



OVERVIEW OF STATE PAIN MANAGEMENT AND PRESCRIBING POLICIES

Research current through January 2016.

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Purpose and Structure of Overview

This overview is divided into two main sections. The first section contains relevant information regarding state statutes, regulations, and guidelines related to the treatment of chronic pain and prescribing practices. Topics include: practitioner education requirements, pain treatment requirements or guidelines, referral of patients, and limitations on the prescribing of Schedule II and Schedule III prescription drugs.

The second section includes information related to the regulation of pain clinics and facilities with a focus on the treatment of pain. Topics include: registration of pain clinics and treatment facilities, restrictions on who may own a pain clinic or treatment facility, and requirement to have and responsibilities of a medical director.

Subsections include a summary of the information within each subsection and may include state specific provisions. At the end of each subsection is a national map or maps reflecting which states have the particular requirement or recommendation.

PRESCRIBING PRACTICES AND TREATMENT OF CHRONIC PAIN

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PRACTITIONER EDUCATION REQUIREMENTS

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One of the main areas that stakeholders have focused on in order to combat the growing tide of prescription drug abuse is in prescriber education, namely in the fields of prescribing controlled substances, pain management, and identifying possible substance use disorders. In the 2015 National Drug Strategy, the Obama Administration stressed that “retraining the prescribing workforce is critical” to raising awareness about the dangers of nonmedical opioid use and has made prescriber education a priority.¹ Additionally, in her 2015 Opioid Initiative, the Secretary of Health and Human Services, Sylvia M. Burwell, included prescriber education as one of her three priority areas to help tackle the opioid crisis.²

Twenty-three states and D.C. have requirements, either in statute, regulation, or board guidelines, for practitioners to obtain a certain number of continuing education hours in one or more of the following: prescribing controlled substances, pain management, and identifying substance use disorders, among others. Some states leave discretion to the state board whether to make such continuing education mandatory, while other states mandate the training by statute. The requirements for each state are summarized below.

Alabama - The State Board of Medical Examiners may, within its discretion and for cause, order and direct that a physician holding a controlled substance registration certificate complete a course or courses of continuing medical education on subjects related to the prescribing, dispensing, administering, or furnishing of controlled substances, which course or courses of instruction may not exceed 25 credit hours of instruction within the calendar year in which the order is entered, and failure to comply shall constitute grounds for suspension of the controlled registration certificate.

Arizona - Dentists are required to obtain 42 hours of continuing education in any of a number of specific course areas, including pain management, and are also required to earn 3 hours of continuing education in chemical dependency (which may include tobacco cessation).

California - All physicians shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients, which is a one-time requirement of 12 credit hours; physicians and optometrists are encouraged to take a course in pharmacology and pharmaceuticals; optometrists who are certified to use therapeutic pharmaceutical agents must obtain 35 hours of continuing education in the diagnosis, treatment, and management of ocular disease in a combination of prescribed areas, including pain management.

Connecticut – Physicians and dentists must obtain at least one contact hour in one of a specified number of areas, which includes prescribing controlled substances and pain management, not less than every two years.

D.C. - Mayor may establish by rule continuing education requirements, provided that the Mayor shall require that any continuing education requirements for the practice of medicine include instruction on pharmacology which shall: 1) be evidence-based; 2)

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provide physicians with information regarding the cost-effectiveness of pharmacological treatments; and 3) not be financially supported by any pharmaceutical company or manufacturer.

Florida - Practitioners are required to have one hour of continuing education regarding the uses and abuses of controlled substances and one hour of continuing education on the federal and state laws related to the prescribing of controlled substances every two years. Practitioners must also take a two-hour prevention of medical errors course every two years which includes information on the five most misdiagnosed conditions, including the following: 1) inappropriate prescribing of opioids in patients in whom there have been misdiagnosis or failure to diagnose addiction, psychiatric conditions, and diversion; and 2) prescribing, dispensing, administering, or using non-FDA approved medications and devices. Finally, physicians prescribing or dispensing controlled substances for pain management who qualify by successful completion of 40 hours of in-person, live-participatory AMA Category I or Category IA CME courses in pain management must also document completion of 15 hours of in-person, live-participatory CME in pain management for every year the physician is practicing pain management.

Georgia - Physicians who do not hold a certification in pain management or palliative medicine, and whose opioid pain management patients comprise 50% or more of the patient population must demonstrate competence by biennially obtaining 20 hours of continuing medical education pertaining to pain management or palliative medicine.

Idaho - Optometrists who are certified to prescribe, administer, or dispense therapeutic pharmaceutical agents must attend 12 hours of continuing education every year in courses involving ocular pharmacology and/or advanced ocular disease.

Iowa - Applicants for reinstatement of a physician's license must provide documentation that they have completed training on chronic pain management within the previous five years. A licensee who regularly provides primary health care to patients in Iowa must complete at least two hours of category 1 credit for chronic pain management every five years. This requirement includes all emergency physicians, family physicians, general practice physicians, internists, neurologists, pain medicine specialists, psychiatrists, and any other physician who regularly provides primary health care to patients.

Kentucky - Physicians who will prescribe or dispense controlled substances to patients at a pain management facility shall successfully complete a minimum of ten hours of Category I continuing medical education in pain management during each registration period throughout the physician's employment agreement with the facility. Beginning on January 1, 2015, for each three-year cycle, a licensee who is authorized to prescribe or dispense controlled substances at any time within that cycle shall complete at least 4.5 hours of approved continuing education hours relating to the use of the PMP, pain management, addiction disorders, or a combination of two or more of those subjects. An optometrist who is authorized to prescribe controlled substances shall earn two credit hours that relate to the use of the PMP, pain management, or addiction disorders.

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Massachusetts - As a prerequisite to obtaining or renewing a medical license, applicants who prescribe controlled substances must complete appropriate training regarding pain management; identification of patients at high risk for substance abuse; counseling patients about the side effects, addictive nature, proper storage and disposal of prescription medications; and opioid education. Pain management training shall consist of at least three credits of Board-approved continuing professional development.

Michigan - Applicants for renewal of their professional medical license must complete an appropriate number of hours or courses in pain and symptom management. Applicants for license renewal as pharmacists must have at least one continuing education hour in pain management. Applicants for license renewal as dentists must have at least one continuing education hour in pain and symptom management which may include, but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interactions. Applicants for license renewal as optometrists are required to have at least one continuing education hour in pain and symptom management, which courses may include, but are not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interactions.

Mississippi - Every Mississippi licensee with an active DEA certificate must obtain five hours of continuing education related to the prescribing of medications with an emphasis on controlled substances. Physicians practicing in a pain management medical practice must have 15 hours of live lecture format, Category I CME in pain management for every year the physician is practicing pain management.

Nevada - The board may enact regulations requiring physicians registered to dispense controlled substances to complete at least one hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. The board may enact regulations requiring a dentist registered to dispense controlled substances to complete at least one hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. The board may enact regulations requiring an optometrist certified to administer and prescribe therapeutic pharmaceutical agents and who is registered to dispense controlled substances to complete at least one hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure.

New Mexico - All health care providers who hold a federal DEA registration and licensure to prescribe opioids shall be required to obtain five hours of pain management continuing education in courses that include: 1) an understanding of the pharmacology and risks of controlled substances; 2) a basic awareness of the problems of abuse, addiction, and diversion; 3) awareness of state and federal regulations for the prescription of controlled substances; and 4) management of the treatment of pain. Practitioners who certify patients for the use of medical marijuana are encouraged to obtain at least two continuing medical education credit hours annually related to the medical use of cannabis. Dentists who hold a federal DEA registration to prescribe controlled substances shall complete

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three continuing dental education hours in pain management in courses that include: 1) an understanding of the pharmacology and risks of controlled substances; 2) a basic awareness of the problems of abuse, addiction, and diversion; 3) awareness of state and federal regulations for the prescription of controlled substances; and 4) management of the treatment of pain. Optometrists must obtain at least one hour of continuing education in pain management or related topic.

North Carolina – Boards shall require continuing education on the abuse of controlled substances as a condition of license renewal for health care providers who prescribe controlled substances, and shall require that at least one hour consists of a course designed specifically to address prescribing practices, which course shall include, but not be limited to, instruction on controlled substance prescribing practices and controlled substance prescribing for chronic pain management.

Ohio - Board shall approve one or more continuing education courses that assist doctors in diagnosing and treating chronic pain. Each physician owner of a pain management clinic and each physician providing care at a pain management clinic shall complete at least 20 hours of Category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. Board encourages practitioners who encounter patients with intractable pain to complete continuing education related to the treatment of chronic pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine.

Oregon - All medical board licensees must complete seven hours of pain management courses, including: 1) one-hour pain management course specific to Oregon; and 2) a minimum of six hours in the subjects of pain management and/or treatment of terminally ill and dying patients. Licensed health care professionals must complete a pain management education program in order to improve the care and treatment of individuals with painful conditions, which includes: 1) six hours of continuing education in pain management, end of life care, or both; and 2) the web-based training offered by the commission. For out of state health care professionals obtaining Oregon licensure or newly licensed professionals, the program must be completed within 24 months of their first license renewal. Dentists shall complete one hour of continuing education in pain management within 24 months of the first renewal of the dentist's license. There is a one-time requirement for pharmacists to complete seven hours of continuing education in pain management, including: 1) a one-hour pain management course specific to Oregon; and 2) a minimum of six hours in pain management.

Pennsylvania - Optometrists who are certified to prescribe and administer pharmaceutical agents must complete a minimum of 6 hours of continuing education in the prescription and administration of pharmaceutical agents for therapeutic purposes.

South Carolina - Physicians must complete two hours of continuing education related to approved procedures of prescribing and monitoring controlled substances.

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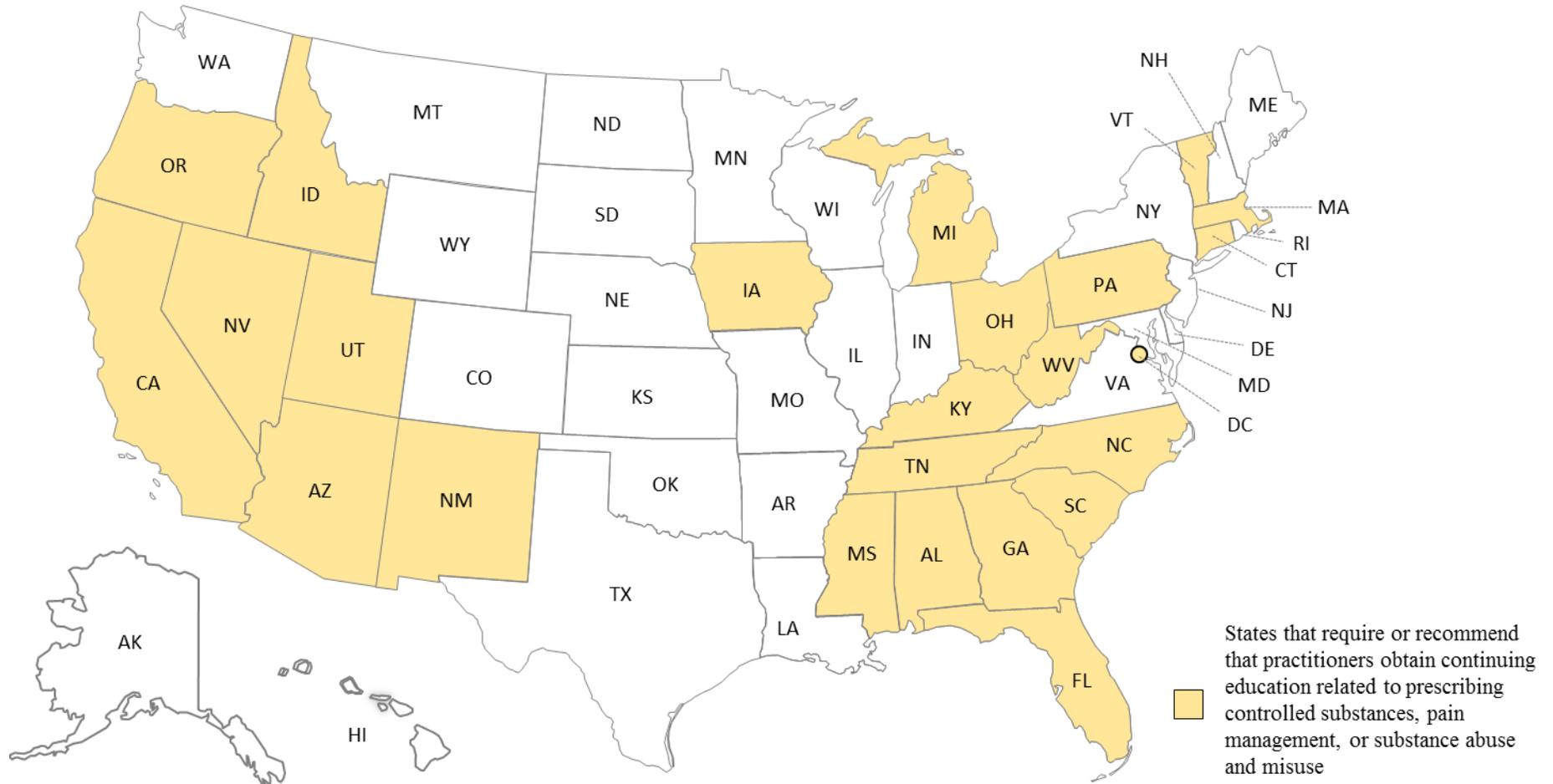
Tennessee - Optometrists who are therapeutically certified must complete at least two hours of continuing education in prescribing practices. All optometrists holding a current Tennessee license must complete two hours of continuing education related to controlled substance prescribing, which must include instruction in the Department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol and may include topics such as medicine addiction, risk management tools, and other topics approved by the Board. All prescribers who hold a current federal DEA license and who prescribe controlled substances shall be required to complete a minimum of two hours of continuing education related to controlled substances prescribing, which must include instruction in the department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol and may include other topics such as medicine addiction, risk management tools, and other topics. Each health care provider providing pain management services at a clinic shall complete ten (10) hours in continuing education courses during each health care provider's licensure renewal cycle which shall address one or more of the following topics related to pain management: 1) prescribing controlled substances; 2) drug screening; 3) pharmacological and non-pharmacological pain management; 4) completing a pain management focused history and physical examination and maintaining appropriate progress notes; 5) comorbidities with pain syndromes; and 6) substance abuse and misuse including diversion, prevention of same, and risk assessment for abuse.

