



August 30, 2010

Submitted via: dea.diversion.policy@usdoj.gov

Michele Leonhart, Acting Administrator
Drug Enforcement Administration (DEA)
8701 Morrisette Drive
Springfield, VA 22152

Attn: DEA Federal Register Representative/ODL

RE: Docket No. DEA-337 – June 29, 2010 Federal Register Notice: Dispensing of Controlled Substances to Residents at Long Term Care Facilities; Solicitation of Information

Dear Administrator Leonhart:

Thank you for the opportunity to provide input in consideration of the Drug Enforcement Administration's (DEA's) analysis of the long-term care (LTC) setting and issues related to the prescribing and dispensing of controlled substances. There are many areas for improvement with respect to facilitating timely access to medications subject to Controlled Substances Act (CSA) regulations for patients residing in long-term care facilities (LTCFs) and patients enrolled in Medicare- or state-certified hospice programs. The American Society of Consultant Pharmacists (ASCP) looks forward to assisting DEA with the development of solutions that could enhance patient care without compromising the DEA's responsibility for preventing illicit diversion of controlled substances.

ASCP is the international professional society of consultant pharmacists whose mission is to promote the appropriate, safe and effective use of medications in the elderly. Our 7,000 members provide LTC and consultant pharmacist services to seniors and individuals with chronic illness wherever they reside. ASCP members serve patients residing in a variety of environments, including nursing facilities, sub-acute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care. ASCP has a long history of advocating for the medical best interests of people who reside in LTCFs and those enrolled in hospice programs.

For many years there has been confusion over the proper interpretation of DEA regulations with respect to communication and workflow between physicians, nurses and pharmacists serving LTC and hospice. Established quality of care standards mandated by the Centers for Medicare & Medicaid Services (CMS) dictate that each of these health care professionals act in the best interests of their patients through efficient and timely administration of medications. Recent DEA enforcement of regulations is now creating barriers to timely patient access to controlled medications. In some cases, internal DEA policy changes led to changes in DEA's interpretation of existing regulations for controlled substances, in the absence of any substantive changes in LTC practices or federal regulations. Subsequent to

these changes, the barriers created are not the result of limited access to quality care, but instead are due to concerns over the regulatory recordkeeping and administrative responsibilities of the businesses that carry out these practices. Sadly, patients are suffering or at risk for delays in administration of medications while an inefficient workflow practice stands in the way.

In response to DEA's request for information, ASCP is providing information that supports the need for regulations or policy changes that recognize nurses as agents of the prescriber in LTC and for patients enrolled in hospice programs, and permits pharmacists to dispense controlled substances based upon chart orders for residents in a LTCF.

ASCP feels the following attributes should be incorporated into any regulatory revisions being considered within the framework of the CSA:

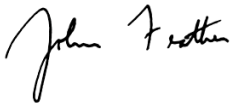
- Nurses working in LTCFs charged with accepting and documenting prescription orders for controlled substances from DEA-authorized prescribers are recognized as the agent of the prescriber.
- Chart orders used to document prescription orders are considered valid prescriptions for the dispensing of controlled medications by pharmacies to LTCFs.
- Nurses working in LTCFs are authorized to accept from prescribers, orders for controlled medication prescriptions, reduce them to writing in chart orders, and transmit those chart orders to the pharmacy for immediate dispensing.
- Controlled medications stored onsite at a LTCF that are pending a valid prescription and authorization for dispensing to a resident must be maintained as part of the inventory of the pharmacy.
- The term "long-term care facility" must include nursing facilities, skilled nursing facilities, and facilities or other settings with patients enrolled in Medicare- or state-certified hospice programs.
- Any regulation or policy change must recognize the unique nature of the LTC setting, especially with respect to utilization of offsite pharmacies and pharmacists.
- Any new policies or regulations must allow for near-simultaneous application throughout all 50 states in a timely manner, and be workable for a majority of LTCFs seeking relief.
- Any new regulations or policy changes must not present an unreasonable burden to stakeholders affected by and seeking a solution for this issue.

