



PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

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“SPECIAL PHARMACY CE: VALIDATION OF PAIN MEDICATION PRESCRIPTIONS & REVIEW OF FEDERAL CONTROLLED SUBSTANCES DISTRIBUTION REQUIREMENTS”

October 2016

SOUND PROFESSIONAL JUDGEMENT. Controlled substances are a valid, ethical and rational therapeutic treatment option in the medical practitioner's armamentarium for treating a myriad of diseases and conditions. We as pharmacy practitioners **MUST** advocate for those patients who **NEED** these medications.

That being said, we **MUST** also be a vital part of the “loop” that is aware of diversion and abuse of controlled substances. To this end, many states are enacting rules, procedures or statutes that provide for a more proactive, involved and rational approach when it comes to distribution of controlled substances.

IN THIS LESSON, we use the model that has been developed in Florida. It deals with modifications for dispensing of pain medications.

Specifically, it is called **VALIDATION OF PRESCRIPTIONS FOR CONTROLLED SUBSTANCES**.

IN THIS LESSON, WE DISCUSS ALL ASPECTS OF THIS NEW PROGRAM.

ADDITIONALLY, WE REVIEW FEDERAL CONSIDERATIONS (ASPECTS OF THE FEDERAL CONTROLLED SUBSTANCES ACT) THAT INVOLVE DISTRIBUTION AND IMPACT DAILY PHARMACY PRACTICE.

NOTE: THIS LESSON SATISFIES THE 2.0 HOUR (0.2 CEU) REQUIREMENT IN FLORIDA FOR “VALIDATION OF PRESCRIPTIONS FOR CONTROLLED SUBSTANCES.”

The goals of this pharmacy CE lesson are:

1. To ensure that valid and legitimate controlled substance medications are available for patients who legitimately need them.
2. To describe, using the Florida model, the necessity for pharmacy to be completely involved and committed to reduce abuse associated with controlled substances.

The objectives of this lesson are such that upon completion pharmacists & technicians will be able to:

1. Describe the responsibility of pharmacy practitioners to determine the validity of controlled substance prescriptions.
2. List factors that pharmacy practitioners might consider in their assessment of a controlled substance prescription's legitimacy.
3. Describe the basic principles for utilization of a Prescription Drug Monitoring Program.
4. List laws & rules related to the prescribing & dispensing of controlled substances.
5. Review Federal Guidelines that impact upon distribution of controlled substances.

The State of Florida has been "out front" in developing what is actually a model for this whole area of consideration. We shall use their program in this lesson because a number of states are following suit. The program itself is called **Validation of Prescriptions for Controlled Substances**. Areas of discussion shall be:

- Ensuring access to controlled substances for all parties with a valid prescription.
- Use of the Prescription Drug Monitoring Program's Database.
- Assessment of prescriptions for appropriate therapeutic value.
- Detection of prescriptions not based on a legitimate medical purpose.
- The laws and rules related to the prescribing and dispensing of controlled substances.

Additionally, as indicated we also review significant concepts of the Federal Controlled Substances Act (DEA) that impact upon pharmacy practice and distribution of controlled substances. That portion of this lesson is a REVIEW. It's important because these concepts impact pharmacy practice every day.

This lesson provides 2.0 contact hours of credit for Florida Pharmacy Practitioners, and 3.0 contact hours (0.3 CEUs) of credit for participants enrolled in the cpeMonitor program. This lesson is intended for pharmacists and technicians in all practice settings.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

The ACPE program ID # for this lesson is 707-000-16-010-H03-P for pharmacists & 707-000-16-010-H03-T for technicians.

CE Provider CE Broker ID # 50-15024. Program Tracking # 20-565068.

Participants completing this lesson by September 30, 2019 may receive full credit. Release date: October 1, 2016. (Deadline for Florida participants is September 30th of odd numbered years, which corresponds to the last day of each license period).

If you have any comments, suggestions or questions, contact us at the above address on page 1, or call 1-847-945-8050. Please write your name, NABP eProfile (CPE Monitor®) ID Number & birthdate (MM/DD) in the indicated space on the quiz page.

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PROVIDE YOUR FLORIDA LICENSE NUMBER IN THE SPACE PROVIDED ON THE QUIZ SHEET.**

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When you return quiz, always keep a copy. You may mail or fax quiz. Fax number is 847-945-5037. Or send a conventional email with your answers. (**ceinfo@wfprofessional.com**).

This aim of this lesson is for educational and informational purposes. It is noncommercial, independent & unbiased.

Contributing Faculty/Authors

David B. Brushwood, RPh, JD
Emeritus Professor of
Pharmaceutical Outcomes & Policy
University of Florida College of Pharmacy
Gainesville, FL

Senior Lecturer
University of Wyoming
College of Pharmacy
Laramie, Wyoming

Executive Editor

William J. Feinberg, RPh, MBA

INTRODUCTION

Pharmacists hold the key to the nation's drug supply. One of the most important responsibilities of pharmacists is to assure that patients who need their medications receive them. At the same time pharmacy, in general, must be actively involved in assuring that persons who would divert and/or abuse medications are denied access to them. In recent years, the challenge of prescription drug abuse prevention has at times led to pharmacy practices that over-emphasize restrictions on access to medications, making it difficult for patients who truly need them to get them. **It is our intent to describe how a balanced approach to pharmacy practice can protect the public from harm due to prescription drug abuse, while at the same time providing necessary medications for patients whose medical conditions require their use.**

Actually, our approach in this lesson is dual pronged:

1. We shall discuss significant aspects related to "Validation of Pain Medication Prescriptions." The model or template that we utilize in this discussion is the new and/or modified regulations in Florida. Several other states are also considering similar approaches.
2. Our second goal in this lesson is to review federal regulations relevant to distribution of controlled substances. This 2nd portion is purely an update and review.

