order and any necessary clinical clarification prior to dispensing;

(3) professional consultation with a patient or his agent regarding a prescription;

(4) evaluation of available clinical data in patient medication record system;

(5) oral communication with the patient or patient's agent of information, as defined in this section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

(6) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription;

(7) drug regimen review, as defined in 61-11-2L;

(8) professional consultation, without dispensing, will require that the patient be provided with the identification of the pharmacist or pharmacy intern providing the service.

B. Only a pharmacist shall perform the following duties:

(1) final check on all aspects of the completed prescription including sterile products and cytotoxic preparations, and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;

(2) evaluation of pharmaceuticals for formulary selection within the facility;

(3) supervision of all supportive personnel activities including preparation, mixing, assembling, packaging, labeling and storage of medications;

(4) ensure that supportive personnel have been properly trained for the duties they may perform;

(5) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories); this does not apply to substitution of generic equivalents;

(6) any other duty required of a pharmacist by any federal or state law.

C. Patient records.

(1) A reasonable effort must be made to obtain, record and maintain at least the following information:

(a) name, address, telephone number, date of birth (or age) and gender of the patient;

(b) individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; and

(c) pharmacists comments relevant to the individuals drug therapy.

(2) Such information contained in the patient record should be considered by the pharmacist or pharmacist intern in the exercise of their professional judgement concerning both the offer to counsel and the content of counseling.

D. Prospective drug review.

(1) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(a) clinical abuse/misuse;

(b) therapeutic duplication;

(c) drug-disease contraindications;

(d) drug-drug interactions;

(e) incorrect drug dosage;

(f) incorrect duration of drug treatment;

(g) drug-allergy interactions;

(h) appropriate medication indication.

(2) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing a controlled substance prescription monitoring report or another states' reports if applicable and available, and consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem.

E. Prescription monitoring report for opiate prescriptions. When presented with an opiate prescription for a patient, obtaining and reviewing a prescription monitoring report for that patient can be an important tool that assists the pharmacist in identifying issues or problems that put his or her patient at risk of prescription drug abuse or diversion. A pharmacist shall use professional judgment based on prevailing standards of practice in determining whether to obtain and review a prescription monitoring report before dispensing an opiate prescription to that patient, and shall document his or her action regarding such reports.

(1) A pharmacist shall request and review a prescription monitoring report covering at least a one year time period and another states' report, where applicable and available if;

(a) a pharmacist becomes aware of a person currently exhibiting potential abuse or misuse of opiates (i.e. over-utilization, early refills, mulitple prescribers, appears overly sedated or intoxicated upon presenting a precription for an opiate or an unfamiliar patient requesting an opiate by specific name, street name, color, or identifying marks, or paying cash when the patient has prescription insurance);

(b) a pharmacist receives an opiat prescription requesting the dispensing of opiates from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (e.i. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area);

(c) providing opiates for a patient that is receiving chronic pain management prescriptions.

(2) After obtaining an initial prescription monitoring report on a patient, a pharmacist shall use professional judgment base on prevailing standards of practice, in deciding the frequency of requesting and reviewing further prescription monitoring reports and other states' reports for that patient. The pharmacist shall document the review of these reports.

(3) In the event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving a report.

(4) A prescription for an opiate written for a patient in a long term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness is exempt from Subsection D of

16.19.29.8 NMAC. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner. The pharmacist shall document whether the patient is “terminally ill” or an “LTCF patient”.

F. Counseling.

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent. Upon receipt of a refill prescription drug order a pharmacy technician may query the patient or patient's agent regarding counseling by the pharmacist or pharmacist intern concerning drug therapy. Such counseling shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling which may include, in their professional judgement, one or more of the following:

(a) the name and description of the drug;

(b) the dosage form, dosage, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescriptions refill information;

(i) action to be taken in the event of a missed dose;

(j) the need to check with the pharmacist or practitioner before taking other medication; and

(k) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) [REPEALED]

(3) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

(4) Patient counseling, as described above and defined in this regulation shall not be required for in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(5) A pharmacist shall in no way attempt to circumvent or willfully discourage a patient or patient's agent from receiving counseling. However, a pharmacist shall not be required to counsel a patient or patients's agent when the patient or patients's agent refuses such consultation.

(6) When the patient or agent is not present when the prescription is dispensed, including but not limited to a prescription that was shipped by the mail, the pharmacist shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, and: (1) of his or her right to request counseling; and (2) a toll-free telephone number in which the patient or patient's agent may obtain oral counseling from a pharmacist who has ready access to the patient's record. For pharmacies delivering more than 50% of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than 6 days per week. The facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

(7) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice concerning available counseling.

G. [REPEALED]

H. Regulatory assessment. Profiles, either electronic or hard copy, shall be available for inspection, and shall provide the capability of storing the described historical information. The profiles must demonstrate that an effort is being made to fulfill the requirements by the completion of the detail required. A patient record shall be maintained for a period of not less than three (3) years from the date of the last entry in the profile record.

[08-27-90; 16.19.4.16 NMAC - Rn, 16 NMAC 19.4.16, 03-30-02; 16.19.4.16 NMAC - Rn, 16.19.4.17 NMAC, 12-15-02; A, 02-01-04; A, 11-30-04; A, 01-15-05; A, 01-31-07; A, 08-31-12; A, 10-25-12]

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New York
Public Health Law § 3343-A

Mckinney's Consolidated Laws of New York Annotated (2013)
Public Health Law
Chapter 45. Of the Consolidated Laws
Article 33. Controlled Substances
Title IV. Dispensing to Ultimate Users

<Text of Section Effective August 27, 2013>

§ 3343-a. Prescription Monitoring Program Registry

1. Establishment of system. (A) The commissioner shall, in accordance with the provisions of this section, establish and maintain an electronic system for collecting, monitoring and reporting information concerning the prescribing and dispensing of controlled substances, to be known as the prescription monitoring program registry. The registry shall include information reported by pharmacies on a real time basis, as set forth in subdivision four of section thirty-three hundred thirty-three of this article.

(B) The registry shall include, for each person to whom a prescription for controlled substances has been dispensed, all patient-specific information covering such period of time as is deemed appropriate and feasible by the commissioner, but no less than six months and no more than five years. Such patient-specific information shall be obtained from the prescription information reported by pharmacies pursuant to subdivision four of section thirty-three hundred thirty-three of this article and by practitioners who dispense pursuant to subdivision six of section thirty-three hundred thirty-one of this article, and shall be processed and included in the registry by the department without undue delay. For purposes of this article, "patient-specific information" means information pertaining to individual patients included in the registry, which shall include the following information and such other information as is required by the department in regulation:

(I) The patient's name;

(II) The patient's residential address;

(III) The patient's date of birth;

(IV) The patient's gender;

(V) The date on which the prescription was issued;

(VI) The date on which the controlled substance was dispensed;

(VII) The metric quantity of the controlled substance dispensed;

(VIII) The number of days supply of the controlled substance dispensed;

(IX) The name of the prescriber;

(X) The prescriber's identification number, as assigned by the Drug Enforcement Administration;

(XI) The name or identifier of the drug that was dispensed; and

(XII) The payment method.

(C) The registry shall be secure, easily accessible by practitioners and pharmacists, and compatible with the electronic transmission of prescriptions for controlled substances, as required by section two hundred eighty-one of this chapter, and section sixty-eight hundred ten of the Education Law, and any regulations promulgated pursuant thereto. To the extent practicable, implementation of the electronic transmission of prescriptions for controlled substances shall serve to streamline consultation of the registry by practitioners and reporting of prescription information by pharmacists. The registry shall be interoperable with other similar registries operated by federal or state governments, to the extent deemed appropriate by the commissioner, and subject to the provisions of section thirty-three hundred seventy-one-a of this article.

(D) The department shall establish and implement such protocols as are reasonably necessary to ensure that information contained in the registry is maintained in a secure and confidential manner and is accessible only by practitioners, pharmacists or their designees for the purposes established in subdivisions two and three of this section, or as otherwise set forth in sections thirty-three hundred seventy-one and thirty-three hundred seventy-one-a of this article. Such protocols shall include a mechanism for the department to monitor and record access to the registry, which shall identify the authorized individual accessing and each controlled substance history accessed.

