



AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

SPECIAL BULLETIN: LONG-TERM CARE PHARMACIES AND THE DRUG ENFORCEMENT ADMINISTRATION (DEA)

FROM: Claudia Schlosberg, Director of Policy and Advocacy
The American Society of Consultant Pharmacists

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The Drug Enforcement Administration recently stepped up enforcement action against several long-term care pharmacies in Ohio. Pharmacies are being cited for common practices that have evolved in long-term care to meet the needs of patients.

In the wake of these enforcement actions, ASCP and the Senior Care Pharmacy Alliance (SCPA) met with DEA officials on April 7, 2009 to seek clarification of the scope of these investigations, to clarify questions regarding the use of chart orders and whether the nurse in the long-term care facility can act as the agent of the prescriber and to obtain assistance in helping educate pharmacists and practitioners about DEA regulations. Here is a summary of what was discussed:

1. We do not know what triggered any of the current investigations. But DEA did state that they are not targeting long-term care pharmacies.
2. DEA interprets the Controlled Substances Act very narrowly and when violations are found, they will enforce the law.
3. Chart orders in long-term care facilities do not constitute valid prescription orders unless they contain all the information that is required under the Controlled Substances Act. As a general rule, chart orders do not contain the required elements.
4. DEA has been considering ASCP's long-standing request to change its interpretation of the law to recognize chart orders and the nurse as agent of the prescriber. DEA does not appear likely to make any changes in policy with respect to Class II controlled substances. However, DEA said they would get back to us in 90 days regarding Class III-V controlled drugs.
5. We informed DEA that long-term care pharmacies will comply strictly with the law, but strict compliance entails changing many SOPs that have been the standard of practice for 30 years. It also affects the entire long-term care system, including hospitals and the physician community.
6. We explained to them the likely consequences of strict compliance:
 - Some residents will not get their medications or get them timely; nursing facilities may be out of compliance with federal requirements for pain management.

- Physicians likely will be very resistant to complying with the changes needed to strictly comply with the law. Physicians who do not wish to comply may decide not to work in the LTC environment -- this may exacerbate the existing shortage of qualified physicians working in the LTC environment.
 - Nursing facilities and will need to retrain staff.
 - Pharmacies and nursing facilities will have to revise SOPs.
7. We asked DEA to send a Dear Registrant letter to help inform physicians and other health care providers about the need for strict compliance. DEA agreed this would be helpful and will consider our request.

We agreed to schedule another meeting in 90 days to discuss the decision on the handling of CIII-Vs. In the meantime, we urge ASCP members to review their pharmacy procedures to ensure compliance with the law.

To help you, we have prepared a Frequently Asked Questions (FAQ) document that provides basic information about the law and the appropriate way to process these prescriptions. It is important to emphasize that you must also check your state law. If your state law is more restrictive than federal law, then you must follow state law. Further, this FAQ is not a substitute for nor does it constitute legal advice.

ASCP will continue monitoring this situation closely. Ultimately, we believe we will need to seek changes in the law and regulations. Until the law is changed, however, we need to help you make good faith efforts to comply with existing law. To that end, we will be hosting a DEA compliance workshop at the ASCP's mid-year meeting in Orlando, Florida, May 7-9. For more information, please go to <http://www.ascp.com/education/meetings/2009/midyear/index.cfm>.

If you have questions about DEA, this bulletin or the FAQ, please contact Claudia Schlosberg, J.D., Director of Policy and Advocacy at 703-739-1316, ext 128, or at cschlosberg@ascp.com if you have any questions.



FREQUENTLY ASKED QUESTIONS ON DRUG ENFORCMENT AGENCY (DEA) REGULATIONS AND LONG-TERM CARE PHARMACY

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Recent DEA enforcement actions have brought to light the need to provide guidance regarding DEA rules and regulations to pharmacists who dispense drugs to long term care facility residents. It is important to emphasize that this FAQ is not a substitute for nor does it constitute legal advice. Further, because every state has its own regulations regarding the prescribing and dispensing of controlled substances, you must also consult with your State Board of Pharmacy or other appropriate state agencies. If your state law is more restrictive than federal DEA requirements, you must follow the stricter law.

