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REVIEW

How Do You Respond to Corresponding Responsibility?

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ABSTRACT
This article provides a structure upon which to build working policies and procedures for implementing the key concepts of corresponding responsibility to pharmacists who dispense controlled substances to outpatient populations. The pharmacist is given the resources to find and archive pertinent data from the "five Ps," purpose, prescriber, practice, patient, and pharmacy, enabling him to develop a database that also incorporates CURES data and applies universal precautions in a way that mitigates most kinds of diversion. Following the California Board of Pharmacy and DEA red flag lists, the paper gives recognizable, real-world examples of these red flags and lists possible ways to resolve them. A sample red flag resolution form is included. Finally, there is a suggested response to unresolved red flags. The pharmacist is encouraged to develop a written policy based on the tools and information presented. Appendices include sections of pertinent law, letters from regulators and sample forms.

OBJECTIVES
After completion of this program, the participant will be able to:

1. Define pharmacists' corresponding responsibility.
2. Develop a database that makes the information essential to corresponding responsibility easily accessible.
3. Understand the strengths and weaknesses of the CURES system.
4. Understand and implement universal precautions principles.
5. Identify a prescription's red flags based on the guidance of the CA Board of Pharmacy and become familiar with some basic ways to resolve those same red flags when possible.
6. Implement this knowledge by developing policy and procedure guidelines that are in compliance with pharmacists' corresponding responsibility regulations.

Introduction

Prescription drug abuse is on the rise. CDC-reported deaths from prescription opioids are over 14,000 persons per year[1]. In light of this staggering loss of life, it is incumbent upon a responsible pharmacist to exercise his corresponding responsibility to mitigate these tragedies, which, in some areas of the country, have surpassed automobile-related fatalities. Pharmacists cannot prevent all drug misuse and abuse or diversion, but there are laws and regulations in place designed to protect the public from rogue prescribers and pharmacists; laws designed to help practitioners avoid inadvertently becoming "rogue" despite their best intentions. Many recent California Pharmacy Board actions, including the precedential decision involving Pacifica Pharmacy[2], focus on the pharmacist's corresponding responsibility to verify that controlled substances are being prescribed for a legitimate medical purpose by a licensed prescriber prescribing within his scope of practice. (This paper's use of the male gender for generic singular pronouns/adjectives is intended to be gender neutral).

The Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the California Medical Board (CMB) and the California Board of Pharmacy (CA BOP) remind pharmacists that they are practitioners and, therefore, are responsible for properly and adequately treating "legitimate patients." This is the last time "legitimate patient" will be used in this paper. The author prefers the term "medical patient" to describe accurately diagnosed and treated patients who may be prescribed controlled substances for their acute or chronic conditions.

The Federation of State Medical Boards (FSMB)[3], the California Medical Board[4] and, most recently, the Centers for Disease Control[5] have each published opioid prescribing guidelines. All practitioners who prescribe or dispense controlled substances should read these guidelines, keep a copy readily accessible, and have developed policies and procedures to ensure that every patient has chart documentation that satisfies these guidelines. The guidance from the CMB is especially helpful here in California, with sample forms and templates in the

appendices. These guidelines continue to advise the practitioners that they have a responsibility to appropriately treat pain. This includes acute pain, pain associated with the disease of cancer, and chronic noncancer pain. In the latest edition of the California guidelines, the Medical Board made some bold statements when defining pain, significantly downplaying the difference between cancer and noncancer pain and emphasizing the difference between nociceptive and neuropathic pain.[6] It further stated that pain is a disease state in and of itself with significant comorbidities if left untreated or undertreated.[7] These guidelines go even further to warn prescribers that they can be held just as accountable for undertreating pain as they can for overprescribing.

How Much is Too Much?

The American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) have also published a set of guidelines for the use of opioids in noncancer pain.[8] These two societies defined "high-dose" opioid therapy as greater than a 200 mg morphine equivalent daily dose (MEDD). They are very clear that this is NOT a maximum dose, but simply an arbitrary point where patient monitoring and prescriber vigilance should increase. The AAPM/APS guideline still recognizes that pure opioids have no ceiling effect, and still allows dose increases as needed to decrease pain and increase function up to the point where adverse effects become intolerable or unmanageable. The 2014 California Medical Board guideline recommended an 80 mg MEDD demarcation for increased vigilance.[9] In 2016, the CDC issued controlled substances prescribing guidelines that indicated the need for increased scrutiny at a 50 mg MEDD and recommended doses no greater than 90 MEDD.[5] It is important to note that neither the FDA, the DEA, the Medical Board, nor the Pharmacy Board have set an upper limit for the dosing of pure opioids; only dose guidelines where increased documentation and scrutiny should be initiated. Practitioners should be aware that some law enforcement groups are being taught otherwise.

Tolerance Versus Addiction

It is this author's experience, as well as that of many leaders and experts in the pain management field, that there is a great deal of confusion about the difference between tolerance and addiction. One national group was even teaching law enforcement that addiction and tolerance are the same thing. There are many pharmacists who also were taught this (this author was one of them). The DSM-V states that tolerance and withdrawal are only two of the required three diagnostic criteria for opioid use disorder.[10] The DSM-V also clarifies that the "tolerance which creates a diminished effect" and "withdrawal" criteria used for the diagnosis of opioid use disorder "do not apply when [controlled substances are] used appropriately under medical supervision." Most national pain management societies, as well as the California Medical Board, choose the following definitions of tolerance, physical dependence, and addiction:

> "*Tolerance:* A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drugs' effects over time."
>
> "*Physical Dependence:* A state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug and/or administration of an antagonist."
>
> "*Addiction:* A primary, chronic, neurobiological disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving."[7]

The Current Law

Both federal and California regulations address a pharmacist's corresponding responsibility. In California, the pharmacist's corresponding responsibility is defined in Health and Safety Code §11153. The Federal Controlled Substances Act addresses pharmacist's corresponding responsibility in 21 CFR 1304.06. The two paragraphs below are taken directly from the California Pharmacy Law Book 2016 and the DEA Pharmacist's Manual. The text of the two regulations is very similar, with the first sentence being almost identical.

"California: Health and Safety Code 11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation[11]

a. A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility [emphasis added] rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions:
(1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or
(2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

"Federal 21 CFR 1306.04 Purpose of issue of prescription.[12]

a. A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility [emphasis added] rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829), and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

b. A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
c. A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter."

What is Corresponding Responsibility?

The five **P**s are the key elements of corresponding responsibility:

1. Legitimate Medical **P**urpose
2. Individual **P**rescriber
3. Usual Course of **P**ractice
4. Medical **P**atient
5. A Well-Managed **P**harmacy

The documentation found and archived for the above keys will be stored in the Controlled Substances Documentation (CSD) file discussed later.