2. Duty to consult prescription monitoring program registry; practitioners. (A) Every practitioner shall consult the prescription monitoring program registry prior to prescribing or dispensing any controlled substance listed on Schedule II, III or IV of section thirty-three hundred six of this article, for the purpose of reviewing a patient's controlled substance history as set forth in such registry; provided, however, that nothing in this section shall preclude an authorized practitioner, other than a veterinarian, from consulting the registry at his or her option prior to prescribing or dispensing any controlled substance. The duty to consult the registry shall not apply to:

(I) Veterinarians;

(II) A practitioner dispensing pursuant to subdivision three of section thirty-three hundred fifty-one of this article;

(III) A practitioner administering a controlled substance;

(IV) A practitioner prescribing or ordering a controlled substance for use on the premises of an institutional dispenser pursuant to section thirty-three hundred forty-two of this title;

(V) A practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity of controlled substance prescribed does not exceed a five day supply if the controlled substance were used in accordance with the directions for use;

(VI) A practitioner prescribing a controlled substance to a patient under the care of a hospice, as defined by section four thousand two of this chapter;

(VII) A practitioner when:

(a) It is not reasonably possible for the practitioner to access the registry in a timely manner;

(b) No other practitioner or designee authorized to access the registry, pursuant to paragraph (B) of this subdivision, is reasonably available; and

(c) The quantity of controlled substance prescribed does not exceed a five day supply if the controlled substance were used in accordance with the directions for use;

(VIII) A practitioner acting in compliance with regulations that may be promulgated by the commissioner as to circumstances under which consultation of the registry would result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient;

(IX) A situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure, as set forth in regulation; or

(X) A practitioner who has been granted a waiver due to technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner, pursuant to a process established in regulation, and in the discretion of the commissioner.

(B) For purposes of this section, a practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that:

(I) The designee so authorized is employed by the same professional practice or is under contract with such practice;

(II) The practitioner takes reasonable steps to ensure that such designee is sufficiently competent in the use of the registry;

(III) The practitioner remains responsible for ensuring that access to the registry by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the registry, and remains responsible for any breach of confidentiality; and

(IV) The ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner and is reasonably informed by the relevant controlled substance history information obtained from the registry.

The commissioner shall establish in regulation reasonable parameters with regard to a practitioner's ability to authorize designees pursuant to this section, which shall include processes necessary to allow the department to:

(a) Grant access to the registry in a reasonably prompt manner to as many designees as are authorized by practitioners, up to the number deemed appropriate by the commissioner for particular professional practices or types of practices, taking into account the need to maintain security of the registry and the patient-specific information maintained therein, and the objective of minimizing burdens to practitioners to the extent practicable;

(b) Require that practitioners notify the department upon terminating the authorization of any designee; and

(c) Establish a mechanism to prevent such terminated designees from accessing the registry in a reasonably prompt manner following such notification.

3. Authority to consult prescription monitoring program registry; pharmacists. (A) A pharmacist may consult the prescription monitoring program registry in order to review the controlled substance history of an individual for whom one or more prescriptions for controlled substances is presented to such pharmacist.

(B) For purposes of this section, a pharmacist may designate another pharmacist, a pharmacy intern, as defined by section sixty-eight hundred six of the Education Law, or other individual as may be permitted by the commissioner in regulation, to consult the prescription monitoring program registry on the pharmacist's behalf, provided that such designee is employed by the same pharmacy or is under contract with such pharmacy. The commissioner shall establish in regulation reasonable parameters with regard to a pharmacist's ability to authorize designees pursuant to this section, which shall include processes necessary to allow the department to:
(a) Grant access to the registry in a reasonably prompt manner to as many designees as are authorized by pharmacists, up to the number deemed appropriate by the commissioner for

particular pharmacies, taking into account the need to maintain security of the registry and the patient-specific information maintained therein, and the objective of minimizing burdens to pharmacists to the extent practicable;

(b) Require that pharmacists notify the department upon terminating the authorization of any designee; and

(c) Establish a mechanism to prevent such terminated designees from accessing the registry in a reasonably prompt manner following such notification.

4. Immunity. No practitioner or pharmacist, and no person acting on behalf of such practitioner or pharmacist as permitted under this section, acting with reasonable care and in good faith shall be subject to civil liability arising from any false, incomplete or inaccurate information submitted to or reported by the registry or for any resulting failure of the system to accurately or timely report such information; provided, however, that nothing in this subdivision shall be deemed to alter the obligation to submit or report prescription information to the department as otherwise set forth in this article or in regulations promulgated pursuant thereto.

5. Guidance to practitioners and pharmacists. The commissioner shall, in consultation with the commissioner of education, provide guidance to practitioners, pharmacists, and pharmacies regarding the purposes and uses of the registry established by this section and the means by which practitioners and pharmacists can access the registry. Such guidance shall reference educational information available pursuant to the prescription pain medication awareness program established pursuant to section thirty-three hundred nine-a of this article.

6. Individual access to controlled substance histories. The commissioner shall establish procedures by which an individual may:

(A) Request and obtain his or her own controlled substances history consisting of patient-specific information or, in appropriate circumstances, that of a patient who lacks capacity to make health care decisions and for whom the individual has legal authority to make such decisions and would have legal access to the patient's health care records; or

(B) Seek review of any part of his or her controlled substances history or, in appropriate circumstances, that of a patient who lacks capacity to make health care decisions and for whom the individual has legal authority to make such decisions and would have legal access to the patient's health care records, that such individual disputes.

Such procedures shall require the department to promptly revise any information accessible through the registry that the department determines to be inaccurate. Such procedures shall be described on the department's website and included with the controlled substances history provided to an individual pursuant to a request made under this subdivision or under subparagraph (IV) of paragraph (A) of subdivision two of section thirty-three hundred seventy-one of this article.

7. Department analysis of data. The department shall periodically analyze data contained in the prescription monitoring program registry to identify information that indicates that a violation of law or breach of professional standards may have occurred and, as warranted, provide any relevant information to appropriate entities as permitted under section thirty-three hundred seventy-one of this article. The department shall keep a record of the information provided, including, but not limited to, the specific information provided and the agency to which such information was provided, including the name and title of the person to whom such information was provided and an attestation from such person that he or she has authority to receive such information.

8. Funding the prescription monitoring program registry. (A) The commissioner shall make reasonable efforts to apply for monies available from the federal government and other institutions, to the extent deemed appropriate by the commissioner, and use any monies so obtained to supplement any other monies made available for the purposes of this title.

(B) Operation of the registry established by this section shall not be funded, in whole or in part, by fees imposed specifically for such purposes upon practitioners, pharmacists, designees or patients subject to this section.

9. Rules and regulations. The commissioner shall promulgate such rules and regulations as are necessary to effectuate the provisions of this section, in consultation with the work group established pursuant to subdivision three of section thirty-three hundred nine-a of this article.

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North Carolina

Per the state PDMP representative, North Carolina requires medical directors of opioid treatment programs to access the PMP database upon admission of a new patient and at least annually thereafter.

Further, the North Carolina Medical Board issued a Position Statement regarding their policy for the use of controlled substances for the treatment of pain which states that physicians treating patients for pain should intermittently check the Controlled Substance Reporting Service for all patients.

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Ohio

ADC 4729-5-20
§ 4731.055
ADC 4731-11-11
§ 4715.302
ADC 4715-6-01
§ 4723.487
ADC 4723-9-12
§ 4725.092
§ 4729.162
§ 4730.53
ADC 4723-6-21.4

Baldwin's Ohio Administrative Code (2013)
4729 Pharmacy Board
Chapter 4729-5. Pharmacy Practice--Administration

4729-5-20 Prospective drug utilization review

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment;

(9) Food-nutritional supplements-drug interactions.

(B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include

requesting and reviewing an OARRS report or another state's report if applicable and available, and/or consulting with the prescriber and/or counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information;

(3) United States pharmacopoeia drug information;

(4) American medical association evaluations.

(D) Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person currently:

(1) Receiving reported drugs from multiple prescribers;

(2) Receiving reported drugs for more than twelve consecutive weeks;

(3) Abusing or misusing reported drugs (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);

(4) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or.

(5) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.

In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

Baldwin's Ohio Revised Code Annotated (2013)
Title XLVII. Occupations--Professions
Chapter 4731. Physicians; Limited Practitioners
State Medical Board

§ 4731.055 Review of patient information available through drug database

(A) As used in this section:

(1) “Drug database” means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(2) “Physician” means an individual authorized under this chapter to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(B) The state medical board shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by a physician regarding the review of patient information available through the drug database.

