SENIOR CARE PHARMACY COALITION

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May 20, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-D-1524

Dear Sir or Madam:

The Senior Care Pharmacy Coalition ("SCPC") appreciates the opportunity to address the Food and Drug Administration's ("FDA") "Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" (Feb. 2015; the "Draft Guidance").

The SCPC is the national association representing independent long-term care ("LTC") pharmacies. Our member pharmacies provide care and services to patients in long-term care facilities in more than 40 states who occupy approximately 350,000 beds across the country. The SCPC advocates for public policies that protect patients, improve the quality of healthcare across a shifting care continuum, and strengthen the economic viability of independent LTC pharmacies and their ability to serve medically compromised seniors.

LTC pharmacies – sometimes called "closed-door" or "institutional" pharmacies – are a distinct subset within the pharmacy community. Skilled nursing facilities ("SNFs"), nursing facilities ("NFs"), and many assisted living facilities ("ALFs") contract with a single LTC pharmacy to prepare and dispense prescription drugs for individual patients, and to provide an array of consulting pharmacy and care planning services required by Medicare, Medicaid, state licensure laws, and professional standards.[1]

[1] As discussed further below, the Social Security Act and regulations of the Centers for Medicare and Medicaid Services ("CMS") require SNFs and NFs to "provide routine and emergency drugs and biologicals to [their] residents, or obtain them under an agreement described in [42 C.F.R. § 483.75(h)]." See 42 U.S.C. §§ 1395i-3(a) and 1396r(a)(4) (provision of services and activities); 42 C.F.R. § 483.60 (pharmacy services). The cross-referenced regulation requires a facility to be "administered in a manner than enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident," and expressly authorizes the engagement of outside professional resources, if that is effective and efficient. See 42 C.F.R. § 483.75(h) ("*Use of outside resources*. (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a

I. Requested Action

The SCPC has carefully reviewed FDA's Draft Guidance and considered the implications for LTC pharmacies and the patients that they serve. At least three important dispensing practices would be inappropriately disrupted by the Draft Guidance. These are discussed in Section III below.

We respectfully request that FDA revise the Draft Guidance to exclude from its scope all dispensing-related activities of LTC pharmacies – even if those activities involve the prepackaging or repackaging and staging of drug products in anticipation of dispensing to individual patients. The practices at issue are actively regulated under state and federal pharmacy law, Medicare and Medicaid law, and health network participation requirements and guidance. In addition, the drug products *remain under the pharmacy's control and responsibility* until they are dispensed to individual patients pursuant to a prescription or chart order. As such, they properly remain within the traditional regulation of practice of pharmacy by state and federal regulators applying well-established professional pharmacy standards.

The SCPC requests that FDA amend the Draft Guidance to expressly exclude prepackaging or repackaging activities of LTC pharmacies in anticipation of dispensing. Appropriate changes include:

- Revise the text at p. 2, lines 38-40 to read as follows (proposed new text underlined): "Upon receipt, or in anticipation of receipt, of an individual patient-specific prescription, a licensed pharmacy removing from one container the quantity of solid oral dosage form drug products necessary to fill the prescription and placing it in a smaller container to dispense directly to its customer."

- Add a new bullet point at p. 2, line 41 to read as follows: "Removing a drug product from the original container for loading it into pharmacy dispensing equipment. FDA does not consider this to be 'repackaging' for purposes of this guidance document."

- Revise footnote 5 to read as follows (proposed new text underlined; removed text stricken): "Distribution means that the repackaged product has left the ~~facility in which it was~~ control of the entity that repackaged it."

- Revise page 8, lines 157-167 as follows (proposed new text underlined): "3. If the drug product is repackaged in a state-licensed pharmacy or a Federal facility (but not an outsourcing facility), it is repackaged and distributed after (a) the receipt of a valid prescription for an identified, individual patient directly from the prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's chart in a health care setting, unless it is repackaged (but not distributed) in advance of receipt of such a prescription or

person or agency outside the facility and under an arrangement [that, among other things ensures] services that meet professional standards and principles [and t]he timeliness of the services."). It typically is most effective and efficient for SNFs and NFs to contract for pharmacy services, rather than having to maintain individual pharmacies and product stocks at each location.