In support of the above listed recommended changes, ASCP is pleased to provide a more detailed examination of these issues in the following sections:

1. Definition of "Agent"
2. Chart Orders
3. Fax Back Forms
4. Emergency Situations and Hospice
5. Diversion and the Role of the Consultant Pharmacist

ASCP is pleased to assist DEA in its goal to seek ways to better facilitate patient access to controlled medications in the LTC setting. Thank you for the opportunity to provide feedback.

Sincerely,



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Executive Director, ASCP



Shelly Spiro, RPh, FASCP
President, ASCP

1. Definition of “Agent”

Physicians and medical directors who practice within LTC are generally not employed by the LTCFs where they practice, nor do they maintain a full-time practice on site at such facilities. Attending physicians are required to visit their patients in LTCFs at a frequency determined by each state, at least every 30-60 days. Licensed nursing staff employed by LTCFs are responsible for communicating the day-to-day status of patients in their care. If a patient’s condition changes or if other needs arise, nursing staff are professionally trained and required by federal law to promptly communicate patient needs to a physician and document a physician’s treatment orders in the medical record as well as carry out those orders.

When an attending physician indicates medication intervention to address a patient’s needs, licensed nursing staff are responsible for documenting the medication orders in a patient’s chart. Those orders could involve starting a patient on a new medication, changing a medication or dose, or discontinuing a medication. Once the orders are documented, the nurse must carry out those orders by obtaining any needed medications and then administering those medications to the patient.

In order to obtain the needed medications for a patient, the medication order given by the doctor via a medication prescription must be delivered to a pharmacy for dispensing. A majority of LTCFs operate without an in-house pharmacy; instead they contract with vendor pharmacies that, in most cases, specialize in providing pharmacy services to LTCFs. The relationship between a vendor pharmacy and LTCF is typically established through a contractual service agreement, which includes policies and procedures for ordering and delivery of prescription drugs for residents in LTCFs. In most instances, a nurse employed by the LTCF communicates on behalf of a patient’s attending physician routine prescription medication orders to the vendor pharmacy through these established policies and procedures. The pharmacy in turn dispenses the medications and in most cases, provides delivery services to the facility.

The aforementioned process beginning with prescribing and resulting in the administration of prescription medications for residents in LTC is part of the recognized standards of practice in LTC. During the course of obtaining and administering needed medications for LTC residents, a licensed nurse, by virtue of the qualifications and training needed to obtain such licensure, is authorized to act in a professional capacity on behalf of a patient’s attending physician. A licensed nurse has a professional responsibility to carry out medication orders on behalf of a physician and in this capacity, acts as the physician’s agent.

In an April 25, 2001 Federal Register Notice, “Preventing the Accumulation of Surplus Controlled Substances in Long-term Care Facilities,” DEA stated:

Generally, residents of LTCFs are visited infrequently by their physicians. Consequently, if a nurse determines that a patient's medications need to be changed, the nurse contacts the physician who authorizes the change. The nurse subsequently calls the pharmacist to relay the change in the treatment. DEA is often advised that physicians consider contacts from

*provider pharmacies burdensome when they have already communicated the patient's medical needs to nursing staff at the LTCF. However, a pharmacist may only fill an order issued by a physician and communicated by the physician or the physician's agent. **Since no legal agency relationship exists between the LTCF nurse and the physician, this widely-used system is not in compliance with legal requirements. [emphasis added]***

This citation is the first and only known official documentation of DEA's current interpretation of an "agent" of the prescribing physician as defined in the Controlled Substances Act (21 USC Sec. 802(3)):

*The term 'agent' means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or **dispenser**;... [emphasis added]*

Since an attending physician is authorized to dispense controlled substances as a DEA registrant (21 USC Sec. 802(10), 21 USC Sec. 822 (a)(2)), and nurses routinely act on their behalf to carry out orders and administer all medications - including medications regulated under the Controlled Substances Act (CSA) - it is unclear how DEA arrives at its narrow interpretation of an agent of the prescribing physician. Further, the CSA articulates at 21 USC Sec. 822 who is required to register with DEA for the purposes of dispensing and the circumstances under which an individual is required to register. In this section the Act describes those persons who may lawfully possess any controlled substance and is not required to register (21 USC Sec. 822 (c)(1)):

An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

Previously, DEA has informally described its interpretation of an "agent" of a prescribing physician to only include those directly employed by the physician. While ASCP agrees an employee of a physician could serve as an agent per the inclusion of the term "employee" in 21 USC Sec. 822 (c)(1), it is unclear why the Agency would exclude anyone except an employee in its interpretation of the definition of "agent" when the aforementioned section clearly distinguishes "agent" and "employee" as two potentially different individuals and not one and the same.