(C) This section and the rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Baldwin's Ohio Administrative Code (2013)
4731 Medical Board
Chapter 4731-11. Controlled Substances

4731-11-11 Standards and procedures for review of Ohio Automated Rx Reporting System (OARRS)

(A) For purposes of this rule:

(1) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(2) "OARRS report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(3) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(4) "Protracted basis" means a period in excess of twelve continuous weeks.

(5) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including:

(a) Controlled substances in schedules II, III, IV, and V, and

(b) All dangerous drug products containing carisoprodol or tramadol.

(B) If a physician believes or has reason to believe that a patient may be abusing or diverting drugs, the physician shall use sound clinical judgment in determining whether or not the reported drug should be prescribed or personally furnished to the patient under the circumstances.

(1) To assist in this determination, the physician shall access OARRS and document receipt and assessment of the information received if the patient exhibits the following signs of drug abuse or diversion:

(a) Selling prescription drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;

(f) Having been arrested, convicted or received diversion, or intervention in lieu of conviction for a drug related offense while under the physician's care;

(g) Receiving reported drugs from multiple prescribers, without clinical basis; or
(h) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs.

(2) Other signs of possible abuse or diversion which may necessitate accessing OARRS include, but are not limited to the following:

(a) A known history of chemical abuse or dependency;

(b) Appearing impaired or overly sedated during an office visit or exam;

(c) Requesting reported drugs by specific name, street name, color, or identifying marks;

(d) Frequently requesting early refills of reported drugs;

(e) Frequently losing prescriptions for reported drugs;

(f) A history of illegal drug use;

(g) Sharing reported drugs with another person; or

(h) Recurring emergency department visits to obtain reported drugs.

(C) A physician prescribing or personally furnishing reported drugs to treat a patient on a protracted basis shall, at a minimum, document receipt and assessment of an OARRS report in the following circumstances:

(1) Once the physician has reason to believe that the treatment will be required on a protracted basis; and

(2) At least once annually, thereafter.

(D) A physician shall document receipt and assessment of all OARRS reports in the patient record.

(1) Initial reports requested in compliance with this rule shall cover a time period of at least one year;

(2) Subsequent reports requested in compliance with this rule shall, at a minimum, cover the period from the date of the last report to present.

(E) In the event an OARRS report is not available prior to writing a prescription for a reported drug or personally furnishing the reported drug, a physician shall document in the patient record why the OARRS report was not available.

(F) Paragraph (C) of this rule does not apply to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code.

Baldwin's Ohio Revised Code Annotated (2013)
Title XLVII. Occupations--Professions
Chapter 4715. Dentists; Dental Hygienists
Disciplinary Action; Prohibitions

§ 4715.302 Review of patient information available through drug database

(A) As used in this section, “drug database” means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(B) The state dental board shall adopt rules in accordance with Chapter 119 of the Revised Code that establish standards and procedures to be followed by a dentist regarding the review of patient information available through the drug database.

(C) This section and the rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Baldwin's Ohio Administrative Code Annotated (2013)
4715 Dental Board
Chapter 4715-6. Automated Prescription Reporting System

4715-6-01 Standards and procedures for review of Ohio Automated Rx Reporting System (OARRS)

(A) For purposes of this rule and sections 4715.30 (A)(13) and 4715.302 of the Revised Code:

(1) "OARRS" means Ohio Automated Prescription Reporting System;

(2) "OARRS report" means a report of information related to a specific patient generated by the drug database established and maintained by the State board of pharmacy pursuant to section 4729.75 of the Revised Code.

(3) "Personally furnishing" does not include the administration of a drug.

(4) "Reported drugs" includes the following:

(a) All controlled substances in scheduled II, III, IV, and V; and

(b) All dangerous drug products containing carisoprodol or tramadol.

(5) "Diversion" includes but is not limited to the following:

(a) Selling drugs;

(b) Borrowing drugs;

(c) Sharing drugs.

(6) "Protracted basis" means for a period in excess of twelve continuous weeks, and for no more than twenty four weeks over a period of one year.

(B) If a dentist knows or has reason to believe that a patient may be abusing or diverting drugs, the dentist shall use sound clinical judgment in determining whether or not a reported drug should be prescribed or personally furnished to the patient under the

circumstances. To assist in this determination, the dentist shall consider whether to access OARRS and document receipt and assessment of the information received if the patient exhibits signs of drug abuse or diversion. These signs may include, but are not limited to, the following:

(1) Engaging in or has a history of drug related criminal activity;

(2) Is receiving reported drugs from multiple prescribers;

(3) Has family members, friends, law enforcement officers, or health care professionals express concern related to the patient's use of illegal or reported drug;

(4) Has a known history of chemical abuse or dependency;

(5) Is requesting reported drugs by street name, color, or identifying marks;

(6) Frequently requesting early refills of reported drugs;

(7) Frequently losing prescriptions for reported drugs.

(C) Following review of OARRS report information, the dentist shall document receipt of the information in the patient's record.

(D) A dentist licensed under this chapter who prescribes or personally furnishes reported drugs to treat a patient on a protracted basis shall, at a minimum, document receipt and assessment of an OARRS report in the following circumstances:

(1) Once the dentist has reason to believe that treatment will be required on a protracted basis;

(2) At least once annually thereafter.

(E) In requesting OARRS reports according to this rule:

(1) Reports requested should cover a time period of at least one year;

(2) In the event an OARRS report is not immediately available prior to writing a prescription for, or personally furnishing, a reported drug, the dentist shall document in the patient record why the OARRS report was not available.

(F) Paragraph (D) above does not apply to a hospice patient in a hospice care program as those terms are defined in Section 3712.01 of the Revised Code.

Baldwin's Ohio Revised Code Annotated (2013)
Title XLVII. Occupations--Professions
Chapter 4723. Nurses
Certificates to Prescribe

§ 4723.487 Review of patient information available through drug database

(A) As used in this section, "drug database" means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(B) The board of nursing shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by an advanced practice nurse with a certificate to prescribe issued under section 4723.48 of the Revised Code regarding the review of patient information available through the drug database.

(C) This section and the rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Baldwin's Ohio Administrative Code Annotated (2013)
4723 Nursing Board
Chapter 4723-9. Prescriptive Authority

4723-9-12 Standards and procedures for review of OARRS

(A) For the purposes of this rule:

(1) "OARRS" means the Ohio automated RX reporting system established and maintained according to section 4729.75 of the Revised Code.

(2) "OARRS report" means a report of information related to a specified patient generated by the drug database established maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(3) "Protracted basis" means a period in excess of twelve continuous weeks.

(4) "Reported drugs" means all drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained according to section 4729.75 of the Revised Code, including:

(a) Controlled substance schedules II, III, IV, and V; and

(b) All dangerous drug products containing carisoprodol or tramadol.

(B) In addition to the requirements set forth in rule 4723-9-08 and rule 4723-9-09 of the Administrative Code, if a nurse who holds a current valid certificate to prescribe believes, or has reason to believe, that a patient may be abusing or diverting drugs, the nurse shall use sound clinical judgment in determining whether or not a reported drug should be prescribed or personally furnished to the patient.

(1) In making this determination, the nurse shall not personally furnish or prescribe a reported drug without first reviewing a patient's OARRS report if the patient exhibits the following signs of drug abuse or diversion:

(a) Illegally selling drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;

(f) Having been arrested, convicted, or received diversion, or intervention in lieu of conviction for a drug-related offense while under the nurse's care;

(g) Receiving reported drugs from multiple prescribers; or

(h) Having a family member, friend, law enforcement officer or health care professional express concern related to the patient's use of illegal or reported drugs.

(2) Other signs of possible abuse or diversion that may necessitate review of the patient's OARRS report include, but are not limited to the following:

(a) A known history of chemical abuse or dependency;

(b) Appearing impaired or overly sedated during an office visit or examination;

(c) Requesting reported drugs by specific name, street name, color, or identifying marks;

(d) Frequently requesting early refills of reported drugs;

(e) Frequently losing prescriptions for reported drugs;

(f) A history of illegal drug use;

(g) Sharing reported drugs with another person; or

(h) Recurring emergency department visits to obtain reported drugs.

(C) A nurse who holds a current valid certificate to prescribe and personally furnishes or prescribes a reported drug to a patient following review of an OARRS report under paragraph (B) of this rule, and determines, based on the OARRS report and indicia described in paragraph (B) of this rule that the patient may be misusing reported drugs, shall first consult with their collaborating physician prior to personally furnishing or prescribing a reported drug at the patient's next visit.

