Chapter 12
From Patient Evaluation to Opioid Overdose Prevention: Ten Steps to Make the Law Work for You and Your Patients

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Introduction

The pain medicine community faces significant challenges every day—a blend of business, clinical, and legal hurdles, ranging from declining reimbursements to changing clinical perspectives on the use of opioids and intense law enforcement and regulatory scrutiny surrounding clinic operations and prescribing decisions. Practitioners and patients may feel as if they have targets on their backs and believe they are caught in the middle of the intense battle over the clinical value of opioids for treating chronic pain. Understandably, practitioners express concern that the clinical side of the practitioner–patient relationship is marginalized and often relegated to a checklist of "cop-like" questions designed to fulfill licensing board rules and meet law enforcement expectations that doctors detect abusers, addicts, and diverters prior to prescribing controlled medication. While most practitioners accept and embrace the obligation to evaluate patients carefully and prescribe controlled medication responsibly [1], the system does not yet uniformly encourage the full development of the practitioner–patient relationship. Thus, practitioners find themselves scrambling to protect their clinical decision-making and patient access to chronic opioid therapy in a system that lacks consistency in stakeholder approach to what constitutes "proper prescribing" of controlled medication in the context of chronic, non-terminal pain.

The federal government, through the US Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (HHS-ASPE), recently announced [2] an initiative geared toward preventing opioid overdose deaths. The initiative is described in an issue brief entitled *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* [2]. HHS-ASPE makes clear that it has secured funds and committed per-

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sonnel to focus on "three priority areas, grounded in the best research and clinical science available, to combat opioid abuse:

(1) Opioid prescribing practices to reduce opioid use disorders and overdose;
(2) The expanded use of naloxone, used to treat opioid overdoses; and
(3) Expanded use of medication-assisted treatment (MAT) to reduce opioid use disorders and overdose." [2]

HHS-ASPE cites three objectives associated with the above-stated priorities:

(1) Improve clinical decision-making to reduce inappropriate prescribing;
(2) Enhance prescription monitoring and health information technology (health IT) to support appropriate pain management; and
(3) Support data sharing to facilitate appropriate prescribing [3].

To effect the initiative, HHS-ASPE announced four immediate areas of focus:

(1) Enhancing prescription drug monitoring databases;
(2) Establishing opioid prescribing guidelines for chronic pain and working to ensure effective implementation of guidelines through information technology (IT) to ensure improved medical record documentation and clinical decision-making;
(3) Expanding utilization of naloxone, accelerating the development and availability of new naloxone formulations and user-friendly products, and identifying and disseminating best practice naloxone delivery models and strategies to help patients "at risk" of overdose; and
(4) Addressing barriers that hinder access to MAT, which includes methadone and buprenorphine, by addressing policy and regulation that limit eligible providers and supporting research that informs effective use and dissemination of MAT and accelerates development of new addiction treatment medications [2].

The HHS-ASPE initiative may help bring some uniformity to increasingly divergent state rules and guidelines on chronic opioid therapy. However, these initiatives must be well thought out or the problems will continue. For example, while making naloxone available to prevent opioid overdose, in the wrong hands this drug may be a gateway to "zeroing-out" receptors to allow for a greater high upon renewed opioid abuse. In addition, these initiatives must consider the various positions adopted by states with guidelines and/or rules on opioid dose triggers for consultations and referrals, such as California, which has a guideline referencing 80-mg morphine equivalent dose (MED) as a *trigger for considering* whether the patient needs a specialty evaluation [4], and Washington State, which uses 120-mg MED and *mandates a consultation*, *unless* the patient's case and physician meet certain criteria [5]. In all cases, initiatives led by the federal government may have desirable goals, but they must also recognize the impact they will have on medical practices, and ensure prescribers have the tools they need to fulfill clinical and regulatory expectations.

Changes are coming to this practice community, and practitioners and patients must strive to work together to understand their respective responsibilities toward the safe use of opioids and do so in a manner that minimizes the potential for adverse outcomes and further encroachment upon the sanctity of the practitioner–patient relationship. This chapter is designed to facilitate physician understanding of current medicolegal obligations relating to the prescribing of chronic opioid therapy to treat chronic, non-terminal pain. Frontline pain practitioners are encouraged to understand the professional licensing board directives on pain management clinic operational standards and chronic opioid therapy. The tone of this chapter is intentionally "how to" and designed to support the physician who wishes to perform a self-evaluation of his/her compliance with medicolegal obligations and to bring their respective practices current and ready for the changes coming through the HHS-ASPE initiative. The main body of this chapter contains ten "how to" suggestions related to patient education and provider self-assessment on specific aspects of controlled substance prescribing compliance. The end of this chapter contains a quick reference tool designed to facilitate the practitioner's understanding of licensing board directives through a short self-audit process. The quick reference tool focuses on key compliance areas, such as patient risk evaluation, stratification, and monitoring, as well as patient education on important topics such as learning the signs of an overdose and steps to prevent an overdose.

Not a day goes by without a reminder of the mounting number of overdose deaths, amended or newly filed legislation purportedly targeting only "pill mills," and political commentary on "how to" address the country's "reliance on opioids." Once again, practitioners and patients find themselves amid a swirling sea of change, wondering what happened and how to stay the course. What is the answer to balancing patient access to quality pain care while also taking reasonable steps to prevent abuse, diversion, and opioid overdose? There is no easy answer, but this chapter endeavors to provide some help to practitioners and patients on key topics of education and preserving the relationship through proper documentation of the medical record.

Then and Now

In 2002, the focus was treating pain—it had become a fifth vital sign. The DEA and 21 Healthcare Organizations were about to embark upon a joint effort to balance patient access to controlled medication with practitioner and other stakeholder efforts to reduce the abuse and diversion of these drugs [6]. Clinical drug testing was not a big emphasis at the time, but by 2006, the DEA would reference it as an example of a treatment agreement provision designed to prevent abuse and diversion [7]. Then, the focus was being "docs" instead of "cops" to the numerous patients suffering from debilitating chronic pain. In 2015, the "now" focus is on controlling much of the clinical decision-making related to medication quantity, MED limits, consult and referral requirements, and even the length of time for

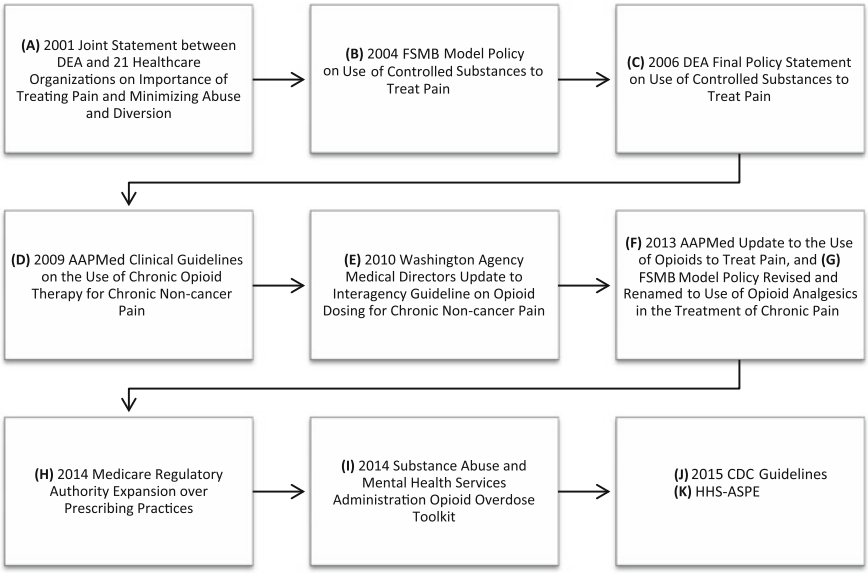

Fig. 12.1 Chronology of basic opioid prescribing policy [8]

overall chronicity of prescribing. Without question, these are important considerations, yet it is equally important to preserve practitioner discretion and patient choice about medication selection, dose, and chronicity of prescribing. Balance is required, and real objectivity should be the goal when third parties evaluate whether or not the underlying prescription was "legally" valid in the context of medical necessity and usual course of professional practice—the two critical elements of a valid prescription.

How did we get to where we are today? Figure 12.1 highlights some critical changes in key policy and professional guideline material between 2002 and 2015. It is important to remember that not all states follow the guidance offered by the American Academy of Pain Medicine (AAPMed), the Federation of State Medical Boards (FSMB), or Washington Agency Medical Directors Group (WA-AMDG). However, the materials published by and through these entities will continue to play an important role in the ongoing development of state regulatory material dealing with chronic opioid therapy and, likely, the Center for Disease Control and Prevention's (CDC) effort to universalize chronic opioid prescribing nationwide through the efforts of HHS-ASPE in reducing opioid overdose.

Practitioners therefore may wish to review the cited items and decide whether the suggestions contained within may be used to improve clinical practice and patient education. Similarly, practitioners may wish to chart out the evolution of pain management rules and guidelines within their states of licensure to better understand licensing board expectations. The last section of this chapter will facilitate a self-audit exercise and empower practitioners to take back some turf and make the law work for them and their patients.

Refresher—Basic Legal/Regulatory Framework

There are two basic levels of legal/regulatory authorities for controlled substance prescribing: federal and state governments and their agencies. Within the federal and state framework, there are three levels of legal/regulatory materials: laws, regulations, and guidelines/position statements (Fig. 12.2) [8].

Typically, *laws* are found in acts, codes, and/or statutes—federal or state. Examples include federal and state Controlled Substances Acts, and state Medical, Nursing, and Pharmacy Practice Acts, state Intractable Pain Treatment Acts, and state Electronic Prescription Monitoring Acts. Laws form the foundation of the legal/regulatory pyramid for prescribing controlled substances in general and for other legal/regulatory materials affecting pain management, such as controlled substance prescribing rules and regulations governing professional conduct.

Laws give permission to federal and state agencies to regulate the flow of controlled substances and, with respect to state licensing boards, to protect the public by setting minimum expectations/standards for the practice of medicine and use of controlled substances for pain management. Laws also contain penalty provisions (civil and criminal), which are enforceable through administrative or legal process.

Regulations and rules explain a corresponding law and set additional boundaries based specifically on the monitoring/sponsoring agency's interpretation of the law. Examples include the Code of Federal Regulations, which explains the Controlled Substances Act of 1970 and gives DEA oversight authority for the flow of controlled substances in the USA. Most states also have regulatory codes and publish rules explaining state controlled substances acts and medical practice acts.