Additionally, in a letter dated September 7, 1995 to Mr. Daniel Crider of the Missouri Department of Health, DEA's Liaison and Policy Section Chief of the Office of Diversion Control, Mr. G. Thomas Gitchel, clearly stated the intent of DEA's interpretation of "agent" during that time period with respect to Schedule III and Schedule IV controlled substances, even after the regulation permitting fax transmission of controlled substance prescriptions was finalized:

In the interest of expediting the delivery of needed medications to patients in LTCFs, DEA will permit a physician or other practitioner to designate, in writing, a responsible individual at a LTCF to act as his or her agent for the purpose of communicating oral prescriptions for controlled substances in Schedules III and IV to a pharmacy servicing the facility.

The letter goes on to say:

Any practitioner granting this authority will be responsible for the activities of the employee or the employees acting as his or her agent, just as he or she would if the agent were an employee under the direct control and supervision of the practitioner.

DEA's current interpretation of "agent" and its discrepancy with the language clearly laid out in the CSA as well as its intent as stated in the September 1995 letter has caused industry wide confusion. DEA to date has not taken steps to dispel this confusion other than through increased enforcement efforts within the last 18 months in specific, limited regions of the country. These increased enforcement efforts, which presume that LTC nurses are not permitted to act as the agent of the prescribing physician, have exposed pharmacists serving the LTC industry in good faith and within established practices to undue liability. It has also resulted in an unanticipated disruption of established workflow policies and procedures between LTCFs and vendor pharmacies, resulting in delays of patient access to controlled medications.

ASCP respectfully requests that DEA formally clarify its interpretation of "agent," particularly in consideration of the unique LTC setting, through any means necessary including but not limited to a revision to the regulations articulating requirements for compliance with the CSA. LTC nurses, acting as an agent of the prescriber, should be considered an integral part of the continuum needed to maintain a closed system for drug distribution. Pharmacists generally view certain licensed nursing staff working at LTCFs as having the capacity to act as the agent of a prescribing physician, because of their professional training and licensure requirements. ASCP feels that by including nurses in its definition of "agent," particularly in circumstances such as emergency situations, workflow disruptions could be avoided and patients would not be at risk for delays in access to controlled medications.

2. *Chart Orders*

In the course of communicating, recording, and monitoring medication orders for residents in long-term care, chart orders are the recognized standard instrument. In the case of non-controlled and non-prescription drugs, chart orders are routinely used to fill physician orders for patient medications. LTC nurses transcribe physician instructions to the patient's chart, then fax or telephone them to vendor pharmacies for new medication orders, re-orders and re-supplies. Vendor pharmacies use the chart orders to process medication orders and per the contractual agreement with the LTCF, they dispense and deliver those medications to the facility. Prescribing physicians countersign these chart orders after the drugs have been dispensed, within a time frame specified by state rules and regulations.

For controlled medications, the Federal Food, Drug and Cosmetic Act defines a "valid prescription" (21 CFR Sec. 1306.05(a)) as:

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

A standard chart order in LTC must be reviewed and signed by a physician a minimum of every 30 days. Medication orders transcribed into a patient's chart are valid for the life of the order within the 30-day period, or until the next time it is reviewed, amended where needed, and signed by a physician. Therefore a chart order generally lacks the prescriber's signature at the time it is submitted to the vendor pharmacy for dispensing since the prescribing physician is not always present at the time the medication order is given. It also does not include a quantity because the order needs to be filled in compliance with the facility's approved drug delivery system and approved policy and procedures. According to 21 CFR Sec. 1306.05(a), chart orders cannot be used as valid prescriptions for the purpose of ordering and dispensing controlled medications without a signature or a quantity.