(D) Following review of OARRS report information, the nurse who holds a current valid certificate to prescribe shall document receipt and assessment of the information in the patient's record, including any consultation with the collaborating physician that occurred based on the OARRS report information or required by paragraph (C) of this rule.

(E) A nurse who holds a current valid certificate to prescribe and utilizes reported drugs to treat a patient on what the nurse has reason to believe will be a protracted basis shall, at minimum, review an OARRS report, and document receipt and assessment of the information in the patient's record:

(1) At the beginning of treatment; and

(2) At least once annually after treatment begins.

(F) In requesting OARRS reports according to this rule:

(1) Initial reports requested shall cover a time period of at least one year;

(2) Subsequent reports requested shall at minimum cover the period of time from the date of the last report reviewed to the present; and

(3) In the event an OARRS report is not immediately available, the nurse who holds a current valid certificate to prescribe shall document the response from the drug database in the patient record.

(G) Paragraph (E) of this rule does not apply to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code.

Baldwin's Ohio Revised Code Annotated (2013)
Title XLVII. Occupations--Professions
Chapter 4725. Optometrists; Dispensing Opticians
State Board of Optometry

§ 4725.092 Review of patient information available through drug database

(A) As used in this section, "drug database" means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(B) The state board of optometry shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by an optometrist who holds a therapeutic pharmaceutical agents certificate regarding the review of patient information available through the drug database.

(C) This section and the rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Baldwin's Ohio Revised Code Annotated (2013)
Title XLVII. Occupations--Professions
Chapter 4729. Pharmacists; Dangerous Drugs
Registration of Pharmacists

§ 4729.162 Review of patient information available through drug database

(A) As used in this section, "drug database" means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(B) The state board of pharmacy shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by a pharmacist regarding the review of patient information available through the drug database.

(C) This section and the rules adopted under it do not apply if the board no longer maintains the drug database.

Baldwin's Ohio Revised Code Annotated (2013)
Title XLVII. Occupations--Professions
Chapter 4730. Physician Assistants

§ 4730.53 Review of patient information available through drug database

(A) As used in this section, "drug database" means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(B) The medical board shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by a physician assistant who holds a certificate to prescribe issued under this chapter regarding the review of patient information available through the drug database.

(C) This section and the rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Baldwin's Ohio Administrative Code Annotated (2013)
4123 Workers' Compensation Bureau
Chapter 4123-6. Health Partnership Program (HPP)

4123-6-21.4 Coordinated services program

The bureau, or a self-insuring employer with a point-of-service adjudication system, may establish a coordinated services program (CSP) that requires an injured worker to obtain prescription medications reimbursed by the bureau or self-insuring employer from a single designated pharmacy and/or prescriber.

(A) Placement in a CSP.

(1) The bureau or self-insuring employer with a point-of-service adjudication system may review an injured worker for possible placement in a CSP if a review of his or her claim indicates the injured worker meets one or more of the following criteria:

(a) Use of three or more different prescribers to obtain prescriptions of the same or comparable medications per three month time frame;

(b) Receipt of prescription drugs from more than two different pharmacies per three month time frame;

(c) Monthly receipt of three or more prescriptions including refills for drugs identified by therapeutic drug class as a narcotic analgesic per three month time frame;

(d) Monthly receipt of more than two concurrent narcotic analgesics in the same therapeutic drug class per three month time frame;

(e) Monthly receipt of more than two narcotic analgesics in the same therapeutic drug class, more than one benzodiazepine, and more than one sedative-hypnotics per three month time frame.

(2) Upon identification of an injured worker meeting one or more of the criteria identified in paragraphs (A)(1)(a) to (A)(1)(e) of this rule, the bureau or self-insuring employer with a point-of-service adjudication system shall obtain a physician review of the injured worker's most recent twelve months history of prescription medications reimbursed by the bureau or self-insuring employer.

(3) If, based on this physician review, the bureau or self-insuring employer with a point-of-service adjudication system determines that the injured worker's utilization of prescription

medications during this period was at a frequency or in an amount that was not medically necessary or appropriate under the criteria set forth in paragraphs (B)(1) to (B)(3) of rule 4123-6-16.2 of the Administrative Code, or was potentially unsafe, the bureau or self-insuring employer may place the injured worker in a CSP.

(4) Notwithstanding paragraphs (A)(1) to (A)(3) of this rule, if the bureau or self-insuring employer with a point-of-service adjudication system determines that an injured worker has been convicted of or pled guilty to an offense under Chapter 2925. of the Revised Code or any other criminal offense related to the misuse of drugs, the bureau or self-insuring employer may place the injured worker in a CSP.

(5) Placement in a CSP shall be for an initial period of eighteen months. The bureau or self-insuring employer with a point-of-service adjudication system may place the injured worker in the CSP for additional eighteen month periods in accordance with paragraph (A)(6) of this rule.

(6) The bureau or self-insuring employer with a point-of-service adjudication system may evaluate an injured worker's medication utilization at the conclusion of each eighteen month period in the CSP. If the bureau or self-insuring employer determines that the injured worker's medication utilization continues to meet the criteria set forth in paragraphs (A)(1) to (A)(4) of this rule, the bureau or self-insuring employer may place the injured worker in the CSP for an additional eighteen month period.

(7) If an injured worker placed in the CSP enters a nursing home, residential care/assisted living facility, or hospice program, the injured worker shall be released from the CSP. If the injured worker is subsequently discharged from the nursing home, residential care/assisted living facility, or hospice program during the CSP period, the bureau or self-insuring employer with a point-of-service adjudication system may place the injured worker back into the CSP.

(B) Selection of designated pharmacy and/or prescriber.

(1) An injured worker placed into a CSP pursuant to paragraph (A)(3) or (A)(4) of this rule shall be given the opportunity to select a designated pharmacy from a list of participating pharmacies maintained by the bureau or self-insuring employer. If an injured worker fails to select a designated pharmacy, or selects a designated pharmacy that is unable or unwilling to accept the injured worker, the bureau or self-insuring employer may select a designated pharmacy for the injured worker.

(2) An injured worker placed in a CSP pursuant to paragraph (A)(3) or (A)(4) of this rule may only change from one designated pharmacy to another in the following circumstances:

(a) The designated pharmacy becomes inaccessible to the injured worker due to relocation or incapacity of the injured worker or closing of the designated pharmacy,

(b) The designated pharmacy chooses to no longer participate in the CSP or to provide services to the injured worker in accordance with paragraph (D)(4) of this rule.

(c) The injured worker requests to be assigned to another designated pharmacy due to personal preference. Not more than one change due to personal preference shall be approved in a rolling twelve-month period.

(3) An injured worker placed in the CSP pursuant to paragraph (A)(4) of this rule shall be given the opportunity to select a designated prescriber from among those bureau certified providers who meet the definition of physician under paragraph (D) of rule 4123-6-01 of the Administrative Code. If an injured worker fails to select a designated prescriber, or selects a designated prescriber that is unable or unwilling to accept the injured worker, the bureau or self-insuring employer may select a designated prescriber for the injured worker.

(4) An injured worker placed in a CSP pursuant to paragraph (A)(4) of this rule may only change from one designated prescriber to another in the following circumstances:

(a) The designated prescriber becomes inaccessible to the injured worker due to relocation or incapacity of the injured worker or closing of the designated prescriber's practice,

(b) The designated prescriber chooses to no longer provide services to the injured worker,

(c) The injured worker requests to be assigned to another designated prescriber due to personal preference. Not more than one change due to personal preference shall be approved in a rolling twelve-month period.

(5) All requests for change of designated pharmacy or designated prescriber must be submitted in writing to the bureau or self-insuring employer.

(C) Operation of the CSP.

(1) An injured worker placed in a CSP pursuant to paragraph (A)(3) or (A)(4) of this rule must obtain covered prescription medications from the injured worker's designated pharmacy. During the period the injured worker is placed in the CSP, the bureau or self-insuring employer shall deny reimbursement for prescription medications obtained from a pharmacy other than the injured worker's designated pharmacy, except in cases of emergency as set forth in paragraph (C)(2) of this rule.

(2) Emergency prescription fills shall be allowed in the following situations:

(a) The injured worker is unable to get to his or her designated pharmacy,

(b) The injured worker's designated pharmacy does not have the prescribed medication in stock.