Utah - Controlled substance prescribers shall complete at least 3.5 hours of continuing medical education hours in one or more controlled substance prescribing classes, except dentists who shall complete at least two such hours, that satisfy the following requirements: 1) must satisfy the division's requirements for the continuing education required for the renewal of the controlled substance prescriber's respective license type; 2) must be delivered by an accredited or approved continuing education provider; 3) must include postcourse knowledge assessment; and 4) must include content covering the following: a) the scope of the controlled substance abuse problem in Utah and the US; b) all elements of the FDA Blueprint for Prescriber Education; c) the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing; and d) office policies, procedures, and implementation. By rule, controlled substance prescribers must obtain four hours of continuing education.

Vermont - All licensees shall obtain at least one hour of CME in the topics of hospice, palliative care, or pain management. All licensees who prescribe controlled substances shall obtain at least one hour of CME related to the topic of safe and effective prescribing.

West Virginia - Unless a physician has completed and timely provided to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every physician as a prerequisite to license renewal shall complete a minimum of three hours of drug diversion training and best practice prescribing of controlled substances training.

States that Require or Recommend that Practitioners Obtain Continuing Education Related to Prescribing Controlled Substances, Pain Management, or Substance Abuse and Misuse



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TREATMENT PLAN AND INFORMED CONSENT AND AGREEMENT FOR TREATMENT OF CHRONIC PAIN

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Another area of emphasis for stakeholders is the need for health care practitioners to have a treatment agreement with their patients as well as an informed consent and agreement for treatment document. The Federation of State Medical Boards' Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain includes recommendations for both a treatment plan and an informed consent and agreement for treatment document.³ Other organizations, including the American Academy of Pain Medicine, the American Pain Society, and the Institute for Clinical Systems Improvement, also recommend that practitioners have a treatment plan and/or an informed consent and agreement for treatment document.^{4,5,6} Thirty-six states require or recommend that practitioners have a treatment agreement, while thirty-two require or recommend an informed consent and agreement for treatment document.

A treatment plan is typically a written document that sets out the goals of treatment, whether further diagnostic evaluations or other therapies are planned beyond treatment with opioid painkillers, and discussion of any non-opioid treatment modalities. The goals of treatment generally include improvement in pain and function; improvement in pain-associated symptoms, such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Treatment plans should be discussed with the patient and such discussions should include a discussion of the risks and benefits of treating pain with opioids.

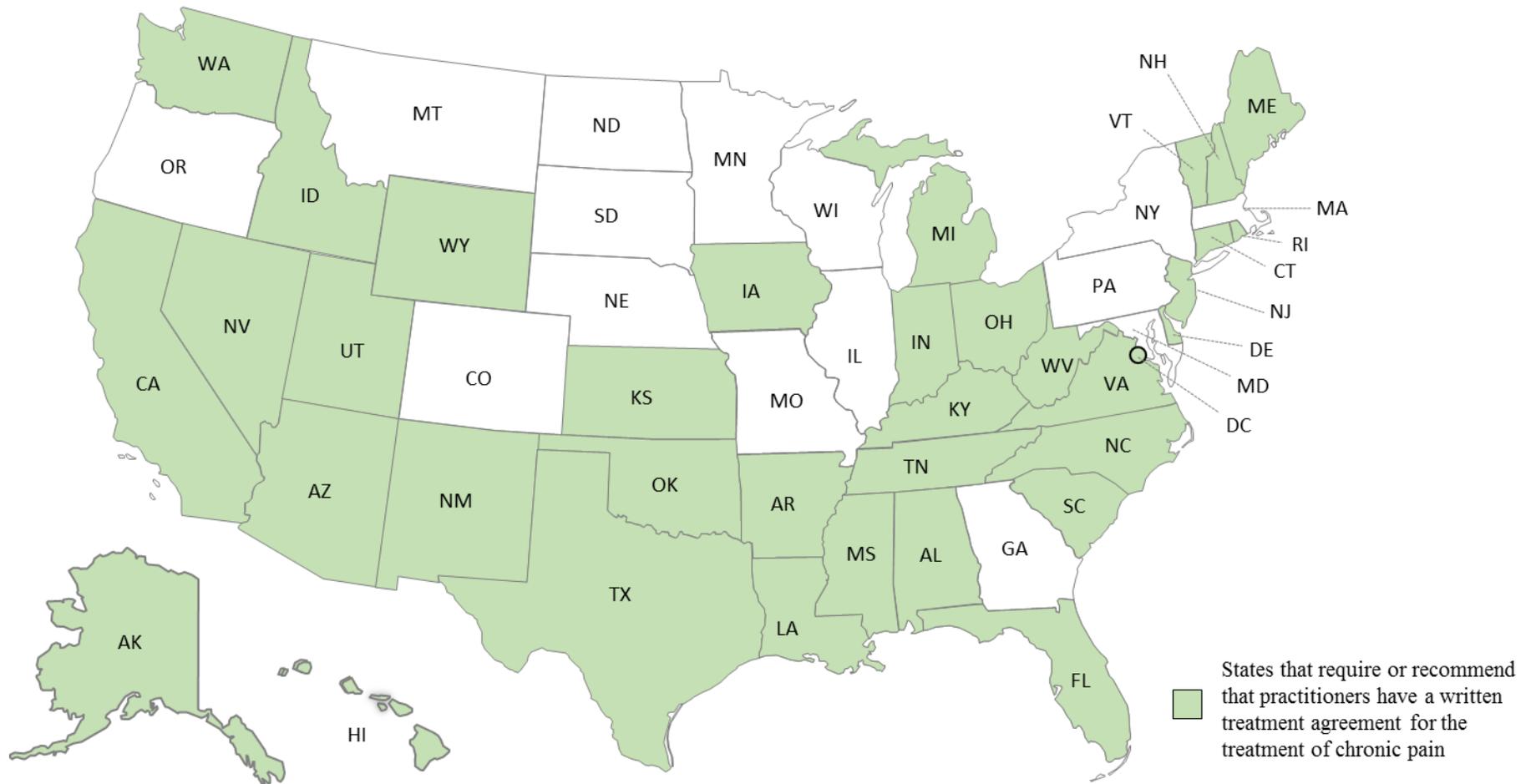
In conjunction with the treatment plan, an informed consent and agreement for treatment is typically signed by the practitioner and patient. Informed consent and agreements for treatment can be two separate documents or combined into one. The informed consent and agreement for treatment document or documents typically address the following:

- Potential risks and anticipated benefits of chronic opioid therapy
- Potential short and long-term effects of the medication
- Risk of opioid misuse, dependence, addiction, and overdose
- Limited evidence of the benefit of long-term opioid therapy
- Prescriber's policies and expectations, including the number and frequency of prescription refills, early refills, and replacement of lost or stolen medications
- Specific reasons for which drug therapy might be changed or discontinued, including resolution of underlying condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve patient's quality of life, deteriorating function, significant aberrant medication use, no discernable functional improvement
- Treatment goals for pain management, restoration of activities, and safety
- Patient's responsibility for using medications safely, including not using more than prescribed, not using an opioid in combination with alcohol or other potentially dangerous substances, storing medications in a secure location, and safely disposing of unused medications
- Patient's responsibility to obtain opioids from only one prescriber and to fill prescriptions at only one pharmacy

- Patient's agreement to submit to random drug screens and random pill counts
- Prescriber's responsibility to be available or have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

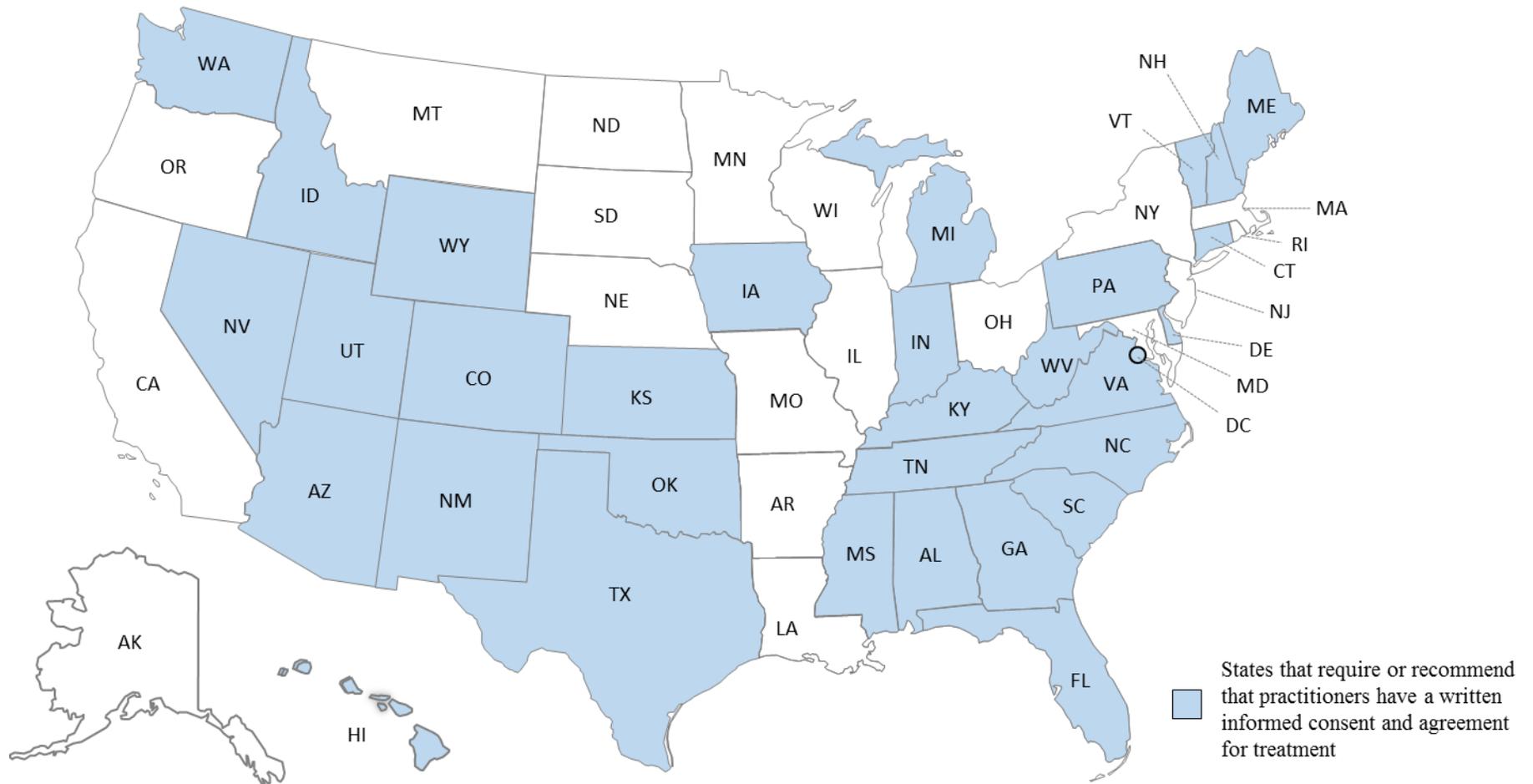
In some cases, states only require or recommend a signed treatment agreement if the practitioner believes the patient is at risk for or is abusing, misusing, or diverting controlled substances. While most states with statutes, regulations, or guidelines related to the treatment of chronic pain require that practitioners obtain informed consent from the patient before beginning treatment with opioids, only the states that require such consent to be in writing in combination with a treatment agreement are included in the maps on the following pages.