> a written order in a patient's chart in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy or the Federal facility repackaged pursuant to patient-specific prescriptions or written orders ~~in a previous, consecutive 14-day period, and based on a history of receipt of prescriptions or written orders over a consecutive 14-day period for such repackaged products~~, based on observed and reasonably anticipated prescribing patterns; or (c) the receipt by a long term care pharmacy, as defined in 42 C.F.R. § 423.100, consistent with state pharmacy law and long term care pharmacy practice."

In the alternative, if FDA is not prepared to deviate from a time-restricted methodology, we request that the Agency expand the period of time for prepackaging/repackaging from 14 to at least 60 days. We appreciate FDA's concerns about product degradation, however this extended timeline presents no substantial risk of product degradation in the context of traditional LTC pharmacy practice. The Agency would have to clarify with specificity how such a period is to be measured, and also would have to allow site-specific deviations for factors such as an expansion of patients served (e.g., if a pharmacy enters a contract with a new healthcare facility) or seasonal product dispensing, justified by the pharmacy in its records.

II. Description Of Long-Term Care Pharmacy Operations

LTC pharmacies are state-licensed pharmacies that operate under traditional state requirements for credentialing, facilities, product handling, dispensing, recordkeeping, and other operations. LTC pharmacies serve the specialized pharmacy needs of long-term care nursing facility residents, including those of SNFs and NFs, and in many cases ALFs. Approximately 1.3 million Medicare beneficiaries, for example, reside in SNFs and NFs and most of these beneficiaries are admitted to nursing facilities for the management of multiple, chronic diseases requiring 24-hour nursing care. These individuals are generally older and frailer than the average beneficiary; in SNFs, NFs, and ALFs combined, each patient takes on average 10 to 12 medications per day. The combination of multiple disease states and chronic conditions requires specialized knowledge of the needs of the frail elderly by clinicians and pharmacists, who must regularly monitor these patients for drug interactions and possible adverse reactions to medications.[2] It also requires extraordinarily attentive daily management to ensure the safe, accurate, and efficient administration of medications to residents, avoid medication mix-ups or administration delays, and prevent both diversion and waste of products stored and administered in these facilities.

Specialized pharmacy services -- including access to a pharmacist 24 hours per day seven days per week and emergency availability of medication – are needed to assure that residents receive timely access to appropriate medication therapies. These services are generally beyond the scope of services provided by traditional retail pharmacies to patients who reside in the community. In order to meet these special needs, SNFs, NFs, and many ALFs contract with LTC pharmacies to provide prescription drugs and consultant pharmacy services. The physical dispensing of prescribed drugs for LTC residents occurs most commonly at closed-door LTC

[2] The Lewin Group, "CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services – Long-Term Care Pharmacy Primer" (prepared for CMS, Dec. 2004).

pharmacy locations (not located within a LTC facility), followed by the delivery of patient-labeled products to LTC staff for their residents.

Not all dispensing activity of LTC pharmacies occurs within the four walls of a LTC pharmacy's primary building, however. In at least two situations – (1) emergency kit dispensing and (2) remote dispensing using automated equipment – the final steps of dispensing occur on-site in a LTC facility. The pharmacist retains ultimate control and responsibility under both of these rubrics. However, the product is staged, in advance of a prescription or chart order, at the usage location for patient safety and accessibility reasons. Specifically tailored pharmacy laws apply in both of these contexts. For example, laws governing remote dispensing commonly require that a managing pharmacist: ensure automated equipment is in good working order and that it accurately dispenses the correct strength, dosage form, and quantity of a product prescribed; implement an ongoing quality assurance program to monitor performance; record patient transaction information for recordkeeping; supervise stocking by qualified personnel; address product security; etc.