Legitimate Medical Purpose

The law states that pharmacists have a corresponding responsibility to know that the controlled substance prescription being presented is for a legitimate medical purpose. Admittedly, a retail pharmacist is at a disadvantage, because he is without access to a patient's chart. So he must use the tools he does have, including an interview with the patient and a query to the prescriber.

Unfortunately, some overzealous pharmacists have made some pretty outrageous demands of prescribers. These demands annoyed prescribers to the point that the "American Medical Association (AMA) House of Delegates adopted [a] policy stating that a pharmacist who makes inappropriate queries on a physician's rationale behind a prescription, diagnosis or treatment plan is interfering with the practice of medicine."[13] Responsible pharmacists mitigate prescriber annoyance by implementing their people skills and filing procedures to reduce repeated queries to prescribers for the same patient.

The first step in a prescriber query is to develop a fax form with a clear request for information that can be easily found and recorded by medical assistants. Medical assistants can record diagnosis codes/dates, prior authorization codes, lists of tried/failed drugs, other/previous prescribers, and other requested information. The form must include all necessary patient demographic information, prescription information, and a return fax number. For each question, include a check box and a line for the answer. It is helpful to include a footnote quoting the HIPAA regulations that allow providers, including pharmacists and pharmacies, caring for a common patient to share information. The pharmacist need only contact the prescriber by telephone for unresolved questions.

Step two is to develop and maintain a permanent database (discussed later as the CSD file) of diagnosis codes for patients who are prescribed controlled substances. Some pharmacy software systems include a field for diagnostic ICD-10 codes. Once this database is developed, it must be easily accessible to pharmacists and technicians. When a patient presents a prescription, a staff member should easily be able to confirm the diagnosis with the database and thereby avoid any further calls to the prescriber for diagnosis verification. This database is the ideal place to store other patient-specific information, HIPAA releases, prior authorizations, identification documents, etc. Remember, diagnosis often happens once; treatment can last a lifetime. Train staff to store all prescriber data and consult it prior to contacting the prescriber. A pharmacist can exercise his corresponding responsibility by consulting the database. A pharmacist uses his expertise so that a prescription for the same drug, or drugs in the same therapeutic class, for an individual patient from an individual prescriber or group will likely not require further contact.

A new patient should be asked, "What are we are treating with this prescription?" The term "we" emphasizes patient-centered, cohesive, supportive care. The pharmacist will evaluate the patient's answer to be either consistent or inconsistent with a condition for which the prescribed medication is a reasonable fit. It should also be a reasonable match to the prescriber's diagnosis code. For example, the patient's complaint of low back pain is consistent with a diagnosis code of M51.3 (DDD at L5-S1) and a prescription for hydrocodone/APAP 10/325 qid, prn. The patient's response should be documented in the patient's file. If that same patient were to state that the medication was for his sore throat, it would be the pharmacist's corresponding responsibility to follow up on the diagnosis or patient's understanding.

The first rule of corresponding responsibility is to discern, and document, document, and document.

By an Individual Prescriber

A pharmacist meets his corresponding responsibility by confirming the identity of the prescriber and determining that the prescriber is appropriately licensed to issue the prescription. In order to accomplish this efficiently, the pharmacist must develop and maintain a database of prescribers (CSD file). For each prescriber, obtain and archive a copy of the information from each of the following websites and be sure it matches the prescription:

1. https://www.breeze.ca.gov: This is the access portal to the Medical Board of California. On this site, one can verify that the prescriber's license is current and check for specialty credentials and disciplinary actions. Unfortunately, the license verification system does not list the prescriber's phone number. Be sure the addresses match. Disciplinary actions are not always a hard stop, but if the pharmacist chooses to fill prescriptions for a disciplined prescriber, he must be conversant in the case and put it in the CSD file along with his explanatory notes. It is possible to choose to fill certain classes, e.g., only noncontrolled or only C-V, for certain prescribers.
2. https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp: This is the DEA portal to validate DEA registration, expiration date, practice location and allowed schedules. Use of this site will require the DEA number of the pharmacy that is requesting the information, its business name (as printed on the DEA Registration), and the business tax ID number.
3. https://npiregistry.cms.hhs.gov [alternatively, use a search engine to find the term "NPPES"] This is the portal to the NPI registry. The information here is password protected and is not easily changed by outsiders, which makes it a good resource to confirm the prescriber's

address and phone number. Be aware that when providers change locations, updating this site is often overlooked. If the provider has moved to a different practice, the NPPES listed provider phone number will often provide a valid contact for forwarding information.

4. Create desktop or browser shortcuts for these sites to facilitate this process. CAUTION: In the case of a questionable document, DO NOT call the phone number printed on the prescription pad; it may be a fraudulent number! Use the number from the NPPES website, Google, Health Grades or similar sites to confirm the prescriber's phone number. For out-of-area prescribers, it is often helpful to contact a pharmacy local to the prescriber's office to confirm contact information. When asked to validate their prescribers as described above, many pharmacists respond, "I can't do this!," "It will take too much time!" or "Who has this kind of time?" However, upon further reflection, most pharmacists will realize that prescriber verification only needs to be done once or annually for an entire pharmacy or company. Many pharmacy software programs do some or all of this in the background. Once shortcuts are created and processes practiced, these three steps can be done in about 15 minutes or less.

The practice address must match that listed on the prescription and on the DEA registration, and it should be validated.

1. Local practice addresses can be easily checked directly. Some pharmacies may choose to keep a photographic log of sites.
2. Use Google Maps or other photographic mapping software to validate that less easily accessible address.
    a. Look at the Street View. Determine if it looks like a reputable medical practice or hospital complex.

3. Prescriptions for multiple patients who are not local to the pharmacy from a single out-of-area prescriber is a red flag.

If the address information on the Medical Board, DEA, and NPPES website match, a pharmacist can make a reasonable determination that the document is from a valid prescriber. The California Board of Pharmacy maintains a list of prescribers who have reported stolen prescription pads, which should be regularly checked and the data added to the prescription software or to the prescriber file.

The responsible pharmacist may choose to establish a "trade area." Prescribers or patients from outside the trade area need extra validation. A pharmacist may choose to fill for a local patient who was treated at an out-of-area specialty clinic such as a cancer, children's, special orthopedic, or research center with documentation of the reason the patient had to travel for treatment and a prescription that might be expected from that specialty center.

