



Idaho State Board of Pharmacy

1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 <http://bop.idaho.gov>
P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

Changes Pharmacists May Make to Schedule II Prescription Drug Orders

Continuing Pharmacy Education (CPE) Information

- This CPE program is approved for 0.5 hours of home study CPE in Pharmacy Law for Idaho pharmacists.
- To satisfactorily complete this CPE program, a pharmacist must:
 - Fully read the CPE monograph and complete the accompanying post-test evaluation;
 - Mail the post-test answer sheet, postmarked no later than December 31, 2016, to:
 - Idaho State Board of Pharmacy, Home Study CPE Program, 1199 Shoreline Lane, Suite 303, Boise, Idaho 83720-0067
 - Pass the post-test with a score of at least 80%; and
 - Include a self-addressed stamped envelope (SASE) for the return of a statement of credit.
No statement of credit will be awarded unless a SASE is provided by the pharmacist.

Background

Prescription drug abuse is the fastest growing drug problem in the United States. Idaho currently ranks as the 4th highest state in the country with respect to the nonmedical use of prescription medications. As such, Idaho pharmacists have a critical role to play in determining that each prescription is issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice.

Per the Drug Enforcement Agency (DEA), “a pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one’s business or professional license.”¹

Thus, prior to filling a controlled substance prescription drug order, a pharmacist must first verify its authenticity and validity. Per Idaho law, a prescription drug order is invalid if it:

- is not issued in good faith;
- is not for a legitimate medical purpose;
- is not issued by a licensed prescriber within the course and scope of the prescriber’s professional practice and prescriptive authority;
- is not issued pursuant to a valid prescriber-patient relationship, unless statutorily exempted; or
- is not in the form and including the elements required by law.

In addition, a prescription drug order is invalid if it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. Similarly, a prescription for a controlled substance is invalid if it is written by a prescriber for his or her own self-use, or for a prescriber’s immediate family member when contrary to the prescriber’s scope of practice.

¹ DEA Pharmacist’s Manual. Available from:
http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf



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Valid Prescription Requirements for a Schedule II Medication

To be valid, a prescription drug order for a schedule II medication must include the following twelve elements:

1. Patient's Full Name;
2. Patient's Address;
3. Date Issued;
4. Drug Name;
5. Drug Strength;
6. Drug Quantity, both in alphabetical and numeric forms
7. Dosage Form;
8. Directions for Use;
9. Prescriber's Full Name;
10. Prescriber Address;
11. Prescriber DEA Registration Number; and
12. Prescriber Signature.

Often, in the course of filling a controlled substance prescription, a pharmacist will verify both the authenticity and validity of the prescription, but will identify a required element of the prescription that is missing or incorrect. For example, a prescriber may forget to include the patient's home address on the prescription.

Because of the frequency of such an omission or inaccuracy, the Idaho State Board of Pharmacy supports policies that allow pharmacists to make certain changes to Schedule II controlled substance prescriptions. The DEA admits that the agency has issued confusing and contradictory information on this topic in recent years, and consequently the agency notes:

“...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.”²

A summary of allowable changes is provided in **Table 1**.

² DEA Questions & Answers. Available from: <http://www.deadiversion.usdoj.gov/fag/prescriptions.htm#rx-7>



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Table 1. Summary of Changes a Pharmacist May Make to a Schedule II Prescription.

Core Element of a Schedule II Prescription Drug Order	Changes Pharmacist May Make	Process Needed to Make the Change	
		Consultation with a prescriber	May verify from a reliable source
1. Patient's name	<p>If a patient name is <u>not</u> specified on the prescription, a pharmacist may <u>not</u> correct the prescription, and a new prescription must be obtained.</p> <p>If a patient's name is indeed written, however, a pharmacist may make minor corrections, such as changing a maiden name to a married name, or correcting a misspelled name.</p>	✓ (Minor changes only; cannot add a missing name)	✓ (Minor changes only; cannot add a missing name)
2. Patient's Address	A pharmacist may change or add	✓	✓
3. Date issued	<p>A pharmacist may add a missing date, or may change an obvious prescriber's error when writing the date of issue. For example, if the prescriber incorrectly listed 2014 when they clearly meant 2015, a change is possible.</p> <p>A date may <u>never</u> be changed, however, to circumvent an expiration date. For example, there is a ninety (90) day time limit with which a patient can fill a CII prescription; if a pharmacist suspects that such a date change is attempting to circumvent this legal limit, a change should not be made.</p>	✓	
4. Drug name	If drug name is <u>not</u> specified on the prescription, a pharmacist may <u>not</u> correct the prescription, and a new prescription must be obtained.	Cannot add or change	Cannot add or change
5. Drug strength	A pharmacist may change or add	✓	
6. Drug quantity	A pharmacist may change or add. In addition, a pharmacist may add the alpha and/or numeric quantity.	✓	
7. Dosage form	A pharmacist may change or add	✓	
8. Directions for use	A pharmacist may change or add. A "fill on" date commonly used for multiple CII prescription drug orders is considered part of the directions for use.	✓	
9. Prescriber's full name	If a prescriber name is <u>not</u> specified on the prescription, a pharmacist may <u>not</u> correct the prescription, and a new prescription must be obtained.	Cannot add or change	Cannot add or change
10. Prescriber address	A pharmacist may change or add	✓	
11. Prescriber DEA registration number	A pharmacist may add	✓	✓
12. Prescriber Signature	A pharmacist may not change or add, and a new prescription must be obtained.	Cannot add or change	Cannot add or change



