

**Q: If a suboxone prescription is written for 90 plus one refill, and the patient is filling 10 at a time, how many times can the prescription be filled? After the 5<sup>th</sup> fill, does the pharmacy need a new prescription?**

This is addressed in 21 CFR § 1306.23 in the federal regulations. Since suboxone is a Schedule 3 controlled substance, you need to look at the total doses that were prescribed, in this scenario #90 plus one refill, thus, you can partially fill with 10 doses up to 18 times as long as no dispensing takes place six months from the date the prescription was written. Each quantity dispensed equal to #90 constitutes one fill or refill.

**Q: The nearest drug incinerator is in Atlanta, GA. It's pretty pricy to get medications there.**

It is our understanding that there is an incinerator in Kent County that can handle hazardous medical waste, which is what medications are currently classified as by the Department of Environmental Quality. There is still an issue with the transportation of these medications across county lines, which poses problems.

**Q: What can we change on a control Rx then?**

**Q: What changes can a pharmacist make to a prescription written for a controlled substance in Schedule 2?**

On Nov. 19, 2007, the 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 the DEA’s previous policy, which permitted the same changes that a pharmacist can make to Schedules 3-5 controlled substance prescriptions after oral consultation with the prescriber. The 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 2 prescription after oral consultation with the prescriber.

Therefore, when information is missing from or needs to be changed on a Schedule 2 controlled substance prescription, the DEA expects pharmacists to use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription.

Visit [www.deadiversion.usdoj.gov/faq/general.htm#rx-8](http://www.deadiversion.usdoj.gov/faq/general.htm#rx-8) for additional information.

**Q: What changes can a pharmacist make to a prescription written for a controlled substance in Schedules 3-5?**

The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations or policies prohibiting any of these changes to controlled substance prescriptions.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

**Q: Which states are complying with the pseudoephedrine law?**

The following states are participating in the National Precursor Log Exchange (NPLEx) program: Alabama, Florida, Indiana, Illinois, Iowa, Kansas, Kentucky, Louisiana, Michigan, Missouri, Nebraska, North Carolina, North Dakota, Tennessee, Texas, South Carolina and Washington.

**Q: We have prescriptions e-mailed to us from our doctors in the building. They are sent by their nurses, then we print the request and call the nurse to verify the prescription e-mailed to us. Is this a legitimate prescription?**

According to Michigan law, 333.17703(6) an electronically transmitted prescription means it's communicated by electronic means, including computer to computer, computer to facsimile machine or electronic mail transmission. Electronically transmitted prescriptions do not include a prescription or refill authorization transmitted by telephone or facsimile machine.

Remember, however, that the receipt of electronic prescriptions by facsimile is not considered electronic by the DEA, and thus requires a manual signature.

**Q: I have not yet been contacted about the NPLEx system. Do I contact them?**

The letter from the Michigan State Police was mailed this week; however, you can contact detective/lieutenant Anthony Saucedo at (517) 241-0586.

**Q: If a physician's assistant (PA) writes a prescription for a Schedule 2 controlled substance, does our label need to show the PA's name on it, or both the doctor and the PA names?**

According to section 333.17757, the receipt shall contain the name of the prescriber or, if prescribed under the prescriber's delegating authority, the name of the delegate. This same language is required on the label if dispensed by a physician with a drug control license. The

intent is that the receipt provided by the pharmacist to the recipient is the same as the label that the name of the delegate who wrote the prescription will appear on the prescription label.

**Q: I was told that as of this time a PA cannot prescribe class II medications because their license does not have class II authority from the DEA yet. Is this true?**

I am not aware of this fact; however, if they could prescribe previously under the three specific scenarios allowed by the Boards of Medicine and Osteopathic Medicine and Surgery, they then would be allowed to prescribe under the new statute. If this is a current restriction, it was never stated in testimony by the PAs or the two Boards representing the practice of medicine nor the Department of Licensing and Regulatory Affairs.

**Q: Does the doctor have to sign prescriptions written by PAs, or does just the name of doctor and his DEA number need to appear on the prescription?**

Prescriptions written by a PA do not need to be co-signed by the delegating physician.

**Q: Must both the mid-level practitioner's name and the name of the supervising physician be present on the prescription label?**

No, both names and their DEA registrations must appear on the prescription form but only the name of the individual who is responsible for the act of prescribing must appear on the prescription label.