Pharmacists are responsible for knowing the license categories that may prescribe controlled substances in California. Physicians, dentists, podiatrists, veterinarians, some midwives, some optometrists, nurse practitioners (under collaborative practice protocol), physician assistants (under protocol)[14] and, yes, pharmacists (under the collaborative practice protocol of a supervising physician (B&P §4052.2) or as a CA BOP Licensed Advance Practice Pharmacist with collaborative practice agreements with diagnosing physicians B&P §4052.6))[15] are all able to prescribe controlled substances if they have the proper DEA registration. The California Board of Pharmacy is expected to issue the first Advanced Practice Pharmacist's (APP) licenses in early 2017. Archive the prescriber data and update it whenever the data changes.

The second rule of corresponding responsibility is "discern, and document, document, and document."

Usual Course of Professional Practice

Pharmacists have the training and critical thinking skills to determine if a prescriber is within his scope of practice. The DEA, Medical Board, and Pharmacy Board have noticed that many retired or close-to-retiring physicians have returned to active practice. Some have fallen prey to unscrupulous confidence artists who recruit unwitting prescribers for "easy work" at a pain clinic. Prescribers and pharmacists in the pain field should ask themselves if they are up to date with current theory and protocols. Dr. Howard Heit likes to ask these five questions of himself and of others he interacts with: "Am I dated? Am I being duped? Am I dishonest? Am I disabled?[22] Am I being defiant [of the law or guidelines]?" The responsible pharmacist will use multiple resources to determine a prescriber's training and usual scope of practice. The first resource is the Medical Board website, which will often list a licensee's practice area or specialty. While that information is self-reported and not verified by the Medical Board, it is often the only source for that information. Using the Medical Board information and information from the prescription itself, the pharmacist can then check the American Board of Physician Specialties website (http://www.abpsus.org). Specialty boards generally are protective of their public information, and it is not easily changed by fraud. Hospital websites will frequently list physicians who have admission privileges. This data is reasonably trustworthy. As part of the physician validation process, the responsible pharmacist will note the date the medical license was issued. The average physician will receive his first license at about the age of 26-30. If a physician is older than 70 years, he requires more scrutiny. For example, if a responsible pharmacist were to receive a prescription for Norco 10/325 qid prn for a diagnosis code of M51.3 (lumbar degenerative disc disease) and the patient reports low back pain, but the prescriber is a 70-year-old board-certified ophthalmologist, the pharmacist could reasonably decline to fill the prescription based on the prescriber's treatment being out of his usual scope of practice. When a pharmacist declines to fill a prescription, he should note the reason and place it in the prescriber and patient database. Most prescription management software programs allow for prescribers to be "blocked from fills." This is a responsible practice and a valuable tool, but must never include defamatory comments. Copies of the medical and specialty board information should be stored in the prescriber database and updated as needed.

The third rule of corresponding responsibility is to "discern, and document, document, and document."

Medical Patient

A responsible pharmacist uses his critical thinking skills to determine that the

patient is properly identified. Generally, this means archiving a copy of the patient's government-issued photo identification (ID). For minors, obtain a copy of the parent's identification. The picture should look like the patient. Ideally, the ID should be current. The ID does not have to be a driver's license; any government issued ID will do, such as a passport, military ID, school ID or driver's license. A Costco card or credit card with a picture on it is neither secure enough nor vetted well enough to establish proper ID. California Business and Professions Code 4075 states that "a pharmacist shall not furnish a controlled substance to a person unknown or unable to properly establish their identity." Patients may be asked to return when they have ID. Gravely ill or disabled patients may not be able to come to the pharmacy in person. The responsible pharmacist will then determine the identity of the person presenting the prescription and their reason for doing so. In some cases, the pharmacist might call the prescriber and get a physical description. A responsible pharmacist may validate the patient's address to be sure that it is a residence and that it is within his trade area. Computer programs with photographs of actual buildings are helpful here, e.g., Google Maps Street View. Validate as much of the information provided as possible. California Board of Pharmacy disciplinary actions and filed accusations often focus on the prescriber's and patient's distance from the pharmacy. The Board does not define a standard service area, but pharmacy patient demographics will. The Board will likely look at pharmacy data and let that data establish the service area. It is probably wise to avoid filling controlled substance prescriptions for distant patients unless there are other, regular, returning patients with prescriptions for noncontrolled drugs from that same area.

The fourth rule of corresponding responsibility is to "discern, and document, document, and document."

A Well-Managed Pharmacy

A responsible pharmacist knows that all the drugs purchased by the pharmacy have a corresponding prescription order or are currently on the pharmacy shelves. The best way to acquire this knowledge is to perform an in-out audit. This audit may take a couple of hours once a month, but will prove invaluable when an inspector visits looking for controlled substances discrepancies. Here's a basic description of how to perform and in-out audit.

1. Run a dispensing report from your prescription processing software.
2. Run a purchase report for the same period from all of your suppliers. Do not rely on a tabulation of invoices, for the invoices of diverted drug may have been destroyed. Download or request a report from your suppliers.
3. Calculate the differences between the two using a spreadsheet.

For any drug with greater than one more package purchased than sold, take a closer look. Ideally, the drug can be located on the correct shelf. If not, investigate further. The pharmacist who cannot satisfy the discrepancy should discretely begin to audit each week. If the source of the discrepancy is still not found, it may be advisable to restrict access to ordering, order check-in, and dispensing. A review of surveillance footage is wise, if suspicious behavior is observed, the footage should be transferred to an independent media device for secure storage. The drug is going somewhere. Having discovered a problem with missing inventory, the responsible pharmacist will find it, stop it, and report it. Remember, pharmacists must report a controlled substances loss to their Drug Enforcement Administration field office with form 106, AND to the Board of Pharmacy within 30 days of discovery[17] (the Board will also accept the DEA 106 Form for reporting loss). A pharmacist continues to meet his corresponding responsibility by monitoring and reporting any unresolved indicators of diversion within the pharmacy.

The fifth rule of corresponding responsibility is discern, and document, document, and document.

Develop a Controlled Substances Documentation (CSD) File System

The rules of corresponding responsibility are discern, and document, document, and document. In order to manage this documentation, the responsible pharmacist will create an easily accessible filing system with which he is comfortable, whether it be paper or highly secure, well-backed-up electronic files. A pharmacist might tie this electronic database into his pharmacy network or isolate the access point to a single computer. This database will contain a lot of very sensitive and HIPAA-protected information; be sure to assign a very strong password for database access. Create folders for patients, prescribers, and one labeled 11153 (named for the section of the California Health and Safety Code that discusses corresponding responsibility). The 11153 file allows the pharmacist to easily locate prescriptions where, in his professional opinion and experience, he felt that he (and no one else) could not fulfill his corresponding responsibility obligations. If a prescription, patient, or prescriber is found in this file, it does not preclude another pharmacist who has more information from filling the prescription.

Regulators have suggested that a pharmacy should be able to document that it does not fill ALL prescriptions for controlled substances that are presented if there are reasons to decline to fill. The 11153 folder in the CSD file meets this potential need.