Federal Standards and Policies Governing LTC Pharmacies. In addition to state pharmacy laws, LTC pharmacies are subject to standards of practice under federal program requirements for Medicare and Medicaid participation. Legal requirements are imposed on SNFs and NFs that serve federal beneficiaries. Key standards – including safety requirements – are imposed by statutes including the Omnibus Budget Reconciliation Act of 1987 and the Affordable Care Act of 2010, as well as CMS regulations and policies establishing Conditions of Participation, Conditions for Coverage and Requirements for SNFs and NFs. Among these are:

- Pharmacy services: A nursing facility must provide "routine and emergency drugs and biologicals to its residents." This provision of pharmaceutical services includes assurances of accuracy in acquiring, receiving, dispensing, and administering medications and biologicals for each resident. In addition, nursing facilities must employ or obtain the services of a licensed pharmacist who provides consultation on the provision of pharmacy services in the facility, establishes a record-keeping system with respect to controlled substances, determines that medication records are in order, and performs drug utilization review and counseling.

- Unnecessary drugs: Residents' drug therapy must be free from unnecessary medications, those given in excessive doses, in excessive duration, or without adequate monitoring.

- Medication error rate: Nursing facilities must ensure that the medication error rate does not exceed five percent.

Consistent with these requirements, standards of practice have developed to emphasize the use of unit dose systems in institutional settings. Published descriptions provide an excellent explanation for this approach, including these pharmacy-related concepts:

- Agencies that oversee long-term care facilities expect medications to be provided to residents accurately and on-time. Medication administration is a key issue that government inspectors/surveyors evaluate when LTC facilities are reviewed for quality. Sanctions (potentially including operating license revocation) can result from failure to satisfy standards.

- LTC facilities use specialized packaging for medications for their residents for several key reasons:

    - Enhanced accuracy of medication administration (fewer errors)
    - Enhanced accountability of controlled substances (less drug diversion)
    - Enhanced efficiency of medication management (saves nursing time)

- Traditionally, most nursing homes have used the specialized blister package or "bingo card" form of medication packaging.

- The Institute of Medicine has endorsed the application of quality improvement principles in healthcare organizations. With respect to medication administration, this means facilities and personnel should follow established procedures.[3] Medication errors also can be reduced when medication packaging and labeling is consistent for every resident, so that nursing personnel can follow the same process in each case.

- The use of traditional bottles by LTC facility nursing staff is unmanageable given the number of medications administered to each patient per day, multiplied by the number of beds in a typical LTC facility. The medication burden may contribute to errors, and it also requires valuable time and skill that might otherwise be devoted to direct patient care.

- Special packaging greatly enhances LTC nursing staff's efficiency in handling and administering medication. Consistent use of one method of special packaging (e.g., blister cards) throughout the facility enables nurses to readily prepare and administer medications to residents, reduces the risk of medication errors and improves patient safety.

[3] This supports the use of a routinized packaging process to focus pharmacy workers and avoid risks from ad hoc processes.

III. Problems Created By The Draft Guidance

Current LTC pharmacy practices have evolved to support the safe, effective, and efficient delivery of pharmaceutical care to residents in LTC facilities. Unfortunately, FDA's Draft Guidance does not reasonably accommodate – and in some instances directly conflicts with – the policy goals, certain legal requirements, and current practices applicable to LTC sites of care. There are multiple examples in which the Department of Health and Human Services in other contexts (such as the Medicare Part D regulations) has recognized that LTC pharmacy is different, and should be treated differently, from traditional retail pharmacy. Yet, the Draft Guidance does not make any such distinction. This should be corrected in an updated FDA guidance document.