Although the use of chart orders to fill all medication orders had been the known standard of practice in LTC, DEA recently began interpreting its rules to preclude anyone other than a prescribing physician, or the physician's agent, from preparing a prescription order. In enforcing this interpretation, DEA cites 21 CFR 1306.03:

A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) either registered or exempted from registration pursuant to Secs. 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

Additionally, since a LTC nurse is not an agent of the prescribing physician, a chart order that is prepared or submitted to a pharmacy by a nurse for medication orders cannot be considered a valid prescription for the controlled medications contained in the chart.

Now that the ability to generate a paper prescription is limited to the prescribing physician, workflow and standard practice for LTC has been disrupted. By not permitting the use of chart orders for filling controlled prescription medications, patients must wait for their medication orders to be initiated until a physician is able to fax a valid prescription to the pharmacy, even though that order has already been transcribed into the patient's chart.

For written prescription orders, requiring a physician to initiate a written, hard-copy prescription after that order has been transcribed into the patient's chart is a duplication of efforts. While it should remain an option for workflow practices in LTC, this system does not accommodate every situation that arises in the LTC setting. Physicians rely on LTCF nursing staff to initiate their orders as part of standard practice and in the best interests of efficient and high-quality patient care. Chart orders also represent the legal documentation used by nurses for administration of the ordered medications. Requiring a physician to initiate a medication order apart from the chart order, or requiring the physician to repeat that order to his or her employee, who may or may not be a trained clinician, raises the potential for medication transcription errors, creates unnecessary delays in medication administration and promotes inefficient workflow practices.

This creates an unreasonable risk to patients who must wait for their prescriptions to be faxed by a physician who is managing a workflow of multiple patients at multiple locations. Additionally, a physician may not be in a location able to accommodate fax prescriptions at the time the order is given. In these situations, what may have started as a routine request for medication is at risk of developing into an emergency situation, should the ability to obtain a fax machine and the turn-around for the prescription submission and dispensing take too long.

The prohibition of the use of chart orders for controlled medication orders in the LTC setting is creating an undue burden for physicians, LTCF nursing staff, and pharmacists charged with acting in the best interests of their patients. To alleviate this burden, ASCP respectfully requests that DEA promulgate regulations that will permit the use of chart orders as valid prescriptions for controlled medications dispensed to residents in LTCFs. If DEA also provides through regulation that a LTCF nurse can act as the agent of the prescriber when transcribing a physician's orders to a patient's chart, and allow the nurse to fax that chart order to a vendor pharmacy for dispensing, DEA would establish a closed system for handling controlled medications in a LTC setting.

3. *Fax-Back Forms*

Previously in an effort to expedite Schedule II controlled (CII) medication orders for patients in LTCFs, pharmacies would fax to prescribing physicians pre-populated forms that included medication orders that were either received orally from prescribing physicians or transcribed from a chart order sent to the pharmacy by the LTCF. The physician reviewed the form and confirmed the medication order by returning the form, including an original, indelible ink signature, to the pharmacy by fax. Upon receiving the signed form at the pharmacy, the pharmacist would file the form into the pharmacy's records as representative of a valid prescription.

Additionally, when orders for compounded controlled medications are received, physicians are often unfamiliar with the information needed to fill out these prescriptions. Orders for oral, topical and infusion compounded medications require very complex instructions to meet federal requirements for these types of prescriptions. Pharmacists commonly assist physicians with incorporating the correct information into a prescription. However communicating these instructions is not as simple as providing them in a telephone conversation; writing out the appropriate instructions for review and signature by the physician is the most efficient way of assisting the physician with these types of orders. It is important for pharmacists to have the ability to use fax-back forms to assist physicians with compounded controlled medication orders, especially in the case of hospice patients who are commonly prescribed these types of medications to treat pain associated with end-of-life symptoms.

Since DEA's current interpretation of "agent" is limited to someone who is directly employed by the prescribing physician, pharmacists are no longer permitted to prepare these fax-back forms for signature. ASCP respectfully requests that DEA provide through regulation or formal, written policy notice the ability for pharmacies to initiate medication orders for CII drugs received orally by a physician, or verify orders for CII drugs received by chart order by using fax-back forms. We also request that DEA provide the ability for pharmacists to use fax-back forms to assist physicians with compounded controlled medication orders. If permitted by regulation, pharmacies would be able to properly track and maintain valid prescription records for CII and compounded medication orders received orally or by chart order.