CURES

One of the most important documents in the CSD file is a patient's CURES report. By now, all licensed pharmacists should have registered for access to the Controlled Substances Utilization Review and Evaluation System (CURES). Use this tool. At this time, pharmacists are not mandated to access CURES data; they are only mandated to have the ability (passwords) to do so. But if a pharmacist does not use his access and the drugs he dispenses are involved in a diversion or overdose situation, lack of CURES data could negatively affect his licensure. Save the CURES report into the CSD file on the day it was accessed, because tomorrow it may read something different. The responsible pharmacist will be able to produce the documentation he had at the time he made his decision, and not the data that was available days, weeks or months later. Unlike the patient chart, the CURES data and reports belong to the California DOJ and not the patient. Part of your access agreement with the DOJ is that you will not share the data you access with ANYONE: insurers, or patients, or even prescribers (they are mandated to have access as well).

Analyze the CURES Patient Activity Report (PAR). Pharmacists have the training and critical thinking skills to make a professional judgement. For each CURES report, the pharmacist analyzes:

1. The number and type of prescribers
   a. Ideally, there is one prescriber or group.
   b. Identify dentists, surgeons, emergency medicine

practitioner, or other specialists.
2. The dispensing intervals.
3. The number and type of pharmacies.
    a. In the current political climate, with wholesalers applying restrictions on controlled substances distributions, many patients need to visit multiple pharmacies to find product available.
4. Conflicting or duplicative therapies.
5. Patient address(es) and date of birth.

If a patient is using multiple prescribers and multiple pharmacies, this is a red flag until resolved. Dispensing intervals for the prescriptions must be considered. The responsible pharmacist must know his prescribers, including members of group practices. The prescription hard copy is the first place to check for group members. If CURES shows consistent, multiple prescriber-pharmacy pairs where prescriptions from Dr. A are consistently filled at Pharmacy X, and prescriptions issued by Dr. B are routinely filled at Pharmacy Y, the responsible pharmacist now has a red flag to discuss with each prescriber to ensure that both prescribers are aware of the other's treatment, or not. The pharmacist should encourage the patient to use only one pharmacy. The responsible pharmacist may choose to not serve a patient who continues to use multiple pharmacies.

Here is an example of the way in which failure to know the prescriber in the CURES report caused a negative outcome for a patient. A worker's compensation patient was denied all pain medication because an ignorant attorney thought the patient was doctor shopping because another prescriber showed up on his CURES report. In fact, the patient was seen by his usual prescriber's partner while the other prescriber was on vacation. Other problems in the case included that the patient was shown his CURES report, which he is not allowed to see except in special circumstances, and that a CURES report should not have been stored in the patient's chart. CURES reports are California Department of Justice documents and cannot be released to anyone, including the patient, without a specific subpoena for the actual CURES document.

How often should the responsible pharmacist access a patient's CURES report? A workable response might be:

1. Every FIRST visit.
2. Upon initiation of controlled substances therapy for an established patient not previously prescribed a controlled substance.
3. At least annually (for cash patients, quarterly).
4. If there is a gap or a missed expected visit. The responsible pharmacist finds out if the patient was on vacation, hospitalized, or on other therapy.
5. Anytime the PBM replies with a DUR overlap or early refill response.
6. Anytime the pharmacist feels like it. A pharmacist's instinct is not to be ignored.

Avoid trouble with the California Department of Justice. A medical professional ONLY accesses CURES data for his patients. Never look up the governor, a celebrity, an ex-spouse, etc. unless it is required to meet corresponding responsibility. Such action is a legal violation.

A final note on the use of CURES data: a CURES report is a strong a tool to show patient compliance with a prescriber's treatment plan, documenting one provider, one pharmacy and appropriate dispensing intervals. Use the CURES tool to support your compliant medical patients in addition to detecting those who may be trying to deceive you.

Universal Precautions

In the same way that medical professionals use universal precautions to treat every patient as if he had a communicable disease, responsible pharmacists politely and professionally treat every patient as if he were at risk for misuse, abuse, or diversion. Dr. Howard Heit, Dr. Douglas Gourlay, and Dr. A. Almahrezi adopted the infectious disease universal precautions model for use in the pain management field.[21] Opioid risk tools are important and helpful, but they only show a statistical rate of risk. And, as we all know, every statistic has outliers. It is also likely that seasoned diverters will already know the "right" answers to the questions presented in the risk tools. A universal precautions approach treats every patient in the same respectful, caring fashion.

When a prescription for a controlled substance is presented, do not profile the patient or discriminate against him based on appearance. Two classic (and true) examples of why profiling doesn't work are the patient covered in tattoos who turned out to be a decorated veteran with nerve damage and phantom limb pain, and the "sweet little old lady" who had her entire senior living complex giving her prescription pills that she then sold to finance her world cruise. The responsible pharmacist uses universal precautions so that every patient, every prescription document, and every prescriber gets the same screening.

A good structure for universal precautions for controlled substances is one that is as thorough as possible without creating a process so burdensome that it will not be consistently used. After all, if it is not used, it's not universal and cannot protect the pharmacist, his practice, his profession, other professionals, patients, and the community he serves. Data must be quickly and easily accessible, and forms must be simple and useful. Demonstrate this consistency to staff and other customers in the area so all are assured that no one is being singled out. Universal precautions include, at a minimum:

- A photo ID for ALL patients
- A CURES PAR for ALL patients, and
- A diagnosis verification for ALL patients.

"All" is a very strong word, and you may not want to use it in your policy manual lest a regulator hold you to it. Always write your policy manual with terms that give you some opportunity for the vagaries of the real world to exist.

Putting Corresponding Responsibility into Practice

In July of 2014, the California Board of Pharmacy published a brochure entitled "Corresponding Responsibility: It's the Law" (www.pharmacy.ca.gov) outlining the top priority red flags of drug diversion. The document contains well-researched descriptions of common indicators of prescription drug diversion by patients as well as providing a list of pharmacy and pharmacists' behaviors that indicate that there may be a diversion problem within the pharmacy itself. The responsible pharmacist must be conversant with all of these red flags and warning signs. The responsible pharmacist evaluates all prescriptions for controlled substances in light of the BOP list of red flags. A pharmacist begins to meet his corresponding responsibility

requirements by declining to fill any prescription that has unresolved red flags.

To repeat: an unresolved red flag is automatically categorized as "do not fill." The responsible pharmacist definitively indicates to staff and other pharmacists that prescription(s) cannot have defamatory statements written on the document. The prescription should be quarantined pending resolution. The "do not fill" data is also recorded in the prescription management software, the patient's profile, the 11153 file, and the prescriber databases. For example, the patient database might record the pharmacist's dated and initialed notes indicating that "The prescription was declined because the patient was from out of the area, could not provide identification, and refused to use prescription insurance."