NOTE: The first portion of this lesson (related to validation of pain medication prescriptions) is the key information that we are conveying.

ENSURING ACCESS TO CONTROLLED SUBSTANCES FOR ALL PATIENTS WITH A VALID PRESCRIPTION

A number of Pharmacy Boards are reacting to the balanced approach of patient protection from abuse, and ensuring access for legitimate use.

Florida is "out front" in these areas, and we shall use their model for purposes of this lesson. Check with other specific state boards of pharmacy in order to determine provisions that may have been modified in those other states.

The Florida Board of Pharmacy has recently modified its regulation establishing standards of practice for the filling of controlled substance prescriptions. (64B16-27.831). The new language of that regulation includes recognition by the Board that it is important for patients in Florida to be able to fill valid prescriptions for controlled substances. The Board specifies that in screening controlled substance prescriptions, pharmacists are not expected to take any specific action beyond exercising **sound professional judgment**. Pharmacists should not fear disciplinary action from the Board, or any other regulatory or enforcement agency, for dispensing controlled substances that have been prescribed for **a legitimate medical purpose and in the usual course of professional practice**. The Board recognizes that each patient's situation is unique, and that prescriptions for controlled substances should be reviewed by a pharmacist based on that fact. Pharmacists are advised by the Board to work with both the patient and the prescriber to assist in determining the validity of each prescription.

The Board defines a "**valid prescription**" as one that is "**based on a practitioner-patient relationship**" and that has been "**issued for a legitimate medical purpose.**" By way of contrast, an "**invalid prescription**" is one that "**the pharmacist knows or has reason to know. . .was not issued for a legitimate medical purpose.**" There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance. However,

a concern with validity does not necessarily mean a prescription should not be filled. The Board instructs pharmacists to attempt to determine the validity of each controlled substance prescription, and to attempt to resolve any concerns about the validity of the prescription by exercising independent professional judgment.

The Board clarifies three important standards related to the validation of a controlled substance prescription by a pharmacist:

1. No person nor a licensee shall interfere with the exercise of a pharmacist's independent professional judgment.
2. The pharmacist shall ensure that all communication with the patient is not overheard by others.
3. If, at any time, the pharmacist determines, based on professional judgment, that concerns with the validity of a prescription cannot be resolved, the pharmacist shall refuse to fill the prescription.

The Board has promulgated minimum standards for refusing to fill a prescription. Pursuant to these standards, a pharmacist is instructed by the Board to attempt validation of a prescription by initiating communication with the patient or with the patient's representative to acquire information relevant to the pharmacist's concern about the validity of a prescription. Pharmacists are also instructed to communicate with the prescriber or prescriber's agent to acquire information relevant to a prescription's validity.

As an alternative to either of these communication efforts, but not both, the pharmacist may access the state's Prescription Drug Monitoring Program (E-FORCSE) to acquire information related to the pharmacist's concern about the validity of a prescription. (E-FORCSE = Electronic Florida Online Controlled Substance Evaluation Program). Should a pharmacist's efforts to communicate with a patient or prescriber be unsuccessful due to refusal by the patient or prescriber to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription need not be met.

The Board recognizes that pharmacists may become aware of a prescriber's involvement with the diversion of controlled substances. When a pharmacist has reason to believe that prescriber involvement with controlled substance diversion is occurring, the pharmacist must report the prescriber to the Florida Department of Health.

USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM'S DATABASE

Pursuant to Florida Statutes (893.055), a Prescription Drug Monitoring Program (PDMP) has been established. Through the PDMP, a pharmacist may request a patient advisory report. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient.

The PDMP is designed to provide information regarding dispensed prescriptions of controlled substances. It is not intended to infringe on the legitimate prescribing of controlled substances by a prescriber or dispenser acting in good faith or in the course of professional practice.

The patient advisory reports provided by the PDMP to pharmacists are created from a database of information accumulated through the aggregation of prescription data provided to the program by dispensing pharmacies. These data include:

1. The name of the prescribing practitioner, the practitioner's Drug Enforcement Administration

registration number, the practitioner's National Provider Identification or other appropriate identifier, and the issuance date of each prescription.

2. The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment.
3. The full name, address, and date of birth of the patient for whom the prescription was issued.
4. The name, national drug code, quantity, and strength of the controlled substance dispensed.
5. The full name, federal Drug Enforcement Registration number, and address of the pharmacy or other location where the controlled substance was dispensed.

Each time a controlled substance is dispensed to an individual, the controlled substance must be reported to the PDMP through the system as soon thereafter as is possible, but not more than seven (7) days after the date the controlled substance was dispensed.

Through the Florida PDMP, (E-FORCSE), pharmacists who request patient advisory reports can equip themselves with a useful tool to support their validation of the controlled substance prescriptions for which concerns of validity exist. An E-FORCSE patient advisory report cannot, by itself, validate or invalidate a prescription. However, the patient's history of controlled substance acquisition can inform the decision a pharmacist independently makes about a prescription's validity, based on the exercise of the pharmacist's professional judgment.

ASSESSMENT OF PRESCRIPTIONS FOR APPROPRIATE THERAPEUTIC VALUE

There are always risks in the use of controlled substances in the treatment of pain. These risks must be considered when evaluating prescriptions for validity. Pharmacists have a responsibility to evaluate each patient's drug therapy and to resolve questions that may arise regarding the appropriateness of the patient's therapy and whether the patient will derive therapeutic value from the drug therapy. In doing this, pharmacists may want to develop and apply specific criteria that can be objectively measured. The use of specific and objective criteria can support concerns that a pharmacist may wish to raise with a prescriber during consultation regarding the therapeutic value of a prescription.

These same criteria may, on the other hand, support an explanation by a pharmacist of why initial concerns about a prescription have been resolved without the necessity of consultation with the prescriber.