(3) Emergency prescription fills shall be limited to a four-day supply. Records of dispensing for emergency prescription fills are subject to review by the bureau.

(4) An injured worker placed in a CSP pursuant to paragraph (A)(4) of this rule must obtain all prescriptions for covered medications from the injured worker's designated prescriber. During the period the injured worker is placed in the CSP, the bureau or self-insuring employer shall deny reimbursement for prescriptions written by providers other than the injured worker's designated prescriber, except:

(a) In cases of emergency as defined in paragraph (O) of rule 4123-6-01 of the Administrative Code;

(b) With prior authorization, prescriptions written by a specialist in cases where the injured worker has been referred to a specialist for care.

(D) Pharmacies participating in the bureau's CSP.

(1) The bureau shall maintain a list of pharmacies participating in the bureau's CSP that are eligible for selection by an injured worker as a designated pharmacy. To participate in the bureau's CSP, a pharmacy must meet the following criteria:

(a) The pharmacy must be enrolled with the bureau and have a signed agreement with the bureau's pharmacy benefits manager.

(b) The pharmacy must enter into a CSP agreement with the bureau.

(2) Pharmacies participating in the bureau's CSP agree to perform the following monitoring activities:

(a) For each injured worker in the bureau's CSP for whom the pharmacy is the designated pharmacy, the pharmacy shall conduct a bimonthly review of the injured worker's OARRS report from the Ohio board of pharmacy (or a similar automated prescription monitoring report from the injured worker's state of residence).

(b) The pharmacy shall notify the injured worker's prescribing physician of any critical findings discovered in the report. Critical findings are indications of any prescription related activity that could cause harm to the patient, including but not limited to:

(i) Duplication of therapy,

(ii) Excessive doses of concurrent medications,

(iii) Potential drug interactions or potentiation of side effects.

(c) The pharmacy shall notify BWC in writing whenever reports are made under paragraph (D)(2)(b) of this rule.

(d) BWC may request quarterly documentation of the pharmacy's monitoring activities under paragraphs (D)(2)(a) to (D)(2)(d) of this rule.

(3) Pharmacies participating in the CSP may receive compensation from the bureau under the CSP agreement for services provided as part of the CSP.

(4) Pharmacies participating in the bureau's CSP may terminate their CSP agreement with the bureau and discontinue their participation in the bureau's CSP at any time upon not less than thirty days written notice to the bureau. Pharmacies participating in the bureau's CSP may discontinue providing services to an individual injured worker at any time upon not less than thirty days written notice to the bureau, the injured worker, and the injured worker's authorized representative.

(5) The bureau may terminate the CSP agreement of a pharmacy participating in the bureau's CSP in accordance with the terms of the CSP agreement.

(E) Pharmacies participating in a self-insuring employer's CSP.

(1) A self-insuring employer with a point-of-service adjudication system who establishes a CSP shall maintain a list of pharmacies participating in the self-insuring employer's CSP that are eligible for selection by an injured worker as a designated pharmacy. The list of participating pharmacies shall cover a geographic area sufficient to provide the self-insuring employer's injured workers with reasonable access to pharmacy providers.

(2) Pharmacies participating in a self-insuring employer's CSP shall provide not less than thirty days written notice to an injured worker and the injured worker's authorized representative prior to discontinuing services to the injured worker.

(F) Disputes.

(1) Decisions by the bureau regarding an injured worker's placement in the bureau's CSP, assignment of a designated pharmacy or designated prescriber, or denial of an injured worker's request for change of designated pharmacy or designated prescriber may be appealed to the industrial commission in accordance with section 4123.511 of the Revised Code.

(2) Decisions by a self-insuring employer regarding an injured worker's placement in the self-insuring employer's CSP, assignment of a designated pharmacy or designated prescriber, or denial of an injured worker's request for change of designated pharmacy or designated prescriber shall indicate that the injured worker has the right to request a hearing before the industrial commission.

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Oklahoma
63 § 2-302

Oklahoma Statutes Annotated (2013)
Title 63. Public Health and Safety
Chapter 2. Uniform Controlled Dangerous Substances Act
Article III. Regulation of Manufacture, Distribution, Dispensing, Prescribing, Administering and Using for Scientific Purposes of Controlled Dangerous Substances
Registration

§ 2-302. Registration requirements

A. Every person who manufactures, distributes, dispenses, prescribes, administers or uses for scientific purposes any controlled dangerous substance within this state, or who proposes to engage in the manufacture, distribution, dispensing, prescribing, administering or use for scientific purposes of any controlled dangerous substance within this state shall obtain a registration issued by the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, in accordance with rules promulgated by the Director. Persons registered by the Director under Section 2-101 et seq. of this title to manufacture, distribute, dispense, or conduct research with controlled dangerous substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this article. Every wholesaler, manufacturer or distributor of any drug product containing pseudoephedrine or phenylpropanolamine, or their salts, isomers, or salts of isomers shall obtain a registration issued by the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control in accordance with rules promulgated by the Director and as provided for in Section 2-332 of this title.

B. Out-of-state pharmaceutical suppliers who provide controlled dangerous substances to individuals within this state shall obtain a registration issued by the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, in accordance with rules promulgated by the Director; provided that this provision shall not apply to wholesale distributors who ship controlled dangerous substances to pharmacies or other entities registered within this state in accordance with rules promulgated by the Director.

C. Manufacturers, distributors, home care agencies, hospices, home care services, and scientific researchers shall obtain a registration annually. Other practitioners shall obtain a registration for a period to be determined by the Director that will be for a period not less than one (1) year nor more than three (3) years.

D. Every trainer or handler of a canine controlled dangerous substances detector who, in the ordinary course of such trainer's or handler's profession, desires to possess any controlled dangerous substance, annually, shall obtain a registration issued by the Director for a fee of Seventy Dollars ($70.00). Such persons shall be subject to all applicable provisions of Section 2-

101 et seq. of this title and such applicable rules promulgated by the Director for those individuals identified in subparagraph a of paragraph 32 of Section 2-101 of this title. Persons registered by the Director pursuant to this subsection may possess controlled dangerous substances to the extent authorized by their registration and in conformity with the other provisions of this article.

E. The following persons shall not be required to register and may lawfully possess controlled dangerous substances under the provisions of Section 2-101 et seq. of this title:

1. An agent, or an employee thereof, of any registered manufacturer, distributor, dispenser or user for scientific purposes of any controlled dangerous substance, if such agent is acting in the usual course of such agent's or employee's business or employment;

2. Any person lawfully acting under the direction of a person authorized to administer controlled dangerous substances under Section 2-312 of this title;

3. A common or contract carrier or warehouser, or an employee thereof, whose possession of any controlled dangerous substance is in the usual course of such carrier's or warehouser's business or employment;

4. An ultimate user or a person in possession of any controlled dangerous substance pursuant to a lawful order of a practitioner;

5. An individual pharmacist acting in the usual course of such pharmacist's employment with a pharmacy registered pursuant to the provisions of Section 2-101 et seq. of this title;

6. A nursing home licensed by this state;

7. Any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substance Abuse Services whose possession of any dangerous drug, as defined in Section 353.1 of Title 59 of the Oklahoma Statutes, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence; and

8. Registered nurses and licensed practical nurses.

F. The Director may, by rule, waive the requirement for registration or fee for registration of certain manufacturers, distributors, dispensers, prescribers, administrators, or users for scientific purposes if the Director finds it consistent with the public health and safety.

G. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, dispenses, prescribes, administers, or uses for scientific purposes controlled dangerous substances.

H. The Director is authorized to inspect the establishment of a registrant or applicant for registration in accordance with rules promulgated by the Director.

I. No person engaged in a profession or occupation for which a license to engage in such activity is provided by law shall be registered under this act unless such person holds a valid license of such person's profession or occupation.

J. Registrations shall be issued on the first day of November of each year. Registrations may be issued at other times, however, upon certification of the professional licensing board.

K. The licensing boards of all professions and occupations to which the use of controlled dangerous substances is incidental shall furnish a current list to the Director, not later than the first day of October of each year, of the persons holding valid licenses. All such persons except persons exempt from registration requirements under subsection E of this section shall be subject to the registration requirements of Section 2-101 et seq. of this title.