States that Require or Recommend that Practitioners Have a Written Treatment Plan for the Treatment of Chronic Pain



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States that Require or Recommend that Practitioners Have a Written Informed Consent and Agreement for Treatment



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PATIENT EXAMINATION AND SCREENING FOR SUBSTANCE USE DISORDERS

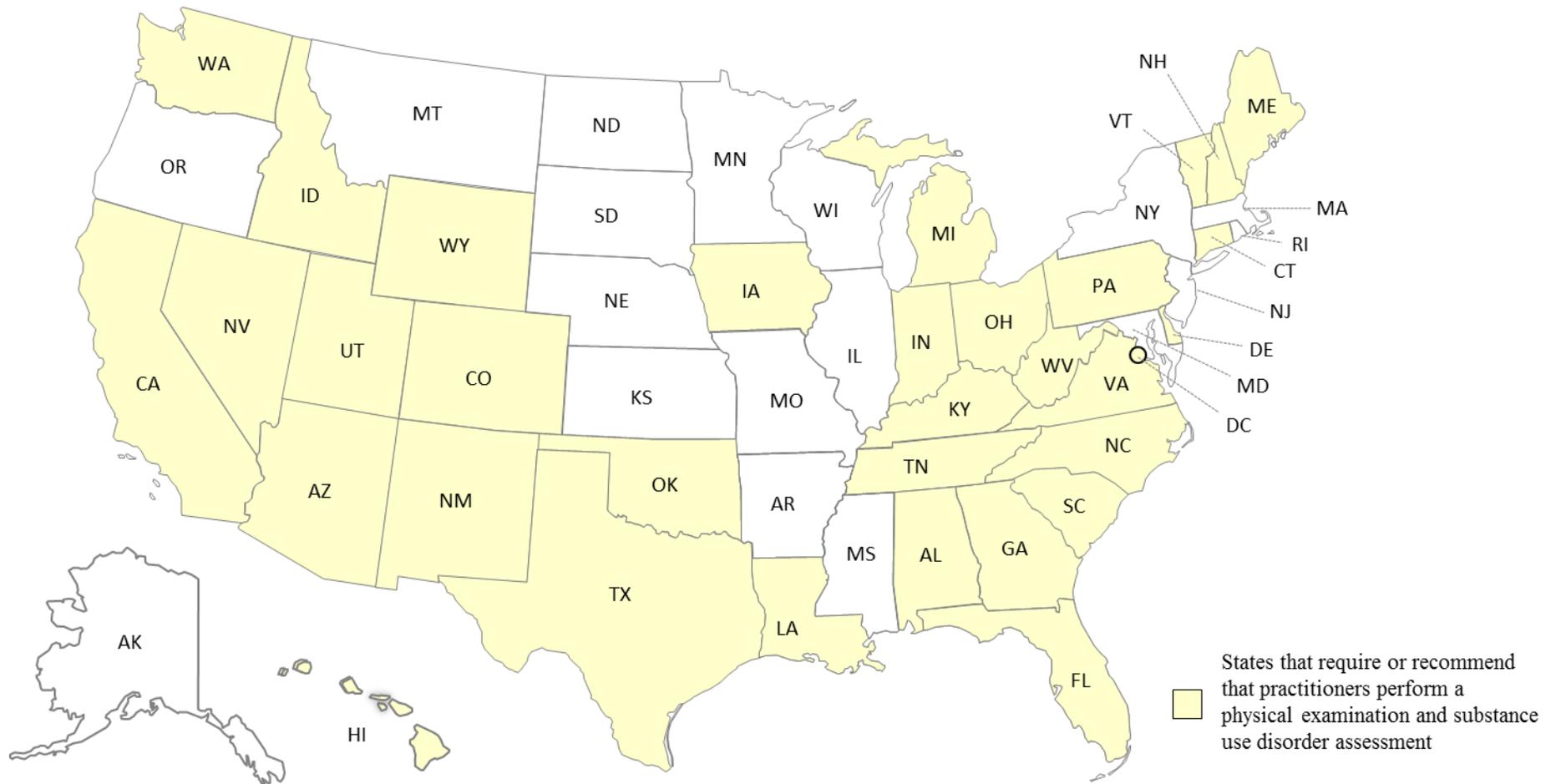
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As part of the initial evaluation of a patient prior to prescribing controlled substances, most states require that practitioners perform a physical examination of the patient in addition to taking a complete medical history. For pain patients, a medical history should typically include documentation in the medical record of the nature and intensity of the patient's pain, any current and past treatments, underlying or coexisting diseases and conditions, the effect of the pain on the patient's physical and psychological function, as well as the presence of one or more medical indications for the use of controlled substances.

Another aspect of the initial evaluation for a patient being treated for chronic pain is the screening for potential substance use disorders. This can include an assessment of the patient's family and personal history of alcohol or drug abuse and his or her relative risk for medication misuse and/or abuse as well as the use of screening instruments. Some states, Arizona, for example, recommend that practitioners consult with an addiction specialist and become knowledgeable about the treatment of addiction when treating patients with a history of substance use disorder, while other states provide that patients with an active substance use disorder should not be prescribed controlled substances until the patient is in an established treatment or recovery program or other alternatives are established, such as co-management of the patient with an addiction professional.

The map on the following page indicates only those states that require *both* a physical examination and an assessment or screening for potential substance use disorders of the patient prior to prescribing controlled substances.

States that Require or Recommend that Practitioners Perform a Physical Examination and Substance Use Disorder Assessment Prior to Prescribing Controlled Substances



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PATIENT REFERRAL TO OR CONSULTATION WITH A SPECIALIST

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Thirty-eight states require or recommend that practitioners consult with or refer their patients to a specialist in certain circumstances. The type of specialist varies depending on the circumstances prompting the consultation or referral, but includes pain, psychiatry, addiction, or mental health specialists as needed. Circumstances prompting such a consultation or referral include, but are not limited to, lack of improvement in level of pain and/or function, current or recent pattern of substance abuse, suspected abuse or misuse of controlled substances or illegal drugs, when contemplating a higher dose of an opioid, or when patient presents with a comorbid psychiatric disorder.

Alabama – Practitioner should be willing to refer the patient as necessary.

Alaska – Practitioner should make referrals to specialists within the profession when indicated.

Arizona – Physician should consult with or refer patient to a pain, psychiatry, addiction, or mental health specialist as needed.

California – 1) Physician must exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient’s treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist. 2) If misuse or abuse is suspected or confirmed, initiate a non-confrontational in-person meeting, present options for referral, opioid tapering or discontinuation or switching to non-opioid treatments. 3) Treating physicians should seek consultations with, or refer patients to, a pain, psychiatry, or addiction or mental health specialist as needed. 4) Board recommends that physicians proceed cautiously (yellow flag warning) once the morphine equivalent dose (MED) reaches 80 mg/day. Referral to an appropriate specialist should be considered when higher doses are contemplated. 5) If patient is dismissed for not honoring treatment agreements, consider referral to addiction resources, including a 12-step program.

Colorado – Opioid doses of greater than 120 mg morphine equivalent per day is a dosage that is dangerous for the average adult over which prescribers should use clinical judgment, put in place additional safeguards for the treatment plan (such as utilizing a treatment plan), consult a specialist, or refer the patient.

Connecticut – Physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients who are at risk of misuse or diversion.

Delaware – Practitioner shall refer the patient as necessary for additional evaluation and treatment.

DC – 1) Practitioner should refer the patient to another physician for additional evaluation and treatment as necessary to reach treatment objectives. 2) Practitioner should consult with or refer to an expert for management of the following types of patients: a)

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patients with a history of substance abuse; and b) patients with comorbid psychiatric disorders that require extra care, monitoring, and documentation.

Florida – 1) Physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Monitoring of patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist. 2) Patients with signs or symptoms of substance abuse shall immediately be referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period before receiving a consultant’s report, the physician shall clearly and completely document medical justification for continuing treatment with controlled substances. Upon receipt of consultant’s report, the physician shall incorporate the consultant’s recommendation for continuing, modifying, or discontinuing controlled substance therapy. Any changes to therapy shall be documented in the patient’s record.

Georgia – 1) If the physician determines that the patient is abusing the medication, s/he shall make an appropriate referral for treatment of substance abuse. 2) If a new medical condition is found to exist that is outside the scope of the physician’s training, s/he shall make a referral to the appropriate specialist.

Hawaii – 1) Legislature finds that patients may require referral to physicians with expertise in the treatment of pain and may require treatment by a team of professionals to address the associated physical, psychological, social, and vocational issues. 2) Referral of patients to substance abuse treatment programs will occur when use of controlled substances is determined to be due to underlying addiction and not pain. 3) Physicians should be willing to refer their patients as necessary for additional evaluations and therapies to achieve treatment objectives.

Idaho – 1) Prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow up monitoring of the patient’s response to treatment as well as his or her safe use of prescribed medications, and should demonstrate that the therapy has been adjusted as needed, as well as documentation of appropriate referrals as needed. 2) Treating physician should seek a consultation with or refer a patient to a pain, psychiatry, addiction, or mental health specialist as needed.

Indiana – When a patient’s opioid dose reaches a morphine equivalent dose of more than 60mg per day, a face to face review of the treatment plan and patient evaluation must be scheduled, including consideration of a referral to a specialist.

Iowa – 1) Consultation with or referral to a physician with expertise in pain medicine, addiction medicine, or substance abuse counseling or a physician who specializes in the treatment of the area, system or organ perceived to be the source of the pain may be

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warranted depending on the expertise of the physician and the complexity of the presenting patient. 2) A specialty consultation may be considered at any time if there is evidence of significant adverse effects or lack of response to the medication. Physician should also consider consultation with or referral to a physician with expertise in addiction medicine or substance abuse counseling if there is evidence of diversion or a pattern of substance abuse. 3) Patient's prior history of substance abuse does not necessarily contraindicate appropriate pain management; however, treatment of patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care and communication with the patient, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

Kansas – 1) Provider should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. 2) The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Kentucky – 1) If unable to develop a working diagnosis, the physician should consider the usefulness of additional information, such as 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. 2) If, after screening, the physician determines that the patient does suffer 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 and shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient. 3) Physician shall use drug screens as appropriate and, if the drug screen indicates the patient is non-compliant, the physician shall refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program, depending on the circumstances. 4) 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; and c) the patient exhibits inappropriate drug-seeking behavior or diversion.

Louisiana – 1) The medical director of a pain management facility or his/her 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 illegal use of drugs. 2) Physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. 3) Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy, which shall only be reinitiated after referral to and written concurrence of the medical necessity of continued drug therapy by an addiction medicine specialist, pain management specialist, psychiatrist, or other substance abuse professional based upon his or her physical examination of the patient and a review of the referring physician's medical record of the patient.

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Maine – Clinician should consult or refer as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Michigan – Physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Mississippi – Periodic review and documentation of the treatment course should be conducted at reasonable intervals of no more than every six months and should include referrals and consultations as necessary.

Nevada – Adopted the Federation of State Medical Boards’ Model Guidelines for the treatment of pain, which indicates that, if the patient’s progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed. Further, the Guidelines state that the treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available. Additionally, physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment, so as to make appropriate referrals when needed. If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist.

New Hampshire – Physician should refer the patient for additional evaluations and treatment as necessary.

New Jersey – If treatment objectives are not being met, physician shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

New Mexico – Physicians shall consult with, and refer patients to, other providers when appropriate.

North Carolina – 1) Physicians who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including recognizing behaviors that indicate addiction, and how and when to refer patients for addiction evaluation and treatment. 2) Physician should seek consultation with or refer the patient to a pain, psychiatry, addiction, or mental health specialist as needed.

Ohio – 1) Physicians may obtain drug screens of the patient based on evidence or behavioral indicators of drug abuse. If patient refuses to submit to a drug screen, the physician shall refer the patient for a consultation with an addiction medicine specialist or other

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substance abuse professional to obtain a formal assessment of addiction or drug abuse. 2) If the physician believes or has reason to believe the patient is suffering from addiction or drug abuse, the physician shall immediately consult with an addiction medicine specialist or other substance abuse professional to obtain a formal assessment of addiction or drug abuse. Physician shall do all of the following: a) document the recommendations of the consultation in the record; b) continue to actively monitor the patient for signs of addiction, drug abuse, or diversion; and c) maintain a copy of any written report made by the addiction medicine specialist or substance abuse professional to whom referral for evaluation was made. Prescription drug therapy may be continued consistent with the recommendations of the consultation. If the consultant believes the patient is suffering from addiction or drug abuse, prompt referral shall be made to one of the following: a) an addiction medicine specialist or substance abuse professional; or b) an addiction medicine or substance abuse treatment facility.

Oklahoma – 1) Physician should be willing to refer the patient, as needed, for additional evaluation and treatment in order to achieve treatment objectives. 2) Providers are encouraged to consider non-pharmacological therapies and/or referral to specialists for follow-up, as clinically appropriate.

Pennsylvania – 1) Clinicians should consider increasing the frequency of ongoing monitoring, as well as referral for specialty care, including psychological, psychiatric, and addiction experts, for patients identified to be at high risk for aberrant drug-related behavior. 2) In patients who have engaged in aberrant drug-related behavior, clinicians should carefully determine if the risks associated with chronic opioid therapy outweigh documented benefit. Should consider restructuring therapy, including frequency or intensity of monitoring, referral for assistance in management, or discontinuation of chronic opioid therapy. Appropriate referral for addiction evaluation and treatment should be provided.

Rhode Island – 1) Practitioners shall consider referral to other professionals as clinically indicated, including: patients self-escalating their doses, early refills, inadequate pain relief, co-existing morbidities, prior history of substance abuse or prior overdose. 2) The consideration and documentation of consideration for consultation threshold for adults is 120 mg morphine equivalent dose per day. If practitioner prescribes a dosage that meets or exceeds that amount, he or she shall consider consultation with a pain medicine physician. If no consultation is obtained, the reasons for not obtaining a consultation shall be noted in the patient's record.

South Carolina – 1) Prescribers who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including behaviors that indicate addiction and circumstances under which it is appropriate to refer a patient for addiction evaluation and treatment. 2) Treatment agreements should include a discussion of the prescriber's responsibility to provide referrals to substance abuse counseling when abuse potential is present and for failed drug screens. 3) Clinicians should reconsider referral to one or more other providers specializing in the treatment of the area, system, or organ of the body perceived to be the source of the patient's pain.

4) Prescriber should seek consultation with or refer the patient to a pain, psychiatric, addiction, or other mental health specialist as needed.

Tennessee – 1) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates and shall make referral to such a physician if the patient requests it. 2) When an opioid dose reaches 120mg MEDD and benzodiazepines are being used for mental health purposes, the provider shall refer the patient to a mental health professional to assess necessity of benzodiazepine medication. 3) Patients on opioid doses of 120mg MEDD or greater should be referred to a pain specialist for a consultation and/or management. If a provider cannot make the required consultation as outlined above, then s/he shall clearly document why not.

Texas – Physician should refer a patient for further evaluation and treatment as necessary.