One of the best practices is for the pharmacist to create a red flag resolution form. This form (see sample in Appendix 1) lists each type of red flag with a check box to indicate its existence, a small field to note the details of the red flag, a copy of the prescription and other documents, prescriber contact information, the patient interview, the CURES report, and the final decision to either a) fill the prescription, b) return the prescription to the patient, or c) retain the prescription. The responsible pharmacist is aware that the DEA or BOP inspector is going to use his prudent, professional judgement to evaluate the red flag resolution. The form and accompanying documents are stored in the CSD file.

The responsible pharmacist understands each of the BOP's red flags and the methods by which they may be resolved. The following are real-world examples of each type of red flag and the kind of documentation needed to resolve or not to resolve the flag. For purposes of this paper, it will be presumed that the pharmacist has completed a red flag resolution form and archived all documentation, with notes regarding prescriber and patient contacts. Law enforcement contact should also be documented.

Red Flag 1: Irregularities on the Face [or back] of the Prescription Itself.

The pharmacist must know the requirements of California Health and Safety Code §11162.1 and have physical access to the hard copy of the prescription. He must know that the document is

filled out correctly and completely. He is responsible for knowing that a prescription for a controlled substance must contain at least the following (see Appendix 3 for more detail) before it is filled:

- The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner, EXCEPT for certain licensed facilities that have 25 or more prescribers, when treating [seeing] patients at that facility. The facility forms have other exceptions, which are found in section 11162.1.
- Latent "void" text that appears when copied or scanned.
- A watermark on the back that says "California Security Prescription," showing those exact words in that exact order. Do not accept the following examples:
  - "Security Prescription" (without "California").
  - "Kant Kopy."
  - A company logo.

That does not mean these elements cannot be present, BUT they do not satisfy the California Security Prescription requirement. Some printers will also include other state-required statements. This does not invalidate the document, but make sure you can locate the phrase "California Security Prescription." An ultraviolet light is often helpful for seeing the watermark.

- Chemical void protection, which is invisible unless the document has been "washed."
- Thermochromic ink feature.
  - Usually a pink or blue feature that pales when warmed.
- The six (quantity range) check boxes (not required for practice groups of 25 or more prescribers) with an extra space provided if the drug is not in tablet or capsule form.
  - The quantity boxes must be checked properly if required.
- An area of opaque writing so that the writing disappears if the prescription is lightened.
- A description of the security features included on each prescription form.
- The statement, "Prescription is void if the number of drugs prescribed is not noted."
  - The "number of drugs prescribed" must be indicated.
    - This author finds that this is the

most common omission error made by prescribers. This is where section §1761 of the California Code of Regulations regarding Erroneous or Uncertain Prescriptions comes into play. If any of the above information is missing or ambiguous, the pharmacist is allowed to call the prescriber and verify the information. The pharmacist CAN clarify or correct any piece of information on the prescription. If the drug is C3-5, simply take the prescription as a new verbal order. If the drug is C-2, make the corrections on the hard copy document.
    - The DEA does not address making corrections to controlled substances prescriptions and "instructs pharmacists to adhere to the state regulation and policy regarding those changes that a pharmacist can make to a Schedule II prescription."[19]
    - See Appendix 2, the "Dear Colleague" letter from the DEA, addressing this question.
- Checkboxes to indicate the number of refills ordered.
- The date of the origin of the prescription.
- A check box indicating the prescriber's order not to substitute.
- A check box by the name of each prescriber when a prescription form lists multiple prescribers, with the appropriate box checked by the prescriber.
    - The correct box must be checked.

Once the paper prescription document itself has been validated, the responsible pharmacist continues to evaluate the document by asking the following questions:

- Is the document signed AND dated in the prescriber's hand? These two entries MUST be in the prescriber's handwriting. (A computer-generated date is allowed for practitioner groups with greater than 25 members.) (H&S § 11162.1(c)(4)(B)).
    - If not, the prescription CANNOT be filled. Advise the patient to return to the prescriber to fix the problem. Notify the prescriber's office of the problem so they can plan ahead to solve it.
    - The responsible pharmacist uses his critical thinking skills to determine that the signature and date are in the same hand. Make a note of the time involved for the prescriber to repair the prescription. Know the expected travel time in case the patient decides to fix the prescription himself.
    - Are there any alterations to drug name, strength, or quantity, and does the written quantity coincide with the quantity check box?
    - Is the document damaged (mutilated)? Is a required element missing because the corner is torn off? Has a required element been masked with a stain (e.g., a coffee stain) or bleached?
    - If the pharmacist is presented with multiple sequential prescriptions, he will make sure the prescriber has dated each document the day it was issued, AND has indicated the earliest date the prescriptions may be filled, AND that each sequential order is written on a separate prescription document AND that the total days' supply of medication issued with the sequential prescription set does not exceed 90 days.

Examples of fill dates include:

- Do not fill until mm/dd/yy.
- Release mm/dd/yy.
- Any other phrase that clearly indicates the earliest fill date.

Finally, the responsible pharmacist knows that there are fraudulent documents in circulation, and they may be difficult to discern. The local DEA office acknowledges that there are printing companies who are in on the scam. A pharmacist may not be able to catch these fraudulent documents. They are better than good counterfeits; they are the real thing, but they are still fraudulent. Be diligent, be observant, and be cautious when presented a prescription for an unfamiliar patient or prescriber.

Red Flag 2: Nervous Patient Demeanor.

- The following are common ways to distract the pharmacist from a careful evaluation of the prescription:
    - Overexplaining the need for the medication.
    - Insisting that the staff hurry for any reason.
    - Provocative dress or behavior.
    - Other suspicious behavior includes:
        - Attempting to watch what is going on behind the counter.
        - Pacing, squirming, fidgeting, and looking about.
        - Taking note of camera locations and avoiding their field of view.
            - A small countertop camera that looks UP into the face of everyone who presents a prescription may deter criminals and is an inexpensive addition to an extant camera system.
        - Using a hat or hood to avoid being seen by cameras.
        - Parking at a distance from the front door when closer spaces are available is odd behavior for a person in pain or a person who is caring for a patient.
    - In the case of any of these behaviors, the responsible pharmacist immediately increases his vigilance.
    - Pharmacy staff must be taught to notice and report these behaviors to the pharmacist.

Red Flag 3: Inappropriate Age or Presentation of the Patient.