The following are examples of factors that a pharmacist may recognize as raising questions about the therapeutic value of a prescription:

1. The patient is using three or more different opioids at the same time.
2. The patient is using an opioid, a benzodiazepine, and a skeletal muscle relaxant such as carisoprodol at the same time.
3. The instruction "PRN" has been used in the directions for an extended release/long acting (ER/LA) opioid.
4. The prescription is for an ER/LA opioid that is intended to be used every 12 hours, yet the instructions on the prescription are to use more often.
5. The prescription is for an ER/LA opioid to be used to treat post-operative pain.

6. The prescription is for a q12 ER/LA opioid, and the quantity prescribed is 14 dosage units or less.
7. The prescription is for a q12 ER/LA opioid, and the quantity prescribed is 65 dosage units or more.

None of these factors is a deal breaker. Although they may raise potential concerns about the therapeutic appropriateness of prescribed medications, they may also be easily explained through consultation with the prescriber and/or patient. The point is not that any of these factors, or even all of them together, should identify a prescription as invalid or valid, rather, the consideration is that by being aware of these factors, and through consultation with the prescriber and/or patient, a pharmacist may be in a solid position to exercise professional judgment regarding the validity of a prescription.

The following are examples of additional factors that a pharmacist may recognize as relieving concerns about the therapeutic value of a prescription:

1. The patient regularly receives prescriptions from a mental health professional who is caring for the patient.
2. The patient has not requested an additional supply of opioids more than 20% "too early" within the previous 6 months.
3. There is documentation of the patient using over 60 mg of oral morphine equivalent daily for 7 previous days.
4. The patient's total opioid dosage is less than 200 mg of oral morphine equivalent daily.
5. The patient uses fewer than 20 total dosage units of controlled substances daily.
6. The directions for use of the prescribed medication are consistent with the dosing frequency in the product labeling (i.e., q12h, q24h).

None of these factors is a deal maker. They are factors that may, or may not, relieve a pharmacist's concerns about the therapeutic value of a controlled substance prescription. They may be useful as subjects of discussion in consultation with either a prescriber or a patient.

DETECTION OF PRESCRIPTIONS THAT ARE NOT FOR A LEGITIMATE MEDICAL PURPOSE

The federal Drug Enforcement Administration has for many years published criteria that may indicate a prescription was not issued for a legitimate medical purpose. Unfortunately, these criteria tend to be non-specific and subjective. They invite speculation rather than providing clear guidance.

The traditional DEA criteria, quoted verbatim from the DEA's "Pharmacist's Manual" are as follows:

1. The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
2. The patient appears to be returning too frequently. A prescription that should last for a month in legitimate use is being refilled on a biweekly, weekly, or even daily basis.
3. The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. (Drug abusers often request prescriptions for "uppers and downers" at the same time).

4. The patient presents prescriptions written in the names of other people.
5. A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
6. People who are not regular patrons or residents of the community show up with prescriptions from the same physician.

One challenge for pharmacists with this list of criteria is that phrases like "significantly more prescriptions," "short period of time," and "residents of the community" are open to interpretation. Criteria are more useful when they provide definite parameters and do not require judgments about what is "significant" or what is "short" or how to define a "community" and whom to consider as a "resident" of that community.

A second challenge with the criteria is determining the weight to attach to a criterion such as a person presenting a prescription in the name of another person, when the patient whose name is on the prescription is incapacitated due to illness, and a relative is providing understandable support for that patient by acquiring the medication from the pharmacy for the patient. Do circumstances matter when a person other than the patient is presenting a written prescription, or is the DEA suggesting that this criterion should necessarily raise concerns about prescription legitimacy regardless of the circumstances?

Having criteria is useful, but being given guidance on how to apply the criteria is even more useful. The DEA criteria lack guidance for use, and the pharmacist must subjectively decide how to use them.

The DEA also publishes criteria that may indicate a forged prescription. These are also from the DEA's "Pharmacist's Manual," and are as follows:

1. Prescription looks "too good." The prescriber's handwriting is too legible.
2. Quantities, directions, or dosages differ from usual medical usage.
3. Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentation.
4. Prescription appears to be photocopied.
5. Directions are written in full with no abbreviations.
6. Prescription is written in different color inks or written in different handwriting.

As was the case with the previous DEA list, these criteria require the application of judgment in the face of uncertainty of meaning. For example, a pharmacist might wonder what makes a prescription look "too good," or what the "usual medical usage" is of a drug like morphine where pharmacotherapy is individualized for each patient, or where to find the "acceptable standard abbreviations" that are used in the community setting, or how to evaluate whether a prescription "appears to be photocopied." The difficulty of using vague criteria such as these may lead pharmacists to seek more specific criteria that can be answered either "yes" or "no," rather than "maybe."

In Florida, the Board of Pharmacy has attempted to provide additional guidance as pharmacists evaluate controlled substance prescriptions for legitimacy. Under the new Florida Board of Pharmacy rule, pharmacists are required to consider the legitimacy of a prescription based on factors both **related and unrelated** to the therapeutic value of the prescription. Therapeutic value is a necessary consideration, but it is not sufficient in the evaluation of prescription

validity. **For a prescription to be valid, the pharmacist must consider factors that go beyond those related to therapeutics. These factors include the circumstances of the prescription (patient's illness or condition), the prescriber, the patient, and the medication itself.**

The following are examples of specific and objective factors that a pharmacist may recognize as raising concerns about the legitimate medical purpose of a prescription:

1. Another person at the same address is also using opioids dispensed by the pharmacy.
2. The patient has reported lost or stolen medications more than once in the past 6 months.
3. The patient resides in a group setting (i.e., college dorm, halfway house) with 3 or more other persons.
4. The patient has been "inherited" from another pharmacy from which the patient was dismissed.
5. Five or more of the exact same prescriptions (same drug, strength, quantity, directions, prescriber) were filled for others on the previous day.
6. The medication is being picked up on a Saturday or Sunday when the prescriber is difficult to locate for verification.
7. The medication is being picked up between 6pm and 9am when the prescriber is difficult to locate for verification.