Regulations and rules give agencies additional permissions to establish guidelines or position statements that further explain the regulations. Some state laws and regulations prohibit state licensing agencies from establishing "explanatory" or "interpretive" materials. Thus, some state medical licensing boards, like the medical boards in Illinois and Wisconsin, do not have expansive authority to adopt

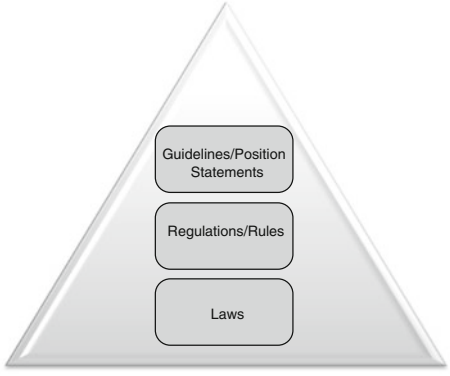

Fig. 12.2 Basic regulatory framework

controlled substance prescribing guidelines for pain management. In these states, practitioners often must look to area medical societies and to national organizations for references on opioid prescribing. Regulations and rules have the force of law, meaning violating regulations normally results in sanctions, such as licensing suspension or revocation, in addition to civil fines and penalties. Some states have both regulations and rules.

Guidelines (sometimes referred to as "position statements") contain an agency's explanation or interpretation of a particular subject. *Guidelines are not clinical care standards*. Rather, agencies use guidelines to establish *minimum* expectations of licensees related to the specific subject matter. Typically, those who fail to follow guidelines may face administrative sanctions (licensing restrictions or educational orders) unless one can show good (and often written) cause for the deviation from or failure to follow guidelines.

Despite these basic distinctions between laws, regulations, rules, and guidelines, lawyers use guidelines to establish the framework of civil and criminal lawsuits, including medical malpractice and wrongful death cases. Guidelines sometimes contain directives and language that are outdated and inconsistent with current clinical care standards. Practitioners located in states that lack or have outdated guidelines may find it useful to review the FSMB materials and materials published by mainstream organizations, such as a professional society or medical association. It is important to keep copies of any materials relied upon as a basis for clinical decision-making and regulatory compliance.

Refresher—What Makes a Controlled Substance Prescription Valid?

When an individual obtains a federal drug registration number, the DEA expects the registrant to follow federal controlled substances laws, regulations, and policies. The DEA expects clinicians to administer, dispense, and prescribe controlled substances for a *legitimate medical purpose while acting in the usual course of professional practice* [9]. The DEA also expects clinicians to *minimize the potential for the abuse and diversion of controlled substances* by adhering to applicable legal/regulatory boundaries and by following current, accepted clinical care standards [10].

A controlled substance prescription is therefore *valid* (1) when it is issued for a legitimate medical purpose, (2) by an individual practitioner who is acting in the usual course of professional practice, (3) while taking reasonable steps to prevent abuse and diversion [11]. Today, this obligation also likely includes "reasonable steps" to prevent opioid overdose, especially in those states with programs allowing easier access to address opioid overdose risk through increased access to naloxone [12]. States may lawfully impose stricter requirements to address state-specific challenges with controlled drugs. Figure 12.3 highlights the elements of a valid controlled substance prescription.

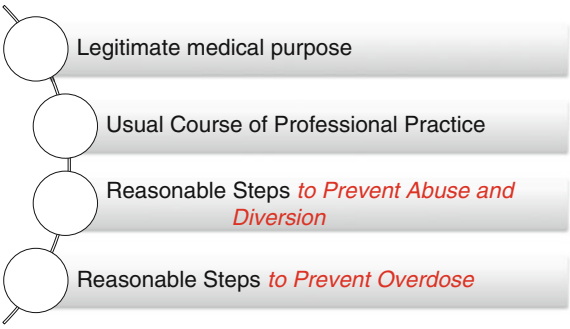

Fig. 12.3 Basic elements of a valid controlled substance prescription

In 2006, the US DEA published a Final Policy Statement on Dispensing Controlled Substances for the Treatment of Pain [7]. This publication, while dated, contains additional insight into the DEA's perspective on the three elements of a valid prescription and includes the following valuable comment about taking "reasonable steps to prevent abuse and diversion":

> Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion. The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, *exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse*. Again, each patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, *based on the physician's sound medical judgment and consistent with established medical standards* [13].

The DEA also publishes online information on cases against physicians [14]. The DEA categorizes this information into criminal and administrative case reports, and practitioners will find value in reviewing the information made public by the agency. In particular, the administrative case opinions offer a look at how government-retained medical experts talk about whether a practitioner acted in the usual course of professional practice when evaluating and monitoring patients using chronic opioid therapy. The true challenge is in the law enforcement and the medical expert interpretation of "usual course of professional practice" and "reasonable steps to prevent abuse and diversion." A discussion of the case law on these topics is beyond the scope of this chapter. Nevertheless, it is fair to say that while a medical expert's assessment of a controlled substance prescription and the clinical underpinnings is supposed to be "objective," the case reports tend to show that medical experts insert their subjective opinions regarding dose, quantity, chronicity, risk evaluation tools and frequency of use, drug testing methods and frequency, and other topics related to use of chronic opioid therapy. Some of the subjectivity may be due to a void in the evidence-based research in this area, leaving room for the expert's personal practices and preferences to supplant those chosen by the defendant-registrant.

Refresher—Breach of the Duty of Trust

In *USA, v. Schneider* [15], the trial judge sentenced Dr. Schneider to a thirty (30) year imprisonment, and the sentence included an enhanced penalty for healthcare fraud "if the violation results in death." 18 U.S.C. § 1347(a). The trial judge also found Dr. Schneider "abused his position of trust" over his patients, meaning when the prescriber does not act as a "reasonably prudent practitioner" (or act in the usual course of professional practice) when issuing a controlled substance prescription, the patient may be harmed (or is harmed) and the prescriber is viewed as abusing his/her position of trust over the patient; harsh penalties may apply, including the potential for a significant term of imprisonment. Similar concepts apply at the state licensing board level, where boards consider aggravating and mitigating information surrounding controlled substance prescribing decisions and practices, and penalties may include revocation of professional licenses as well as referral to law enforcement authorities for further investigation, including criminal prosecution.

Recently, a federal judge sentenced an Akron, Ohio, physician, to five years' imprisonment following a guilty plea to conspiracy to illegally distribute drugs and twenty (20) counts of illegal distribution [16]. The physician was registered with the State of Ohio Medical Board as a medical doctor specializing in family medicine, obstetrics, and gynecology. In court, the physician entered a guilty plea, admitting he distributed and dispensed more than 30,000 tablets of oxycodone, Oxycontin, and Opana, to various individuals without a legitimate medical purpose. He also admitted he *did so by acting outside the usual course of professional practice, because he prescribed the controlled medication without*:

(1) Adequate verification of the patient's identity or medical complaint;
(2) Adequate and reliable patient medical history;
(3) Performance of a complete or adequate examination;
(4) Establishment of a true diagnosis; and
(5) The use of appropriate diagnostic or laboratory testing, among other methods.

The physician and his staff used presigned blank prescription forms to facilitate their controlled substance prescribing to patients. The government asked the court to apply a two-point increase to the physician's overall sentence potential, agreeing with the government's claim the physician used a special skill to accomplish the crime and abused his position of trust relative to his patients and the public [17].

There are many more examples of cases against physicians, but it is not the purpose of this chapter to focus on these bad actors. It is, however, important to understand the "position of trust/special skill" argument and how violating the trust associated with medical degrees and controlled substance prescribing registrations may lead to enhanced penalties and terms of imprisonment in administrative and criminal prosecutions. Cases against prescribers often reference expert opinions about prescriber action or inaction [18] constituting activity outside the usual course of professional practice—activity that constitutes the breach of trust and misuse of a special skill. Such references to what a prescriber did or failed to do may be helpful

to the practitioner seeking to compile a checklist for use during a self-audit of prescribing habits and medical record documentation, and ultimately turned into a risk management work plan to support their good faith prescribing of controlled medication. Those wishing to know more about "Cases Against Doctors" will find many examples on the DEA's Web site [19]. Criminal prescribing [20] is a slap in the face to all the practitioners who work hard to do it right and legitimately prescribe controlled medication to treat pain.

Shall and Should, and the Reasonably Prudent Practitioner

So what is it that a "reasonably prudent" practitioner does to meet the "usual course of professional practice" standard for a valid prescription? DEA regulations do not give much insight as to what the agency means by "usual course of professional practice." There are federal case opinions that attempt to explain what is meant by this element of a valid prescription, and most acknowledge the relevance of state licensing board rules and guidelines in making the determination. Once again, a discussion of the legal analysis associated with the "usual course of professional practice" standard is beyond the scope of this chapter.

State licensing boards use "directive" language in rules and guidelines, such as the practitioner "shall" perform a task or document certain information, and the practitioner "should" take certain steps when re-evaluating a patient. These terms are often associated with the board's explanation of how it intends for its licensees to use a rule or guideline. For example, the Texas Medical Board (TMB) has a rule (Chapter 170) on pain management, and the rule also contains the board's policy for "proper" pain management. A guideline within a rule usually means the document is replete with "directive" language on what the board thinks the physician is required to do and what he/she should do absent a good and documented reason to do otherwise. Here is the relevant language from the TMB's Chapter 170:

> The intent of these guidelines is not to impose regulatory burdens on the practice of medicine. *Rather, these guidelines are intended to set forth those items expected to be done by any reasonable physician involved in the treatment of pain*. The use of the word "shall" in these guidelines is used to identify those items a physician is required to perform in all such cases. The word "should" and the phrase "it is the responsibility of the physician" in these guidelines are used to identify those actions that a prudent physician will either do and document in the treatment of pain or be able to provide a thoughtful explanation as to why the physician did not do so [21].

Understanding the state licensing board's policy for proper pain management is critical to a comprehensive compliance program—clinical and regulatory. As the next section reveals, a solid working knowledge of licensing board expectations is critical in light of Medicare's expanded authority to examine prescribing patterns of its enrolled providers or provider applicants.