A. Emergency Kits

The Draft Guidance would limit the ability of LTC pharmacies to fulfill important functions where prepackaged pharmaceutical products are sent from the pharmacy – albeit still under the pharmacy's control – in advance of (but in anticipation of) being dispensed pursuant to individual prescriptions or chart orders. The result would be a denial of emergency care for nursing home and other institutional residents who cannot otherwise access needed medications quickly. Thus, as written, the Draft Guidance would prohibit LTC facilities and pharmacies from satisfying the LTC patient protection standard of having adequate emergency medication available on-site.

In accordance with state pharmacy and controlled substances law, as well as federal Medicare and Medicaid requirements, LTC pharmacies currently stock small quantities of prescription medications in emergency kits (sometimes also called interim/supplemental kits) on-site at LTC facilities where they can be dispensed urgently to LTC residents (e.g., when an acute illness has been diagnosed by a treating physician and a patient-specific prescription or chart order has been issued). Most kits contain a supply of controlled substance pain medications, oral antibiotics, seizure medications, and other medications necessary to immediately manage emergency situations.[4] Typically the medical director, nursing facility professional staff, and the LTC pharmacy work together to determine what medications are necessary for the emergency kits, according to each state's regulatory requirements. State prescribing and dispensing laws traditionally govern the manner in which drug products may be used from an emergency kit; how the provider pharmacy must be notified; and how and when the dose must be replenished.[5] The LTC pharmacy is responsible for ensuring that the emergency kit is properly stocked, and the legal responsibility for managing the products and dispensing remains with the pharmacy until a prescription or chart order has been issued by a treating physician.

Given the relatively small quantities of drugs needed (i.e., only for sporadic use), emergency kits are commonly stocked with unit dose quantities of medicine prepared and maintained by the LTC pharmacy. Pertinent medications often are not commercialized in unit

[4] Due to restrictions on emergency drugs and the follow-up, documentation, and replacement required with emergency drug kits, many states indicate that they must be provided by only one pharmacy (e.g., Indiana, Iowa, Montana, North Dakota, Rhode Island, South Carolina).

[5] Seventy-two hours is the most common timeframe within which emergency drug doses must be replenished and prescriptions documented by a licensed practitioner. The shortest turnaround time is 24-hours or next business day, whereas some states specify only "within a reasonable timeframe."

dose quantities, and it would undermine patient safety, and be wasteful and unnecessarily expensive to stock entire containers of medication in emergency kits. In addition, certain applicable state laws affirmatively restrict the quantity of emergency kit stocks and dosages to minimal quantities (as a diversion control measure).[6]

FDA's Draft Guidance, as written, would threaten patient safety and disrupt current traditional LTC pharmacy practices by *prohibiting* the distribution of repackaged drug products for stocking or replenishing emergency kits (which, by their very nature, must be shipped to LTC facilities, prior to obtaining a patient-specific prescription or chart order, for storage until they are needed for urgent patient dispensing). Quantitative restrictions on prepackaging are unworkable for emergency kit medications because it is not predictable when individual items will have to be prescribed and replenished. We are confident that FDA does not intend to prevent patients from having access to emergency medications, or to undercut compliance with other federal legal program rules (e.g., Medicare and Medicaid). Accordingly, the SCPC requests that emergency kit preparation and maintenance (even if in advance and off-site) be clearly exempted from the Draft Guidance's restrictions.

B. Automated Dispensing

Similar to the impact on emergency kits, the Draft Guidance would prohibit the use of automated dispensing technology in two important respects. When read literally, the Draft Guidance prevents *any* dispatch of prepackaged/repackaged pharmaceuticals from the pharmacy, in advance of receiving patient-specific prescriptions or chart orders. In effect, LTC pharmacies could not dispatch filled cassettes, canisters, or other containers of prescription drugs for placement into automated dispensing machines located at LTC facility sites. These systems also are used for emergency and first-dosing at an LTC facility. Therefore, similar to the emergency kit scenario above, it is not possible to predict the prescribing pattern, which will depend on the need of the patient residing in or being admitted to a facility at any given time. Furthermore, even if a quantity-limited approach were adopted, any restriction of the volumes currently allowed would de facto increase the number of preparation, delivery, and other steps, increasing the risk of medication errors, undermining patient safety and reducing efficiency.