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Elements a Pharmacist May Never Add to a Schedule II Prescription Drug Order

Thus, a pharmacist may never add the following four elements of a Schedule II prescription if they are missing:

- Patient's Name;
- Drug Name;
- Prescriber's Name; and
- Prescriber Signature.

Of these aforementioned elements, while a patient's name may never be added if it is missing, the patient's name may be changed, but only in the rare instance of an obvious error, such as a misspelling, or if the physician accidentally wrote the patient's maiden name. The remaining elements may never be added or changed.

Elements a Pharmacist May Change on a Schedule II Prescription

Other elements of a Schedule II prescription drug order may be changed by a pharmacist, as described in Table 1, using his or her professional judgment, in consultation with and upon agreement of the issuing prescriber.

Any such change after consultation with the prescriber must be immediately reduced to writing by the pharmacist. For example, if an otherwise valid Schedule II prescription left off the alphabetical quantity, a pharmacist may add this element to the prescription and should document the change on the hard copy prescription or through another suitable documentation system.

Only three items may be changed without a consultation with the issuing prescriber:

- Patient's Full Name (*corrected; not added*);
- Patient Address; and
- Prescriber DEA Registration Number.

These three elements must, however, be verified through a reliable source. For example, the patient's name or address may be verified through a government issued identification card. Similarly, the prescriber's DEA registration number may be verified through the pharmacy's management system.

Documenting a Change to a Schedule II Prescription Drug Order

After the pharmacist contacts the prescriber and obtains verbal permission for an appropriate change, the pharmacist should document the change on the prescription, or another suitable documentation system. Specifically the pharmacist should note the following information:

- Change that was authorized;
- Date of the consultation;
- Name or initials of the individual granting authorization; and
- Initials of the pharmacist.



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Schedule II Multiple Prescription Drug Orders

While refills are not permissible for a Schedule II medication, a prescriber may issue multiple prescription drug orders written on and dated with the same date, that allow the patient to receive up to a ninety (90) day supply of a Schedule II controlled substance. To be consistent with both federal and Idaho law, the following conditions must be met:

- Each prescription must be issued on a separate prescription blank;
- Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
- The individual practitioner must provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription; and
- The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

Thus, the prescriber can provide written instructions on each prescription drug order indicating the earliest date on which a pharmacy may fill each prescription. As such, pharmacists often have questions about the “fill on” date, and how that differs from the “date of issue.” **Table 2** differentiates these two dates.

Table 2. Date of Issue vs. “Fill On” Date

Date	Description	Changes Pharmacist May Make	Process Needed to Make the Change
Date of Issue	This is the date that the prescription is written and signed by the issuing prescriber.	<p>A pharmacist may add a missing date, or may change an obvious prescriber’s error when writing the date of issue. For example, if the prescriber incorrectly listed 2014 when they clearly meant 2015, a change is possible.</p> <p>A date may <u>never</u> be changed, however, to circumvent an expiration date. For example, there is a ninety (90) day time limit with which a patient can fill a CII prescription; if a pharmacist suspects that such a date change is attempting to circumvent this legal limit, a change should not be made.</p>	Consultation with and agreement by a prescriber.
“Fill On” Date	Indicates the earliest date on which a pharmacy may fill a prescription. This is considered part of the directions for use.	A pharmacist may add or change.	Consultation with and agreement by a prescriber.



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Thus, the date of issue may only be changed in the instance of obvious error as described previously. A “fill on” date, by contrast, is considered part of the directions of use, and may be changed in consultation with and by agreement from the issuing prescriber. As with all changes, the pharmacist must document any change that is made to the “fill on” date.

Another question that pharmacists commonly ask relates to legal quantity limits on individual Schedule II prescriptions, given the 90-day supply limit on multiple Schedule II prescription drug orders issued simultaneously. There is no express federal or Idaho limits with respect to the quantities of drugs dispensed via an individual prescription, though many insurance carriers may limit the day supply that can be dispensed. However, the quantity dispensed must be consistent with the requirement that it is for a legitimate medical purpose within the prescriber’s usual course of professional practice.

Expiration of Schedule II Prescriptions

A prescription drug order for a Schedule II controlled substance must not be filled or dispensed more than ninety (90) days after its date of issue. Further, the date of issue reflected on the prescription must be the date the prescription is signed by the prescriber. A prescription drug order is invalid if it is antedated or postdated and may not be dispensed.