L. The licensing board of any professional defined as a mid-level practitioner shall notify and furnish to the Director, not later than the first day of October of each year that such professional holds a valid license, a current listing of individuals licensed and registered with their respective boards to prescribe, order, select, obtain and administer controlled dangerous substances. The licensing board shall immediately notify the Director of any action subsequently taken against any such individual.

M. Beginning November 1, 2010, each registrant that prescribes, administers or dispenses methadone shall be required to check the prescription profile of the patient on the central repository of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

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Rhode Island
ADC 46-1-13:45.0

West's Rhode Island Administrative Code (2013)
Title 46. Mental Health Retardation & Hospitals Department
Division 1. General
Rule 13. Rules and Regulations for the Licensing Behavioral Healthcare Organizations
Part VI. Services and Programs

46-1-13:45.0. Opioid Treatment Programs

This section applies to all public or private opioid treatment and maintenance programs. These programs must also comply with all applicable sections of the General Regulations and with 42 CFR Part 8 (DHHS/SAMHSA, DEA Regulations), and Rhode Island General Laws section 21-28-1 et seq. (Uniform Controlled Substance Act), Rhode Island General Laws section 21-28.2-1 et seq. (Drug Abuse Control Act), Rhode Island General Laws section 21-28.3-1 et seq. (Drug Abuse Reporting System), Rhode Island General Laws section 5-19-1 et seq. (Pharmacy Statute), and Rhode Island State Methadone Authority. Programs shall reference the State Methadone Treatment Guidelines/ TIP1 (Treatment Improvement Protocol Series/CSAT) and Buprenorphine Treatment Guidelines.

45.1 Opioid treatment programs (OTPs) shall use only opioid replacement treatment medications that are approved by the Food and Drug Administration, and the Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction.

45.2 All federal laws and regulations that pertain to the handling of any opioid replacement medication shall apply in these regulations.

45.3 All opioid treatment programs shall be open seven (7) days per week - or have the capacity to arrange for dispensing medication(s) to clients on Sundays or Holidays should the program be closed or have reduced hours. Any such closure or reduction in clinic hours would require pre-approval by the State Opioid Treatment Authority. A closure request or a request to reduce clinic hours shall be made in writing to the State Opioid Treatment Authority.

45.4 Each OTP shall have written policies and procedures describing admission requirements that shall include:

45.4.1 Documentation of a one (1) year history of opioid addiction for persons eighteen (18) years of age and over. Exceptions may be granted by the program physician for applicants who have been released from prison or from chronic care facilities, are HIV positive, are pregnant, and/or have previously been treated for opioid addiction.

45.4.2 For individuals under eighteen (18) years of age, the program must verify a minimum of two (2) prior short term detoxifications or drug free treatment episodes in a twelve (12) month period and must obtain parental or legal guardian's consent.

45.4.3 No person under sixteen (16) years of age may be admitted to an opioid treatment program unless the program has received prior written approval of the admission from the State Methadone Authority.

45.4.4 All women of childbearing potential shall be tested for pregnancy:

A. Before admission to an OTP

B. Before any detoxification or medially supervised withdrawal is initiated.

C. Medical staff shall document test results in the woman's treatment record.

45.4.5 A physical health assessment, including a medical history and physical examination, shall be completed within the first twenty-four (24) hours of a person's admission to the program.

A. This assessment shall include: an assessment of the possibility of: infectious diseases, including HIV, TB, Viral Hepatitis and sexually transmitted diseases; pulmonary, liver, and cardiac abnormalities; dermatological and neurological consequences of addiction; and possible concurrent surgical problems.

B. The assessment shall include laboratory tests, the results of which must be returned no later than fourteen (14) days after admission. The licensee shall ensure that such laboratory tests are completed by licensed facilities which shall comply with all applicable federal and state laboratory licensure and certification requirements. The laboratory tests shall include the following:

1. Tests to determine liver function;

2. Complete blood count and lipid panel; and

3. Screening test for syphilis.

C. If the Medical Director determines that laboratory tests are not clinically indicated at the time of admission, this justification shall be documented in the patient record.

D. Programs are required to check Department of Health's Prescription Monitoring Program for each new admission.

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45.16 OTP's shall develop policies and procedures that ensure compliance with federal and state regulations before take-home medication privileges are granted. In addition, prior to advancement to a new take-home phase, programs are required to check the Department of Health's Prescription Monitoring Program. The policies and procedures shall, at a minimum, include the following:

45.16.1 The following treatment schedule shall be implemented:

A. At least a two (2) month probationary period with daily doses of medication ingested under appropriate supervision. During this time the individual must satisfactorily meet all requirements of the program. In the event that a program is closed on a Sunday or Holiday during a patient's two (2) month probationary period, if the patient meets the criteria established by the program and approved by the State Opioid Treatment Authority, the patient may receive one (1) take-home during this period. Written closure requests to the State Opioid Treatment Authority (as required in section 45.3 of these regulations) shall also include written detailed plans containing: patient inclusion/exclusion criteria, patient notification, diversion control, a documented history of take-home safety, and the submission of exception requests. Documentation of appropriateness shall be noted in the patient record.

B. During the first ninety (90) days of take-home privileges, the take-home supply shall be limited to a single dose each week. The individual shall ingest all other doses under appropriate supervision.

C. During the second ninety (90) days, the take-home supply shall be limited to two (2) doses per week.

D. During the third ninety (90) days, the take-home supply shall be limited to three (3) doses per week with no more than two (2) consecutive days supply of medication.

E. After one (1) year the individual may be permitted to reduce attendance to two (2) visits weekly and may be given no more than three (3) consecutive days supply of medication.

F. After two (2) years, the individual may be permitted to reduce program attendance to once weekly and may receive no more than six (6) days take-home supply of medication.

G. After three (3) years, the individual may be permitted to reduce program attendance to two (2) visits monthly and receive no more than a fourteen (14) day supply of medication.

H. After four (4) years, the individual may be permitted to reduce program attendance to once monthly. OTPs are required to inform the State Opioid Treatment Authority of all individuals advanced to this take-home phase.

45.16.2 In an emergency situation or severe illness, individuals may be given up to ten (10) days supply of medication based on the judgment of the OTP physician.

45.16.3 Prior to the initiation of take-home privileges, the following shall be confirmed and documented:

A. The individual shall receive instructions regarding safety. Such instructions shall include but not be limited to, child safety measures and the storage of medications.

B. The individual shall obtain an agency approved locked box for storage of take-home medication.

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Tennessee
§ 53-10-310
ADC 1140-11-.06
ADC 1200-34-01-.07

West's Tennessee Code Annotated (2013)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-310. Electronic access to controlled substance database; penalty

<Text of section effective until July 1, 2016>

(a) Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a prescriber or dispenser provides healthcare services to a human patient potentially receiving a controlled substance.

(b) This section shall not apply to any dispensers that are not required to report pursuant to § 53-10-304(d) or § 53-10-305(g).

(c) A violation of subsection (a) is punishable by a civil penalty not to exceed one hundred dollars ($100) per day assessed against the person or entity operating the practice site; provided, however, that the penalty shall only be imposed when there is a continued pattern or practice of not providing electronic access to the database.

(d) Any prescriber, dispenser, individual or entity who is authorized to access the database by this part shall not be subject to a suit for civil damages or held civilly liable for the failure to register in, report to, or check the database, or for actions taken after reasonable reliance on information in the database, or accessing the database to determine whether or not the prescriber or dispenser's professional medical credentials are being inappropriately used or for reporting the same to the appropriate authorities, except as otherwise provided in this part.

(e)(1) All prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one of the controlled substances identified in subdivision (e)(3) to a human patient at the beginning of a new episode of treatment and shall check the controlled substance database for that human patient at least annually when that prescribed controlled substance remains part of the treatment.

(2) Before dispensing, a dispenser shall have the professional responsibility to check the database or have a healthcare practitioner extender check the database if the dispenser is

aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of § 53-11-402.

(3) The controlled substances which trigger a check of the controlled substance database pursuant to subdivision (e)(1) include, but are not limited to, all opioids and benzodiazepines. By rule, the committee may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee as demonstrating a potential for abuse.

(4) The board shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, that establish standards and procedures to be followed by a dispenser regarding the review of patient information available through the database.

(5) Prescribers are not required to check the controlled substance database before prescribing or dispensing one of the controlled substances identified in subdivision (e)(3) or added to that list by the committee if one (1) or more of the following conditions is met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) The committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;

(C) The controlled substance is prescribed or dispensed to a patient as a non-refillable prescription as part of treatment for a surgical procedure that occurred in a licensed healthcare facility;

(D) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill.