Expanded Agency Authority—CMS and Prescribing Patterns

Healthcare professionals, facilities, and equipment suppliers must be enrolled in the Medicare program to receive payment for covered items and services. In 2006, the Centers for Medicare & Medicaid Services (CMS) adopted a comprehensive set of enrollment rules purposed to protect the Medicare fund and to ensure payments are made only to qualified providers and suppliers [22]. In 2014, CMS took additional steps to revise and supplement enrollment regulations to further protect the integrity of program payments, and several other rules take effect throughout 2015. This section focuses on CMS's expanded authority to review the prescribing practices of Medicare program enrollees and to take action against those who are believed to be "inappropriately prescribing" controlled medications under Medicare Part D.

CMS references an Office of the Inspector General (OIG) report that highlights instances in which physicians and eligible professionals prescribed "inordinate amounts" of drugs to Part D beneficiaries in 2009, as well as prescribers of high percentages of Schedule II and III drugs [23]. In the same report, OIG recommends that CMS exercise greater oversight of the Part D program. Consequently, CMS added a new provision to its enforcement regulations allowing the agency to deny an enrollment application if the prescriber's DEA Certificate is suspended or revoked or if the prescriber's ability to prescribe drugs has been suspended or revoked by the state licensing or administrative body in which the prescriber practices [24]. CMS's rationale for expansion of its authority here pertains to its belief that the loss of the ability to prescribe drugs via a suspension or revocation of a DEA Certificate or by state action is a "clear indicator" that a physician or eligible professional may be misusing or abusing his or her authority to prescribe such substances.

CMS also has authority to initiate action against an enrollee if it determines that a physician or eligible professional has engaged in improper prescribing practices [25]. One way CMS might make such a determination is if the agency finds that the prescribing pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. Another way CMS might use its expanded authority is when the agency finds the pattern or practice of prescribing fails to meet Medicare requirements. Figure 12.4 shows the "criteria" CMS may use to make its determinations, and provides support for the self-audit proposed at the end of this chapter.

Clearly, CMS's expanded authority to evaluate prescribing practices, and to do so under these vague terms, suggests the time is ripe—whether or not you are an enrolled Medicare provider—to ensure clear documentation of practitioner prescribing rationale matched against the facts of each individual patient's medical situation.

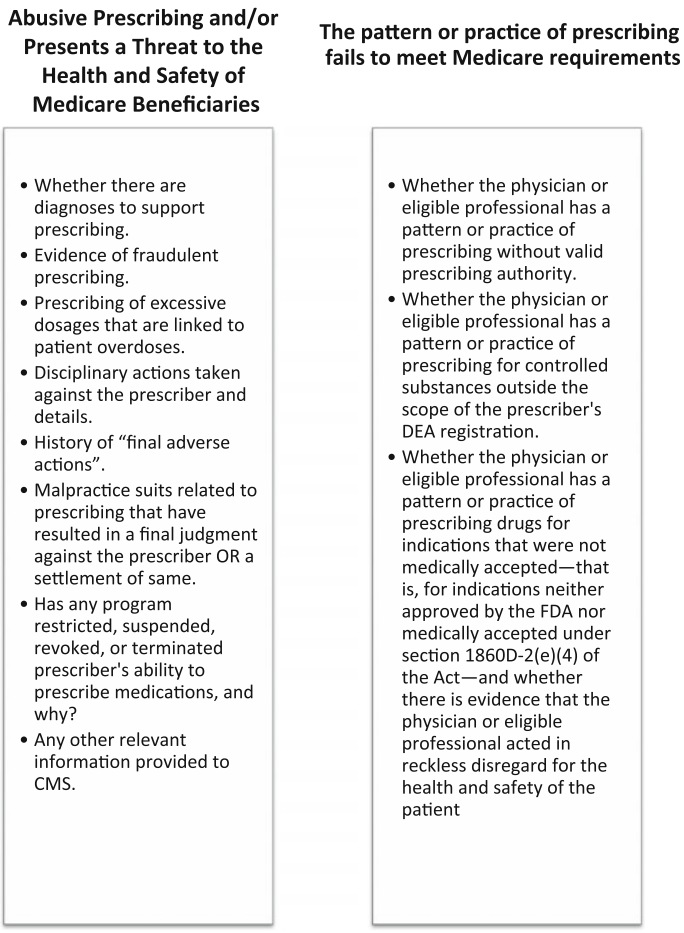

Fig. 12.4 Medicare criteria for abusive prescribing and problematic patterns

Self-Assessment of Prescribing Compliance—Ten Steps

Prescribing compliance is generally not something one can self-assess in a single setting. Similarly, the patient's clinical need for controlled medication is not easily evaluated in a single visit, as the patient's full history and medical condition may not known be until several months into the practitioner–patient relationship. The tension here is obvious: Regulatory authorities view prescribing practices in a silo, but the development of a treatment plan and the prescriber's rationale develops over a series of visits and a constant filter of information—incoming and outgoing. Practitioners need time to gather facts, identify boundaries, and apply knowledge to the task at hand.

This section describes the basic self-assessment process for evaluating whether the practitioner is "acting in the usual course of professional practice," as a reasonably prudent practitioner, when prescribing controlled medication. Intentionally omitted are points about the more technical aspects of issuing a controlled substance prescription, such as how to properly date and sign a prescription or what type of information is required to be on the prescription pad or how e-prescribing works. It is the author's hope that practitioners will incorporate the following ten suggestions into their overall plan to minimize the potential of a "hit-and-run" patient experience. The self-audit process is intended to help the prescriber improve his or her documentation of the prescriber–patient experience and better situate the medical record in the event of an audit.

The Ten Steps You Can Do to Take Back Your Turf

The goal of a self-audit is to develop and protect your position as a "reasonably prudent" practitioner. The ten-step process will also facilitate interaction with legal counsel, should you be in that position (Fig. 12.5) [26].

It will take time to accomplish the ten-step review described below; there really is no way to shortcut these tasks, as each of them is critical to a complete self-assessment. If, however, you already have a prescribing compliance notebook (Step 1) and you have reviewed your state licensing board materials in the past three months (Step 2), you may wish to start at Step 3 or Step 4. Whatever the case, the steps outlined below will contribute to the overall success of your efforts to perform a complete self-audit and ultimately create a comprehensive compliance program for controlled substance prescribing in the medical practice.

Fig. 12.5 Ten-step summary

Step 1—Create and Keep a Compliance Notebook—Hardcopy or Virtual

Goal: *To create a go-to resource for major clinical and regulatory resources on controlled substance prescribing; to create a resource for use in practitioner self-audit and with legal counsel when working on risk management policies and protocols or an active legal matter.*
Rationale: The body of clinical and legal materials governing controlled substance prescribing is large, and compiling a notebook proactively can minimize stressors associated with the task and avoid panic should the need for the information arise in connection with legal proceedings.
Considerations and Recommendations: Obtain and label a three-ring binder "Prescribing Compliance Handbook," or create a virtual binder online in a Dropbox or basecamp-type solution. Assign someone on your staff to take responsibility for organizing the binder and making sure it stays current. Use this binder: when you have questions about compliance; when you host internal education for your staff; if you face a payor inquiry about your prescribing policies, or; if you come under investigation by your licensing board or DEA. You may find that your business attorney does not have a solid working knowledge of all of the clinical and regulatory material governing pain management and controlled substance prescribing; thus, the binder may be useful in communications with your business attorney. While the handbook is not a substitute for good legal counsel and consulting expert input, having it will facilitate everyone's understanding of current expectations for the "reasonably prudent" pain practitioner.

Step 2—Review Your Licensing Board Materials; Keep the Most Relevant Items in your Notebook

Goal: *To ensure your compliance handbook contains relevant licensing board materials on prescribing controlled medications, pain management—acute, chronic, and palliative—medical office-based treatment of opioid addiction, pain clinic registration and operation, prescription drug monitoring databases, and use of naloxone to prevent opioid overdose.*
Rationale: This one is obvious: You need to fill your notebook with relevant licensing board materials and take steps to ensure you have the most current material relating to your licensing board's expectations when controlled medications are part of the treatment plan.
Considerations and Recommendations: Go online and search for your licensing board's home page. If you are licensed and treat patients in more than one state, then you will need to repeat the process for each licensing board and create a separate notebook for each state. Most licensing board Web sites offer a search feature, so enter common search terms such as "opioid guidelines," "pain management," and "treatment of addiction." Some licensing boards are better than others at providing licensees with easy access to pain management and addiction treatment materials. A good example is the State Medical Board of Ohio [27],

which publishes its own prescriber resources page for licensees. When you search your licensing board's Web site, look for the following commonly grouped items: (1) Practice Act (medical, nursing, pharmacy); (2) Pain Clinic Registration Act (most states do not have these, but several southern states do, including, but not limited to, Florida, Georgia, Kentucky, Mississippi, Tennessee, and Texas); (3) Controlled Substances Act (more about authority to schedule and control the flow of drugs within the state, but often supplying information about criminal acts related to controlled substances); (4) Prescription Drug Monitoring Database Act and Data Monitoring Program Rules (PDMP), relating to your responsibilities to look up and handle information about patient pharmacy utilization for controlled medications; (5) Licensing Board Rules, including those specific to unprofessional conduct, pain management, addiction treatment, and pain clinic operation; and (6) Licensing Board Guidelines and Position Statements, again specific to pain management, addiction treatment, PDMP, and pain clinics. There are many more areas of licensing board and state regulatory material that may impact controlled substance prescribing, so check with your legal counsel to ensure you have all the material that contains rules and guidelines governing your daily medical practice operations and controlled substance prescribing standards.

Step 3—Identify and Review Major Government and Professional Organization/Society Materials on Chronic Opioid Therapy, Office-Based Treatment of Addiction, and Opioid Overdose Prevention; Keep Highly Relevant Documents in Your Notebook

Goal: *To identify and review, as well as maintain copies of, major government and professional organization/society articles, guidelines, and tools related to chronic opioid therapy, office-based treatment of opioid addiction, and opioid overdose prevention, including material on pain management decision-making, patient risk evaluation and monitoring, opioid selection, and the use of naloxone with patients at risk for opioid overdose.*

Rationale: Licensing boards and medical experts often refer to major clinical articles and publications released by government and major professional organizations when evaluating a practitioner's controlled substance prescribing practices and related treatment practices. Licensing boards also use this material to create licensing board rules and guidelines. A review of these materials will facilitate the practitioner's goal of creating a comprehensive checklist for a self-assessment of controlled substance prescribing practices and overall adherence to "reasonably prudent" practitioner standards for the area of practice. This review will help the practitioner identify common threads between licensing board rules and guidelines, and mainstream clinical literature, on using chronic opioid therapy to treat chronic pain, delivering addiction treatment in the medical office, and opioid overdose prevention. The exercise will also facilitate the creation of written practice protocols and common tools for gathering patient information and documenting the medical record.