- The pharmacist uses his medical knowledge to evaluate his patient.
- The pharmacist will assess:
    - Gang tattoos, colors, or dress.
    - The responsible pharmacist will make himself aware of local gang colors and dress and remember that tattoos last a lifetime, while gang affiliation may not. Groups such as the NADDI (National Association of Drug Diversion Investigators) are teaching dispensing pharmacists to be observant of gang affiliations, dress, colors, and hand gestures.
- Slurred speech.
    - The pharmacist should interview the patient or check the ICD-10 code to evaluate whether this may be a sign of intoxication or of a brain injury.
- Unstable gait.
    - The pharmacist should know the patient well enough and/or check the diagnosis code to evaluate whether this has a medical cause or is a sign of intoxication.
- The pharmacist will understand that young age is a risk factor for diversion but uses his critical thinking skills to evaluate a youthful patient fairly, because he knows that:
    - Young people do have surgeries and/or get hurt.
    - Our returning wounded veterans are often young men and women. These men and women were injured defending their country, and they deserve respect. However, veterans do not get carte blanche; universal precautions apply.

Red Flag 4: Multiple Patients with the Same Address.

- The pharmacist should not underestimate the significance of this red flag and should interview the patients, asking:
    - If they are members of the same family.

- If there was a common traumatic event.
  - It may be helpful to have different members describe the event.
  - Common, reasonable answers include the same motor vehicle accident or fire.
- If they are family members with a genetic disease. Common reasonable answers include:
  - Ehlers-Danlos syndrome,
  - Fibromyalgia,
  - Huntington's disease,
  - Multiple sclerosis,
  - Rheumatoid arthritis, or
  - Sickle cell disease.
  - Palliative care conditions that are hereditary will often present in patients who are only in their 20s to 30s
- The absence of a reasonable explanation for multiple patients with the same address is a valid reason to decline to fill a prescription.
- Make no assumptions, and document the reasons for your decision.

Red Flag 5: Multiple Prescribers for the Same Patient for Duplicate Therapy.

- The responsible pharmacist evaluates California's CURES PAR for every new patient with a controlled substances prescription or for established patients with new controlled substances prescriptions.
- The responsible pharmacist will use the CURES report to verify providers and appropriate fill rates. He may choose to decline to fill the prescription based on the CURES data.
  - The pharmacist may choose to delay filling a controlled substances prescription until the CURES system can be accessed.
  - In order to protect his community, the responsible pharmacist will contact all involved prescribers when he discovers credible evidence of a patient using multiple prescribers for the same condition and document the contact.
    - HIPAA regulations allow medical providers, such as pharmacists, to share a patient's information with the patient's other providers
  - Multiple prescribers for the same condition may trigger the pharmacist to refuse to fill a controlled substances prescription.
    - Apart from multiprescriber practices, there are very rare exceptions to this general rule. Any exceptions must be made using the pharmacist's best professional judgement and require extensive, archived documentation of the pharmacist's consultation with the prescribers.
- Know the patient as well as the provider's prescribing habits.
- Know current standards—a long-acting opioid plus a short-acting opioid for breakthrough pain is not duplicative.
  - There are at least four subtypes of the Mu receptor, which could warrant multiple opioids for resistant patients.
  - Genetic mutations of CYP450 enzymes can cause some people to metabolize a drug more quickly or extremely quickly, which requires shorter dosage intervals. Slower metabolizers may keep a drug in the system much longer or may not have the active metabolite of a pro-drug in the system at all. There are genetic tests that can be done to support this phenomenon in your patient.
  - Understand multiple mechanisms of action that may appear to be duplicative therapy. For example, methadone exhibits dual action as Mu agonist and NMDA antagonist; tapentadol and tramadol exhibit Mu and SNRI reuptake inhibition.

Red Flag 6: Cash Payments.

Not all patients will have health or prescription insurance. The responsible pharmacist will develop a system to document and archive the justification for cash payment. Some common, acceptable reasons for the lack of prescription insurance are:

- The patient cannot afford the insurance (commonly $600+/month).
- The patient is between carriers.
- The patient has settled a worker's compensation case.
  - Many patients accept a settlement of their worker's compensation case.
  - When a worker's compensation case is settled, the settlement funds are placed into an escrow account, which is then managed similarly to a health savings account. When the account is exhausted, health care expenses related to the claim become the responsibility of Medicare.
- The patient is with a new employer and has not completed the waiting period after which health insurance may be offered.
- Like every insurance claim, there may be an unusual reason for lack of coverage. The pharmacist may contact the insurance provider for documentation, or the lack of coverage may be listed on the prescription management software.
- If the insurance provider has denied coverage, print the reason for the denial and store it in the patient file, because this information typically disappears if the claim is covered at a later date.

Red Flag 7: Requests for Early Refills of Prescriptions.

The pharmacist will evaluate early refill requests and may contact the prescriber for verification of a change in the patient's condition that required a change in dose. The pharmacist should:

- Document early fills for travel. He will set and inform the patient of the appropriate "resume" date, note the date in the file and enforce it.
- Document early fills for therapy changes and new diagnosis codes.
- Establish a policy for responding to lost or stolen controlled substances medications. The policy should consider a limit to refills for these occurrences, e.g., none or one.
  - The pharmacist's response to lost medications should include a documented security consultation with the patient/caregiver.
  - The pharmacist's response to stolen medications should include at least:
    - An archived copy of a police report or incident card with case number.
    - A documented security consultation and recommendation that the patient purchase a lockable storage device.
      - Safes are preferred, but can be costly.

Red Flag 8: Prescriptions Written for an Unusually Large Quantity of Drugs.

The pharmacist should use his medical knowledge to evaluate the controlled substances prescription for a larger MEDD than is typical for a particular prescriber or type of prescriber. For example:

- Three hundred sixty tablets may be an unusual or an already resolved amount for a particular patient. The responsible pharmacist will check the patient database or the prescription software to resolve the red flag in this case.
- One hundred twenty tablets may be an unusually large quantity from a dentist who normally only prescribes 12 Norco® for a painful procedure. In this case, the pharmacist will first evaluate the prescription for alterations before contacting the prescriber.
- The CURES report can validate the history of a high-dose patient new to the pharmacy.

- There are metabolic considerations and genetic mutations of CYP450 enzymes that can warrant higher doses.
  - There are many genetic testing companies that can answer this question from a simple cheek swab. These tests can be expensive and so are rarely done.
  - Malabsorption disorders are another reason for high doses.
- Patients may be restricted to immediate release dosage forms secondary to:
  - Gastric bypass surgery.
  - Short gut:
    - Ileostomy patients.
    - Colostomy patients.
  - Diverticular conditions.
  - Other conditions or causes of decreased transit time in the GI tract that would limit the utility of extended-release delivery mechanisms.
- Cost. Extended-release/long-acting (ER/LA) drugs are much more expensive than immediate-release (IR) drugs. This may be so even if the patient has insurance.
- The CDC guidelines encourage short-acting drugs in many cases.