(E) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68 or a mental health hospital licensed under title 33.

(f) Each appropriate licensure board shall promulgate rules pursuant to the Uniform Administrative Procedures Act, to establish procedures, notice requirements, and penalties for prescribers and dispensers who fail to register in, report to, or check the controlled substance database as required.

(g) Notwithstanding any other provision of this part to the contrary, a prescriber, dispenser or healthcare practitioner extender shall not be in violation of this part during any time period in which the controlled substance database is suspended or not operational or the Internet is not

operational or available as defined by rules promulgated by the commissioner after consultation with the committee.

Tennessee Rules and Regulations (2013)
1140. Board of Pharmacy
Chapter 1140-11. Controlled Substance Monitoring Database

1140-11-.06 PRESCRIBER AND DISPENSER RESPONSIBILITIES (EFFECTIVE APRIL 1, 2013).

(1) All prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted by T.C.A. Title 53, Chapter 10, part 3, shall check the database prior to prescribing one of the controlled substances identified below in paragraph (3) to a human patient at the beginning of a new episode of treatment and shall check the database for the human patient at least annually when that prescribed controlled substance remains part of treatment.

(2) Before dispensing, a dispenser shall have the professional responsibility to check the database or have a healthcare practitioner extender check the database, if the dispenser is aware or reasonably certain, that a person is attempting to obtain a Schedule II-V controlled substance, identified by the Committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of T.C.A. § 53-11-402.

(3) The controlled substances which trigger a check of the database pursuant to paragraph (1) above include, but are not limited to, all opioids and benzodiazepines.

(4) Prescribers are not required to check the database before prescribing or dispensing one of the controlled substances identified in paragraph (3) above or added to that list by the Committee if one (1) or more of the following conditions is met:

(a) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(b) The Committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;

(c) The controlled substance is prescribed or dispensed to a patient as a non-refillable prescription as part of treatment for a surgical procedure that occurred in a licensed healthcare facility;

(d) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill.

Tennessee Rules and Regulations (2013)
1200. Department of Health, Department of Environment and Conservation, and Department of Finance and Administration
1200-34. Division of Pain Management Clinics
Chapter 1200-34-01. Pain Management Clinics

1200-34-01-.07 MEDICAL DIRECTOR RESPONSIBILITIES.

(1) Clinic Operation and Personnel.

(a) The medical director of a pain management clinic shall:

1. oversee all of the pain management services provided at the clinic;

2. be on-site at the clinic at least twenty percent (20%) of the clinic's weekly total number of operating hours;

3. ensure that each supervising physician for each of the health care providers working at the clinic complies with the supervision requirements contained in Tenn. Comp. Rules and Regulations Chapter 0880-03 and Chapter 0880-06, or Rule 1050-02-. 15, as applicable. Should the medical director of the clinic serve as a health care provider's supervising physician, the medical director must ensure that he or she complies with Chapter 0880-03 and Chapter 0880-06. or Rule 1050-02-. 15, as applicable;

4. ensure that all health care providers employed by or working at the pain management clinic comply with applicable state and federal laws and rules relative to the prescribing of controlled substances in the pain management clinic;

5. ensure the establishment of protocols for the health care providers employed by or working at the pain management clinic as provided in Tenn. Comp. Rules and Regulations Chapter 0880-03 and Chapter 0880-06 and ensure that providers comply with such protocols, as well as any other established policies and procedures;

6. ensure that, in the event that the medical director for the clinic is unable to fulfill his or her duties on a temporary basis because of illness, vacation, or unavailability, there is an alternate or substitute medical director meeting the same qualifications as a medical director under 1200-34-01-.09;

7. establish quality assurance policies and procedures, which, at a minimum, include, but are not limited to:

(i) documentation of the background, training, licensure, and certifications for all pain management clinic staff providing patient care;

(ii) a written drug screening policy and compliance plan for patients to include random urine drug screening as clinically indicated, but at a minimum, upon each new admission and once every six (6) months thereafter;

(iii) use of substance abuse risk assessment tools upon new patient admission and periodic review or re-assessment;

(iv) evaluating and monitoring the quality and appropriateness of patient care, the methods of improving patient care as well as identifying and correcting deficiencies, and the opportunities to improve the clinic's performance and quality of care;

(v) medication counts for any controlled substances prescribed by the clinic to the clinic's patients;

(vi) use of patient agreements and periodic review of such agreements;

(vii) health care provider access to and review of patient information contained in the controlled substance monitoring database in accordance with T.C.A. §§ 53-10-301 - 53-10-309, as clinically indicated, but at a minimum upon each new admission and once every six (6) months thereafter;

(viii) documentation of requests for records from other health care providers;

8. establish an infection control program to provide a sanitary environment for the prevention, control, and investigation of infections and communicable diseases, including, but not limited to:

(i) written infection control policies and procedures;

(ii) techniques and systems for identifying, reporting, investigating and controlling infections at the clinic;

(iii) written policies and procedures relative to the use of aseptic techniques;

(iv) training for clinic staff providing direct patient care relative to infection control and aseptic techniques; and

(v) a log of incidents related to infectious and communicable diseases and the corrective action taken;

9. establish written policies and procedures for health and safety requirements at the clinic;

10. ensure compliance with the patient safety standards established by the licensing boards for each health care provider;

11. establish written policies and procedures to assure patient access to their medical records and continuity of care should the pain management clinic close.

(2) Records, Reporting Requirements, and Patient Billing Procedures.

(a) The medical director shall ensure that each health care provider employed by or working at a certified pain management clinic shall maintain complete and accurate medical records of patient consultation, examination, diagnosis, and treatment, which shall include, but not be limited to the following:

1. patient medical history;

2. physical examination;

3. diagnostic, therapeutic, and laboratory results;

4. evaluations and consultations;

5. treatment objectives;

6. documentation of informed consent and discussion of risks and benefits of treatment provided;

7. treatments and treatment options;

8. medications prescribed (including date, type, dosage and quantity prescribed);

9. instructions and agreements;

10. periodic reviews;

11. reason for prescribing or dispensing more than a seventy-two (72) hour dose of controlled substances for the treatment of chronic nonmalignant pain;

12. a notation indicating whether the controlled substance monitoring database had been accessed for a particular patient;

13. copies of records, reports, or other documentation obtained from other health care providers;

14. results of urine drug screens to be performed as clinically indicated, but at a minimum upon each new admission and once every six (6) months thereafter.

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Vermont
18 § 4289
18 § 4290

West's Vermont Statutes Annotated (2013)
Title Eighteen. Health
Part 5. Foods and Drugs
Chapter 84A. Vermont Prescription Monitoring System

§ 4289. Standards and guidelines for health care providers and dispensers.

(a) Each professional licensing authority for health care providers shall develop evidence-based standards to guide health care providers in the appropriate prescription of Schedules II, III, and IV controlled substances for treatment of chronic pain and for other medical conditions to be determined by the licensing authority. The standards developed by the licensing authorities shall be consistent with rules adopted by the Department of Health.

(b)(1) Each health care provider who prescribes any Schedule II, III, or IV controlled substances shall register with the VPMS by November 15, 2013.

(2) If the VPMS shows that a patient has filled a prescription for a controlled substance written by a health care provider who is not a registered user of VPMS, the Commissioner of Health shall notify the applicable licensing authority and the provider by mail of the provider's registration requirement pursuant to subdivision (1) of this subsection.

(3) The Commissioner of Health shall develop additional procedures to ensure that all health care providers who prescribe controlled substances are registered in compliance with subdivision (1) of this subsection.

(c) Each dispenser who dispenses any Schedule II, III, or IV controlled substances shall register with the VPMS.

<Text of subsection (d) effective November 15, 2013>

(d) Health care providers shall query the VPMS with respect to an individual patient in the following circumstances:

(1) at least annually for patients who are receiving ongoing treatment with an opioid Schedule II, III, or IV controlled substance;

(2) when starting a patient on a Schedule II, III, or IV controlled substance for nonpalliative long-term pain therapy of 90 days or more;

(3) the first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat chronic pain; and

(4) prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance pursuant to section 4290 of this title.