Considerations and Recommendations: Start with major federal agencies, such as the DEA, the FDA, and SAMHSA. Use agency Web sites [28] for easy access to DEA Registrant Manuals, FDA REMS Material, the CDC Guidelines, and SAMHSA Opioid Overdose Prevention Toolkits and related items. When reviewing professional organizations/societies, you may wish to first consider the Model Policy documents published by the FSMB [29]. You may also find helpful material through the AAPMed [30], the American Society of Pain Educators (ASPE) [31], and the American Academy of Pain Management (AAPMgmt) [32].

The pool of materials in Step 3 is significant, and you may wish to narrow it down a bit by focusing first on FSMB materials and then turning to educational items derived from the federal agencies and professional societies. Some may find it helpful to include copies of DEA regulations, all of which are available through the DEA Office of Diversion Control's Web site [33].

Step 4—Create a Basic Self-Audit Checklist and Perform an Internal Review of Three to Five Medical Charts; Review the Results with Practice Managers and Legal Counsel

Goal: *To create a checklist of items the prescriber can use to evaluate his/her adherence to state licensing board rules and guidelines on the use of chronic opioid therapy for pain management.*

Rationale: Practitioners like to know that when they provide treatment with controlled substances, they are doing so in a way that maximizes benefits to the patient and minimizes the potential of a bad outcome—for both the patient and the practitioner. Licensing boards provide some sense of the "board's" idea of what is expected when chronic opioid therapy is part of the treatment plan. It is important to understand that a licensing board's expectations are often described as "minimum standards" to maintain licensing in the state, meaning practitioners will be expected to meet the minimum standards and then some to demonstrate that they have acted in a "reasonably prudent" fashion when prescribing controlled medications.

Considerations and Recommendations: To create a checklist tool focused on your licensing board's materials (or FSMB materials if you are in a state that lacks licensing board guidelines/rules), divide a piece of paper (or create three columns in a computer document) into three columns: Column 1—topic area; Column 2—shall/must; and Column 3—should/may. As you read each article/item, highlight and write down any directive language and specific instructions from your licensing board. Ultimately, you will use this checklist in Step Five, below.

Sample Self-Audit Checklist

Though simplified, Table 12.1 contains a sample checklist on the seven basic elements of most licensing board rules and guidelines on the use of opioid analgesics for the treatment of chronic pain.

Table 12.1 Sample self-audit checklist [45]

Topic area	Shall/Must	Should/May
Patient history	*Shall* obtain a medical history of the patient—general and specific to the pain complaint.	*May* wish to contact prior treating practitioners to fill in any gaps related to medical records of the patient's history.
Physical examination	*Shall* perform a physical examination prior to prescribing a controlled substance.	The examination *may* be focused and tailored to the patient's specific complaint of pain.
Treatment plan	*Shall* create a written treatment plan, containing (a) the goals for treatment, (b) diagnostic test orders, and (c) orders for non-drug treatment, as appropriate, and identifying the terms of an opioid trial, if this course of treatment is selected. An opioid trial *shall* be for a reasonable period commensurate with the patient's specific pain needs and be explained and fully specified in the medical record. The treatment plan *shall* also include a written plan for discontinuing the opioids.	*Should* document specifically other treatments tried and failed (or inappropriate) prior to prescribing opioid therapy.
Informed consent	*Shall* discuss the risks and benefits of opioid therapy with the patient (or caregiver/guardian), along with special issues for the use of this medication and treatment alternatives, if any.	*Should* document the informed consent process in the medical record and revisit consent issues as dose changes, medication adjustments are made, including the addition of other controlled medication.
Treatment agreement	*Shall* use a written treatment agreement outlining the patient's responsibilities when treatment involves controlled substances, *including* the responsibility to use only one provider for controlled substance prescribing, to fill prescriptions at a single pharmacy, and to provide a urine (or other) specimen for drug testing when asked to do so by the practitioner, etc. *This agreement shall* (a) contain provisions for monitoring the patient's compliance with the treatment plan, including notification to the patient that the practitioner will check and use information from the state's prescription drug monitoring	*The practitioner should* review the terms of the agreement prior to prescribing controlled substances to the patient. *The practitioner should* allow the patient sufficient opportunity to ask questions about the agreement and the specifics of treatment with controlled substances, and document the questions asked and the answers given in the medical record to ensure understanding between the parties.

(continued)

Table 12.1 (continued)

Topic area	Shall/Must	Should/May
	program; (b) contain notification of the consequences if the patient does not keep his/her promises as made in this document; (c) be reviewed, signed by the patient, and kept in the medical record; and (d) be updated at least annually, and when monitoring circumstances change.	
Drug testing	*The practitioner shall* drug test patients placed on chronic opioid therapy, and such testing shall take place (a) prior to issuing the first prescription for a controlled medication and (b) periodically thereafter at least twice every twelve (12)-month period, or more if the patient's medical history and risk level warrant. *The practitioner shall* document test orders, test results, and clinical decision-making following the review of test results in the medical record.	*The practitioner should* test for common drugs of abuse, including illicit drugs, and consider whether to add or subtract drugs from the test panel based on the individual patient's medical history and properly evaluated risk potential for drug abuse, addiction, diversion, and overdose.
Periodic review	*The practitioner shall* periodically review the patient's progress under the treatment plan and make adjustments, as necessary, to evaluate whether controlled medication remains indicated in the patient's individual case. "Periodically" means the practitioner shall evaluate the patient at least every twelve (12) weeks, or more frequently if warranted by existing or developing clinical and/or risk factors. All follow-up evaluations shall include a written assessment of activity, analgesia, adverse events, aberrant behavior, and affect.	*The practitioner should* carefully monitor the patient's opioid use using medication counts, database checks, drug testing, behavioral health evaluations, and referrals to specialty resources.
Morphine equivalent dose (MED)	**Not all states have a mandate on this topic, so no example is provided to avoid confusion on this very hot topic.*	***Example from California Guidelines Only***: *The practitioner should consider a consult with or a referral to an appropriate specialist as the patient approaches a MED value of* ***80 mg.*** [46]

(continued)

Table 12.1 (continued)

Topic area	Shall/Must	Should/May
Consultations and referrals	*The practitioner shall use consultations and make referrals as necessary to accomplish the directives in these rules and to ensure the patient's initial and ongoing use of controlled medication is for a legitimate medical purpose and appropriate in the usual course of professional medical practice.*	*The practitioner should document all consultations and referrals and relate them to the ongoing treatment plan and medical decision-making.*

You may wish to perform this same exercise using government or mainstream professional organization/society materials. If you decide to do so, you may need to alter the table slightly when you do as these groups do not typically use "shall" and "must" terminology to describe recommendations to practitioners. In any case, the point of the exercise is to create a checklist by which you can measure your own practices and make any necessary improvements. Very recent government publications on preventing opioid overdose are likely to lead soon to changes in licensing board guidelines on the same topic. For example, the SAMHSA Opioid Overdose toolkit [34] contains a recommendation that practitioners *consider* prescribing naloxone to patient's "at risk" of opioid overdose. If a practitioner faces a legal challenge related to an opioid overdose, it is very likely that the medical expert for the opposing party would testify "a reasonably prudent practitioner would consider whether naloxone is appropriate for his/her patients and discuss the matter during office visits." This same medical expert would also likely state "a reasonably prudent practitioner would prescribe naloxone to patients identified in an "at-risk" category, even if ultimately the patient does not fill the prescription because of cost (the government is working hard to drive down costs associated with equipping patients "at risk" of opioid overdose with a naloxone kit)" [2]. Of course, much back-and-forth battle would take place over the challenges associated with identifying "at-risk" patients, and the realities associated with supply of these kits, but the damage is often done when the prescriber failed to address the matter at all.

The overall goal in creating this self-audit checklist is to facilitate a practitioner's ability to create a framework for controlled substance prescribing due diligence and the practitioner's ability to demonstrate "good faith" compliance with published guidelines and rules—the ability to demonstrate "reasonable prudence" with the prescription pad.

Step 5—Review Your Forms and Make Necessary Changes to Render Them Consistent with Your Self-audit Checklist

Goal: *To align common practice forms with licensing board rules and guidelines on opioid prescribing and pain management; to ensure consistent use of terminology used in licensing board rules and guidelines.*

Rationale: When practice forms, such as informed consent and treatment agreement documents, contain words and phrases used by state licensing boards in rules and guidelines on opioid prescribing and pain management, documentation tends to demonstrate your familiarity with the rules and guidelines and help prescribers and practice staff set boundaries consistent with board expectations. Additional benefits are realized when documentation lines up with licensing board expectations and terminology in current, peer-reviewed literature. Proper documentation is also critical to overcoming an investigation tied to inappropriate prescribing.
Considerations and Recommendations: Gather standard patient forms, including informed consent and treatment agreement documents. Print out a copy of current state licensing board rules and guidelines on the use of chronic opioid therapy to treat pain (or similar). If you practice in a state lacking such rules and guidelines, consider using the FSMB's 2013 Model Policy Statement on the Use of Opioid Analgesics to Treat Chronic Pain and compare the language in your forms to the language used in the FSMB document. The major focus of your review will be a comparison of your licensing board's terminology with the terminology in your practice forms. If you start with your treatment agreement document, your review will go like this: compare the language of your state board's rule/guideline (or the FSMB 2013 Model Policy) on "treatment agreements" with the language used in your "treatment agreement."

Ideally, your treatment agreement should include and track the language used by your state licensing board to refer to this concept. Pay special attention to whether the board's rule/guideline refers to the patient agreement as a "treatment agreement" or "narcotic contract." Most states use the phrase treatment agreement, but some may use "informed consent." Similarly, compare the actual terms of your treatment agreement provisions with the terms set forth in the board's rule or guideline. Your treatment agreement should contain the same provisions used by your licensing board. If your board's materials are outdated, use the treatment agreement provisions cited by the FSMB in its 2013 Model Policy, so you have a nationally recognized resource to cite if questioned on your treatment agreement (or similar document). The FSMB's 2013 Model Policy, as well as most state medical licensing boards, more clearly differentiates between the concepts of informed consent and treatment agreement, even though the FSMB suggests it may be acceptable to combine the provisions or terms of each concept into a single document for convenience purposes [35]. Figure 12.6 contains the language from the FSMB Model Policies from 2004 and 2013 on the subject of "treatment agreement." Figure 12.7 contains the language from these two resources on the subject of "informed consent."