Red Flag 9: Prescriptions Written for Duplicative Drug Therapy.

See Red Flag 5.

Red Flag 10: Initial Prescriptions Written for Strong Opiates.

- Use CURES data to identify the opioid-naïve patient presenting with strong opioids, high doses, ER/LA drugs, and any methadone dose greater than 5 mg BID. An opiate-naïve patient who is prescribed high-dose opiates is at real risk of serious adverse events, especially life-threatening respiratory depression to the point of brain damage or death.
- The responsible pharmacist is aware that not all entities report to CURES, including:
  - Veterans Affairs Hospitals. (It appears that some VA hospitals started reporting as of mid-October 2016. This is only an observation and has not been confirmed with DOJ or the VA.)
  - Military base dispensaries/pharmacies.
  - The Indian Health Service.
  - Methadone clinics.
  - Departments of corrections (prisons/jails).
- Ask the patient where he has been receiving controlled substances medication.
- Validate any other sources of medically approved controlled substances.
- CURES can support the decision to fill or not fill a prescription. Document the decision with enough detail to defend it three or more years later.

Red Flag 11: Long Distances Traveled from the Patient's Home to the Prescriber's Office [and] or the Pharmacy.

- This is a high-priority issue for BOP inspectors and investigations. Pay attention to the distance patients are traveling to get to the pharmacy!
- It is not uncommon for patients to travel a great distance to see a recognized specialist, either in private practice or in a tertiary care facility.
- It may not be reasonable to travel a great distance to see a general practitioner.
- Know the prescriber.
- The pharmacy should be within reasonable proximity of the prescriber, the patient's home, or the patient's place of work, or possibly along the route among the three.
- Some CA BOP actions reference a five-mile radius as a usual pharmacy service area.
  - This may be usable in urban settings, but not suburban or rural areas.
  - Specialty service pharmacies will present a larger service radius.
  - The responsible pharmacist will identify outlying communities or small towns in the area that do not have a drugstore.
  - Documentation to support the pharmacy's service area includes prescriptions from patients who are not prescribed controlled substances.

Red Flag 12: Irregularities in the Prescriber's Qualifications in Relationship to the Type of Medications Prescribed.

- This includes prescriptions written outside the prescriber's scope of practice.
- Be certain that the prescriber's DEA registration is valid for the schedule of controlled substances prescribed.
- The pharmacist should be aware that certain medications, such as chemotherapeutics, should only be prescribed by a specialist.

Red Flag 13: Prescriptions Outside the Prescriber's Specialty.

- Use the steps in the Prescriber Validation section to document this.
- Be familiar with the latest Medical Board opioid prescribing guidelines.
- Know when a patient should be referred to a specialist.
- Know which prescribers have DATA 2000 waivers.
  - The DEA validation website will indicate if a prescriber has a DATA 2000 waiver (the "X" DEA number) and whether he is licensed to treat 30 patients (DW30) or 100 patients (DW100). The allowed number of patients is soon to be 275.
  - Buprenorphine (Suboxone/Subutex®) may be prescribed to treat pain. This does NOT require a DATA 2000 waiver ("X" DEA number). It IS off label.
- It may well be within the scope of practice for a dentist to prescribe a cough syrup to enable dental treatment.
- It may be very difficult to justify #180 Oxycodone 30 gm for lower back pain from an 80-year-old board-certified ophthalmologist.
- Use caution with pediatricians treating adults, except for some contagious diseases.
- Use caution with an OB-gyn treating a male patient, except for some contagious diseases.

Red Flag 14: Prescriptions for Medications with No Logical Connection to an Illness or Condition.

- Review the pharmacist's corresponding responsibility as defined in Health and Safety Code 11153, "Legitimate medical purpose."
- Ask the patient what he is treating: it should correlate with the prescribed drug.
- Know (or at least be able to look up) the approved and off-label uses of the drug(s) prescribed.
  - Lexicomp subscription service lists many off-label uses in its drug monographs.
- If the drug's applicability is unclear, contact the prescriber. Most prescribers using cutting-edge therapy will be willing to share their validation.

Red Flag 15: Patients Coming in Groups from the Same Prescriber.

- This red flag is difficult to resolve, and any resolution should be documented
- Be cautious and vigilant. This is a BIG red flag.

Red Flag 16: Patients with the Same Diagnosis Codes from the Same Prescriber.

- A specialist's patients will have diagnosis codes for similar conditions, but they should not all be identical.

Red Flag 17: Prescriptions Written for Potentially Duplicate Drug Therapy.

See Red Flag 5.

Red Flag 18: The Same Combination of Drugs Prescribed for Multiple Patients.

Specialists will often prescribe similar, but not identical, drug combinations, especially on days that are routinely set aside for special procedures.

Red Flag 19: Excessively Celebratory Patient Demeanor.

- A patient who has been having problems with insurance coverage or drug shortages may be relieved, but not celebratory.
- Train staff to report this behavior.

The most important part of any patient encounter involving red flags is professionalism. The responsible pharmacist interacts with the patient from a position of knowledge and authority and does not demonstrate his emotional response to a prescription he will not fill. He will not be rude to the patient, throw the prescription back at him, mark up or deface the prescription, or express in a loud voice (or at any volume) than he "does not fill prescriptions for addicts here." The pharmacist explains to the patient that there are aspects of the order that he cannot reconcile, and so he cannot fill the order at this time. The professional pharmacist has no need to lie or state that a drug is out of stock. It is acknowledged that declining to fill a prescription can be uncomfortable or stressful, but the pharmacist who decides to not fill a prescription is able to back up that decision with documentation and reasoning that will stand up to a Board of Pharmacy investigation and will stand firm with his decision. The wording in the lower right corner of the "Notice to Consumer" poster in every California pharmacy references Business and Professions Code §733, which essentially says that valid prescriptions must be filled, with few exceptions. The pharmacist's inability to satisfy corresponding responsibility is one of those few exceptions.

When the responsible pharmacist has confirmed with the physician that he has been presented with a forged prescription, he may decide to call 9-1-1 for an arrest. This is done only if, in his professional judgement, he believes it will not endanger patients or staff, either at that time or later. Even if the pharmacist chooses not to call law enforcement, he may submit his written documentation to the local DEA field office.

Establish a Written Policy

The responsible pharmacist develops a written policy to resolve red flags, if he has that authority, and enforces it. Other pharmacists develop their own policy and use it consistently, and store supporting data readily retrievable in the pharmacy. Once the policy is written, it should be handy for staff, who should be encouraged to know the contents. The responsible pharmacist models proper documentation and decision making at every opportunity. A written policy and a trained staff makes it easier for a relief pharmacist to be consistent.