Q1. When can a pharmacist dispense a controlled substance listed in Schedule II to a resident in a long-term care facility?

A1. The most important rule to remember is that a pharmacist is only permitted to dispense a CII controlled drug to a nursing facility resident pursuant to a valid, written prescription signed by the practitioner, unless an exception applies.

(Source: 21 CFR 1306.11(a))

Q2. What constitutes a valid, written prescription?

A2. In order to be considered valid, a prescription for a controlled drug (Classes II-V) must be dated and signed on the date it is issued and contain ALL of the following:

1. the full name and address of the patient
2. the drug name, strength, dosage form, quantity prescribed and directions for use
3. the name, address and registration number of the practitioner.

(Source: 21 CFR 1306.05(a))

Q3. Is a chart order a valid written prescription for a controlled drug?

A3. A chart order can only be a valid written prescription for a controlled drug if it contains all of the information listed in A2. If any of those items are missing, the prescription drug order is invalid and the pharmacist legally cannot fill the prescription.

(Source: 21 CFR 1306.05(a))

Q.4 Who can sign a written prescription order for a controlled drug?

A4. Only the practitioner can sign the prescription order.

(Source: 21 CFR 1306.05(a), 1306.11(a))

Q5. May the pharmacist dispense a CII if the prescription is transmitted to the pharmacy by facsimile?

A5. Yes, but only under the following conditions:

1. The prescription must be written either for a resident in a long-term care facility or in a Medicare hospice program.
2. The facsimile must meet all of the requirements of a valid, written prescription order. This means it must contain all the information listed in A1 above, and it must be signed by the practitioner.
3. In the case of hospice patients, the practitioner or the practitioner's agent must note on the prescription that the patient is a hospice patient.
4. The facsimile must be maintained in the same manner as other prescriptions for controlled drugs.

(Source: 21 CFR 1306.11(f)&(g))

Q6. Currently, we receive most of our CII prescriptions on Chart Orders that are faxed to our pharmacy by the nurse in the nursing facility. Often, physicians just call us. Is this allowed?

A6. While this is common practice in long-term care facilities, it technically violates DEA regulations. Pharmacists who dispense CII's based on chart orders that are faxed by the facility to the pharmacy or verbal orders for CII's made by telephone potentially face civil fines and penalties and may be prosecuted for violated the Controlled Substances Act.

(Source 21 C.F.R. 1306.05(a), 1306.11).

Q7. What can we do to get physicians to fax us signed prescription orders that meet DEA regulations?

- A7. We need to help educate the physician community that we can no longer fill prescription orders that do not comply with DEA requirements. One way to do this is to prepare a notice to prescribers that you can fax to their office immediately upon receipt of an order that does not comply with the law. The notice should state:

Dear Physician — this fax message is a confirmation of a verbal C-2 order you provided for the patient listed below. Regrettably, we are unable to fill this order because it does not comply with DEA regulations. DEA only allows us to fill a prescription for a CII based on a verbal order if it is an emergency. In non-emergency cases, if you fax us an order for a CII, it must include all the information needed for a written prescription including the quantity of the drug ordered, as well as your signature. We have prepared this form containing all the information that is required by law. Please complete this form and return it to us as quickly as possible. We will not be able to fill this prescription unless all information is received. We appreciate your cooperation with this process.

Q8. When can a pharmacist dispense a CII based upon the verbal order of the practitioner?

- A8. The only time that a pharmacist can dispense a CII upon the verbal order of a practitioner is in an emergency situation. Pharmacies may only dispense a quantity limited to the amount adequate to treat the patient during the emergency period. The DEA defines emergency very narrowly. The term emergency situations means: (1) immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; (2) no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II, and (3) it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to dispensing.

(Source: 21 CFR 290.10)).

In addition, upon receipt of the verbal order, the pharmacist must reduce the verbal order to writing. The writing must contain all of the information required for a valid written prescription (See A1), except for the signature of the practitioner. If the pharmacist does not know the physician, the pharmacist must make a reasonable attempt to determine that the oral authorization came from a registered individual practitioner. Additionally, within 7 days after authorizing an emergency oral prescription, the practitioner must deliver a valid, written prescription to the dispensing pharmacist. In addition to the required elements of a valid written prescription, it must include the words, "Authorization for Emergency Dispensing" and the date of the oral order. Upon receipt, the pharmacist

must attach the written authorization form to the pharmacist's transcription of the oral prescription.