Utah – 1) Clinicians who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. 2) Prescribers should consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment: a) patient has a complex pain condition and the clinician wishes to verify the diagnosis; b) patient has significant co-morbidities; c) patient is high-risk for aberrant behavior or addiction; or d) clinician suspects development of significant tolerance, particularly at high doses. 3) Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment. 4) Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or substance use disorder specialist, if available, for recommendations on the treatment plan and possibly assistance in management. 5) Patients with coexisting psychiatric disorders should receive ongoing mental health support and treatment while receiving opioid medication for pain control.

Vermont – 1) The prescriber shall consider referring a patient for a consultation with an appropriate specialist, such as a pain specialist or substance abuse specialist, when: a) the patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain; b) the patient is at high risk for substance misuse, abuse, diversion, addiction, or overdose as determined by the patient's history or a screening; c) the prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances; d) the patient is seeing multiple prescribers and/or utilizing multiple pharmacies; or e) the patient has been prescribed multiple controlled substances. 2) Physician should seek consultation with, or refer the patient to, a pain, psychiatry, addiction, or mental health specialist as needed.

Virginia – Physician should seek consultation with or refer the patient to a pain, psychiatry, addiction, or mental health specialist as needed.

Washington – 1) Physician shall consider, and document the consideration, referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. 2) Mandatory consultation threshold for adults is 120 mg MED (oral). In the event a physician prescribes a dosage that meets or exceeds the consultation threshold, a consultation with a pain management specialist is required. Not required to consult with a specialist when s/he has documented adherence to all standards of practice and when any one or more of the following apply: a) the patient is following a tapering schedule; b) the patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in dosage, with expected return to or below their baseline dosage level; c) physician documents reasonable attempts to obtain a consultation and the circumstances justifying prescribing above the threshold without first obtaining a consultation; or d) the physician documents the patient's pain and function is stable and the patient is on a non-escalating dosage of opioids. Further not required to consult with a specialist if one or more of the following qualifications is met: a) physician is a pain management specialist; b) physician has successfully completed, within the last two years, a minimum of 12 CME hours on chronic pain management with at least two of those hours dedicated to long acting opioids; c) the physician is a pain management practitioner working in a multi-disciplinary chronic pain treatment center or a multi-disciplinary academic research facility; or d) the physician has a minimum three years of clinical experience in a chronic pain management setting, and at least 30% of his or her current practice is the direct provision of pain management care. 3) Referral for counseling or other support during the tapering or discontinuation of opioids is recommended if there are significant behavioral issues. Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

West Virginia – Physician should seek consultation with or refer the patient to a pain, psychiatry, addiction, or mental health specialist as needed.

Wyoming – Prescriber should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.



LIMITATIONS ON THE PRESCRIBING OF SCHEDULE II CONTROLLED SUBSTANCES

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Controlled substances are typically scheduled in one of five schedules under the federal Controlled Substances Act. Substances included in Schedule II are: 1) drugs with a high potential for abuse; 2) drugs that have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and 3) where abuse of the drug or other substances may lead to severe psychological or physical dependence.⁷ Schedule II substances include opiates, including, but not limited to, methadone, fentanyl, codeine, morphine, hydrocodone, amphetamine, and methamphetamine.⁸ Because of the high potential for abuse and risk of dependence, prescribing of Schedule II substances is typically restricted in most states. Restrictions include, but are not limited to: limitations on faxing of prescriptions; limitations on oral prescriptions; days' supply limitations; limitations on how long after a prescription is written that it may be dispensed; and restrictions on issuing multiple prescriptions. Below is a description of each of these restrictions, including specific state information in some cases, and followed by maps reflecting each of the states with the specific restriction in place.

Faxing of Schedule II prescriptions. Prescriptions for Schedule II controlled substances may only be faxed in certain circumstances. Although allowed under federal law pursuant to 21 CFR § 1306.11, not all states have specific provisions for faxing of Schedule II prescriptions in their statutes or regulations. Schedule II prescriptions may be faxed only for Schedule II narcotic substances to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion or for dispensing to patients of a long term care facility or for hospice patients.

Oral prescriptions. Federal law allows the dispensing of a Schedule II substance in an emergency situation on the oral authorization of a prescribing practitioner, provided that: 1) the amount dispensed is limited to an amount adequate to treat the patient during the emergency period; 2) the prescription is immediately reduced to writing by the pharmacist and contains all information required for written prescriptions except the prescriber's signature; 3) if the prescriber is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call back to the prescriber using the phone number as listed in the telephone directory and/or other good faith efforts to ascertain the prescriber's identity; and 4) a written prescription must be delivered to the pharmacist within seven days after authorizing an emergency oral prescription.⁹

An emergency situation is that situation in which the prescriber determines: 1) that immediate administration of the controlled substance is necessary for proper treatment of the patient; 2) that no alternative treatment is available, including administration of a drug which is not a Schedule II controlled substance; and 3) that it is not reasonably possible for the prescriber to provide a written prescription to the dispenser prior to dispensing.¹⁰

Forty-seven states and DC include specific language in their statutes and/or regulations related to oral prescriptions for Schedule II substances. (The three states that do not are Alaska, Kentucky, and New Hampshire.) Eight states and DC provide a specific limit on the quantity of a Schedule II substance that may be dispensed on the oral prescription of a practitioner. Mississippi limits the quantity to an amount adequate to treat the patient for 48 hours. Alabama, Arkansas, Colorado, Florida, New Jersey, and Utah limit the amount to 72 hours, while New York and DC limit it to five days and seven days, respectively.

Days' supply. There is no limit on the number of days' supply for which a Schedule II prescription can be written under federal law. However, a number of states do impose such restrictions, typically limiting a single prescription to a 30-day supply. Illinois, Rhode Island, and South Carolina have such a restriction. Delaware limits Schedule II prescriptions to either 100 dosage units or a 31-day supply, while Utah limits it to a one-month supply. In Massachusetts, Schedule II prescriptions are limited to a 30-day supply except that prescriptions for dextro amphetamine sulphate and methyl phenidate hydrochloride, if such substances are being used for the treatment of minimal brain dysfunction or narcolepsy, may be issued for up to a 60-day supply, while prescriptions for implantable infusion pumps consisting of Schedule II substances may be filled for a maximum of 90 days. Missouri also limits Schedule II prescriptions to a 30-day supply, except that the amount may be increased to a three-month supply if the prescriber describes on the prescription form or otherwise indicates the medical reason for requiring a larger supply. New Hampshire allows only a 34-day supply for a single Schedule II prescription. In New Jersey, physicians may not prescribe more than 120 dosage units, or a 30-day supply of a Schedule II controlled substance except in cases where the prescription is issued for the treatment of pain associated with cancer, terminal illness, or if the patient is suffering from intractable pain. In those cases, the practitioner must have a treatment plan and must discuss the risks and benefits of the use of controlled substances with the patient. Finally, Tennessee limits the prescribing of opioids to a 30-day supply, but places no days' supply limitations on any other category of Schedule II substances.

Expiration of Schedule II prescriptions. As with the days' supply restriction, federal law does not include a provision for expiration of Schedule II prescriptions. Many states, however, do include such an expiration date. Arizona, Louisiana, Maine, Rhode Island, South Carolina, and West Virginia all provide that a Schedule II prescription becomes invalid after 90 days. Arkansas, California, Kansas, Mississippi, Missouri, Nebraska, New Hampshire, North Carolina, North Dakota, Pennsylvania, Virginia, Washington, and Wyoming provide for expiration at the end of six months. DC, Massachusetts, New Jersey, New York, Oklahoma, and Utah expire after 30 days. Kentucky and Wisconsin provide for expiration after 60 days. Delaware Schedule II prescriptions become invalid after seven days. Maryland Schedule II prescriptions expire after 120 days, while Colorado prescriptions don't expire until after one year.

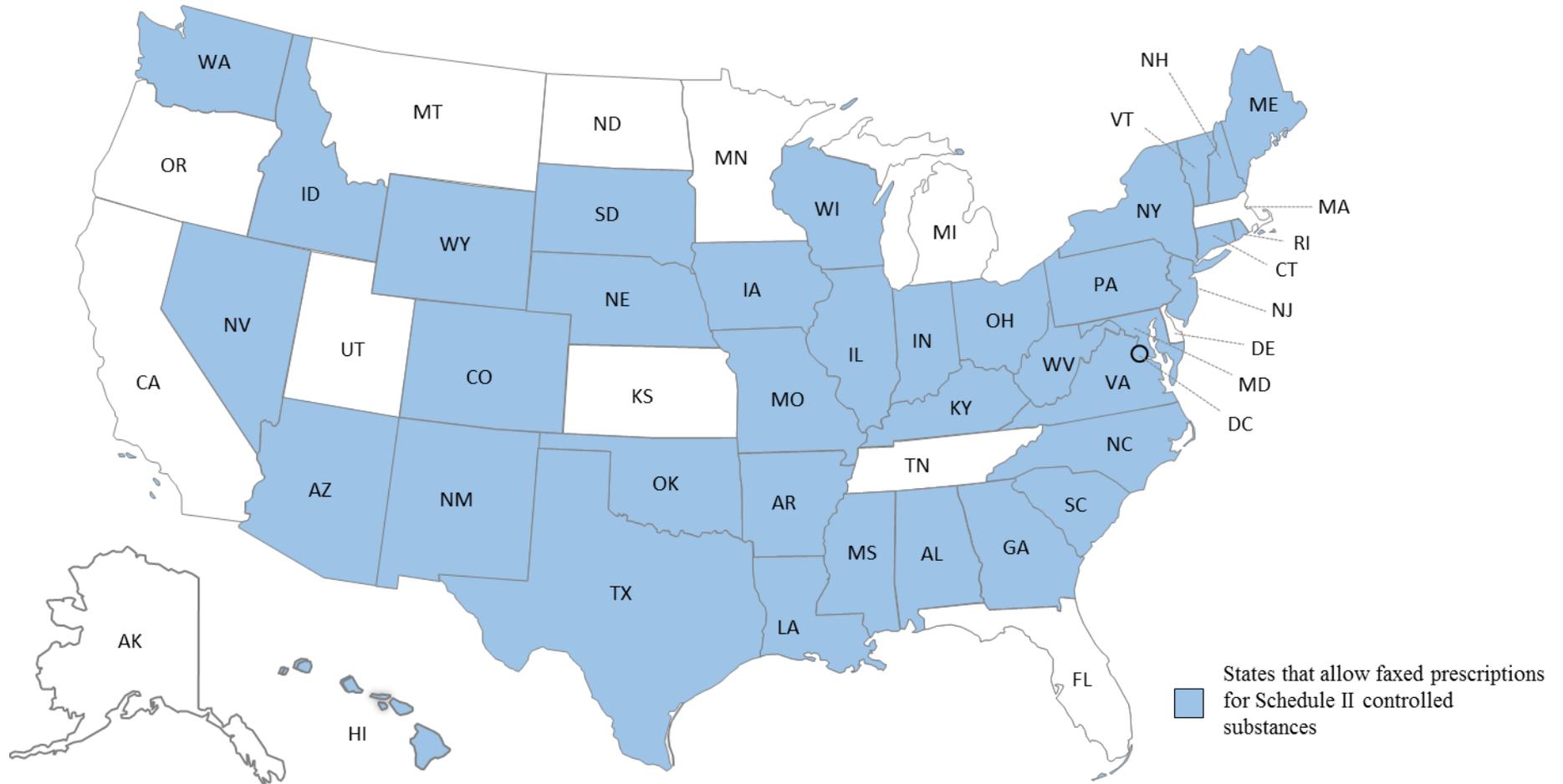
In Hawaii, by statute, Schedule II prescriptions must be filled within seven days. However, a Hawaii regulation provides that no Schedule II prescription shall be filled later than the third day following issuance. Illinois law provides that Schedule II prescriptions are valid for up to 90 days after issuance; however, as in Hawaii, an Illinois regulation states that prescriptions may not be filled more than seven days after the date issued. Michigan law provides that Schedule II prescriptions for non-terminal patients must be filled not

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more than 90 days after being written, while prescriptions for terminally ill patients must be filled within 60 days. In Minnesota, Schedule II prescriptions for patients in a long term care facility and terminally ill patients are valid for up to 60 days after being issued, unless terminated sooner by discontinuation of the medication. Finally, Vermont law provides that no Schedule II prescription written without a future fill date may be filled more than 30 days after originally written, while no prescription written to be filled at a future date may be filled more than 90 days after written.