These are all objective factors that may cause a pharmacist to be concerned that a prescription may not have been issued for a legitimate medical purpose. None of these factors alone can lead to a firm conclusion one way or another. However, taken together, these factors may be relevant to a pharmacist's independent exercise of professional judgment in the evaluation of a controlled substance prescription for legitimacy.

The following are examples of factors that a pharmacist may recognize as alleviating concerns about the legitimate medical purpose of a prescription:

1. Patient's address is same 3-digit zip code as pharmacy's address.
2. Pharmacy's address is same 3-digit zip code as prescriber's address.
3. Patient's address is same 3-digit zip code as prescriber's address.
4. The patient is willing to accept generic products.
5. The patient's controlled substances are paid for by a third-party payer.
6. The pharmacist has determined that the patient's PDMP report is non-problematic.
7. The prescribed drug is an abuse-deterrent formulation.
8. The pharmacy has dispensed non-controlled substance medications to the patient each month for the past 6 months.
9. The prescriber is a pain specialist known to the pharmacy.
10. The patient has signed a medication use agreement that has been shared with the pharmacy.
11. The patient is a "regular customer" at the pharmacy.

These factors may offset concerns about prescription legitimacy that have developed based on other factors that have raised concerns for a pharmacist. The totality of the circumstances

can be considered by a pharmacist in making an independent professional judgment about prescription validity.

LAWS AND RULES RELATED TO THE PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES

All controlled substance prescriptions must adhere to a specified format. According to Florida Statutes (456.42) the following requirements must be met for a prescription:

1. Legibly printed or typed so as to be capable of being understood by the pharmacist.
2. Must contain the name of the prescriber, the name and strength of the drug prescribed, the quantity prescribed, and the directions for use.
3. Must be dated and signed by the prescriber on the date of issuance.

In addition, for controlled substance prescriptions, Florida Statutes require the following:

1. The quantity of the drug must be specified in both textual and numerical formats.
2. The date of the prescription must be stated in numerical month/day/year format, or with the abbreviated month written out, or the month written out in whole.
3. Prescriptions must be issued either on a standardized counterfeit-proof prescription pad produced by a vendor approved by the Florida Department of Health, or issued through electronic means that satisfy legal requirements.

In addition to these state requirements, the federal Drug Enforcement Administration requires these pieces of information on a controlled substance prescription (21 CFR 1306.05):

1. Full name and address of the patient.
2. Dosage form of the drug.
3. Address and DEA registration number of the prescriber.

Federal and state laws impose additional requirements related to controlled substance prescribing and dispensing. Several of these requirements are particularly relevant to the reduction of prescription drug abuse, due to the possibility of misunderstandings created by well-intentioned parties. For example, some prescribers have recently suggested that they would prefer to allow their patients to acquire controlled substance medications at periodic intervals over a month's time. The purpose of this approach is to prevent intentional or inadvertent overuse of a large amount of medication by dispensing only small amounts of medication at one time. While this is an approach that has traditionally not been allowed under many insurance plans, recently there have been discussions of the value of controlling access to an entire month supply, and some insurance companies have indicated a willingness to allow periodic acquisition of a 5-day or 10-day supply over the course of a month. This approach, while it is perhaps a useful technique to prevent uncontrolled access to large quantities of medication at one time, nevertheless is subject to DEA rules for prescribing and dispensing.

The challenge presented by any plan to allow periodic acquisition of Schedule II medications over a period of time is that the DEA restricts partial filling (21 CFR 1306.13). Schedule II prescriptions cannot be refilled, so providing periodic refills of an amount prescribed through a single prescription will not work for Schedule II medications as could be done for controlled substances in Schedules III, IV and V. A one-time partial supply of Schedule II medications can be provided when a pharmacist is "unable to supply" the full quantity prescribed, but the balance must be dispensed within a 72-hour period. For patients who are either "terminally ill"

or an "LTCF patient," partial filling may be conducted of a single prescription for up to a 60-day period. Thus, the partial filling approach to the provision of periodic supplies of Schedule II medication over a period of time pursuant to a single prescription is not allowed under federal law for most patients.

Fortunately, DEA regulations provide an approach that can be used to provide periodic supplies of Schedule II medications over time. This approach requires the issuance of multiple prescriptions on the same day (21 CFR 1306.12). All prescriptions must be dated as of the date of issuance. On the first prescription, no additional information need be provided. But on each of the additional prescriptions, the prescriber must indicate the earliest date on which they may subsequently be filled. Pursuant to this multiple prescriptions process, patients may be authorized to receive up to a 90-day supply, dispensed periodically over a specified time.

Schedule II prescriptions have additional requirements under DEA regulations. They must be in writing or be issued through a compliant electronic prescribing program. Emergency authorization of C-II dispensing is permitted through verbal order in the case of a true emergency. In such circumstances, the quantity authorized must be limited to that necessary to treat the patient during the emergency. The order must be immediately reduced to writing by the pharmacist, with all necessary information for a C-II prescription, other than the prescriber's signature. If the prescriber is unknown to the pharmacist, then the pharmacist must make a reasonable effort to identify the prescriber and assure that the prescriber is authorized to prescribe the ordered drug. Within seven days after the verbal emergency prescription, the prescriber must deliver to the pharmacist a written prescription that states "authorization for emergency dispensing" on it.

Facsimile transmission of C-II prescriptions from prescriber to pharmacist is always allowed as an accommodation to permit the pharmacist to prepare the medication while the patient travels to the pharmacy to obtain it. But the patient must present the original hard copy of the faxed prescription to the pharmacist prior to receiving the medication.