(Source: 21 CFR 1306.11(d)).

Q9. We have difficulty getting practitioners to send us the authorizations within seven days; sometimes we do not get them at all. What should we do?

A9. DEA regulations state that a pharmacist *must* notify the nearest DEA office if a practitioner fails to deliver a written prescription within the seven-day time period. If the pharmacist fails to report the practitioner, the authority to fill an oral order is voided. In other words, the pharmacist will be liable for violating the Controlled Substances Act. Pharmacists must have tickler or other systems in place to ensure that practitioners are complying with the seven-day rule. If practitioners fail to send the written prescription, pharmacists **must** report them to DEA. Practitioners should be reminded of this periodically.

(Source: 21 CFR 1306.11(d)(4)).

Q10 Long-term care facilities receive new admissions at all times of the day and night and on weekends. Practitioners are not always available or near fax machines when we get orders for new admissions. Is it an emergency if the practitioner is not near a fax machine, the resident needs pain medication and no other medication will do?

A10 You need to apply the definition of what constitutes an emergency situation. The term emergency situations means: (1) immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; (2) no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II, and (3) it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to dispensing. If all of the above factors apply, then an emergency situation has been established, and the physician may call in the prescription to the pharmacy.

Q11. How can we ensure that patients receive timely and adequate pain management?

A11. To avoid the need to utilize the emergency rule in non-emergency situations, pharmacists can promote and facilitate the use of multiple prescriptions or partial fills. Here is how this works:

Multiple prescriptions: DEA rules allow practitioners to issue multiple prescriptions authorizing the patient to receive a total of up to a 90 day supply of a Schedule II controlled substance. In each case, the prescription must be for a legitimate medical purpose. The practitioner also must provide written instructions on each prescription indicating the earliest date on which a pharmacy may fill each prescription. This practice must also be allowed under State law, so pharmacists will need to check with local authorities. Pharmacies can use fax back forms to request that the practitioner issue multiple prescriptions at one time. The form should clearly state that the decision to issue multiple prescriptions for a particular patient is based on the practitioner's own sound, medical judgment and is in accordance with established standards of practice. In addition, the practitioner must determine that the issuance of multiple prescriptions does not create an undue risk of diversion or abuse.

(Source: 21 CFR 1306.12(b)).

Partial fills: A prescription for a Schedule II controlled substance written for a long-term care facility resident or a patient with a terminal illness may be filled in partial quantities to include individual dosage units. Both the practitioner and the pharmacist have a duty to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is terminally ill or an LTCF patient. A pharmacist who partially fills and dispenses a medication based upon a prescription that does not contain this notation violates the Controlled Substances Act. For each partial fill, the dispensing pharmacist must record on the back of the prescription (or other appropriate record) the date of the partial filing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity dispensed in all partial filings must not exceed the total quantity prescribed. Finally, these prescriptions are only valid for a period not to exceed 60 days.

(Source: 21 CFR 1306.13).

For example, a practitioner could write one RX for 200 pills. Using the same RX number, the pharmacist can fill and dispense smaller quantities from this one RX for up to 60 days. Practitioners should be reminded to write a new RX before the old prescription expires.

Q12. When can a pharmacist dispense a controlled substance that is in Schedule III, IV or V?

A12. A pharmacist may only dispense a Schedule III-V pursuant to:

1. a written prescription signed by the practitioner, or

2. a facsimile of written, signed prescription, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, or
3. pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription, except for the signature of the practitioner.

(Source: 21 CFR 1306.21)

Q13. When is it permissible for a LTC facility to remove a controlled drug from an e- box?

A13 Controlled drugs in e-boxes are treated the same way as all other controlled drugs. You must have a valid written RX unless the emergency exception applies. E-boxes should never be used routinely to dispense drugs that should have been reordered. Rather, e-boxes should be used only for unanticipated emergencies such as a new admission or new orders.

For further information, please contact Claudia Schlosberg, Director, Policy and Advocacy, 703-739-1316, ext 128 or email cschlosberg@ascp.com.