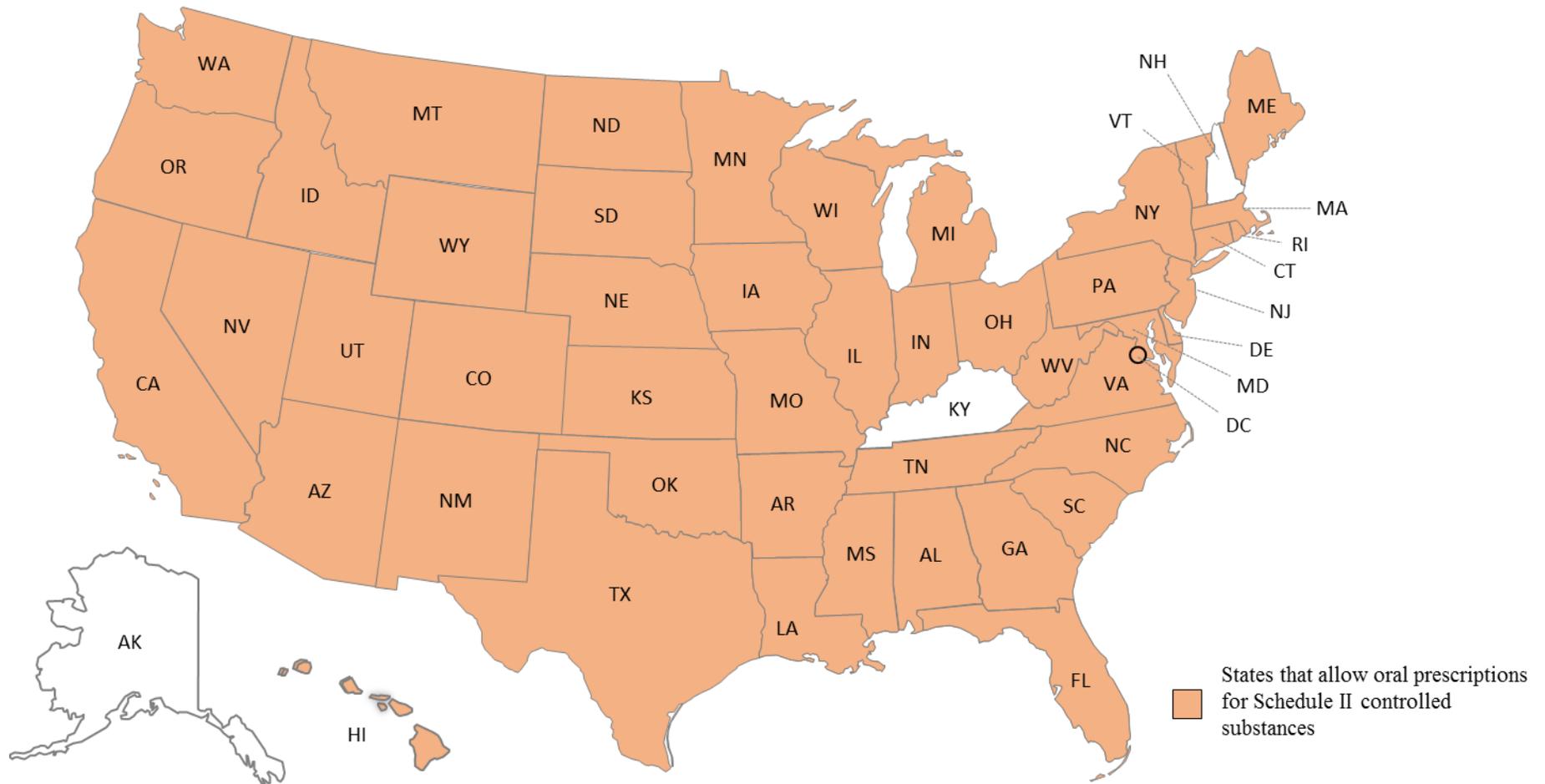
Issuing multiple prescriptions. Pursuant to federal law, prescriptions for Schedule II controlled substances may not be refilled. However, federal law does allow practitioners to issue multiple prescriptions for a total of up to a 90-day supply of Schedule II controlled substances at one time. Each prescription must be for a legitimate medical purpose, and the practitioner must provide written instructions on each prescription indicating the earliest date on which the prescription can be filled. Further, the practitioner must conclude that providing the patient with multiple prescriptions does not create an undue risk of diversion or abuse. Finally, issuance of multiple prescriptions must be permissible under state law.¹¹ At this time, thirteen states and D.C. permit physicians to issue multiple prescriptions.

States that Allow Faxed Prescriptions for Schedule II Controlled Substances



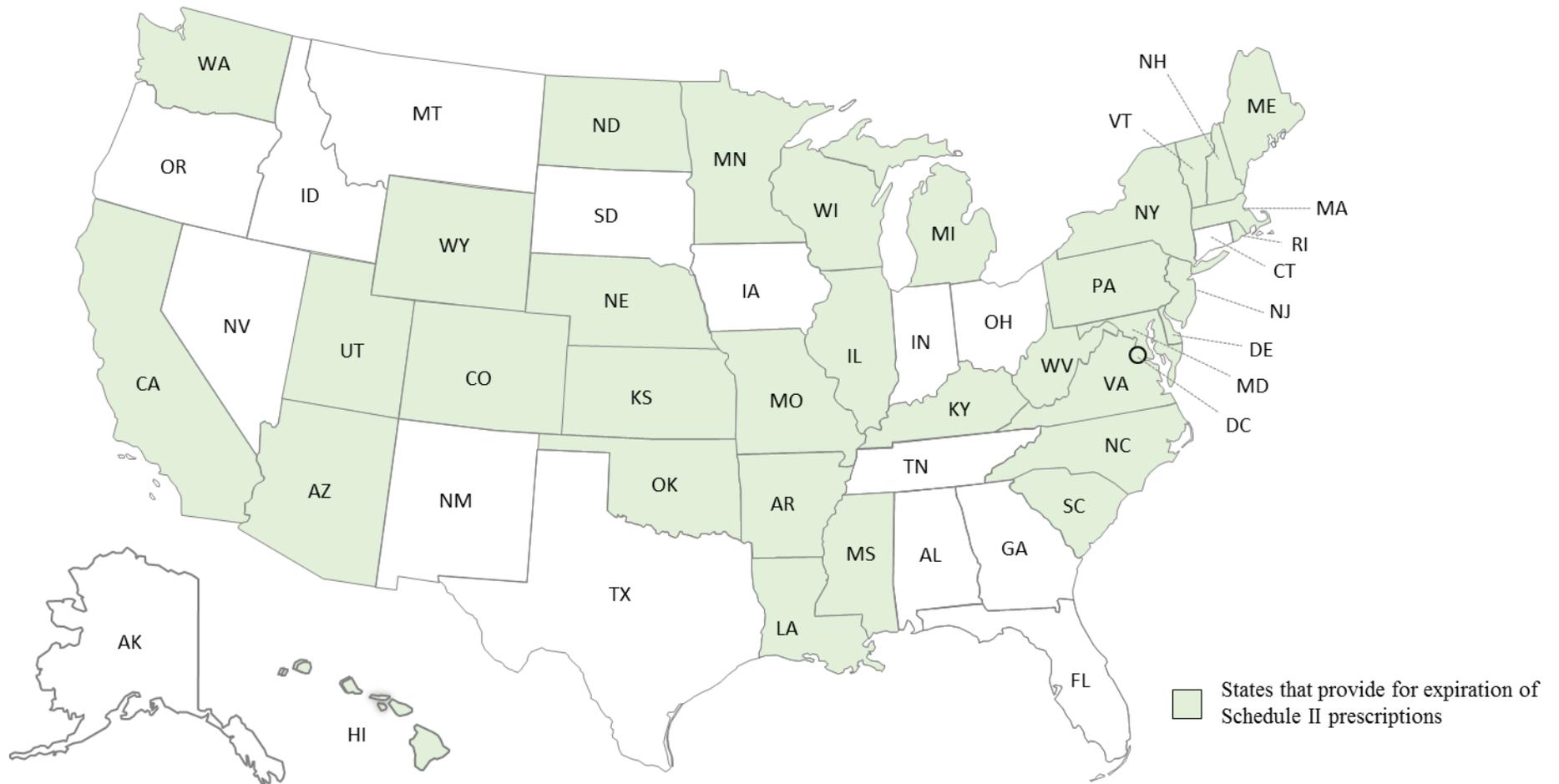
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States that Allow Oral Prescriptions for Schedule II Controlled Substances



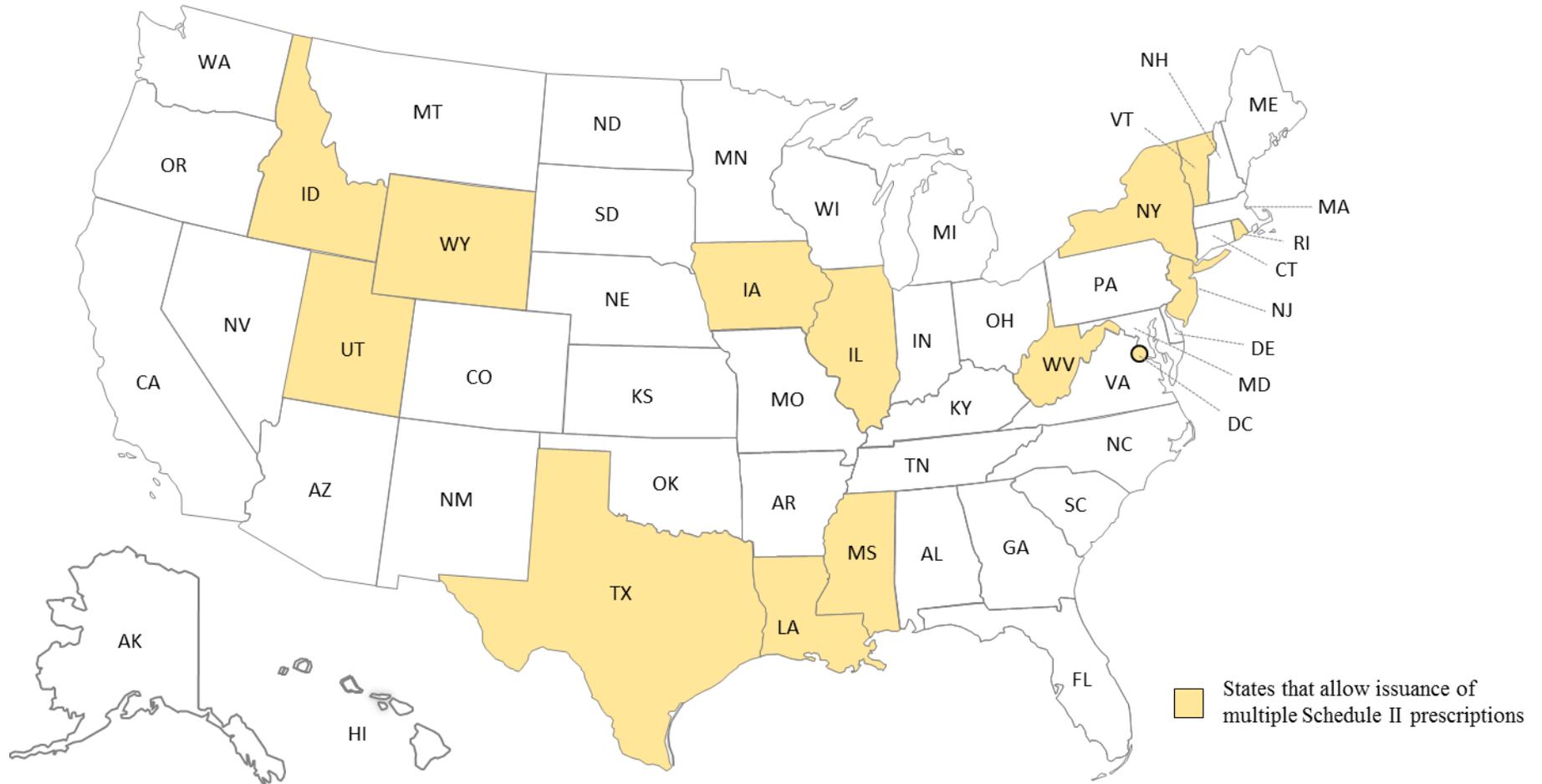
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States that Provide for Expiration of Schedule II Prescriptions



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States that Allow Issuance of Multiple Schedule II Prescriptions



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LIMITATIONS ON THE PRESCRIBING OF SCHEDULE III CONTROLLED SUBSTANCES

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Schedule III controlled substances are those substances: 1) that have a potential for abuse less than the drugs or other substances included in Schedules I or II; 2) that have a currently accepted medical use in treatment in the United States; and 3) where abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.¹² Substances in Schedule III include, but are not limited to, certain combination products containing codeine and morphine, buprenorphine, secobarbital, and pentobarbital.¹³ Because Schedule III substances have less potential for abuse or dependence than Schedule II substances, there are fewer restrictions placed on the prescribing of those substances. As with Schedule II substances, some states limit the number of days' supply that can be prescribed, provide for expiration of the prescription, and limit the amount that can be dispensed in an emergency.

Refills of Schedule III prescriptions. Pursuant to federal law, Schedule III prescriptions may not be filled more than six months after written nor refilled more than five times.¹⁴ However, Hawaii provides that Schedule III prescriptions may not be filled more than three months after written nor refilled more than twice. California law provides that a Schedule III prescription may not be refilled more than five times and in an amount, when taking all refills of that prescription together, exceeding a 120-day supply. Kansas law provides that, if a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled, except that it may not be refilled after the expiration of the time specified on the prescription or one year after the prescription was originally issued, whichever occurs first. The statute does not specify to which schedule of controlled substances it applies.

Oklahoma follows federal law with regard to all Schedule III prescriptions except those containing hydrocodone with another active ingredient, providing that those prescriptions shall not be refilled. As all hydrocodone combination products have been rescheduled to Schedule II under federal law, this provision likely no longer applies.

Finally, New York law provides that prescriptions for certain Schedule III substances shall not be refilled.¹⁵

Days' supply. As with Schedule II substances, federal law does not provide a limitation on the days' supply of Schedule III substances that may be prescribed. However, eight states do have such restrictions. Delaware limits Schedule III prescriptions to 100 dosage units or 31 days. Florida limits oral Schedule III prescriptions to 30 days, while Rhode Island limits them to 100 dosage units. Massachusetts provides that Schedule III prescriptions shall not be filled for more than a 30-day supply, except that they may be filled for up to a 60-day supply for dextro amphetamine sulphate and methyl phenidate hydrochloride if such substance is being used for the treatment of minimal brain dysfunction or narcolepsy. Missouri law provides that Schedule III prescriptions shall be limited to a 90-day supply, which may be increased to three months if the physician describes on the prescription form or otherwise indicates the medical reason for requiring a larger supply. New Hampshire limits Schedule III prescriptions to a 34-day supply, except that substances commercially packaged for dispensing directly to the patient may be filled for greater than a 34-day supply but not more

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than a 60-day supply, utilizing the smallest available product size. Additionally, amphetamines and methylphenidate hydrochloride prescriptions may be filled for up to 60 days if either such prescription specifies it is being used for the treatment of ADD, ADHD, or narcolepsy. New Mexico law provides that a new telephone prescription for a Schedule III opioid shall not exceed a 10-day supply and cannot be refilled.