From a legal perspective, it may not be wise to combine the concepts and specific provisions of informed consent with the specific provisions of a treatment agreement; patients may claim a failure of a true informed consent process, and practitioners may be tempted to relegate the informed consent process to a piece of paper, which further increases the potential for legal exposure. Remember, if you are investigated or prosecuted, most of your prescribing-related documentation will

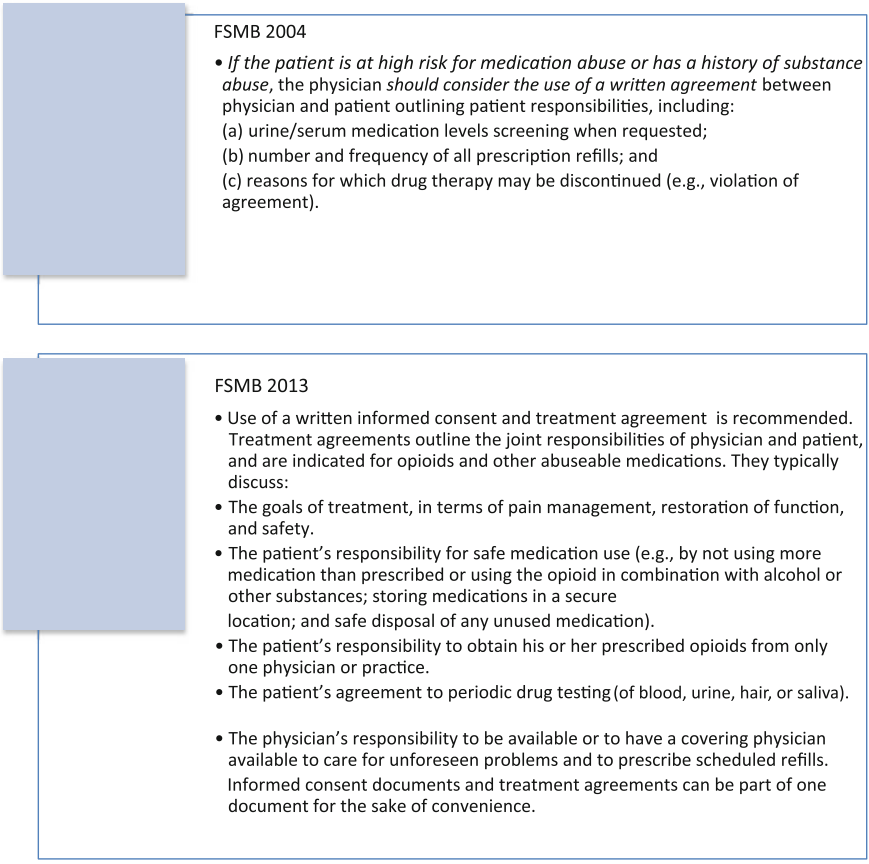

Fig. 12.6 Basic evolution of treatment agreement language in policy statements and licensing board rules

end up literally on a courtroom wall making it very easy to see whether you put some thought into patient boundaries and obligations or simply copied a document from someone else without first considering whether it followed licensing board rules/guidelines. If you use a document supplied by a medical society or other professional organization, it is advisable to compare the terminology in the document with the terminology contained within your state board's pain guideline or rule. A professional society's silence in a sample treatment agreement on controversial issues, such as marijuana use with opioids, alcohol and opioids, and drug testing frequency, may not offer you much protection. Your position may be more defensible in that situation, but be sure to consider community standards and your licensing board's position.

In any case, pay close attention to the emphasis your state licensing board places on the process of informed consent and make sure you take your cues from your

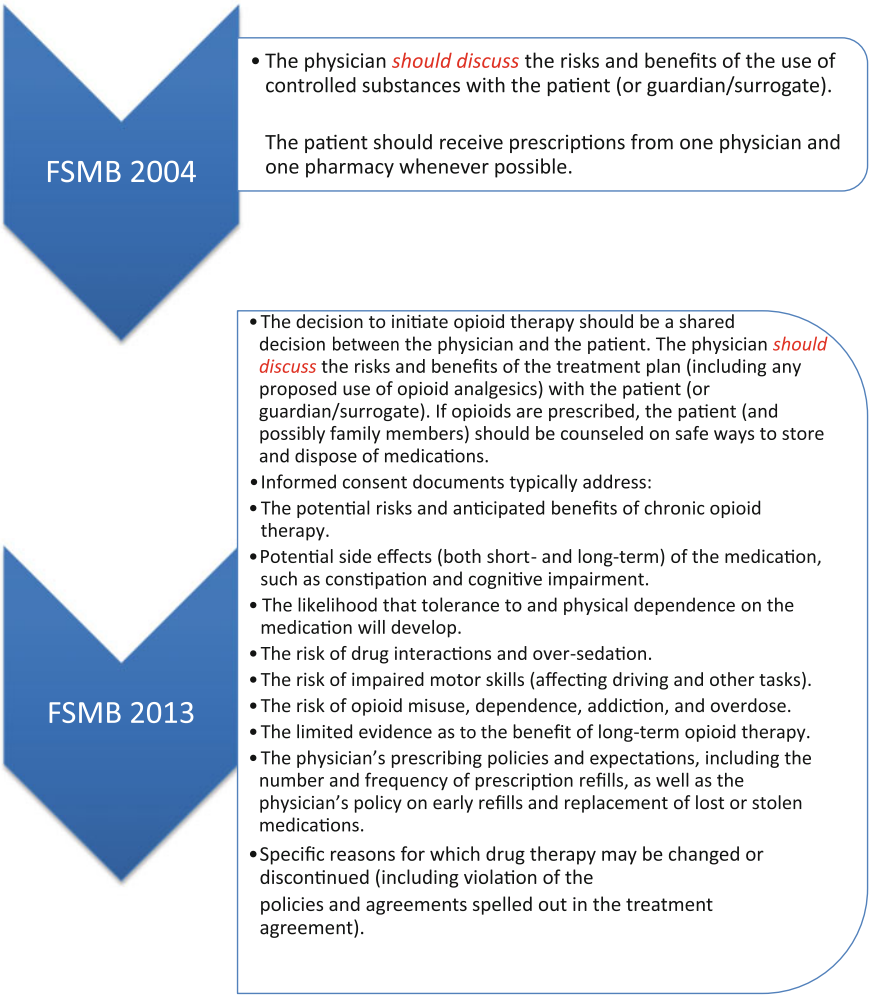

Fig. 12.7 Basic evolution of informed consent language in the FSMB 2004 and 2013 Model Policy

licensing board and the FSMB, so you have something to point to if someone challenges your informed consent process. Informed consent directives have similarly changed over time and merit review.

Step 6—Review SAMHSA Opioid Overdose Toolkit

Goal: *To gather current educational information related to opioid overdose prevention, along with current data on patients believed to be "at risk" of potential overdose; to understand how the use of naloxone kits (injectable or intranasal) may fit into an overall risk management strategy to minimize the potential of overdose in all patients.*

Rationale: Opioid overdose is a major problem in this country. "At-risk" patients go well beyond the traditional abuser and addict population, and include patients using high doses of extended release/long-acting opioid formulations [36], patients with medical conditions that cause some sort of respiratory distress [12], and patients undergoing rotation from an opioid, like hydrocodone or morphine, to methadone [36]. Practitioners should assess all patients who are or will be receiving opioid analgesics, especially when prescribing involves chronic opioid therapy—for more than 90 consecutive days. Once assessed, practitioners should consider whether the patient is a candidate for a naloxone overdose prevention kit. The use of naloxone in combination with chronic opioid therapy is a relatively new concept. Proactive prescribing of naloxone kits may not be fully embraced by state medical and nursing boards; it may not even be legal in some states. Practitioners should actively seek more information from licensing boards and professional medical organizations.

Considerations and Recommendations: Those who prescribe controlled substances to treat pain have always been held accountable for preventing opioid overdose, but not to the same degree seen today in media headlines, federal and state law enforcement efforts, and courtrooms nationwide. Opioid overdose prevention is now among one of the most talked about topics when it comes to addressing the prescription drug abuse problem in the US. Federal agencies, such as the Substance Abuse Mental Health Services Administration (SAMHSA) and the CDC, are now actively pursuing a universal approach to stemming the tide of overdose deaths associated with prescription medication misuse, especially opioid misuse. Practitioners should read the documents shown in Fig. 12.8 to facilitate understanding of the federal government's position on preventing overdose and professional licensing board involvement in adopting more localized guidelines for licensees.

Note, the SAMHSA Opioid Overdose Toolkit contains several versions—one each for practitioner, patient, community, family member, and first responders. At the

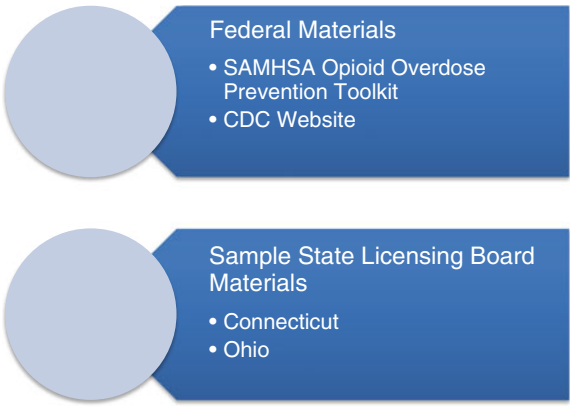

Fig. 12.8 Add to your library—federal and state opioid overdose prevention materials

OPIOID OVERDOSE
The risk of opioid overdose *can be minimized* through adherence to the following clinical practices, which are supported by a considerable body of evidence.

ASSESS THE PATIENT. Obtaining a history of the patient's past use of drugs (either illicit drugs or prescribed medications with abuse potential) *is an essential first step* in appropriate prescribing.