There are three circumstances in which a facsimile of a C-II prescription can serve as the original:

1. A patient who resides in a long-term care facility.
2. A patient who is enrolled in a state or federally recognized hospice program, or
3. A drug that is to be delivered to the patient through parenteral administration.

The rules for C-III, C-IV and C-V controlled substances are significantly less stringent. Prescriptions for drugs in these schedules can be transmitted verbally, in addition to being written or issued through a compliant electronic prescribing program. Refills of prescriptions for drugs in these schedules are permitted up to five times within six months of the date of issuance, as long as the refilling is authorized by the prescriber. Partial filling with a quantity less than the face amount of the prescription is permitted, as long as the partial filling is documented and the total quantity dispensed pursuant to the prescription does not exceed the total quantity authorized by the prescription.

SUMMARY

The rules for prescribing and dispensing controlled substances have been developed to deter drug diversion and abuse. At times, these rules can appear to be a hindrance to the acquisition of controlled substances by patients who need their medication for legitimate

reasons. Yet, despite the barriers to drug acquisition that can be presented by adherence to the rules applicable to controlled substances, any temptation to bend the rules for the benefit of the patient should be resisted. Knowing and following the rules is an important component of the pharmacist's responsibility to prevent drug diversion.

Pharmacists are faced with significant challenges in determining the validity of prescriptions for pain medications. The law requires that pharmacists use their **professional judgment** in determining whether a prescription is valid. This use of **professional judgment** requires the application of therapeutic expertise and the assessment of circumstances that may suggest a prescription has not been issued for a legitimate medical purpose. In fulfilling this responsibility, pharmacists are required to refuse prescriptions that they know, or have reason to know, are invalid. Pharmacists are also required to attempt to determine the validity of prescriptions, and attempt to resolve any concerns about prescription validity by exercising their **professional judgment**.

IN ORDER TO BEST REACT TO THE CONCEPTS PREVIOUSLY DISCUSSED, WE ARE PRESENTING A REVIEW & UPDATE OF A NUMBER OF SIGNIFICANT CONSIDERATIONS RELATED TO CONTROLLED SUBSTANCES.

DEPENDENCE AND PATIENT MONITORING

Often times the terms addiction and dependence are used interchangeably even though there are many similarities and differences making this inaccurate. Prior to May 2013, in a clinical context and in terms of a framework established by the Diagnostic and Statistical Manual of Mental Disorders (DSM), the terms *substance abuse* and *substance dependence* were most often used. In DSM-IV and previous additions, the distinction between abuse and dependence was based on the concept of abuse as a mild or early phase and dependence as the more severe manifestation. In practice, the abuse criteria were sometimes quite severe. In DSM-V, the revised *substance use disorder*, a single diagnosis, better matches the symptoms that patients experience. Additionally, the diagnosis of dependence caused much confusion. Most people link dependence with addiction when in fact dependence can be a normal body response to opioid use. In DSM-V, the former criteria of both substance abuse and dependence have basically been combined. The removal of the criteria of recurrent substance related legal problems was removed and a criteria dealing with substance cravings was created. If 2-3 criteria are met, then the disorder is classified as mild, 4-5 criteria met then the disorder is classified as moderate, and 6-7 criteria met is classified as severe. These criteria are:

1. Recurrent substance use in situations in which it is physically hazardous.
2. Repeatedly unable to carry out major obligations at work, school, or home due to substance use.
3. Continued substance use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by the effects of the substance.
4. Continuing to use substance despite negative personal consequences.
5. Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount.
6. Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal.

7. Using greater amounts or using over a longer time period than intended.
8. Persistent desire or unsuccessful efforts to cut down or control substance use.
9. Spending a lot of time obtaining, using, or recovering from using substance.
10. Stopping or reducing important social, occupational, or recreational activities due to substance use.
11. Consistent use of opioids despite acknowledgment of persistent or recurrent physical or psychological difficulties from using substance.
12. Craving or a strong desire to use substance.

The first three criteria were from the former diagnosis of substance abuse and the last criterion was added to DSM-V. It is also common for a patient to become physically dependent to opioids through normal, prescribed use and this symptom alone does not suggest a substance use disorder.

With the move of hydrocodone to Schedule II and state programs to help monitor prescriptions filled by patients no matter which pharmacy they use, it has become increasingly difficult for abusers to obtain prescriptions by forgery and doctor shopping. Passage of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 closed many loopholes allowing people to obtain opioids by internet. While a patient who is using street drugs, trying to use his or her prescriptions by chewing, snorting or injecting, or going to multiple doctors would be easy to spot as more than likely abusing opioids, a patient showing more subtle signs and aberrant behavior may be more difficult to determine as to what their intentions are. Pseudoaddiction is when the patient mimics behavior associated with true addiction, but the behavior is fueled by inadequate pain management often due to the distrust between patient and prescriber. Some signs of pseudoaddiction include aggressive complaining about the need for more medicine, drug hoarding during periods of reduced symptoms, repeating specific drugs, reporting psychic effects not intended by the physician, resistant to change in therapy, unsanctioned dose escalation on occasion. Initiating a discussion with the patient about potential aberrant behaviors can be difficult but it provides very useful information as to whether they are under medicated or abusing their prescriptions. It is best to take a nonjudgmental stance, making it more out of concern than an inquisition. This will allow the patient to be more forthcoming. Start with broad, generalized questions regarding therapy overall, avoiding yes or no questions. The patient will be more likely to share how they are taking the medicine which could give more clues as to whether or not the patient is taking their medicine correctly. Proper communication between all clinicians involved in a patient's care will ensure that a patient is being monitored effectively.

THE FOLLOWING IS, PRIMARILY, A REVIEW OF FEDERAL GUIDELINES REGARDING DISTRIBUTION OF CONTROLLED SUBSTANCES.

PROCEDURES THAT ARE INTENDED TO SAFELY FURNISH CONTROLLED MEDICATIONS TO PATIENTS, AND TO AVOID DIVERSION AND ABUSE

There is special confusion when it comes to controlled substance distribution, recordkeeping, and administrative matters. One of the most important responsibilities within pharmacy is to comply with Drug Enforcement Administration (DEA) requirements for the distribution of controlled substances. Not only must pharmacists assure that controlled substance prescriptions

are valid, but all valid prescriptions must be filled in a pharmacy that meets the structure and process requirements of the Controlled Substance Act (CSA) and DEA regulations.

Note: The material that follows is based on information provided by the DEA in its publication "The Pharmacist's Manual." This material is not intended as legal advice. Any pharmacy practitioner who needs legal advice should consult an attorney.

DEA REGISTRATION

Every pharmacy that dispenses a controlled substance must be registered with the DEA. First, a state license or permit must be obtained. After obtaining a state license or permit, the DEA registration may be obtained. To register as a new pharmacy, DEA Form 224 must be completed. The certificate of registration issued by DEA must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered. A pharmacy registration must be renewed every three years utilizing DEA Form 224a. If the expiration date has passed and no renewal has been received by DEA, the pharmacy has no authority to handle controlled substances.

Corporations that own or operate a chain of pharmacies may submit a single DEA Form 224b, Retail Pharmacy Registration Affidavit for Chain Renewal. This affidavit, along with a list of the corporation's registrations, is provided in lieu of a separate registration application for each pharmacy registration.

TRANSFER OF CONTROLLED SUBSTANCES

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.

To transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

TRANSFER TO A PHARMACY

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to the DEA.

DISPOSAL OF CONTROLLED SUBSTANCES

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

REQUESTS FOR EMPLOYMENT WAIVERS FOR CERTAIN PHARMACY EMPLOYEES

Under DEA regulations, a registrant must not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, the regulations permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances.

CONTROLLED SUBSTANCE THEFT OR SIGNIFICANT LOSS: PREVENTION OF ILLEGAL DIVERSION

Should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss.

1. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

2. Complete DEA Form 106

A pharmacy must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved.

If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office and keep a copy for its records. The DEA Form 106 must include the following information:

- Name and address of the firm (pharmacy),
- DEA registration number,
- Date of theft or loss (or when discovered if not known),
- Name and telephone number of local police department (if notified),
- Type of theft (e.g., night break-in, armed robbery),
- List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
- A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

3. If Investigation Finds No Theft or Loss

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, the registrant must notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

4. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- The actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances;
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known;

- Whether the specific controlled substances are likely candidates for diversion; and
- Local trends and other indicators of the diversion potential of the missing controlled substances.

If it is determined that the loss is not significant, the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion.

RECORDKEEPING REQUIREMENTS

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records.

REQUIRED RECORDS

The records which must be maintained by a pharmacy are:

- Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
- Power of Attorney authorization to sign order forms
- Receipts and/or invoices for schedules III, IV, and V controlled substances
- All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
- Reports of Theft or Significant Loss (DEA Form 106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
- Records of transfers of controlled substances between pharmacies
- DEA registration certificate
- Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005

CENTRAL RECORDKEEPING

A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/her intention by registered or certified mail, return receipt requested, in triplicate, to

the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located. Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification.

PRESCRIPTION RECORDS

Pharmacies have two options for filing prescription records under federal regulations. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be *readily retrievable* for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:

Option 1 (Three separate files):

- A file for schedule II controlled substances dispensed.
- A file for schedules III, IV and V controlled substances dispensed.
- A file for all noncontrolled drugs dispensed.

Option 2 (Two separate files):

- A file for all schedule II controlled substances dispensed.
- A file for all other drugs dispensed (noncontrolled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a **red "C" stamp** not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

CONTROLLED SUBSTANCE INVENTORIES

An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II controlled substances and an estimated count or measure of the contents of a schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made). The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

INITIAL INVENTORY

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

BIENNIAL INVENTORY

Following the initial inventory, the registrant is required to take a biennial inventory (every two years), which requires the same information as the initial inventory of all controlled substances

on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.

NEWLY SCHEDULED CONTROLLED SUBSTANCE INVENTORY

When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.

ORDERING SCHEDULE II CONTROLLED SUBSTANCES

Only schedules I and II controlled substances are ordered with an official order form, DEA Form 222, or the electronic equivalent. A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II controlled substance.

When a controlled substance has been moved by DEA from schedule II to another schedule at the federal level, in many states it may remain a schedule II controlled substance pending any legislative or administrative action that may result from the federal action. Many states require transactions that involve substances they classify as schedule II be made via official order forms (DEA Form 222) or the electronic equivalent. When federal law or regulations differ from state law or regulations, a pharmacy is required to abide by the more stringent aspects of both the federal and state requirements. When the use of DEA Form 222 or the electronic equivalent for the transfer of a controlled substance is not required under federal law, its use as mandated by these states does not violate federal law and is therefore permitted.

POWER OF ATTORNEY TO SIGN AN OFFICIAL ORDER FORM

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Form 222.

LOST OR STOLEN ORDER FORMS

When a pharmacist has not received an expected shipment of controlled substances, he/she should first contact the supplier to determine whether the original DEA Form 222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form's serial number and date, and verify that the drugs ordered were never received. The pharmacy must attach a copy of the statement to the second order form that is sent to the supplier. In addition, the pharmacist must keep a copy of the statement with copy three from the first and second order forms.

A pharmacy, upon discovery of the loss or theft of used or unused order forms, must immediately report the loss to the local DEA Diversion Field Office and provide the serial numbers of each lost or stolen order form. If an entire book or multiple books of order forms are lost or stolen, and the serial numbers of the missing forms cannot be identified, the pharmacist must report the approximate date of issuance (in lieu of the serial numbers) to the DEA. If an unused order form reported stolen or lost is later recovered or found, the pharmacy must immediately notify the local DEA Diversion Field Office.

PHARMACY CONTROLLED SUBSTANCE DISTRIBUTION – “FIVE PERCENT RULE”

A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:

- The pharmacy or practitioner that will receive the controlled substances is registered under the CSA to dispense controlled substances;
- The distribution is recorded by the distributing practitioner in accordance with DEA regulations and the receipt is recorded by the receiving practitioner in accordance with DEA regulations;
- If the pharmacy distributes a schedule II controlled substance, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent.

Under the “Five Percent Rule” the total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a distributor.

ORDERING SCHEDULES III-V CONTROLLED SUBSTANCES

The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. These receipts must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received. In addition, these receipts must be maintained in a readily retrievable manner for inspection by the DEA.

RESTRICTIONS ON INTERNET PHARMACY

On October 15, 2008, the President signed into law the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, often referred to as the *Ryan Haight Act*. This law amends the CSA by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called “rogue Internet sites” that unlawfully dispense controlled substances by means of the Internet. The *Ryan Haight Act* applies to all controlled substances in all schedules.

This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy. Thus, any person who knowingly or intentionally dispenses a controlled substance by means of the Internet and does not have a modification of DEA registration allowing such activity is in violation of the CSA and subject to potential criminal prosecution and (in the case of DEA registrants) loss of DEA registration.

STATE LICENSURE REQUIREMENTS

An online pharmacy must comply with the requirements of all applicable State laws concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses, or offers to deliver, distribute, or dispense, controlled substances by means of the Internet. In addition, online pharmacies must certify they are in compliance with

these requirements when completing an *Application for Modification of Registration for Online Pharmacies*.

The requirement that an online pharmacy list the States in which it is licensed to dispense controlled substances is designed to ensure that an online pharmacy only dispenses controlled substances to patients in States in which it is authorized to practice pharmacy. Dispensing beyond the scope of State licensure is one of the recurring transgressions of some rogue online pharmacies and generally violates State law. Under this Act, a State may bring civil action in federal court to enjoin any violation of the Ryan Haight Act – not merely those violations of State law – and to obtain other appropriate legal or equitable relief.

CONTROLLED PRESCRIPTION REQUIREMENTS

In order for a prescription to be valid, it must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or by a covering practitioner. An in-person medical evaluation is a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

FILLING NEW PRESCRIPTIONS FOR CONTROLLED SUBSTANCES—SCHEDULES III-V

The term “filling new prescriptions for controlled substances in schedule III, IV, or V” means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if:

- The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of the CSA and DEA regulations (for purposes of this definition, such a prescription shall be referred to as the “original prescription”);
- The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance; and
- The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

REFILLING PRESCRIPTIONS FOR CONTROLLED SUBSTANCES IN SCHEDULES III-V

The term “refilling prescriptions for controlled substances in schedule III, IV, or V” means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of the CSA and DEA regulation; and does not include the issuance of a new prescription to an individual for a controlled substance that the individual was previously prescribed.

CENTRAL FILL PHARMACY

A “central fill pharmacy” fills prescriptions for controlled substances on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with pharmacies who share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a

"central fill" activity. Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely reflect the disposition of all controlled substance prescriptions dispensed. Central fill pharmacies are required to comply with the same security requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. Retail pharmacies that also perform central fill activities are allowed to do so without a separate DEA registration, separate inventories, or separate records.

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. Both the retail and central fill pharmacists have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. Prescriptions for controlled substances listed in schedules II, III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

- Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
- Ensure that all information required to be on a prescription is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
- Maintain the original prescription for a period of two years from the date the prescription was last refilled;
- Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the retail pharmacy employee accepting delivery;
- For schedules III-V prescriptions, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining (refills for schedule II prescriptions are not permitted).

The central fill pharmacy receiving the transmitted prescription must:

- Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and the DEA registration number of the retail pharmacy transmitting the prescription;
- Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription; and
- Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common, or contract carrier).

Central fill pharmacies must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e. the central fill pharmacy's DEA registration number)

indicating that the prescription was filled at the central fill pharmacy. Central fill pharmacies must comply with the provisions of the C.F.R. when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy (and likewise for retail pharmacies retrieving filled prescriptions from a central fill pharmacy) for delivery to the ultimate user.

LONG TERM CARE FACILITIES

A Long Term Care Facility (LTCF) is defined in the C.F.R. as a nursing home, retirement care, mental care, or other facility or institution, which provides extended health care to resident patients. In most cases, these facilities are not registered with DEA, yet these health care facilities routinely maintain controlled substances issued via prescription to their residents. These controlled substances are already outside the CSA's closed drug distribution system since they have been dispensed to the ultimate user.

LTCFs frequently need to dispose of unused medications due to a change in the resident's medication or the resident's death. Accordingly, LTCFs should contact the local DEA Diversion Field Office for drug disposal instructions. The DEA is aware of issues currently facing LTCFs concerning the dispensing and handling of controlled substances, which are affected by a variety of state laws and circumstances. Pharmacists should check with their state agency for guidelines concerning controlled substances at LTCFs.

USE OF AUTOMATED DISPENSING SYSTEMS BY RETAIL PHARMACIES AT LONG TERM CARE FACILITIES

If state law or regulations permit, the DEA will allow a retail pharmacy to register at the site of the LTCF and store controlled substances in an Automated Dispensing System (ADS). In an ADS, a pharmacy stores bulk drugs in the machine in separate bins or containers. The pharmacy programs and controls the ADS remotely. Only authorized LTCF staff is allowed access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a valid prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. A registered retail pharmacy that possesses additional registrations for ADS machines at LTCFs may keep all records required for those additional registered sites at the retail pharmacy or other approved central location.