As such, when changing the date on a prescription in consultation with a prescriber, a pharmacist must make effort to ensure that any change is not intended to circumvent an expiration date. Changes to the date of issue may only correct obvious errors, such as the prescriber listing the wrong year when a new year has begun. A date may not be changed if the patient did not fill the prescription within the ninety-day window. In such an instance, a new prescription must be obtained.

Conclusion

Prescription drug abuse is a growing public health problem and pharmacists have an important role to play in ensuring that prescriptions are authentic, valid, and for a legitimate medical purpose. Pharmacists may make certain changes to Schedule II controlled substance prescriptions if they are authentic, valid, and for a legitimate medical purpose, yet missing a required element. Proper documentation of such changes is imperative, and incumbent on the pharmacist.



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Post-Test Questions

1. A pharmacist identifies that a prescription for Hydrocodone is missing the prescriber's DEA registration number. Which of the following is true:
 - A. No DEA number is required for this prescription drug order.
 - B. A pharmacist may not add this element to the prescription and a new prescription must be obtained.
 - C. A pharmacist may add this element by using a reliable source, and does not necessarily need to consult with a prescriber.
 - D. A pharmacist may only add this element by consulting with the prescriber.
2. A pharmacist may change the following elements based on a reliable source, and without necessarily having to consult with the prescriber:
 - A. Patient's Name
 - B. Patient's Address
 - C. Prescriber Name
 - D. A and B only
 - E. A, B and C
 - F. None of the Above
3. A pharmacist identifies that a prescription written for Oxycontin has all the required elements, but is missing the patient's name. Which of the following is true:
 - A. The pharmacist may fill the prescription after adding the name listed on the state-issued driver's license of the individual who dropped off the prescription.
 - B. The pharmacist may fill the prescription after consulting with the prescriber and confirming that the missing name was an oversight.
 - C. The pharmacist may not fill the prescription as a missing name may not be added.
4. A pharmacist receives a prescription written for Vicodin 20 mg. Upon consulting with the prescriber, the prescriber confirmed that she intended to write the prescription for Oxycontin 20 mg. Which of the following is true:
 - A. The pharmacist may fill the prescription after consulting with the prescriber and documenting the drug name change on the hard copy prescription.
 - B. The pharmacist may not fill the prescription as a drug name may not be changed.
5. Which of the following elements may be changed or added to a Schedule II prescription only after consultation with and agreement by a prescriber?
 - A. Drug strength
 - B. Drug quantity
 - C. Directions for use
 - D. All of the above
 - E. A and B only
6. A pharmacist receives a prescription for Adderall more than 180 days from the date of issue. In consulting with the prescriber, the pharmacist identifies that the date of issue as written is accurate,



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- but the prescriber would like to change it to today's date so that the patient may still fill the prescription, which he attests is for a legitimate medical purpose. Which of the following are true:
- A. The pharmacist may fill the prescription after consulting with the prescriber and documenting the date change on the hard copy prescription.
 - B. The pharmacist may not fill the prescription, as such a date change is intended to circumvent the prescription's legal expiration date
 - C. The pharmacist may not change a date of issue under any circumstance
 - D. None of the above
7. The following changes can be made to a Schedule II prescription without consulting a prescriber, but by using a reliable source:
- A. Changing the patient's maiden name to a married name
 - B. Correcting an address for a patient who recently moved
 - C. Adding the prescriber's missing DEA registration number
 - D. All of the Above
 - E. None of the Above
8. A patient brings in multiple prescriptions for a Schedule II substance issued on separate prescription blanks but with the same date of issue. On two of the prescriptions the prescriber indicated a date on which the prescription may be filled, but the pharmacist noticed this date listed 2014 instead of the present year. Which of the following is true:
- A. The pharmacist may fill the prescription after consulting with the prescriber, determining that the year was in error, and documenting the "fill on" date change on the hard copy prescription.
 - B. The pharmacist may not fill the prescription, as such a date change is clearly intended to circumvent the prescription's legal expiration date.
 - C. The pharmacist may not change a "fill on" date under any circumstance
 - D. None of the above
9. Which of the following is true:
- A. The date of issue is the date that a prescription is written and may not be changed under any circumstances.
 - B. The "fill on" date indicates the earliest date on which a pharmacy may fill a prescription, and can be changed in consultation with a patient.
 - C. Both the "date of issue" and "fill on date" may be changed as appropriate, in consultation with a prescriber.
 - D. None of the Above
10. When a pharmacist makes an appropriate change to a Schedule II prescription, he or she should document the following elements on the prescription:
- A. Change that was authorized
 - B. Date of the consultation
 - C. Initials of the individual granting authorization
 - D. Initials of the pharmacist
 - E. All of the above



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Post-Test Answer Sheet

- Mail the post-test answer sheet, postmarked no later than December 31, 2016, to:
 - Idaho State Board of Pharmacy, Home Study CPE Program, 1199 Shoreline Lane, Suite 303, Boise, Idaho 83720-0067
- Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

Pharmacist Name: _____

Idaho License Number: _____

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

7. _____

8. _____

9. _____

10. _____

Feedback on this CPE Program:

Ideas for future Board-approved Home Study CPE Programs: