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Associate Director for Policy, CDER
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Re: Docket No.: FDA–2014–D–1524: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities; Draft Guidance for Industry; Availability

Dear Associate Director Axelrad:

Thank you for the opportunity to submit our comments on the Draft Guidance on the Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities. As the FDA considers repackaging by state-licensed pharmacies, Federal facilities, and facilities that register with FDA as outsourcing facilities, the National Community Pharmacists Association (NCPA) is committed to working with the FDA and other interested stakeholders on these critical issues.

NCPA represents the interests of America's community pharmacists, including the owners of nearly 23,000 independent community pharmacies. Together they dispense nearly 40% of all retail prescriptions, and employ more than 300,000 individuals, including over 62,000 pharmacists. In addition, 34% of our members serve patients in long term care (LTC) facilities and 48% serve patients in an assisted living facility. In summation, approximately 40% of the long term care market is serviced by independent community pharmacy. Policies impacting the provision of long term care pharmacy services are critical to our membership and the patients they serve.

Long Term Care Pharmacy Background and State-Allowed Practices

Long term care pharmacies are licensed by state boards of pharmacy in their respective states. Some long term care pharmacies are closed door, in that they serve no retail patients and only provide pharmacy services for residents of nursing and related facilities. Additionally, some long term care pharmacies are combination shops that serve both retail customers and nursing and related facilities. The draft guidance, as written, will drastically impact these pharmacies and the facilities they service and ultimately the patients residing in the facilities. NCPA has concerns that the Draft Guidance, by trying to limit the amount of product that a pharmacy can

repackage at one time, will inadvertently negatively impact these critical patients' access to medications.

To address the urgent needs of these critical care patients, NCPA LTC pharmacy members provide many of these facilities with medication cabinets or automated remote dispensing and first dose systems in addition to emergency kits or crash carts that could drastically be affected by any day supply limit. In addition, pharmacies that pre-package medication in unit-dose cards in advance of receipt of a patient specific prescription or chart order will be affected.

As in hospitals, these technologies are essential to minimizing waste and decreasing wait times for urgently needed medications. These devices are loaded in advance of the pharmacy receiving a specific patient order and the draft guidance would sharply hinder their use.

For example, containers for automated dispensing machines located in nursing facilities are filled at the pharmacy in advance with non-sterile solid oral dosages (tablets and capsules) based on the needs of the facility residents. The devices may be loaded with antibiotics or other short term, frequently used medications. Depending on usage at the facility, the antibiotics may be loaded in anticipation of a patient medication order and not utilized within a 14-day period. In some cases, the devices may be loaded with enough medication doses to meet the needs of the facility for a 1-2 month period. The medications contained within the canisters or containers are typically labeled with the medication lot number and expiration date. The canisters or containers of the loaded product are light-proof and maintain stability of the drug product through its expiration date.

In the Draft Guidance, as FDA provides background information on repackaging in general, the need of elderly patients residing in nursing facilities is not mentioned. These patients have special needs as they are admitted to nursing facilities for the management of multiple chronic conditions and require around-the-clock, 24/7 care. Heavy medication burdens are a concern as well as this population on average takes 10 medications per day. The repackaging activities in which our members are engaged in to serve their facilities and patients are activities necessary to filling prescriptions. That is, the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. The FDA currently considers this activity as part of the necessary steps in filling a prescription and has recognized the state's authority in regulating it.

LTC Pharmacy Repackaging Activities Serve to Meet Laws and Regulations Governing Nursing Homes

These repackaging activities serve to meet needs of the nursing home and related facilities that are regulated by state and federal laws and regulations. Nursing home standards are established within the Centers for Medicare and Medicaid Services (CMS) and enforced by state agencies that conduct routine inspections. Included in the performance standards for nursing homes is the requirement to provide routine and emergency drugs and biologicals to its residents.[1] In addition, the CMS Medicare Prescription Drug Benefit Manual – Chapter 5, includes requirements for

[1] 42 CFR §483.60

Medicare Part D plans related to pharmacy services to be provided to residents of long term care facilities. Among these requirements:

- **Special Packaging:** Network Long Term Care Pharmacies [NLTCPs] have the capacity to provide specific drugs in Unit of Use Packaging, Bingo cards, Cassettes, Unit Dose or other special packaging commonly required by LTC facilities. [Pharmacies] must have access to, or arrangements with, a vendor to furnish supplies and equipment including, but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.