Such a history *should include very specific questions.* For example:
1. "In the past 6 months, have you taken any medications to help you calm down, keep from getting nervous or upset, raise your spirits, make you feel better, and the like?"
2. "Have you been taking any medications to help you sleep? Have you been using alcohol for this purpose?"
3. "Have you ever taken a medication to help you with a drug or alcohol problem?"
4. "Have you ever taken a medication for a nervous stomach?"
5. "Have you taken a medication to give you more energy or to cut down on your appetite?"
6. "Have you ever been treated for a possible or suspected opioid overdose?"

Fig. 12.9 Basic "at-risk" questions from SAMHSA Opioid Overdose Toolkit. From Substance Abuse Mental Health Services Administration [37]

very least, read the practitioner and patient versions. Look for "should" directives within the practitioner version and make a list of SAMHSA's recommendations for assessing patients for "risk of overdose" and taking preventative action by prescribing naloxone kits and through other boundaries, such as visit frequency and other monitoring tools. Make a list of these "directives" and use the list to evaluate your current practices. Figure 12.9 contains a sample set of patient assessment questions excerpted from the SAMHSA prescriber's opioid overdose toolkit [37] to help determine whether a patient might be "at risk" of an opioid overdose based on their past relationship with medication.
Your assessment should also include a specific review of the other characteristics SAMHSA designates as placing a patient "at risk" of opioid overdose, as reflected in Fig. 12.10.
The language of the SAMHSA Opioid Overdose Toolkit encourages practitioners to make naloxone kits available to patients who fall into one of these "at-risk" groups [34], and failure to properly consider and document medical decision-making on this issue may give rise to potential for legal liability.

State materials are not as widely available on the topic of opioid overdose prevention as one might think. The first large-scale opioid overdose prevention project began in Wilkes County, North Carolina, with an initiative now widely known as Project Lazarus [38], the first program designed to distribute naloxone kits to at-risk patients and caregivers/family members. The North Carolina Medical Board was the first licensing board to adopt an opioid overdose prevention position statement [39]. More recently, Ohio took action to adopt one of the first (and most comprehensive) joint guidance documents on opioid overdose prevention through its medical, nursing, and pharmacy boards. The Ohio guideline contains a broader set of "at-risk" patient groups [12] than does the SAMHSA toolkit, as illustrated in

CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT'S INITIAL OPIOID PRESCRIPTION

Naloxone competitively binds opioid receptors and is the antidote to acute opioid toxicity. With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit containing naloxone, syringes and needles or prescribing Evzio® which delivers a single dose of naloxone via a hand-held auto-injector that can be carried in a pocket or stored in a medicine cabinet to use in the event of known or suspected overdose.

Patients who are candidates for such kits include those who are:

Taking high doses of opioids for long-term management of chronic malignant or non- malignant pain.

Receiving rotating opioid medication regimens (and thus are at risk for incomplete cross-tolerance).

Discharged from emergency medical care following opioid intoxication or poisoning.

At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids.

On certain opioid preparations that may increase risk for opioid overdose such as extended release/long-acting preparations.

Completing mandatory opioid detoxification or abstinence programs.

Recently released from incarceration and a past user or abuser of opioids (and presumably with reduced opioid tolerance and high risk of relapse to opioid use).

It also may be advisable to suggest that the at-risk patient create an "overdose plan" to share with friends, partners and/or caregivers. Such a plan would contain information on the signs of overdose and how to administer naloxone (e.g.: using a FDA-approved preparation of naloxone, a naloxone auto-injector or other FDA approved devices as they become available) or otherwise provide emergency care (as by calling 911).

Fig. 12.10 SAMHSA "at-risk" patient populations and overdose prevention recommendations. From Substance Abuse Mental Health Services Administration [37]

Fig. 12.11. Practitioners may wish to consider the Ohio guideline if practicing in a state lacking opioid overdose prevention guidelines [12]. It is important to stay current in this developing area, and you can do so by assigning someone in your practice to check your licensing board's Web site monthly to determine whether opioid overdose prevention rules or guidelines have been adopted.

When a state licensing board lacks a rule or guideline on opioid overdose prevention, practitioners should consider the "at-risk" patient populations named in

Patients with the Risk Factors Below May be in Danger of an Opioid Overdose

These risk factors may be indicators for prescribing or personally furnishing naloxone directly to the patient or to a third party that is in a position to assist an individual who meets these risk factors. The factors include, but are not limited to:

1. Recent medical care for opioid poisoning/intoxication/overdose
2. Participant in Medication-Assistance Treatment (MAT) for opiate addiction
3. Suspected or confirmed history of heroin or nonmedical opioid use
4. High-dose opioid prescription (≥80mg/day morphine equivalence)
5. Any Methadone prescription for opioid naïve patient
6. Recent release from jail or prison with a history of opioid abuse
7. Recent release from mandatory abstinence program or drug detoxification program
8. Enrolled in Methadone or buprenorphine detoxification or maintenance program (for either addiction or pain management)
9. Any opioid prescription, known or suspected: smoking, COPD, emphysema, asthma, sleep apnea, or other respiratory system disease, renal or hepatic disease, alcohol use, concurrent benzodiazepine use or any concurrent sedating medication use, concurrent antidepressant prescription, remoteness from or difficulty accessing medical care, voluntary patient request for naloxone, or any other factor that makes the patient at high-risk for opioid overdose.

Fig. 12.11 Ohio factors for "overdose risk." From State of Ohio, Regulatory Statement [12]

both the SAMHSA and Ohio documents and adopt their own "at-risk" criteria. Carefully evaluate patients for their opioid overdose risk status and, at the very minimum, educate them about the possibility and signs of overdose. Use the SAMHSA patient and family member portion of the opioid overdose prevention toolkit as an educational handout, and consider prescribing a naloxone kit if the patient presents with any of the "at-risk" criteria or makes a supportable request for a kit. Failure to take these steps may be viewed by licensing boards and controlled substance authorities, including the DEA, as acting outside the usual course of professional practice when prescribing opioids.

Patient education is crucial to a proper informed consent process. The SAMHSA Opioid Overdose Prevention Toolkit for Prescribers contains a discussion of informed consent topics related to opioid overdose prevention. Consider giving copies of the toolkit to clinical staff and designate someone in your practice to serve as a patient education coordinator. Decide how you will go about educating your patients on this important topic. Will you give your patients their own copies of the toolkit? Will you make available waiting room copies? Will you take excerpts from the toolkit and turn them into posters for your examination rooms? How will you handle medical record documentation of your educational efforts here? Naloxone

kits are not presented here as the be-all and end-all solution to opioid overdose prevention, and the kits certainly present their own risks, as they may precipitate severe withdrawal symptoms in patients physically dependent on opiates, and present other challenges to practitioners attempting to properly use them with patients [40]. Despite potential side effects and safe use challenges, both federal and state governments have seen fit to use them on the front lines in the fight to stop opioid overdoses and save lives.

Step 7—Prepare a Work Plan Using Core Risk Metrics to Improve your Practice Protocols on Critical Risk Issues

Goal: *To identify and use core risk metrics, such as dose, drug combinations, risk level associated with opioid use and potential for opioid overdose, need for consult/referral (or internal peer review or consult with peer if specialist), visit frequency, and various aspects of risk monitoring, to create a more universal approach to setting boundaries in chronic opioid therapy*.

Rationale: Licensing board material (rules, guidelines, enduring educational material), DEA Administrative Case Opinions and Federal Appellate Court Opinions, and a developing body of clinical literature discuss various risk metrics used to evaluate whether the prescriber acted "within the usual course of professional practice" when prescribing controlled medications to patients. A review of the 2013 FSMB Model Policy on the Use of Opioid Analgesics to Treat Chronic Pain, reveals core risk metrics, including the potential relevance of dose, drug combinations, patient risk level, visit frequency, risk monitoring, including the use of prescription drug monitoring databases, medication counts, and drug testing, among other measures, and all play a role in the proper and safe prescribing of opioids [41]. Therefore, the practitioner should identify as many of these core risk metrics as possible through review of licensing board material and current clinical literature, at a minimum, and perform an analysis of his/her integration of the same into daily, routine medical practice. After identifying core risk metrics, the practitioner should use the checklist in Table 12.2 and build upon it during the self-audit process.

Considerations and Recommendations: Use the checklist in Table 12.2 to begin the process of organizing and assessing your prescribing of opioids to treat pain and risk management of your patients on chronic opioid therapy. Consider your overall patient population and pick a patient demographic, such as MED, to use as a sorting factor when identifying which charts to assess first during your self-audit process. I recommend you keep action steps associated with each file reviewed so you are able to return to each chart assessment and determine what, if anything, needs to be done to render the chart complete and sufficient such that a peer could review it and discern your clinical rationale for the prescribed treatment and opine that you prescribed for a "legitimate medical purpose" while acting within the "usual course of professional practice" and taking "reasonable steps to prevent abuse and diversion, as well as opioid overdose." Remember, Table 12.2 contains just a few examples of the considerations relevant to each core evaluation area. Keep track of

Table 12.2 Examples of core areas of patient groupings to address during self-audit

Core evaluation area	Other/related	Next steps
Risk evaluation tools	Do I use a validated risk assessment questionnaire? Am I appropriately assessing patients who are potentially "at risk" of opioid overdose?	Do I have a process by which to confirm proper assessment of questionnaire results? Do I have a process by which to ensure I am using the most current and validated risk assessment tool? Am I permitted to prescribe a naloxone kit proactively if my patients are "at risk" of opioid overdose? How will I educate my patients on overdose and naloxone?
Risk stratification and keeping track	Low, moderate, high risk (or similar)	Do I have a process by which to ensure patients are properly risk stratified? Do I have a protocol for ensuring patients are not skipped around inappropriately between risk categories?
Current informed consent	Does my informed consent process include proper documentation of state licensing board provisions or specific terms of informed consent?	Create a true process of informed consent.
Current treatment agreement	Does my treatment agreement track my state licensing board rule or guideline and include specific terminology and provisions used by my licensing board?	Do I have a protocol for ensuring my office documents interaction with clinical decision-making?
Dose levels (markers for next steps or board-required steps)	Consider where you need to set boundaries for patient risk levels associated with morphine equivalent doses of opioid (MED values). For example, consider using 80-mg MED or less as one boundary; 80-mg MED to 120 mg as the next boundary, and 120-mg MED or above as your final dose-related boundary.	Use these boundaries as a starting point for chart selection associated with your self-audit. Start auditing charts with the patients on 120-mg MED or more.
Drug testing	Have you matched your drug testing protocols with your patients and their risk potentials? Am I using proper patient testing profiles tied to risk potentials?	Consider what the licensing board says about drug testing. Adopt a drug testing protocol. Practitioners may also need to consider payor coverage determinations and, if applicable, discuss with the patient the potential that drug testing may not be covered.