A sample written policy begins by creating the forms/documents in this paper, which are adjusted for the pharmacist's specific practice. The corresponding responsibility policy will define which forms are to be used under which circumstances and make clear when, how and by whom those forms will be accessed. It will also delegate "fill/do not fill" responsibility to certain positions. The corresponding responsibility policy may, at the discretion of the pharmacist in charge, set boundaries at which staff pharmacists may not fill a prescription without written PIC approval. Basic forms might include:

1. Patient data forms for demographic data with copies of ID, CURES, diagnosis codes, PAs, insurance information, tried/failed drug list, prior prescribers, problematic behavior, list of those who may share HIPAA information, list of people authorized to pick up prescriptions, etc.
2. Prescriber data forms for CMB, DEA, NPPES, address validation, specialty validation, FAX form for data request.
3. Red Flag Resolution Form: see Appendix 1.

Conclusion

The responsible pharmacist knows that corresponding responsibility is more than just filling out a series of forms. Corresponding responsibility is the pharmacist's judicious application of his knowledge and expertise to the data he has collected in order to make a prudent decision about dispensing a controlled substance, and complying with the law.

The processes in this paper may seem like a lot of extra work at first. They are a lot of extra work for new patients and providers, but a validated patient file may only need to be updated once or twice a year. Prescribers may not need to be updated as often.

In order to dispense controlled substances as safely as possible, the responsible pharmacist will satisfy the principles of corresponding responsibility. He protects his license, his patients, and his community by establishing a universal precautions policy for all controlled substance prescriptions. The pharmacist is reminded that CA B&P code §11153 reads "knowing violation," and that meeting his corresponding responsibilities should preclude any knowing violation. The responsible pharmacist demonstrates that he is executing his due diligence and using the available tools to prevent controlled substance diversion.

Author Credits

Dr. Scott Guess is the owner/operator of two independent retail pharmacies specializing in treating patients who suffer with intractable pain. He has over 20 years of direct patient care experience in the field. Dr. Guess received his Doctor of Pharmacy from the University of the Pacific in 1983, and his Master of Science in Pharmacy from the University of Florida, Gainesville, in 2016. Dr. Guess also holds a Diplomate Certificate from the Academy of Integrative Pain Management. Dr. Guess also holds one of the new Advanced Practice Pharmacist Licenses in California. In 2012, the California Pharmacists Association named Dr. Guess the Innovative Pharmacist of the Year for his work in the pain management field and corresponding responsibility, and in 2017, Cardinal Health Generation Rx Honor for his work in drug misuse, abuse and overdose prevention.

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- Pain Management Pharmacy, Inc., owner
- En Soleil Pharmacy, Inc., owner
- PainTrac,™ a corresponding responsibility compliance tool, developer
- VeraPharm, Inc., a palliative care patient care clinic, owner

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that you attribute the board as the author or source of these documents.

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Appendix 1

Red Flag Resolution

☐ Irregularities on the Rx/Missing required elements
☐ Missing date or signature in prescriber's handwriting
☐ Nervous or celebratory patient
☐ Age or presentation of patient
☐ Multiple patients/same address
☐ Multiple prescribers/duplicative Tx
☐ Cash payment (use cash payment justification form)
☐ Request for early refill

☐ Unusual quantity/directions
☐ Duplicative Tx
☐ Initial Rx for strong opioids
☐ Distance from home or prescriber
☐ Scope of usual practice/outside of specialty
☐ No logical correlation of meds to Dx
☐ Other_____

Details of red flag:_____

Resolution:

☐ Rx classified as DNF, red flag NOT resolved

☐ Rx filled, red flag RESOLVED_____

_____

☐ Documentation attached ☐ Rx returned to patient ☐ Rx rescinded by prescriber

ATTACH A PHOTOCOPY OF THE RX AND OTHER DOCUMENTS:

RPh Signature Date

Appendix 2

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

www.dea.gov

OCT 15 2008

Dear Colleague:

On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to policy posted on the DEA Diversion website regarding changes a pharmacist may make to a schedule II prescription after oral consultation with the prescriber. In a Question and Answer section, the website instructed that a "pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner."

DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Questions regarding this correspondence may be directed to the Liaison and Policy Section, Office of Diversion Control, DEA at (202) 307-7297.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator/
Deputy Chief of Operations
Office of Diversion Control

Appendix 3

Law pertaining to pharmacists' changes to prescriptions

1761. Erroneous or Uncertain Prescriptions.

a. No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
b. Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code, and Section 11153, Health and Safety Code.[18]

The official instruction from the California Board of Pharmacy was in "SB 151 Q&A," a document posted on its website:

"As of January 1, 2005, a Schedule II prescription containing errors should be handled as any other prescription that is uncertain, unclear, and/or ambiguous: the pharmacist must contact the prescriber to obtain the information to validate the prescription (Title 16 of the California Code of Regulations section 1761, subdivision (a).)"[20]

This statement clearly states that 1761 does apply to Schedule II drugs and fulfills Mr. Rannazzisi's instructions to his pharmacy colleagues.[19]

Appendix 4

CURES is a great tool, but at this time, it has its limitations.

- The pharmacist must apply for use of the CURES system. It is some effort, but worth it. It was required beginning July 1, 2016.
- CURES users will be issued a password.
  - The password must be renewed every 90 days; if not, the user will be locked out and required to supply the answers to all the security questions entered at the time of registration. A "change password" reminder will appear during login starting 10 days before the current password expires.
  - The subscriber may not reuse any of the previous 24 passwords.
  - It is wise to create a password metric that can be easily tracked and remembered.
- Know the rules:
  - Do not share the CURES report with ANYONE, except the prescriber.
    - Not patients.
    - Not third party companies.
    - Not worker's comp.
  - ONLY access data for YOUR patients. People have lost their jobs for violating this rule.

Appendix 5

Excerpts from the [California] 2016 Lawbook for Pharmacy.

Health and Safety Code

11162.1. Form and Content of Prescription Blanks for Controlled Substances

a. The prescription forms for controlled substances shall be printed with the following features:
   1. A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
   2. A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
   3. A chemical void protection that prevents alteration by chemical washing.
   4. A feature printed in thermochromic ink.
   5. An area of opaque writing so that the writing disappears if the prescription is lightened.
   6. A description of the security features included on each prescription form.
   7. (A) Six quantity check-off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:
      1-24
      25-49
      50-74
      75-100
      101-150
      151 and over.
      (B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
   8. Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

9. The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.
10. Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
11. The date of origin of the prescription.
12. A check box indicating the prescriber's order not to substitute.
13. An identifying number assigned to the approved security printer by the Department of Justice.
14. (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
    (B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

b. Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

c.

1. A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.
2. Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.
3. Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
4. (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.
   (B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

d. This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.