4. *Emergency Situations and Hospice*

Elderly, frail and chronically ill patients residing in LTCFs can at times suffer from a rapid decline in failing health conditions. Such circumstances often mean these patients experience extreme levels of pain and discomfort. In some instances, this rapid decline may also be accompanied by acute medical crises such as seizures or high anxiety. In these instances the need for immediate administration of medications is emergent, and the safest, most appropriate medications are often subject to controlled substance regulations.

The CSA contains special provisions to address emergency situations that may occur in the LTC setting, such as 21 CFR 1306.11(d) which allows vendor pharmacies to receive oral prescriptions for CII medications under certain circumstances:

(d) In the case of an emergency situation, as defined by the Secretary in §290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of §1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority

conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with §1304.04(h) of this chapter.

There is also a provision for LTC that allows vendor pharmacies to receive CII medication orders by fax (21 CFR 1306.11 (f)):

(f) A prescription prepared in accordance with §1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with §1304.04(h).

Additionally, DEA allows LTCFs to store a contingency supply of controlled medications in an “emergency kit” in the event of an acute medical crisis of a patient as stated in an April 9, 1980 Federal Register Notice:

The placement of emergency kits containing controlled substances in non-federally registered Long Term Care Facilities (LTCF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:

A. The source from which an LTCF may obtain controlled substances for emergency kits. The source of supply must be a DEA registered hospital/clinic, pharmacy, or practitioner.

B. Security safeguards for each emergency kit stored in the LTCF which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

C. Responsibility for proper control and accountability of such emergency kits within the LTCF to include the requirement that the LTCF and the providing DEA registered hospital/clinic, pharmacy, or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances plus the requirement to take periodic physical inventories.

*D. The emergency medical conditions under which the controlled substances may be administered to patients in the LTCF to include the requirement that medication be administered by authorized personnel **only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21. (emphasis applied)***

E. Prohibited activities which can result in the state revocation, denial, or suspension of the privilege of having or placing emergency kits, containing controlled substances, in an LTCF.

While these accommodations have provided some relief from possible delays in obtaining CII medications, in practice they do not fully accommodate many of the scenarios encountered in LTCFs. Even with these accommodations, a LTC nurse must wait for verification from a pharmacist that a valid prescription has been received at a vendor pharmacy from the prescribing physician. Time may be lost in the time that a nurse must give pharmacy contact information to the physician to call in an order for controlled medications. Even in the case of oral orders, nurses sometimes find themselves waiting to access the emergency kit for needed contingency supplies of controlled medications when the medication order has already been recorded in the patient's chart.

In the case of patients enrolled in Medicare- or state-certified hospice programs, the need to communicate medication orders in a timely manner is also urgent. Although many hospice patients reside in LTCFs, many remain in their homes supported by caregivers and nurses provided by hospice service organizations. In order to care for patients experiencing end-of-life symptoms, which commonly include pain and anxiety, hospice nurses and hospice program medical directors maintain constant contact to assess the changing needs and evolving condition of the patient. In the event that a new order for a controlled medication is needed, a hospice nurse is in the best position to communicate those orders to a pharmacy, since that nurse is restricted to treating a single patient or a very limited number of patients at a time.

Although physicians have seven days to provide the pharmacy with a valid, hard copy prescription, it can be difficult for pharmacists to track and remind those physicians who do not immediately fax their hard copy prescriptions to submit them to the pharmacy for recordkeeping. Many pharmacists report having to spend an unreasonable amount of administrative time tracking and sorting these emergency prescriptions. Fax-back forms initiated by a pharmacist, who must reduce the emergency oral prescription to writing at the time the prescription is received, would not only save time and create efficiency when creating the hard copy prescriptions, it would reduce the time spent tracking the outstanding prescriptions.

ASCP respectfully requests that DEA promulgate regulations or issue a formal, written policy notice that would provide, in emergency situations, for nurses acting as agents of the prescriber to communicate oral orders for prescription drugs to the pharmacy. This provision is most important for nurses providing care to patients enrolled in hospice programs,

regardless of the setting under which care is being provided. We also respectfully request that pharmacists be permitted to use pre-populated fax-back forms for transcribing emergency orders of controlled drugs by pharmacists. The transcribed orders can be faxed immediately to a location to be determined by a physician, who would then have seven days to return the signed copy to the pharmacy.