DEA registered pharmacies wishing to operate an ADS at an LTCF must contact the DEA Office of Diversion Control, Registration Section for registration instructions.

CONCLUSION

As pharmacy practitioners, we are in a new era of proactiveness. As always, we MUST be involved with the ever increasing sophistication of drug therapies for patients. Secondly, and unfortunately, we MUST be aware, alert and empowered to react to controlled substance diversion and abuse. Our pharmacy regulators are requiring these activities, but as healthcare practitioners, we MUST embrace these issues in order to ensure the health and safety of our patients and the public in general who require controlled substance medications for legitimate uses. It's our responsibility.

MARK CORRECT ANSWER(S)

1. **What is the purpose of a balanced approach to pharmacy practice with regard to controlled substances?**
 - A. Protect the public from harm due to prescription drug abuse, but not provide necessary medications for patients whose medical conditions require their use.
 - B. Provide necessary medications for patients whose medical conditions require their use, but not protect the public from harm due to prescription drug abuse.
 - C. Both protect the public from harm due to prescription drugs abuse and provide necessary medications for patients whose medical conditions require their use.
 - D. Neither protect the public from harm due to prescription drug abuse nor provide necessary medications for patients whose medical conditions require their use.
2. **What specific actions does the Florida Board expect pharmacists to take in validating controlled substance prescriptions?**
 - A. Require a pain management agreement with each patient.
 - B. Conduct a pain assessment of each patient.
 - C. Utilize an abuse and diversion evaluation tool with each patient.
 - D. None, other than exercising sound professional judgment.
3. **What is the basis of a "valid prescription" according to the Florida Board of Pharmacy?**
 - A. The practitioner-patient relationship.
 - B. The evaluation by a Board inspector.
 - C. Concerns expressed by a patient's family member.
 - D. The length of time a patient has used a controlled substance.
4. **Which of the following is a standard established by the Florida Board of Pharmacy regarding validation of a controlled substance prescription by a pharmacist?**
 - A. No person nor a licensee shall interfere with the exercise of a pharmacist's independent professional judgment.
 - B. The pharmacist shall ensure that all communication with the patient is not overheard by others.
 - C. If, at any time, the pharmacist determines based on professional judgment that concerns with the validity of a prescription cannot be resolved, the pharmacist shall refuse to fill the prescription.
 - D. All of the above.
5. **What is the name of the Florida Prescription Drug Monitoring Program?**
 - A. E-FORCSE.
 - B. MONITORx.
 - C. DUR.
 - D. CQI.
6. **From what source does the Florida Prescription Drug Monitoring Program acquire the data they use?**
 - A. The DEA.
 - B. Pharmaceutical manufacturers.
 - C. Dispensing pharmacies.
 - D. The FBI.
7. **Which of the following factors, if recognized by a pharmacist, may raise questions about the therapeutic value of a prescription?**
 - A. An opioid is to be used for non-cancer pain.
 - B. An opioid is to be used in a geriatric patient.
 - C. The patient is using three or more opioids at the same time.
 - D. The patient appears sloppy or unkempt.
8. **Of the following factors that a pharmacist may recognize as relieving concerns about the therapeutic value of a prescription, which is a "deal maker" that guarantees the prescription has therapeutic value?**
 - A. The patient's total opioid dosage is less than 200 mg Oral Morphine Equivalent daily.
 - B. The patient uses fewer than 20 total dosage units of controlled substances daily.
 - C. The directions for use of the prescribed medication are consistent with the dosing frequency in the product labeling.
 - D. None of the above.
9. **A prescriber authorizes partial filling of a prescription for a patient who is "terminally ill." For up to what period of time may the prescription be partially filled under DEA regulations?**
 - A. 30 days.
 - B. 60 days.
 - C. 90 days.
 - D. 120 days.

10. Pursuant to the DEA regulation authorizing the use of multiple prescriptions issued on the same day, patients may receive up to what day's supply dispensed periodically?
- A. 30 days.
 - B. 60 days.
 - C. 90 days.
 - D. 120 days.
11. DEA registration consists of 2 steps: DEA licensure & state licensure.
- A. Obtain DEA approval first
 - B. Doesn't matter which is obtained 1st
 - C. Obtain state approval 1st
 - D. Obtain both simultaneously
12. What form is used to initially register with DEA?
- A. Form 224
 - B. Form 224a
 - C. Form 222
 - D. Form 222a
13. How often must DEA registration be renewed?
- A. Annually
 - B. Biannually
 - C. Every 3 years
 - D. Every 5 years
14. A pharmacy may not employ a person who has at any time been denied a DEA registration and there are no exceptions to this requirement.
- A. True
 - B. False
15. A pharmacy must notify, in writing, the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss of controlled substances.
- A. True
 - B. False
16. The "5 percent rule" refers to:
- A. Basketball
 - B. Registration as a distributor
 - C. Number of online pharmacies
 - D. None of these
17. The Ryan Haight Online Pharmacy Consumer Protection Act became effective in which year?
- A. 2007
 - B. 2008
 - C. 2009
 - D. 2010
18. To transfer a Schedule II drug, you need:
- A. DEA Form 224
 - B. DEA Form 222
 - C. UPS Order Book
 - D. None of these
19. Executed DEA Form 222s must be kept separate from other pharmacy records.
- A. True
 - B. False
20. The Ryan Haight Law:
- A. Amends CSA
 - B. Only refers to Schedule II drugs
 - C. Only applies to foreign pharmacies
 - D. All of these

Fill in all information on the quiz, answer questions and return **Quiz Only** for certification of participation to:
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