(continued)

Table 12.2 (continued)

Core evaluation area	Other/related	Next steps
Prescription drug monitoring program database	Am I using my state's database as my professional licensing board intended?	Develop a protocol to avoid confusion and inappropriate disclosures and use of personal health information associated with database checks.
Consultations and referrals	Keep track of patients referred to you; Specialists you consult with for patients where consults are needed.	Develop a protocol to track incoming and outgoing consultation and referral paperwork. Be sure to track outcomes—did the patient follow-through on the referral you made? If no, why not? A decision tree may be helpful here, especially when the patient skips referrals, but not their medication appointments.
Older adults	Older adults may be at higher risk of adverse events relating to opioids, especially when opioids are prescribed to an older individual using benzodiazepines. Check out the California Board of Medicine Guidelines on Prescribing Controlled Substances to Treat Pain [47] and the comments relating to prescribing this therapy to older persons.	Consider whether you should adopt protocols for prescribing opioids to older adults, including boundaries related to initiating opioid therapy with lower starting doses, slower titration, longer dosing intervals, and more frequent patient monitoring. Also, consider whether tapering of benzodiazepines is indicated to reduce the potential for respiratory depression. All of these suggestions and more may be found in the California Board of Medicine's 2014 controlled substance prescribing guideline cited in the previous column.
Patients using opioids and benzodiazepines	What, if anything, does your licensing board say about prescribing opioids to patients using benzodiazepines? Does your licensing board impose any special requirements if patients are on chronic benzodiazepine therapy?	Review current clinical literature relating to the potential for increased risks associated with chronic opioid therapy and prescribing benzodiazepines. Consider whether additional protocols are necessary for your practice.

(continued)

Table 12.2 (continued)

Core evaluation area	Other/related	Next steps
High-dose therapy —identification and monitoring	Review current literature on "high-dose" opioid therapy, and determine how this literature may impact your MED boundaries mentioned above.	Determine whether and what type of additional monitoring is recommended for patients on high-dose opioid therapy. Determine whether your state requires you to make an attempt to taper the patient down from the high doses or something similar. Consider discussing these more difficult boundaries with legal counsel and experts in opioid risk management. Make sure your documentation adequately reflects clinical decision-making associated with long-term, high-dose opioid therapy.

other considerations under each core area, and add your own at the end so you have a comprehensive checklist for future audits.

Step 8—Update Patient Education Materials

Goal: *To ensure the practitioner is supplementing the informed consent process with the most current patient education material, and to facilitate improved communication between the practitioner and the patient regarding common patient education issues.*

Rationale: Informed consent is a process not just a piece of paper. Informed consent involves the ongoing education of the patient in a manner that allows the patient to make "informed" healthcare choices. Many informed consent documents confuse the elements of informed consent (risks, benefits, expected treatment alternatives, and special issues associated with the prescribed medication or treatment) with the elements of a treatment agreement (patient obligations when the treatment plan involves controlled substances and consequences for failing to follow the treatment plan and medication safety requirements). While an argument can be made for the convenience of combining these concepts into one document, the practitioner must never lose site of the fact the informed consent requirement is not met by paper alone, but instead requires a true process by which the patient is educated and informed, and allowed to seek clarity on treatment recommendations, risks, benefits, alternatives, and special issues, before and during treatment. During today's litigation over controlled substance prescribing practices, it is highly unlikely that the prescriber accused of inappropriate prescribing will survive to

practice another day unless he/she has a true informed consent process—one that includes regular patient education.

Overall, your goal in Step 8 is to adopt an informed consent process robust enough to allow the prescriber to show they did more than hand the patient a piece of paper with informed consent terminology contained within. The informed consent process should contain high-profile educational items published by the US Food & Drug Administration (FDA) and SAMHSA, such as the 2007 FDA consumer piece on "Safe Use of Pain Medication" [42] or the 2014 SAMHSA Opioid Overdose Toolkit for Patients [43]. It is helpful to compile a list of key patient educational topics and to develop a process by which to use cited items to educate patients on a regular basis. Not only will you improve your informed consent *process*, but your efforts will also serve to put the patient on notice that they too have important responsibilities when seeking out medical treatment that involves controlled medication.

Considerations and Recommendations: If you have not already done so, review your state's informed consent requirements and make sure you have the most current opioid education published by the FDA and SAMHSA. Check your state licensing board for additional recommended patient educational material. Identify someone in your practice to serve as an educational coordinator. This person should have authority to research, review, and make recommendations about patient educational material on a variety of topics, especially safe use, safe storage, and safe disposal of opioids and other controlled medication, along with opioid overdose prevention. Patient education should be routine and documented in each patient's file. Tailor education to the extent possible. For example, it is okay to educate every patient on the safe storage and disposal of medication, but not every patient needs education on benzodiazepine use. Patient education does not have to be expensive or time-consuming. Patient education should take place at every visit in some small way. On the first visit, your education might consist of a "Dear Patient" Letter, welcoming the patient to your practice and giving them basic boundaries about how you run your practice, how patient evaluations are conducted, and when and why opioids might prescribed or not. You might find it more useful to adopt a policy of not prescribing opioids on the first visit and to save the review of the written treatment agreement with the patient for the second or third visit. You may also wish to obtain copies of the FDA's "Safe Use of Pain Medication" publication and frame them for hanging in examination rooms; you may also give them out to patients and obtain each patient's signature on the last page of the document and save it in the patient file. Some patients may be at increased risk of overdose, and you may wish to provide them with a copy of or guidance on how to access the SAMHSA Opioid Overdose Toolkit for Patients and Family Members. Similarly, some patients may require education if they fail to uphold the treatment agreement and put you in a position of having to change their treatment plan (more frequent visits, change in medication, discontinuation of medication, or even discontinuation of care) because of their inappropriate or unacceptable conduct or failure to abide by the terms of your plan of care.

Patient education has always been an important aspect of a sustainable business platform for a medical practice. Patient education is also critical to a sound informed consent policy, especially when treatment involves controlled medication. Today, patient education goes a long way to ensuring the patient bears part of the burden of responsibility when it comes to safe use, storage, and disposal of controlled medication; patient education also facilitates the understanding regarding the potential for and symptoms of a drug overdose. For these reasons and more, practitioners may wish to evaluate their plan for educating patients about controlled medication. Proper documentation of educational efforts goes a long way toward supporting the prescriber and his/her quest to balance patient access to controlled medication with the prescriber's responsibility to prevent abuse, diversion, and overdose. Informed consent is largely about patient education.

Whatever you decide, educate your staff on the importance of consistent patient education and take the necessary steps to ensure each staff member understands his/her role in the patient education process. If you take these steps, both your patients and your staff will be better prepared to speak up about your educational efforts if interviewed during a licensing board or DEA/law enforcement investigation of your prescribing practices. Education counts!

The Ethics of Informed Consent

Practitioners have an ethical obligation to ensure that competent patients (or patient caregivers/guardians) are made aware of and understand enough about the intended benefits and possible risks of proposed treatment to make an informed decision, e.g., to use or not use an opioid. The American Medical Association (AMA) publishes the Code of Medical Ethics. Most, if not all, medical licensing boards in the country have adopted and incorporated the AMA Code of Medical Ethics into its state's Medical Practice Act, meaning the subject matter of the code and guidance is relevant to ensuring a compliant practice. Specifically, the AMA has also published an Opinion on Informed Consent, and it is set forth in detail below.

Opinion 8.08–Informed Consent

According to the AMA Code of Medical Ethics, Opinion 8.08—Informed Consent, "the patient's right of self-decision, can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good

medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information, (see Opinion E-8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate." [44]

Patient education is part of a valid informed consent for medical treatment, including controlled medication. The challenge of informed consent in connection with the prescribing of controlled medication is reviewing and narrowing down the possible educational tools to facilitate the informed consent process when chronic opioid therapy is part of the treatment plan.

Step 9—Educate Colleagues and Staff

Goal: *To educate practice partners and clinical staff on the topics within this chapter and to create an internal process for ongoing education and peer review on these matters.*

Rationale: If your staff is with you on the clinical and regulatory boundaries associated with controlled substance prescribing, you will more likely have support if your prescribing practices are challenged. In most administrative and criminal cases, the medical staff is interviewed and often called to testify against the prescriber. Staff testimony typically focuses on the prescriber's overall routine for evaluating, treating, and monitoring patients. Very often, staff members are asked to testify about the prescriber's amenability toward and role in patient and staff education on critical topics, such as safe use, storage, and disposal of medication, and opioid overdose prevention. Staff members may also be asked about existing protocols for handling patient assessment, including risk evaluation, and monitoring, including any internal process for handling patients who violate the treatment plan and treatment agreements. Investigators typically interview staff members about, or even explore in an undercover capacity, the internal processes for handling complaints about patients, drug testing and test results, doctor-shopping allegations, medication count problems, etc. Practice staff who do not believe their voices are reasonably heard on these important topics typically become whistle-blowers—directly or indirectly. Thoughtful education of medical staff will not only minimize the potential of creating internal strife and adverse witnesses, but it will also help you determine whether someone on your staff has a different opinion regarding chronic opioid therapy.

Considerations and Recommendations: When creating an educational program for practice staff, ask all staff members to provide input and opinion on educational topics. Give each staff member a voice and seek their "buy-in" on patient education topics as well, as active staff member participation may make the difference in the

overall outcome of any controlled substance prescribing inquiry or investigation, and may result in patient lives saved. An educated staff may also help when DEA representatives visit your practice or irate family members or reluctant pharmacists call over your prescribing decisions.

Whatever the challenge, do your best to involve your staff in the educational process, which starts with their education and access to you to express ideas and opinions on these challenging topics. You will need to select a staff member to (a) take the lead on organizing a survey for staff member input, (b) keep track of your checklists and collection of Internet resource material, (c) put together educational handbooks for staff members, and (d) organize and keep track of patient education material, among other related tasks. This staff member should be well respected by the majority, if not all, of your staff. Determine whether you are able to make participation in educational sessions mandatory and part of the staff member's performance review, especially at the administrative, clinical, and practitioner levels.