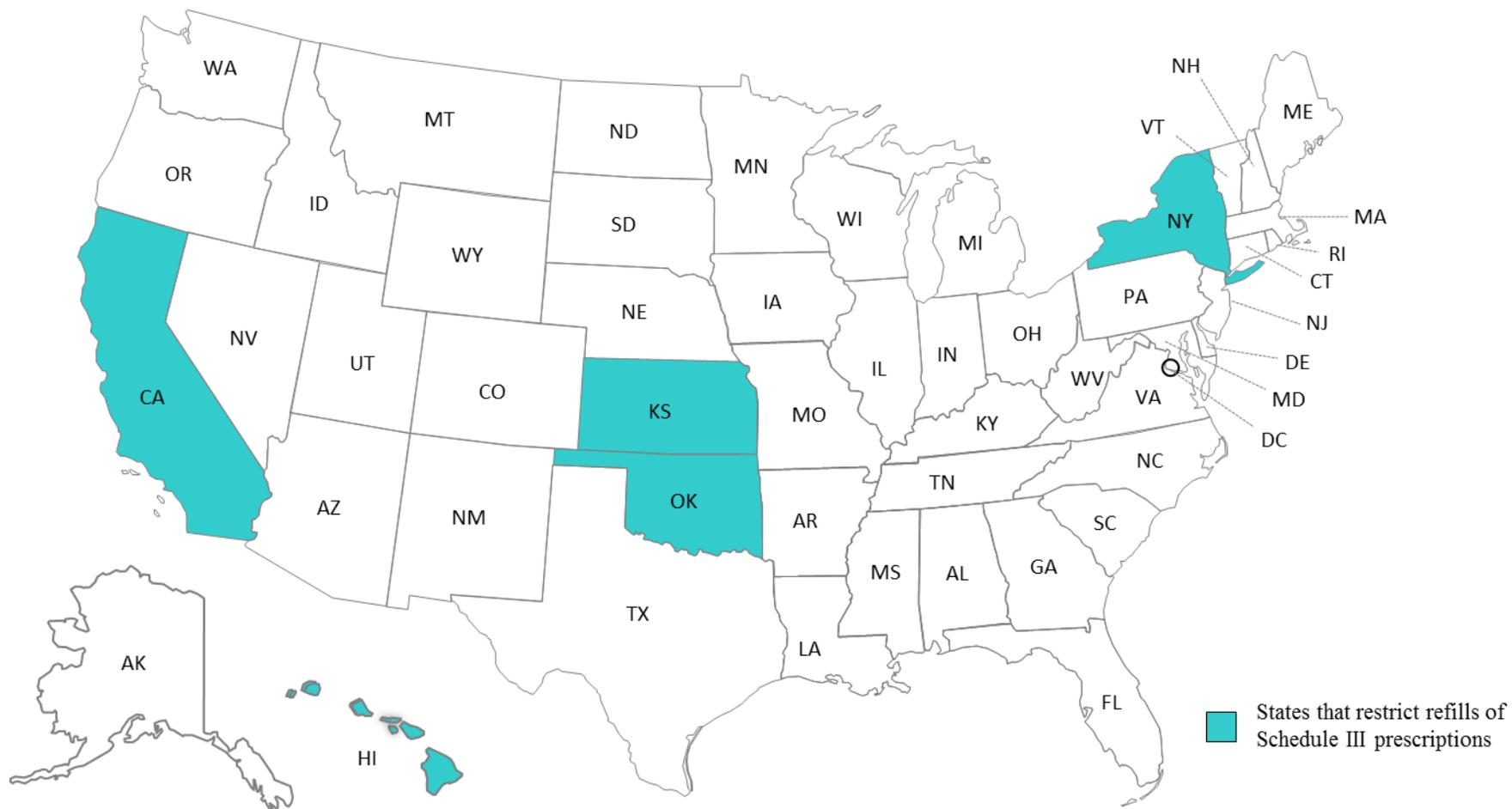
No prescription for a Schedule III substance in New York may be written for a greater than 30-day supply. However, a practitioner may issue a prescription for up to a three-month supply provided that the prescription has been written for the treatment of certain named conditions and such prescription shall state the name of the condition being treated on the face of the prescription. New York law also provides that an oral prescription may not be filled for more than a five-day supply. Further, no additional prescriptions for certain listed Schedule III substances may be issued by a practitioner within 30 days of the date of a previously issued prescription for the same substance unless and until the patient has exhausted all but a seven days' supply of that substance.

Emergency refills of Schedule III prescriptions. Sixteen states include specific language allowing the emergency refill of Schedule III prescriptions – Alabama, California, Colorado, Florida, Kansas, Louisiana, Montana, Nevada, New Jersey, North Carolina, Ohio, Oregon, Rhode Island, Texas, Utah, and West Virginia. Emergency refills are typically only allowed if the medication is essential to the maintenance of life or to the continuation of therapy for a chronic condition, the interruption of therapy might produce undesirable health consequences, and the dispenser makes a good faith effort to notify the prescriber of the emergency dispensing.

Of the states that allow emergency refills, Alabama, Colorado, Florida, Louisiana, New Jersey, Ohio, Oregon, Rhode Island, Texas, and Utah limit the quantity to an amount sufficient to treat the patient for a period of 72 hours. Kansas provides for a 7-day limit, while West Virginia allows a 10-day supply. North Carolina provides that a pharmacist may dispense a one-time emergency refill of up to a 30 or 90-day supply. The remaining states provide no quantity or days' supply restrictions.

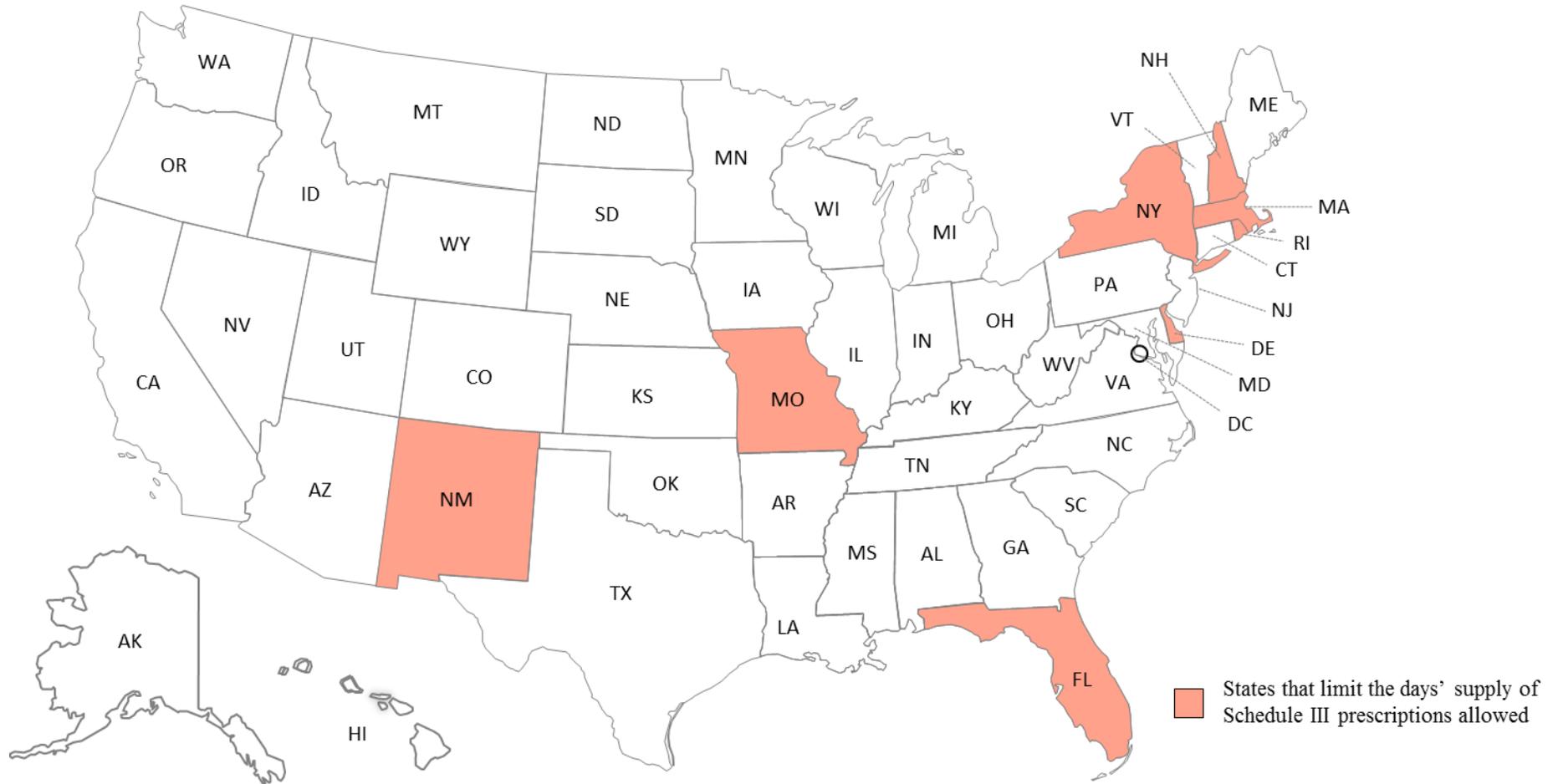
Expiration of Schedule III prescriptions. As mentioned above, federal law requires that a prescription for a Schedule III substance be filled within six months. Five states have more restrictive limits on such prescriptions. Delaware law provides that Schedule III prescriptions become void if not filled within seven days of being written unless the original prescriber authorizes the dispensing past the seven-day period. Maine provides for expiration after 90 days, while New Jersey and New York Schedule III prescriptions expire after 30 days. Finally, Maryland law provides that Schedule III prescriptions shall not be filled more than 120 days after being written unless the prescriber instructs otherwise, but in no case shall it be filled more than six months after being issued.

States that Restrict Refills of Schedule III Prescriptions



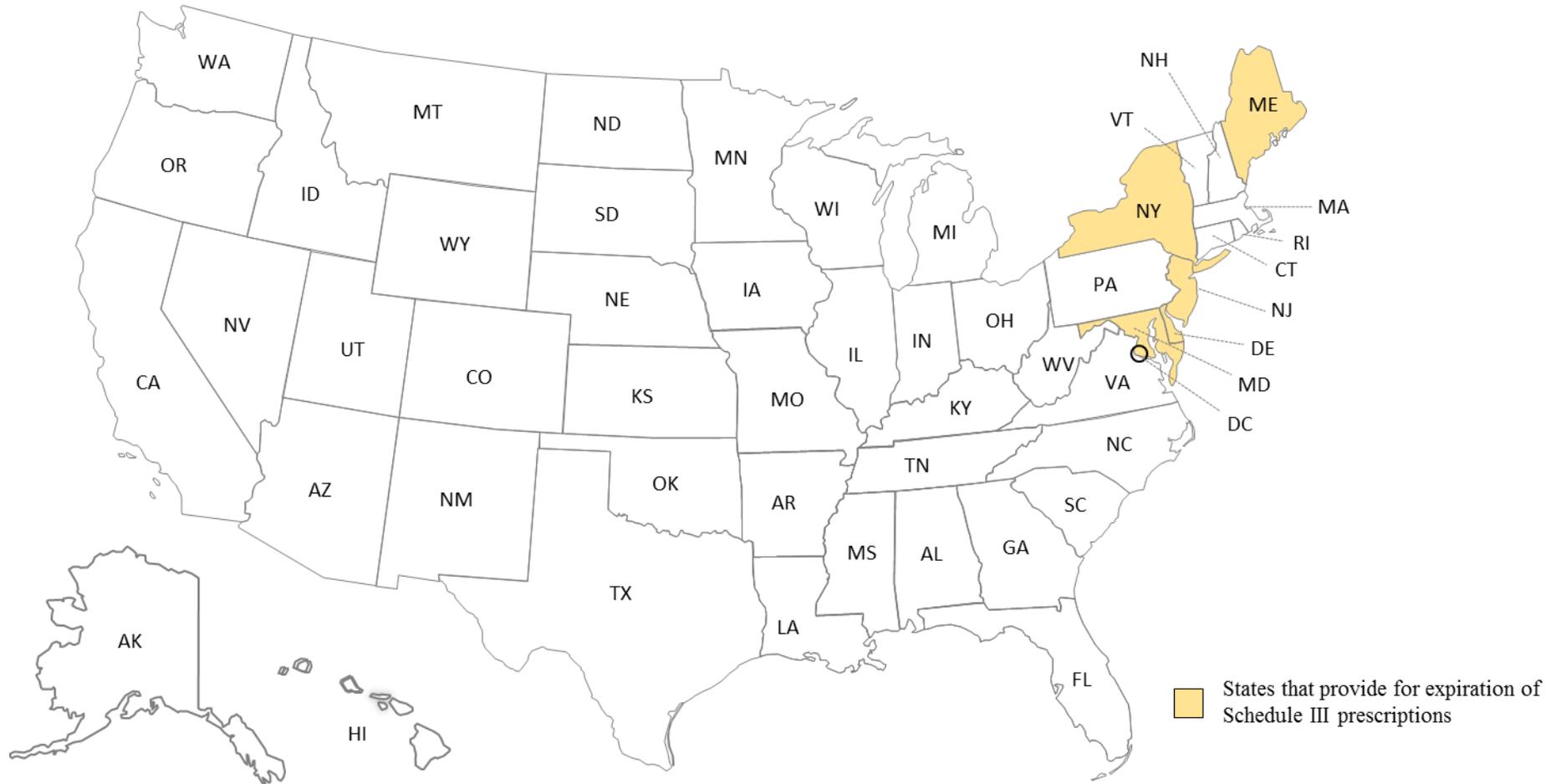
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States that Limit the Days' Supply of Schedule III Prescriptions Allowed



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States that Provide for Expiration of Schedule III Prescriptions



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PAIN CLINICS AND PAIN TREATMENT FACILITIES

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WHAT CONSTITUTES A PAIN MANAGEMENT CLINIC OR PAIN TREATMENT FACILITY

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Only ten states – Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, Ohio, Tennessee, Texas, and West Virginia – currently have laws regulating pain clinics and/or pain treatment facilities. Each state has different criteria for what qualifies as a pain management clinic or pain treatment facility, although there are some similarities.