**Q: Today, can a prescription for MS Contin 30mg # 30 1 tab qd be changed by a pharmacist to MS Contin 15 mg 2 tabs qd with verbal consent of the prescriber?**

According to the DEA statement, if state law allows pharmacists to make the above change, since the actual drug is not being changed, it would be allowed. Michigan state law does not address specifically what a pharmacist can change. This is why language was included in House Bill 5131 to specifically allow such changes. While it is our belief that neither the DEA nor the Board of Pharmacy would take action on a pharmacist who made and documented such changes, our concern is more with the pharmacy auditors and what action they may take; hence, why we have requested an amendment to the Public Health Code to allow such actions.

**Q: Under dispense prescriptions without bias, is refusing to fill a legal Schedule 2 prescription because you don't agree with the physician's prescribing habits included? For example, a physician who was recently writing prescriptions and patients were selling the drugs in his parking lot.**

The legislation (Senate Bill 735) as introduced states that a pharmacist would not be in violation if they refused to dispense a prescription that is potentially fraudulent.

**Q: Thanks Greg, always a great job!!! Katina**

You are welcome! Thank you.

**Q: For technicians in my situation (college health center), I use students as clerks that have limited technician roles. Will I be required to have all student employees licensed as technicians?**

Not knowing what limited technician roles means, the legislation, Senate Bill 591, specifically identifies what is restricted to only a licensed pharmacy technician. An individual would not be required to be licensed if they were functioning as a cashier or performing billing functions.

**Q: If you know that a Subutex / Suboxone prescription is being used for addiction but the directions say ‘for pain,’ is there any liability on the pharmacist’s part if the physician does not have a DEA number? For example, the pharmacy has access to hospital records which show that the patient is being treated for addiction but the written prescription does not state this.**

Not being an attorney, I cannot provide an opinion. However, if you have access and knowledge of the medication being used in this manner, according to federal regulations, you have a corresponding responsibility for the proper prescribing and dispensing of controlled substances, 21 CFR § 1306.04(a). Additionally, 21 CFR § 1306.05 specifically addresses the required information that must be included on a prescription for a Schedule 3, 4 or 5 narcotic drug approved by the FDA specifically for “detoxification treatment” or ”maintenance treatment.” Also, refer to 21 CFR § 1301.28.

**Q: If on a controlled substance script, can the pharmacist spell out the quantity of the drug if the doctor omitted doing this after verifying Rx with the office, or do they have to return the Rx to the patient? Also, on faxed scripts for controls, if the pharmacist verify the Rx or count or anything (not CII), when you input the info in computer for processing, does the pharmacist indicate this is now a voice Rx or is it still considered a faxed RX?**

The requirement of having the quantity in both written and numeric format as required in the Michigan Public Health Code can be added to the prescription by the pharmacist as long as it is verified and documented by the pharmacist. This would certainly be legal according to the Code but the issue may be with the third-party carrier and their willingness to accept as valid based upon your contract with them.

Regarding the faxed prescription for controlled substances, according to the DEA, these are not considered electronic prescriptions but I would consider it as a faxed prescription if you are not making any corrections to the prescription – just validating based upon corresponding responsibility as required by the DEA.

**Q: Reports from the NPLEx system will default to 30 days prior when requesting but the question that came up was: do we need to maintain copies of the reports (electronic or paper) on-site to comply with state requirements? Will the records held by NPLEx software be sufficient to comply with state and/or federal reporting requirements if we are audited?**

The answer to your question should be found in section (2)(b).

Sec. 17766e. (1) Except as otherwise provided under this section, a person who possesses ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78, shall maintain all products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine in accordance with 1 of the following:

(a) Behind a counter where the public is not permitted.

(b) Within a locked case so that a customer wanting access to the product must ask a store employee for assistance.

(2) A person who sells a product described in subsection (1) shall do each of the following:

(a) Require the purchaser of a product described under subsection (1) to produce a valid government-issued photo identification that includes the individual's name and date of birth.

(b) Maintain a log or some type of record detailing the sale of a product described under subsection (1), including the date of the sale and the time of purchase, the name, address, and date of birth of the buyer, the amount and description of the product sold, and a description of the identification used to make the purchase, such as the state in which a driver license used for identification was issued and number of that license. The seller shall also require the purchaser to sign the log at the time of sale. **Information entered into the national precursor log exchange (NPLEX) satisfies the requirement to maintain a log or some type of record detailing the sale under this subdivision. The log or other means of recording the sale as required under this subdivision shall be maintained for a minimum of 6 months and made available to only a law enforcement agency upon request.** The log or other means of recording the sale is not a public record and is not subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246. A person shall not sell or provide a copy of the log or other means of recording the sale to another for the purpose of surveys, marketing, or solicitations.