[6] For example, California allows 48 different medications to be stored in the emergency supply containers, and not more than 16 doses of each of those medications. See Cal. Health & Safety Code § 1261.5(a).

The use of automated technology is *affirmatively promoted* by other agencies because it helps to advance patient safety and reduce pharmaceutical waste:

- CMS found "that automated dose dispensing systems reduce medication errors by ensuring the accuracy of the medication dispensed to the patient by eliminating many manual steps…. In addition, these systems free up nursing time allowing nurses to focus more on patient care."[7]

- The Drug Enforcement Administration ("DEA") addressed the issue of excess controlled substances in the LTC settings by amending its regulations to allow pharmacies to install and operate remote automated dispensing equipment.[8] DEA acknowledges that remote automated dispensing systems help with diversion efforts, as they reduce the number of controlled substances in free circulation at the facility and decrease the need for disposal of controlled substances that are no longer needed by the patient.

- The Affordable Care Act of 2010 encouraged the use of technology to reduce pharmaceutical waste (meaning product dispensed but not actually consumed), and the Congressional Budget Office projected that such reduced pharmaceutical waste would save federal healthcare programs $5 billion to $7 billion dollars over 10 years. CMS is definitively on the record stating that automated technology located at LTC facilities "is likely the most efficient dispensing methodology and the most effective in reducing waste." Dispensing machines can provide just-in-time dispensing on a daily basis, and virtually eliminate dispensed-but-unused product compared to the traditional 14- or 30-day dispensing models.

Again, we do not believe that FDA intends to prohibit or starkly limit the use of advanced technologies by LTC and other institutional pharmacies dispensing individual patient prescriptions. Because product in automated dispensing equipment remains under the ownership, control, and responsibility of the pharmacy pending dispensing, and also because it improves patient safety and promotes more accurate and efficient dispensing, FDA should defer associated activities to regulation by state boards of pharmacy (who have governed here for many years), and not impose unnecessary functional limitations that will undermine use and benefit.

[7] 76 Fed. Reg. 21463 (Apr. 15, 2011).

[8] 70 Fed. Reg. 25462 (May 13, 2005).

C. Prepackaging In Anticipation Of Patient-Specific Dispensing

Finally, the Draft Guidance would undermine safe and effective LTC pharmacy dispensing in ways that increase the risk of error and patient harm:

- *First*, criterion 3 on p. 5 (lines 157-167) would limit an LTC pharmacy's ability to prepare blister/bingo cards or other packages in advance of receiving prescriptions or chart orders, *even if the drug products remain in the pharmacy pending individualized labeling and dispensing*.

  If prepackaging had to occur more frequently to conform to the Draft Guidance's parameters (for example, more numerous and repeat efforts to package bulk product into blister cards over weeks or months, rather than accomplishing the packaging in one process when bulk product is received), there would be more frequent opportunity for error and a greater safety risk. To promote continued safety and efficacy, repackaging should be done as few times as possible using bulk product received by an LTC pharmacy. Unfortunately, the Draft Guidance would lead to the opposite result.

  LTC pharmacies commonly do – and are encouraged to – dispense prescription drug products in unit dose containers for individual LTC residents. The Draft Guidance would, without justification, limit prepackaging to levels linked with individual patients' prescriptions or chart orders received over a previous, consecutive 14-day period. LTC pharmacies, however, have extensive and historic knowledge of broader institutional prescribing needs, measured at the facility and service area levels. Once again, the SCPC appreciates FDA's legitimate concerns that too extensive a time period raises questions about product degradation. In the context of traditional LTC pharmacy practice, however, there is no incentive to prepackage for periods longer than those reasonably predictable based on known and identifiable practice patterns. Instead, prepackaging is performed precisely to align products with patient needs and patient safety.