- **Compounding /Alternative Forms of Drug Composition**: NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.

- **Emergency Boxes** -- NLTCPs must provide "emergency" supply of medications as required by the facility in compliance with State requirements.

Because of the needs of the facilities that LTC pharmacies serve, it is common practice for LTC pharmacies to repackage medications, and in certain situations, distribute to the facilities the repackaged medications, in advance of receipt of a prescription or a chart order. **It is important to note that the repackaged medications remain in possession and under the control of the pharmacy until such time that they are dispensed pursuant to a prescription or chart order.**

Retail Pharmacy Practices Surrounding Compliance Packaging Also Potentially Impacted

There are also many community pharmacies that are utilizing packaging machines in order to drive better compliance with drug regimens for their chronically ill patients. These patients typically get 28-30 day regimens and they are usually prepared for the patient well in advance of the next start date for that period of treatment. These drug regimens may be prepared in advance of actually getting the refill authorization approved by the prescriber. While the regimen does not normally leave the pharmacy in advance of that approval, the packaging process can already be done in anticipation of that occurring.

NCPA Specific Concerns with FDA Draft Guidance

In the Draft Guidance, FDA specifies conditions that must be met in order for FDA to not take action for violations of section 501(a)(2)(B) of the FD&C Act. In particular, NCPA is concerned with condition number 3 and specifically condition (b):

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 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 drug products.

Because of the common LTC pharmacy practices, as governed by state boards of pharmacy, and described in this letter, NCPA understands that our members would not be able to comply with supply limits for an individual patient's prescription or chart order. Medications for orders received are commonly repackaged well in advance of the receipt of the patient's medication order. This improves medication availability and reduces opportunity for medication errors. To require this supply limit would impede current state allowed practice and requirements that facilities must meet to provide timely care to their residents and place patients in jeopardy.

Our LTC pharmacy members, as a common practice, regularly prepackage commonly dispensed non-sterile tablets and capsules into specialized packaging, exceeding 14-day supplies, and prior to receipt of a valid prescription or chart order. The medications will be dispensed to patients in the facilities upon receipt of a valid prescription or chart order. To require more frequent repackaging would run counter to continued safety associated with the current processes.

In addition to this practice, LTC pharmacies maintain remote dispensing equipment within the facilities, which is owned, operated and controlled by the dispensing pharmacy. Medications are not released from these devices until a valid prescription or chart order is written. Also, LTC pharmacies are required to maintain non-patient specific emergency supplies of medicines within the facilities they serve which again are owned and controlled by the dispensing pharmacy until they are needed for emergent patient needs.

Our members and the facilities who currently utilize these technologies do so under the complete authority and oversight granted by their respective boards of pharmacy. For example, Minnesota laws governing pharmacy allow (via **151.58 AUTOMATED DRUG DISTRIBUTION SYSTEMS)** that a pharmacy may use an automated drug distribution system to fill prescription drug orders for patients of a health care facility provided that the policies and procedures {required by this section} have been approved by the board. The automated drug distribution system may be located in a healthcare facility that is not at the same location as the managing pharmacy. **When located within a health care facility, the system is considered to be an extension of the managing pharmacy.**

NCPA Recommendations

FDA should address LTC pharmacy practice within the Guidance, and clarify that LTC pharmacies are permitted to repackage medications in compliance with state pharmacy laws. Current practice within the LTC environment provides that medications in the facility and not yet assigned or dispensed to a patient are inventory of the providing pharmacy. That is, the repackaged product remains under ownership and in control of the dispensing pharmacy until it is dispensed to the patient pursuant to a valid prescription or chart order. In addition to these

LTC pharmacy practices, FDA should recognize retail pharmacy practices that, again under oversight of the state in which the pharmacy resides, serve to increase patient compliance with their medication regimens.

The FDA should apply the FD&C Act, as it has for many years, in a manner such that products in the course of being "dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug" are regulated as traditional dispensing operations and not subject to FD&C Act sections 505, 502(f)(1) and 501(a)(2). This should apply even when a LTC or retail pharmacy may prepackage a prescription drug product in advance of dispensing.

In conclusion, NCPA believes the impact on LTC pharmacies and the facilities they serve is an unintended consequence of the draft guidance and we ask that FDA fully take into consideration the LTC community when finalizing this guidance.

Sincerely,

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VP Pharmacy Affairs