5. *Diversion and the Role of the Consultant Pharmacist*

In accordance with CMS regulations, a requirement for nursing facilities eligible for Medicare and Medicaid reimbursement services is the need for consultant pharmacist services. Consultant pharmacists provide a variety of services to LTCFs including, but not limited to:

- Medication regimen review (MRR)
- Disease assessment/management
- Medication therapy management services (MTM)
- Formulary management
- Drug information
- Medication research programs
- In-service education programs
- Consultation on medication delivery systems
- Controlled substance destruction
- Medication cost analyses
- Emergency services
- IV therapy support services
- Medication administration or “med pass” audits
- Nutritional assessment and support services
- Patient counseling
- Pharmacokinetic dosing services
- Physical assessment
- Policy and procedure development
- Quality assurance programs
- Computer-generated forms and reports
- Technology integration

CMS defines the role of the consultant pharmacist in LTC at Tag F425, Section 483.60 in the nursing facility State Operations Manual (SOM):

(b) The facility must employ or obtain the services of a licensed pharmacist who

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

At least once a month, consultant pharmacists must conduct a MRR for each patient. Consultant pharmacists must also assist LTCFs with developing and establishing an accountability system to help prevent and detect diversion of controlled medications. Consultant pharmacists periodically audit LTCF records to ensure that established systems are being followed and that the intended outcomes are achieved. When diversion occurs, consultant pharmacists are critical in facilitating the detection of such incidents. The

pharmacist must report any irregularities to the attending physician or director of nursing. When such reports are received, they must be acted upon. Although LTCFs are responsible for reporting incidents of diversion when they occur, consultant pharmacists are key to assisting LTCFs in reporting losses to local authorities and with the development of procedures for reporting such losses before they occur.

Vendor pharmacies that provide services to LTCFs employ many methods for deterring and detecting diversion including:

- Packing Lists – included in each delivery so that facility staff can quickly identify and verify controlled medications included in the delivery.
- Count Sheet – an accountability form to verify the quantity of controlled medication dispensed by the pharmacy and verified by a LTCF nurse.
- Receipt and Storage Procedures – controlled medications are placed in an appropriate locked storage location and incorporated into the LTCF’s inventory tracking system by two members of the staff. CII medications are typically stored using a double-lock system in a permanently affixed compartment.
- Security and Access Systems - CII drugs and other medications subject to abuse must not use the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access to these drugs and when access is used.
- Foil-backed Packaging – for tablets and capsules to permit easy counting of contents and make tampering easier to detect.
- Medication Reconciliation – controlled medications are counted and reconciled at shift changes by the oncoming and exiting nurses to establish accountability through the chain of custody.
- Automated Dispensing Systems – in LTCFs that use them, they allow for dispensing of single dose units of prescription controlled medications on an as-needed basis. Commonly used for dispensing contingency supplies of controlled medications stored in an emergency kit.

Many LTCFs maintain an emergency kit, which contains a contingency supply of medications including controlled medications, to be used for administration in case of an emergency. The medications stored in the emergency kit are considered part of the vendor pharmacy’s inventory stored onsite at the LTCF. Since the supplies contained in the kit are not prescribed to a specific patient, they are not considered dispensed by the pharmacy. There are procedures in place to document access to the emergency kit, which can only be accessed by authorized staff.

Pharmacists and LTCFs continuously work together to detect tampering and to improve diversion monitoring and detection. Despite the best efforts of all those involved with establishing the best possible policies and procedures, those individuals seeking opportunities for illicit diversion of controlled substances will persist in their efforts. ASCP respectfully asks DEA to recognize the existing role of the consultant pharmacist in the LTC setting and to work with ASCP and other stakeholder organizations to optimize existing industry-recognized policies and procedures designed to fight opportunities for diversion. ASCP shares DEA's mission of mitigating incidents of diversion, but we encourage DEA not to pursue this goal at the expense of the comfort and dignity of elderly, frail and dying patients in need of pain relief.


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