- *Second*, the timeframe of "a previous, consecutive 14-day period" in the Draft Guidance is unworkable for several reasons, including:

  - It is not clear how this standard would be applied in the face of ever-evolving patient populations. It does not appear to allow prepackaging based upon known, aggregate pharmacy demand patterns, but rather would restrict activities according to individual prescriptions actually written during a previous 14-day period.

  - It is unclear whether the intended calculation period is a rolling, immediately-preceding 14-day period, or any similar reasonably representative period.

  - If rolling calculations and system adjustments were required, pharmacies would have to recalibrate every day to determine the acceptable numbers for hundreds of different medications and doses, in order to account for continually changing patients and prescribers. LTC pharmacies lack the capacity to develop and adopt such elaborate, unsustainable administrative systems. This administrative burden

also would unnecessarily drain resources that could otherwise be directed to patient care and ultimately would increase the cost of prescription medications and related pharmacy services under government payment programs, including Medicare and Medicaid.

- It does not allow for prepackaging of medicines that may be less frequently used (e.g., there is a known demand pattern but where no prescriptions or chart orders have been issued during a preceding 14-day period).

- It does not allow planning for anticipated, legitimate dispensing increases (e.g., if a new LTC facility contracts the pharmacy for services) or for the anticipation of seasonal products (such as antihistamines) which may be needed only during certain periods of the year.

The SCPC respectfully suggests that there is no need for FDA to subject the well-established and carefully overseen dispensing practices of LTC pharmacies to the "repackaging" requirements applicable to certain commercial processing entities. Our members have a longstanding and effective working relationship with state boards of pharmacy, FDA, and other federal agencies toward goals of excellence, LTC resident service, and safety. Furthermore, as noted, FDA should tread carefully in the LTC area because strong policies and requirements of other federal agencies support the very arrangements and practices that would be hindered by the Draft Guidance.

IV. Conclusion

A significant set of principles is at stake, and the SCPC respectfully suggests that routine LTC pharmacy practices have been, and remain, well-regulated and utterly unobjectionable under traditional pharmacy dispensing rubrics. We request that FDA expressly address LTC pharmacies within the Draft Guidance, and clarify that LTC pharmacies operating in compliance with state pharmacy laws are permitted to prepackage and repackage medications in anticipation of dispensing, so that regulation does not unintentionally hinder acceptable and desirable patient-supportive practices.[9]

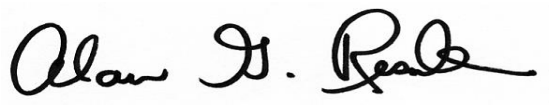
The recommendations in Section I above strike a fair delineation between commercial production activities on the one hand, and pharmacy dispensing to support individual patient care on the other hand (e.g., providing easy–to-administer single dosage containers to busy nursing staff; enabling specific dispensing via automated equipment controlled by the pharmacist; enabling the upkeep of emergency kits with individual dosage quantities of mandatory medications). This approach is consistent with, and supported by, the policies and requirements of other federal agencies. In important respects, current practices reduce the number and

[9] It is important that the scope of any guidance be clear. In addition to federal issues (e.g., would any given inspection be conducted under the limited pharmacy authority or the broader manufacturing authority of the FDCA?), our members have experience where state agencies seek to interpret and enforce under FDA's guidance. Therefore, there is a very real possibility that a state agency could allege violation of an applicable standard, or there could be question about coverage or payment for medicines if there are questions presented about its compliance status.

complexity of human interventions and thereby help to reduce the incidence of medication errors and significantly improve patient safety.

Thank you for your attention to this correspondence. The SCPC will appreciate FDA's clarification that the Draft Guidance does not capture the operations of LTC pharmacies within its scope, a clarification that certainly will benefit patients in LTC facilities and better align legal requirements and system incentives across the multiple federal agencies with oversight responsibilities for LTC pharmacies.

Sincerely,



Alan G. Rosenbloom
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