(e) The Commissioner of Health shall, after consultation with the Unified Pain Management System Advisory Council, adopt rules necessary to effect the purposes of this section. The Commissioner and the Council shall consider additional circumstances under which health care providers should be required to query the VPMS, including whether health care providers should be required to query the VPMS when a patient requests a renewal of a prescription for an opioid Schedule II, III, or IV controlled substance written to treat acute pain.

(f) Each professional licensing authority for dispensers shall adopt standards, consistent with rules adopted by the Department of Health under this section, regarding the frequency and circumstances under which its respective licensees shall:

(1) query the VPMS; and

(2) report to the VPMS, which shall be no less than once every seven days.

(g) Each professional licensing authority for health care providers and dispensers shall consider the statutory requirements, rules, and standards adopted pursuant to this section in disciplinary proceedings when determining whether a licensee has complied with the applicable standard of care.

West's Vermont Statutes Annotated (2013)
Title Eighteen. Health
Part 5. Foods and Drugs
Chapter 84A. Vermont Prescription Monitoring System

§ 4290. Replacement prescriptions and medications

<Text of section effective October 1, 2013>

(a) As used in this section, "replacement prescription" means an unscheduled prescription request in the event that the document on which a patient's prescription was written or the patient's prescribed medication is reported to the prescriber as having been lost or stolen.

(b) When a patient or a patient's parent or guardian requests a replacement prescription for a Schedule II, III, or IV controlled substance, the patient's health care provider shall query the VPMS prior to writing the replacement prescription to determine whether the patient may be receiving more than a therapeutic dosage of the controlled substance.

(c) When a health care provider writes a replacement prescription pursuant to this section, the provider shall clearly indicate as much by writing the word "REPLACEMENT" on the face of the prescription. The health care provider shall document the writing of the replacement prescription in the patient's medical record.

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West Virginia
§ 60A-9-5a

West's Annotated Code of West Virginia (2013)
Chapter 60A. Uniform Controlled Substances Act
Article 9. Controlled Substances Monitoring

§ 60A-9-5a. Practitioner requirements to conduct annual search of the database; required rulemaking

(a) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient and at least annually thereafter should the prescriber or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and, who are licensed by the Board of Medicine as set forth in article three, chapter thirty of this code, the Board of Registered Professional Nurses as set forth in article seven, chapter thirty of this code, the Board of Dental Examiners as set forth in article four, chapter thirty of this code and the Board of Osteopathy as set forth in article fourteen, chapter thirty of this code shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program database for the patient shall be documented in the patient's medical record. A pain-relieving controlled substance shall be defined as set forth in section one, article three-a, chapter thirty of this code.

(b) The various boards mentioned in subsection (a) above shall promulgate both emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.

West Virginia Code of State Rules (2013)
Title 64. Bureau for Public Health -- Department of Health and Human Resources
Legislative Rule (Ser. 90)
Series 90. Regulation of Opioid Treatment Programs

§ 64-90-40. Toxicology Screens.[1]

40.1. Urine drug screening and other adequately tested toxicological procedures shall be used as an aid in monitoring and evaluating a patient's progress in treatment.

[1] ADC § 64-90-40 will be repealed effective August 12, 2013, but will be reenacted in an as yet unknown location.

40.2. Drug screening procedures shall be individualized and shall include:
40.2.a. At least eight random drug screens per year for each person receiving methadone maintenance services. The program shall test new patients upon admission and at approximately fourteen days of treatment, then monthly through the remainder of the first year;

40.2.b. More frequent collection and analysis of samples during medically-supervised or other types of withdrawal;

40.2.c. Collection of observed specimens on an unannounced basis when using urine as a screening mechanism if the staff believes that observation is necessary based on patient behavior or need. Collection shall be done in a manner that assures respect for the patient and minimizes the chance of adulterating or substituting another individual's urine; and

40.2.d. Toxicological analysis for drugs of abuse, including, but not limited to:

40.2.d.1. Opiates including oxycodone at common levels of dosing;

40.2.d.2. Methadone or any other medication used by the program as an intervention for that patient;

40.2.d.3. Benzodiazepines (including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam);

40.2.d.4. Cocaine;

40.2.d.5. Methamphetamine/ amphetamines; and

40.2.d.6. Other drugs as determined by community standards, regional variation or clinical indication (e.g., carisoprodol, barbiturates).

40.3. Marijuana shall be included in the testing process on a random basis at least three times per year. Positive marijuana screens shall be carefully clinically evaluated and shall in most cases result in reduction in take-home privileges unless other action is considered appropriate by the medical director or program physician and primary counselor.

40.4. Collection and testing shall be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection.

40.5. Any refusal to participate in a random drug test shall be considered a positive test.

40.6. When necessary and appropriate, breathalyzers or other testing equipment may be used to screen for possible alcohol abuse. No individual shall receive a daily dose who has a breathalyzer result which is equal to or greater than .02. The individual may return to the clinic for dosing during the same day if the breathalyzer results reach acceptable limits.

40.7. A positive test is a test that results in the presence of any drug or substance listed in Subdivision 40.2.d of this rule, or any other drug or substance prohibited by the opioid treatment program; provided that the presence of medication which is part of the patient's treatment plan shall not be considered a positive test.

40.8. A positive drug test result after the first six months in an opioid treatment program shall result in the following:

40.8.a. Upon the first positive drug test result, the opioid treatment program shall:

40.8.a.1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program; and

40.8.a.2. Immediately revoke the take-home privilege for a minimum of thirty days;
40.8.b. Upon a second positive drug test result within six months of a pervious positive drug test result, the opioid treatment program shall:

40.8.b.1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

40.8.b.2. Immediately revoke the take-home privilege for a minimum of sixty days; and

40.8.b.3. Provide mandatory documented treatment team meetings with the patient;

40.8.c. Upon a third positive drug test result within a period of six months the opioid treatment program shall:

40.8.c.1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is licensed, certified, or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

40.8.c.2. Immediately revoke the take-home privilege for a minimum of one hundred twenty days; and

40.8.c.3. Provide mandatory and documented treatment team meetings with the patient which will include, at a minimum: the need for continuing treatment; a discussion of other treatment alternatives; and the execution of a contract with the patient advising the patient of discharge for continued positive drug tests; and

40.8.d. Upon a fourth positive drug test within a six month period, the patient shall be immediately discharged from the opioid treatment program, or, at the option of the patient, shall

immediately be provided the opportunity to participate in a 21-day detoxification plan, followed by immediate discharge from the opioid treatment program.

40.9. Programs shall document both the results of toxicological tests and the follow-up therapeutic action taken in the patient record.

40.10. Treatment programs shall work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing. Testing shall be done only by laboratories with appropriate federal certification.
40.11. The program shall ensure that physicians demonstrate competence in interpretation of "false negative" and "false positive" laboratory results as they relate to physiological issues, differences among laboratories, and factors that impact absorption, metabolism and elimination of opiates.

40.12. The program physician shall thoroughly evaluate a positive toxicological screen for any potentially licit substance such as benzodiazepines, carisoprodol, barbiturates and amphetamines. The program shall verify with appropriate releases of information that:

40.12.a. The patient has been prescribed these medications by a licensed physician for a legitimate medical purpose; and

40.12.b. The prescribing physician is aware that the patient is enrolled in an opioid treatment program.

40.13. If the patient refuses the release of information to contact his or her physician but can produce prescriptions and/or other evidence of legitimate prescription (such as current medication bottles, fully labeled), the team shall consider the patient's individual situation and the possibility that he or she may be dismissed from the care of his or her physician if the physician discovers that the patient is in medication-assisted treatment. The program physician shall make the ultimate decision as to the patient's continuing care in the clinic and the circumstances of that care.

40.14. Absence of methadone or other medications prescribed by the program for the patient shall be considered evidence of possible medication diversion and evaluated by the physician and interdisciplinary team accordingly.

40.15. As appropriate and necessary, the state authority shall develop guidelines for frequency of toxicological screening for alternative treatment modalities such as buprenorphine.

40.16. The program shall comply with policies and procedures developed by the designated state oversight agency and the West Virginia Board of Pharmacy to allow access to the Prescription Drug Registry maintained by the West Virginia Board of Pharmacy:

40.16.a. Before the administration of methadone or other treatment in an opioid treatment program;

40.16.b. After any positive drug test; and

40.16.c. At each ninety-day treatment review.

40.17. Each Prescription Drug Registry access shall confirm that the patient is not seeking prescription medication from multiple sources.

40.18. Nothing contained in this rule shall preclude any opioid treatment program from administering any additional drug tests it determines necessary.

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