Step 10—Consult Outside Experts—Legal and Medical—To Ensure a Sufficient Self-audit and to Address Specific Risk Management Issues

Goal: *To identify when it might be time to consult with outside experts—legal or medical—to ensure a proper self-audit and overall approach to controlled substance prescribing risk management, and to tackle specific risk management issues*.

Rationale: Without question, there are times when you should consult with outside legal and even experienced medical experts to address scope and sufficiency issues associated with your self-audit, and to tackle specific risk management issues. Legal and medical experts may offer improved insight into licensing board expectations and standard of care questions. Similarly, legal and medical experts may have input on recent cases—administrative and criminal—and thereby be in a better position to offer supplemental detail to the items raised in this chapter about self-audit areas. If you (a) face notices of over payment, especially from Medicare contractors, (b) are under a licensing board audit, or (c) have had a recent visit from the DEA or other federal or state law enforcement authority, it may help to discuss the need for and scope of a self-audit with your legal counsel and perhaps even a risk management expert. The main purpose of the visit would be to ensure your proactive action plan is supportive of your reactive action plan tied to your response to any of the three circumstances listed above.

Considerations and Recommendations: There are many considerations associated with the selection of outside legal counsel and medical experts, and most of these are beyond the scope of this chapter. Suffice it to say, you want to select legal counsel and medical experts who are truly experts on the subject matter (or are willing to engage subject matter experts). It will not do you any good to engage counsel and experts who do not understand the challenges brought about by a financial or prescribing audit related to the prescribing of controlled substances to treat pain. The stakes are high whether you face a financial inquiry or a direct challenge to your prescribing practices. Perhaps, one of the best reasons to walk

through the exercises in this chapter is to ready a handbook for use with your legal counsel or medical expert. Many lawyers and medical experts do not stay current with changing rules and guidelines specific to the use of controlled substances to treat pain; some lack familiarity with them altogether, which likely means they are not true experts on the subject matter. Save yourself some time and money by keeping the notebook referenced in Step One, above. Take notes when you speak with legal counsel or medical experts. Interview them, just as they will interview you. Take the time you need to decide whether legal counsel truly understands the complexity of the issues associated with the prescribing of controlled substances to treat pain. If they do not, explore whether they are truly willing to work with a subject matter expert of your choice without feeling as if their role in the case (or financial gain) is threatened. Good lawyers welcome the opportunity to work with subject matter experts. Good medical experts welcome the opportunity to work with other clinical experts and should have familiarity with the courtroom and arguments on both sides of the opioid issue. Good legal counsel and medical experts cost money, but they can save you a great deal of aggravation and money in the long run, and they typically have (or should have) good relationships with third parties undertaking your investigation and prosecution. Even if you only consult with legal counsel a couple of times per year to ensure you are on the correct path for practice risk management protocols and educational efforts, your money will be well spent. Finally, do not hesitate to engage physicians as mentors or practice reviewers. Input from a true medical expert may make the difference between a letter of reprimand and medical license suspension. It helps to get medical experts on your team early and keep them engaged proactively to minimize the potential for a bad legal outcome.

Summary

This chapter was intended to provide practitioners with a few tools to facilitate a self-audit of controlled substance prescribing practices. This chapter was not intended to be a comprehensive source on each of the topics raised within or all of the legal issues a prescriber may potentially face in an administrative audit or criminal investigation of his/her prescribing practices or financial underpinnings of the medical practice. The landscape for the use of opioids to treat chronic pain is rapidly changing, and federal and state agencies are focused on opioid overdose prevention. Much of this chapter is likewise focused on opioid overdose prevention through patient and staff education, and proper patient evaluation for overdose risk and receipt of a naloxone overdose prevention kit.

Practitioners should make time to perform a self-audit of their prescribing practices and to educate patients and practice staff on critical issues associated with the use of opioids to treat pain. The checklists referenced in this chapter will help

practitioners accomplish a self-audit and improve risk management programs tied to controlled substance prescribing. Practitioners should strive to stay current with changing licensing board rules and guidelines, as well as clinical standards of care, and focus on accurately and completely documenting clinical rationale and decision-making to ensure there is no question as to whether there exists a legitimate medical reason for the use of a controlled substance and whether prescribing took place within the usual course of professional practice. Practitioners are held in a position of trust over the patient and must exercise good faith when prescribing controlled medications to all patients. Federal and state laws, as well as clinical standards of care, play a role in defining what constitutes "reasonable measures to prevent abuse and diversion" or a controlled medication; the same applies to the evaluation of "reasonable measures to prevent opioid overdose." While this chapter was not intended to provide an in-depth legal analysis of "reasonable measures," the self-audit tools will facilitate the prescriber's demonstration of "good faith" fulfillment of his/her clinical and legal obligations, and will also facilitate improved dialogue with local legal counsel and medical experts who are cast in risk management and litigation roles. Our country depends on practitioners like you who are willing to be proactive in the effort to combat prescription drug abuse, diversion, and overdose deaths, while at the same time remaining committed to providing quality pain management.

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15. *United States v. Schneider*, 594 F.3d 1219 (10th Cir. 2010), specifically Document 525 (Sentencing Memorandum).
16. *US v. Brian Heim*, et al. DEA press release dated 16 Mar 2015. Available online at http://www.dea.gov/divisions/det/2015/det031615.shtml.
17. *US v. Brian Heim*, et al. Case: 5:14-cr-00412-DAP, Doc #: 11, Sentencing Memorandum, Filed: 03/16/15, available through the United States Court System known as PACER, see https://pacer.login.uscourts.gov (subscription required).
18. In 2015, following a hearing and expert testimony, a DEA Administrative law judge issued a decision with an extensive opinion finding against the DEA Registrations for Reynolds BD, Killebrew TL, Stout DR. Federal Register, Vol. 80(96) (Tuesday, 19 May 2015), p. 28643–67, available online via the Government Publishing Office [www.gpo.gov] [FR Doc No: 2015-12038]. This case involved inappropriate controlled substance prescribing by three Tennessee-licensed Nurse Practitioners (NPs), who were each authorized to prescribe controlled medications. The government engaged an advanced practice nurse expert to review patient files and present expert testimony on a variety of facts and findings related to the issue of whether the NPs prescribed outside the usual course of professional practice. Focusing in on the role of drug testing in chronic pain management, the government's expert made the following statements during the revocation hearing: The Expert noted the attending practitioner properly ordered a Urine Drug Screen (UDS) for patient "N.S." According to the Expert, a UDS is a particularly useful tool when the practitioner is presented with a red flag indicating the patient may not be in compliance, such as when the patient presents at the office exhibiting the behaviors N.S. did on this visit. As the Expert explained, a UDS can assist the practitioner in determining whether the patient has been taking the drug(s) prescribed and if the patient was ingesting non-prescribed controlled substances, including illicit substances. Thus, UDS results help practitioners to determine whether a patient is abusing and/or diverting controlled substances. While this other practitioner appropriately ordered a UDS, according to the Expert, ***he then inappropriately issued to N.S. another prescription for thirty tablets of*** 60 mg of [a long-acting morphine product] at this visit. As the Expert found, at this visit, N.S. 's file still lacked any information of her prior treatment history and substance abuse history. **According to the Expert, in the absence of this information, and in light of the fact N.S. presented at this visit demonstrating slurred speech and somnolence, the issuance of the**

[morphine] prescription was below the standard of care in Tennessee and outside the usual course of professional practice and actually medically contraindicated given the mental status changes documented in her record. The Expert further explained under the circumstances presented by N.S., the standard of care and usual course of professional practice required the patient's referral for a comprehensive evaluation (the emergency room) to determine the underlying cause of the symptoms of her increased heart rate, slurred speech, and somnolence. **Moreover, the patient should not have received prescriptions (of any type) at this visit until medical clearance was provided, confirming she was not experiencing drug intoxication or an acute neurologic event. … [B]ecause N.S. was not referred or transferred for further evaluation, she should not have received any controlled medications until the urine drug screen results were available to the provider**. Nearly three months later (on September 29, 2004), N.S. returned … for her next visit and was seen by [another NP]. Prior to this visit, the practice had received the report of the results of the UDS administered to N.S. at her July 7, 2004 visit. According to the Expert, on the date of the UDS, N.S. should have had [morphine] left from the prescription issued at her first visit and should have still been taking the drug. However, the UDS was negative for opiates, positive for benzodiazepines, and positive for cocaine. **According to the Expert, these results should have been a "huge red flag of abuse and diversion" for [the NP] because not only did N.S. test positive for cocaine, she also tested positive for three different benzodiazepines, none of which had been prescribed to her at her first visit**. The Expert further explained … the presence of the three benzodiazepines, in addition to the presence of cocaine, were consistent with the somnolence, slurred speech, and increased pulse rate documented during the July 7, 2004 visit. The Expert also noted … N.S. tested negative for opiates, when she should have tested positive for the [morphine], which she should have still been taking. This case contains many additional points of discussion, all of which support the proactive self-assessment of practice routines to ensure compliance with applicable standards of care and regulatory prescribing requirements.

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20. In 2006, DEA made the following comment in its Final Policy Statement: "DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials." U.S. Drug Enforcement Administration. Final policy statement on dispensing controlled substances for the treatment of pain, Vol. 71(172), 6 Sept 2006. Federal Register; 2006. p. 52716–23. Available online at www.deadiversion.usdoj.gov or www.gpo.gov.
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24. **42 CFR §424.535 Revocation of enrollment in the Medicare program. In (13) *Prescribing authority***. (i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or (ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs. **(14) *Improper prescribing practices.*** CMS determines whether the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories: **(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors**: (A) Whether there are diagnoses to support the indications

for which the drugs were prescribed. (B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit). (C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages linked to patient overdoses. (D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s). (E) Whether the physician or eligible professional has any history of "final adverse actions" (as the term is defined in §424.502). (F) The number and type(s) of malpractice suits filed against the physician or eligible professional related to prescribing and which have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined). (G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination. (H) Any other relevant information provided to CMS. **(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors**: (A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority. (B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration. (C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications generally viewed as medically unacceptable—that is, for indications neither approved by the FDA nor medically accepted under section 1860D-2(e)(4) of the Act—and whether there is evidence the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

25. 42 CFR § 424.530(14).
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of a state guideline analysis. To ensure complete understanding of prescriber legal obligations, consult with qualified legal counsel in an attorney-client setting.

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