In Alabama, pain management services are defined as medical services that involve the prescribing of controlled substances to treat chronic non-malignant pain by a physician who treats pain. Provision of pain services means: 1) a physician practice which holds itself out or advertises itself as a provider of pain management services; 2) a physician practice which dispenses opioids; or 3) a physician practice in which any of the providers of pain management services are rated in the top 3% of practitioners who prescribe controlled substances in Alabama as determined by the Alabama prescription monitoring program on an annual basis. All physicians providing pain management services and all physicians who otherwise meet the criteria established by the board must obtain a pain management registration from the board which must be renewed annually. Pain management statutes and regulations do not apply to licensed hospice programs or physicians performing work for a hospice program or to a facility maintained or operated by the United States or any of its departments, offices, or agencies, or any physicians while performing work for that facility.

Florida pain clinics are those facilities which are publicly or privately owned and advertise in any medium for pain management services or where in any month a majority of the patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic non-malignant pain. Pain clinics must be registered separately with the department regardless of whether the clinic is operated under the same business name or management as another clinic. Clinics are not required to register if: it is licensed as a hospital; the majority of physicians who provide services at the clinic primarily provide surgical services; the clinic is owned by a publicly held corporation whose shares are traded on the national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceed \$50 million; the clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows; the clinic does not prescribe controlled substances for the treatment of pain; the clinic is owned by a 501(c)(3) corporate entity; the clinic is wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or, the clinic is wholly owned and operated by a physician multi-specialty practice where one or more board-eligible or board-certified medical specialists who have also completed approved fellowships in pain medicine, or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

Pain management clinics in Georgia are medical practices advertising “treatment for pain” or using “pain” in the name of the clinic or medical practice, or a clinic with greater than 50% of its annual patient population being treated for chronic pain for non-terminal conditions by the use of Schedule II or III substances. All clinics must be licensed by the board, and all clinics that dispense controlled substances or dangerous drugs must be registered with the Board of Pharmacy. Pain management clinics do not include a

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clinic or practice owned, in whole or in part, or operated by a hospital, health system, ambulatory surgical center, skilled nursing facility, hospice, or home health agency.

In Kentucky, pain management facility means a facility where the majority of patients of the practitioners of the facility are provided treatment for pain that includes the use of controlled substances and the facility's primary practice component is the treatment of pain or the facility advertises in any medium for any type of pain management services. Every pain management facility operating in Kentucky as a private office or clinic of a physician shall register with the board. As part of the initial or annual registration, the facility shall identify each practitioner who is employed at the facility in any capacity who will be prescribing or dispensing controlled substances to patients at the facility. Pain management clinics do not include: a hospital, a facility owned by a hospital, or the office of a hospital-employed physician; a school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians; hospice programs or residential hospice facilities; ambulatory surgical facilities; or long term care facilities.

Louisiana law provides that a pain management clinic is a privately or publicly owned clinic which primarily engages in the treatment of pain by prescribing narcotic medications. All clinics must be licensed by the department, which license shall be renewed annually.

Pain management medical practice in Mississippi is defined as a public or privately owned medical practice that provides pain management services to patients, a majority (more than 50%) of whom are issued prescriptions for, or are dispensed, opioids, barbiturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol for more than 180 days in a twelve-month period. All pain management medical practices must receive a certificate from the Mississippi Board of Medical Licensure which must be renewed annually. A pain management medical practice does not include: licensed hospitals, state health department facilities, federally qualified community health clinics, volunteer clinics, hospice services, outpatient surgical clinics or physician/clinic practices at which the majority of patients are treated for pain as a result of terminal illness.

In Ohio, pain management clinic means: 1) the primary component of the practice is the treatment of pain or chronic pain; or 2) the majority of the patients of the prescribers of the facility are provided treatment for chronic pain through the use of controlled substances, tramadol, or other drugs as specified in regulation. Calculation of the majority of patients will be based on the number of patients treated in a calendar month. Patients receiving controlled substances for treatment of an injury or illness that lasts or is expected to last 30 days or less is not considered in the calculation. Each clinic must be licensed as a category III terminal distributor of dangerous drugs with a pain management classification. Pain management clinic does not include: hospitals, facilities operated by a hospital for the treatment of chronic pain, a physician practice owned or controlled by a hospital or other entity that owns or controls a hospital, an educational institution to the extent that it provides instruction to health care practitioners, hospice programs, ambulatory surgical facilities, interdisciplinary pain rehabilitation programs, nursing homes, or facilities conducting clinical research.

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Tennessee law provides that a pain management clinic is a privately-owned clinic, facility, or office in which any health care provider licensed in Tennessee provides chronic non-malignant pain treatment to a majority of its patients for 90 days or more in a twelve-month period. The caseload of patients who received medical treatment from all medical doctors, osteopathic physicians, advanced practice nurses, and physician assistants who serve in the clinic, facility, or office shall be counted. It also means any privately-owned clinic, facility, or office that advertises in any medium for pain management services of any type. It does not include any clinic, facility, or office that provides interventional pain management and whose clinic, facility, or office does not provide chronic non-malignant pain treatment to a majority of its patients. It also does not include any clinic, facility, or office that is wholly owned and operated by a physician multi-specialty practice in which one or more board-eligible or board-certified medical specialists who have also completed fellowships in pain medicine, or who are also board-certified in pain management, perform the pain management services for chronic pain patients. Pain management clinics, and practitioners working at pain management clinics, may not dispense controlled substances, but may provide, without charge, a sample of a Schedule IV or V substance in a quantity limited to an amount adequate to treat the patient for a maximum of 72 hours or a sample of a non-narcotic Schedule V substance in a quantity limited to an amount adequate to treat the patient for a maximum of 14 days.

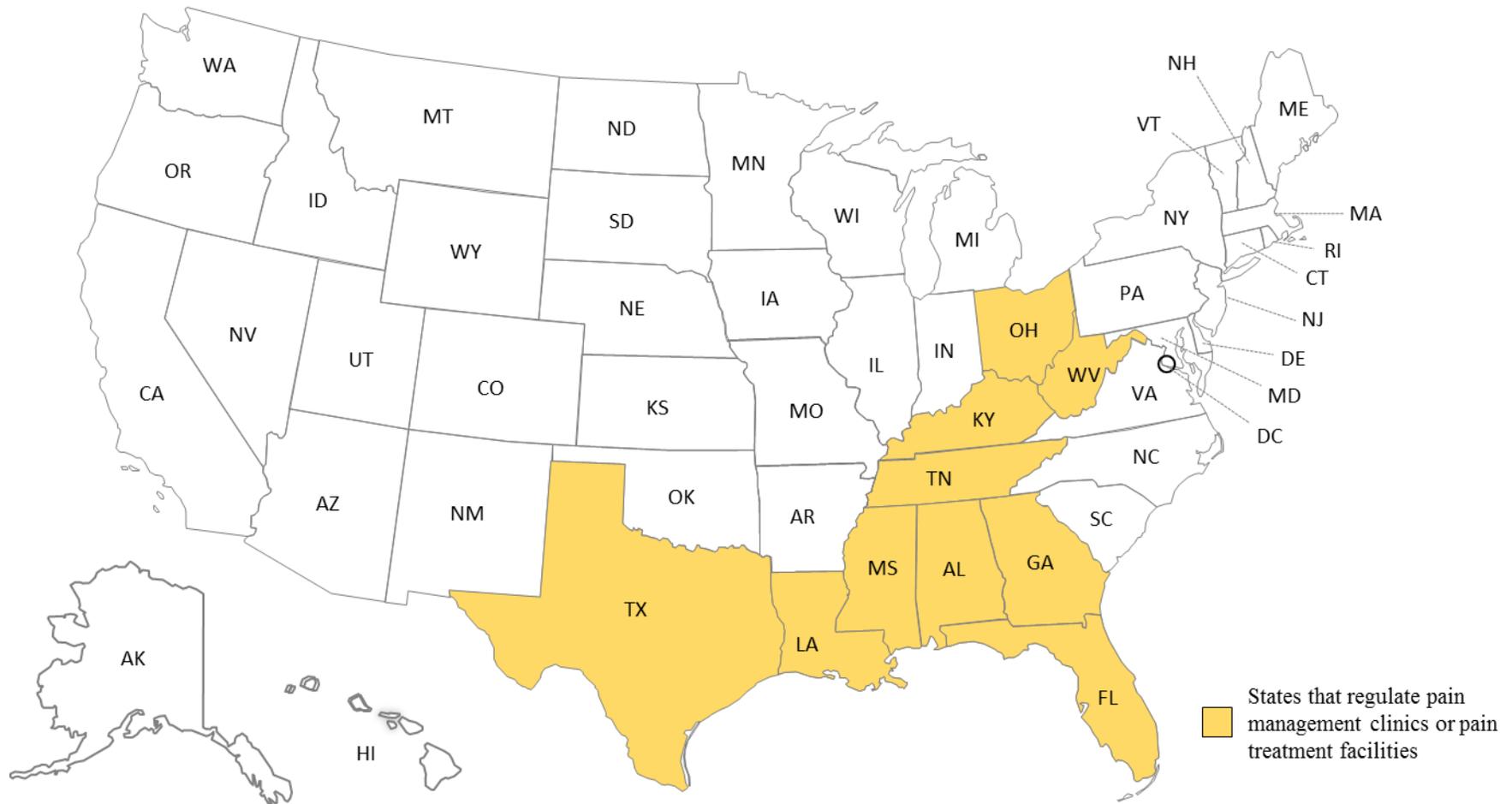
Pain management clinics in Texas are those facilities that are publicly or privately owned for which a majority of patients are issued, on a monthly basis, a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone. Pain management clinics are required to obtain certification from the board. Pain management clinics do not include: medical or dental schools or outpatient clinics associated with a medical or dental school; a hospital, including any outpatient facility or clinic of a hospital; a hospice; a facility owned or operated by the state; a clinic maintained or operated by the United States; a nonprofit health organization; a clinic owned or operated by a physician who treats patients within the physician's area of specialty and who personally uses other forms of treatment, including surgery, with the issuance of a prescription for a majority of patients; or a clinic owned or operated by an advanced practice nurse in Texas who treats patients in the nurse's area of specialty and who personally uses other forms of treatment with the issuance of a prescription for the majority of patients.

West Virginia law provides that a pain management clinic is a privately owned clinic, facility, or office not otherwise exempted which meets both of the following criteria: 1) where in any month more than 50% of patients of the prescribers or dispensers are prescribed or dispensed opioids or other controlled substances for chronic pain resulting from non-malignant conditions; and 2) the facility meets any other identifying criteria established by rule. A pain management clinic does not include: a facility associated with a medical school at which training is provided for medical or osteopathic students, residents, or fellows, podiatrists, nurses, dentists, physician assistants, veterinarians, or any affiliated facility to the extent that it participates in the provision of the instruction; a facility that does not prescribe or dispense controlled substances for the treatment of pain; a hospital licensed in West Virginia, a facility located on the campus of a hospital that is owned, operated, or controlled by that licensed hospital, and an ambulatory health care facility that is owned, operated, or controlled by that licensed hospital; a physician practice owned or controlled, in whole or in part, by a licensed

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hospital or by an entity that owns or controls, in whole or in part, one or more licensed hospitals; a hospice program; a nursing home; an ambulatory surgical facility; or a facility conducting clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs. Each pain management clinic must be licensed by the secretary and renewed annually.

States that Regulate Pain Management Clinics or Pain Treatment Facilities



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WHO MAY OWN/OPERATE A PAIN MANAGEMENT CLINIC OR PAIN TREATMENT FACILITY

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Nine of the ten states that regulate pain clinics and pain treatment facilities include restrictions on who may own or operate a pain clinic or pain treatment facility. Tennessee is the lone state without such a restriction.

Alabama law requires that all registrants providing pain management services must be at a facility owned and operated by: one or more physicians licensed to practice in Alabama; a business entity registered with the Secretary of State; or a governmental body or entity, or political subdivision, or any combination thereof, including state universities and schools.

Florida will deny registration to any pain clinic that is not fully owned by a physician, a group of physicians, or that is not a licensed health care clinic. It will also deny registration for any clinic owned by or with any contractual or employment relationship with a physician whose DEA number has been revoked; whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or who has been convicted of or plead nolo contendere to an offense that constitutes a felony for receipt of illicit or diverted drugs, including controlled substances listed in Schedules I – V.

In Georgia, all clinics must be owned by physicians licensed in Georgia with the exception of pain management clinics in existence prior to June 30, 2013 that are jointly owned by one or more physician assistants or advance practice nurses and one or more physicians and clinics in existence prior to June 30, 2013 that are not majority owned by physicians licensed in Georgia with the caveat that such person may not own more than one clinic in Georgia. The board will deny a license to a pain management facility if a physician practicing at the clinic has been convicted of a felony unless the board finds through satisfactory evidence that the felony is no longer relevant to the physician's ability to safely practice in a pain management clinic.

Kentucky law provides that only a physician having a full and active license to practice in Kentucky shall have an ownership or investment interest in a pain management facility. At least one of the owners or an owner's designee who is a physician employed by and under the supervision of the owner shall be physically present practicing medicine in the facility at least 50% of the time that patients are present at the facility, and the physician owner or designee shall: hold a current subspecialty certification in pain management or current certificate of added qualification; hold a current subspecialty certification in hospice and palliative medicine or a current certificate of added qualification; hold a current board certification by the American Board of Pain Medicine; hold a current board certification by the American Board of Interventional Pain Physicians; have completed a fellowship in pain management or an accredited residency program that includes a rotation of at least five months in pain management; or, if the facility is operating under a registration filed with the Kentucky Board of Medical Licensure, have completed or hold, or be making reasonable progress toward completing or holding, a certification or training substantially equivalent to the certifications or training specified in this subsection, as authorized by the Board.

Louisiana law requires that all pain management clinics must be owned and operated by a physician certified in the subspecialty of pain management, while in Mississippi, a physician must possess and maintain a majority (more than 50%) ownership of a pain management medical practice.

In Ohio, each clinic must be owned and operated by one or more physicians. Physician owners must meet one of the following requirements: hold current subspecialty certification in pain management or hold a current certificate of added qualification in pain management; hold current subspecialty certification in hospice and palliative medicine or hold a current certificate of added qualification in hospice and palliative medicine; hold current certification by the American Board of Pain Medicine; hold current certification by the American Board of Interventional Pain Physicians; or meet both of the following: hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology and demonstrate conformance with the minimal standards of care.

Texas law requires that pain clinics be owned and operated by a medical director who is a physician that practices in Texas, has an unrestricted medical license, and holds a certificate issued by the board. Finally, West Virginia law provides that at least one owner of a pain management clinic must be a physician actively licensed in West Virginia.



REQUIREMENTS OF OWNER OR MEDICAL DIRECTOR

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Each of the states that regulates pain management clinics or pain treatment facilities requires that the clinic or facility have either an owner or medical director to oversee the operation of the clinic or facility and, in most cases, the owner or medical director must meet certain other requirements.

In Alabama, a physician serving as the medical director at a pain management practice location must meet one of the following requirements: 1) successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry; 2) board certification in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry; 3) specialty certification in pain management, pain medicine, hospice and palliative medicine, geriatric medicine, rheumatology, hematology, medical oncology, gynecologic oncology, infectious disease, pediatric hematologyoncology, or pediatric rheumatology; 4) board certification by the American Board of Pain Medicine; 5) board certification by the American Board of Interventional Pain Physicians; or 6) at least one of the following: a) completion of 40 in-person, live participatory AMA PRA Category 1 Credit or AOA Category 1-A credits in the area of pain management completed within three years of implementation of this article or prior to serving as a medical director for the practice location, whichever of them is most recent; or b) completion of a board approved course of medical education in the area of prescribing controlled substances completed within three years of implementation of this article or prior to serving as medical director for the practice location, whichever of them is most recent, and completion of 40 in-person, live participatory AMA PRA Category 1 Credit or AOA Category 1-A credits in the area of pain management within three years of commencement of service as medical director.

Clinics in Florida must designate a physician who is responsible for complying with all requirements related to registration and operation of the pain management clinic, and the physician must practice at the location for which he or she has been designated as the responsible party. The designated physician must ensure compliance with quality assurance requirements, data collection and reporting requirements, and shall make reports to the Board of Medicine on a quarterly basis.

Physicians in Georgia owning or practicing in a pain management clinic must biennially document competence to the board for purposes of clinic registration renewal by providing evidence of having obtained 20 hours of continuing medical education pertaining to pain management or palliative medicine or evidence of current certification or eligibility for certification in pain management.

Kentucky law requires that each pain management facility have a medical director who shall be responsible for complying with all requirements related to the licensure and operation of the facility; be physically present and practicing medicine in the facility at least 50% of the time that patients are present in the facility; be board certified and have a full, active, and unencumbered license to practice

medicine in Kentucky; and not be permitted to serve in a dual role as the medical director of both the parent facility and a satellite facility.

Pain clinics in Louisiana must be under the direction of a medical director who shall be a physician who possesses a current, unrestricted license from Louisiana and has a certification in the subspecialty of pain management except that a clinic verified to have been in operation on or before June 15, 2005 shall have a medical director but said director is not required to have a subspecialty in pain management. The medical director is responsible for the daily operation of the clinic and must be on-site for at least 50% of the time during the operational hours of the clinic. If the director is not on-site, he or she must be available by telecommunications and shall be on-site within 30 minutes. The medical director shall oversee all medical services provided at the clinic and ensure that all qualified personnel perform the treatments or procedures for which each is assigned. Additionally, the medical director or his/her 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 illegal use of drugs. Further duties of the medical director include: ensuring that drug screens of each patient are obtained as part of the initial evaluation and periodically thereafter; ensuring that patients are informed of the after-hours contact and treatment procedure; and are responsible for applying to access and querying the prescription monitoring program. The prescription monitoring program is to be used by the medical director and the pain specialist as part of the clinic's quality assurance program to ensure adherence to the treatment agreement.

Mississippi law requires that a physician or medical director who owns, operates, or is employed in a pain management medical practice must be a physician practicing full-time in Mississippi (full-time defined as at least 20 hours per week of direct patient care), must hold an active, unrestricted license, and hold a certificate of registration for that pain management practice.

Each owner of a pain management clinic in Ohio must supervise, control, and direct the activities of each individual, including an employee, volunteer, or individual under contract, who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment. The physician owner shall establish and ensure compliance with all of the following: 1) a requirement that a log of patients be maintained for each day the clinic is in operation, which log sheets shall contain the date, the legible first and last name of each patient, and shall be signed by the patient at each visit; 2) a requirement that providers obtain informed consent for each patient prior to the commencement of treatment; 3) an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides the opportunities to improve the clinic's performance and quality of care; 4) a requirement that the background, training, certification, and licensure of all clinical staff be documented; 5) a requirement that adequate billing records be maintained for all patients and made available to the board immediately upon request; and 6) a requirement that adequate patient records are maintained for all patients and made available to the board immediately upon request.

Pain management clinics in Tennessee must have a medical director who is a physician that practices in Tennessee. The medical director must meet qualify as a pain management specialist. A pain management specialist is one who; 1) has a subspecialty certification in pain medicine as accredited by the Accreditation Council for Graduate Medical Education (ACGME) through either the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA), or is eligible to sit for the board examination offered by ABMS or AOA, holds an unencumbered Tennessee license, and maintains the minimum number of continuing medical education (CME) hours in pain management to satisfy retention of ABMS or AOA certification, or 2) who attains American Board of Pain Medicine (ABPM) diplomate status, holds an unencumbered Tennessee license, and who maintains the minimum number of CME hours in pain management to satisfy retention of ABPM diplomate status, or 3) is board certified by the American Board of Interventional Pain Physicians (ABIPP) by passing exam 1, and holds an unencumbered Tennessee license and maintains the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status, or 4) has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the commission on accreditation of rehabilitation facilities or any successor organization and holds an unencumbered Tennessee license.

Tennessee medical directors can serve as the director for no more than four pain management clinics. The medical director shall: 1) oversee all of the pain management services provided at the clinic; 2) be on-site at least 20% of the clinic's weekly total number of operating hours; 3) ensure that health care providers comply with federal and state law regarding the prescribing of controlled substances; 4) ensure the establishment of protocols for health care providers and ensure compliance with said protocols; 5) ensure that there is an alternate medical director available in the event the medical director is unable to fulfill his duties for a time; 6) establish quality assurance policies and procedures, which, at a minimum, include, but are not limited to: a) documentation of the background, training, licensure, and certifications for all pain management clinic staff providing patient care; b) written drug screening policy and compliance plan for patients to include random drug screening as clinically indicated, but at a minimum upon each new admission and once every six months thereafter; c) use of substance abuse risk assessment tools upon each new patient admission and periodic review or re-assessment; d) 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; e) medication counts for any controlled substance prescribed; f) use of patient agreements and periodic reviews of such agreements; g) health care provider access and review of patient PMP information, as clinically indicated, but at a minimum upon each new admission and once every six months thereafter; h) documentation of requests for records from other health care providers; 7) establish an infection control program; 8) establish written policies and procedures for health and safety requirements at the clinic; 9) ensure compliance with the patient safety standards; and 10) ensure that health care providers maintain complete and accurate patient records.

In Texas, the medical director of a pain management clinic must: 1) be on-site at the clinic 33% of the clinic's total number of operating hours; 2) review at least 33% of the total number of patient files of the clinic, including the patient files of a clinic employee

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or contractor to whom authority for patient care has been delegated by the clinic; 3) establish protocols; 4) establish quality assurance procedures to include, at a minimum: a) a practice quality plan that requires the medical director to complete at least ten hours of continuing medical education in the area of pain management every two years; b) documentation of the background, training, and certifications for all clinical staff; c) a written drug screening policy and compliance plan for patients receiving chronic opioids; d) performance of periodic quality measures of medical and procedural outcomes and complications that may include questionnaires or surveys for activities of daily living scores, pain scores, and standardized scales; and 5) on an annual basis, ensure that all personnel of the clinic are properly licensed and, if applicable, trained to include ten hours of continuing education related to pain management.

Finally, in West Virginia, each pain management clinic must designate a physician owner who shall practice at the clinic and who will be responsible for the operation of the clinic and who shall have an active, unencumbered license to practice medicine, surgery, or osteopathic medicine or surgery in West Virginia and meet one of the following requirements: 1) complete a pain medicine fellowship; or 2) hold current board certification by the American Board of Pain Medicine or current board certification by the American Board of Anesthesiology or such other board certification as may be approved by the secretary. The designated physician must practice at the licensed clinic location for which the physician has assumed responsibility and shall be responsible for complying with all requirements related to the licensing and operation of the clinic and shall supervise, control, and direct the activities of each individual working or operating at the facility, including any employee, volunteer, or individual under contract, who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment.



PRESCRIBING AND DISPENSING LIMITATIONS FOR PAIN MANAGEMENT CLINICS AND PAIN TREATMENT FACILITIES

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In addition to more general restrictions on the prescribing and dispensing of controlled substances that most states have, five of the ten states that regulate pain management clinics and pain treatment facilities also have restrictions on the prescribing and dispensing of controlled substances in the clinic or facility.

Florida law prohibits anyone from dispensing any medications on the premises of a pain management clinic unless that person is a physician. Physicians, physician assistants, and advanced practice nurses are required to perform a physical examination of the patient on the same day that the physician prescribes a controlled substance and, if the physician prescribes more than a 72-hour dose of a controlled substance, the physician must document in the record the reason for prescribing that quantity.

Kentucky law requires that each physician who will prescribe or dispense controlled substances to patients at a pain management facility shall successfully complete a minimum of ten hours of Category I continuing medical education in pain management during each registration period throughout the employment agreement with the facility.

In Louisiana, clinics must verify the identity of each patient who is seen and treated for chronic pain management and who is prescribed a controlled substance. Prescriptions for controlled substances may have a maximum quantity of a 30-day supply and shall not be refillable. On each visit to a pain clinic which results in a prescription for a controlled substance, the patient shall be personally examined by a pain specialist.

No pain management clinic or practitioner working at a pain management clinic in Tennessee shall be permitted to dispense controlled substances. The clinic or practitioner may provide, without charge, a sample of a Schedule IV or V controlled substance in a quantity limited to an amount that is adequate to treat the patient for a maximum of 72 hours or a sample of a non-narcotic Schedule V substance in a quantity limited to an amount adequate to treat the patient for a maximum of 14 days. If any practitioner prescribes controlled substances for the treatment of chronic non-malignant pain, the practitioner must document in the patient's record the reason for prescribing that quantity.

Finally, in West Virginia a person may not dispense any medication, including a controlled substance, on the premises of a pain management clinic unless he or she is a physician or pharmacist licensed in West Virginia. Prior to dispensing, the physician must check the prescription monitoring program and at every patient examination thereafter or a minimum of every 90 days. Clinics may not dispense to any patient more than a 72-hour supply of a controlled substance. A physician, physician assistant, certified registered nurse anesthetist, or advanced nurse practitioner shall perform a physical examination of the patient on the same day the physician initially prescribes, dispenses, or administers a controlled substance to the patient and at least four times a year thereafter.

¹ 2015 National Drug Strategy, p. 90

² “Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths.” U.S. Department of Health and Human Services, March 26, 2015 (accessed February 5, 2016).

³ “Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain.” Federation of State Medical Boards, July 2013, pp. 10-11 (accessed February 11, 2016).

⁴ “Use of Opioids for the Treatment of Chronic Pain.” Statement from the American Academy of Pain Medicine, February 2013 (accessed February 11, 2016).

⁵ “Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain.” *Journal of Pain*, American Pain Society, February 2009, Vol. 10, Iss. 2, pp. 113-130 (accessed February 11, 2016).

⁶ “Healthcare Guideline: Assessment and Management of Chronic Pain.” Institute for Clinical Systems Improvement, November 2013 (accessed February 11, 2016).

⁷ 21 USC § 812 (2016).

⁸ 21 CFR § 1308.12 (2016).

⁹ 21 CFR § 1306.11 (2016).

¹⁰ 21 CFR § 290.10 (2016).

¹¹ 21 CFR § 1306.12 (2016).

¹² 21 USC § 812 (2016).

¹³ 21 CFR § 1308.13 (2016).

¹⁴ 21 CFR § 1306.22 (2016).

¹⁵ See, New York 10 ADC 80.67 (2016) for a complete list of the specific substances that cannot be refilled.