May 19, 2015

Stephen Ostroff, M.D., Acting Commissioner
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

Dear Dr. Ostroff:

Innovatix appreciates the opportunity to comment on the U.S. Food and Drug Administration (FDA) draft guidance on Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities. Innovatix is one of the nation's largest non-acute care group purchasing organizations, with a national membership of over 26,000 non-acute care providers. Prior to submitting these comments, Innovatix held an Advisory Group meeting with approximately 50 of its members, mostly composed of long-term care providers, and six Innovatix staff pharmacists. Innovatix has also participated in several stakeholder meetings to develop a clear understanding of the draft guidance and the impact of the proposed language.

Based on insight from our provider members, Innovatix believes the proposed draft guidance will negatively affect our members' ability to deliver timely, essential care to patients. It will also create new operational inefficiencies. Specifically, Innovatix is concerned that this draft guidance document, if implemented in its current form, will

1) prevent pharmacies from preparing and providing emergency kits to long-term care facilities (LTCFs), correctional institutions, hospice organizations, and other patient-care environments;

2) prevent pharmacies from using remote dispensing technologies; and

3) severely limit, or eliminate altogether, prepackaging medications designed to increase quality patient care, ensure compliance, and provide efficient dispensing.

All three of these areas are of significant concern because they will

- compromise patient access to medications;
- increase rehospitalizations;
- place pharmacies and facilities at risk of violating Medicare and Medicaid policies regarding patients having timely access to medications;
- create inefficiencies for pharmacies, providers, patients; and
- generate additional costs for Medicare, Medicaid, and other payers.

Emergency Kits and Remote Dispensing

Many pharmacies provide small quantities of prescription medications—such as antibiotics, anticoagulants, and stroke rescue medications—in emergency kits for on-site storage and urgent dispensing to patients. Of importance, most patients who reside in LTCFs, correctional facilities, and other patient care settings are not located in close geographic proximity to their provider pharmacy, so emergency kits are critical.

State and federal laws are already in place to ensure the safe practice of limited medication dispensing from emergency kits. Some state regulations include state prescription and dispensing laws to direct the use of drugs from emergency kits, to specify how and when a written prescription must be obtained from a prescriber, and what the process is for replenishing medications in an emergency kit. Additionally, federal regulation and Medicare Part D guidance requires the availability of emergency medications for residents of LTCFs. Emergency medications are distributed by the pharmacy to the nursing facility in advance of a valid prescription or chart order, but the medications are only dispensed and administered in response to a patient-specific prescription or chart order.

Similar to emergency kits, medications in remote dispensing equipment are secured at the facility prior to a patient-specific prescription or chart order, but the medications are also only dispensed with a prescription or chart order. Remote dispensing equipment is maintained in accordance with standards established by various state and federal agencies. It is critical to note that with both emergency kits and remote dispensing, the medications are owned and controlled by the pharmacy up to the moment they are dispensed.

Innovatix Advisory Board members confirmed that maintaining emergency kits and remote dispensing units is essential for patient care. Emergency kits and remote dispensing are especially significant for

- geographically remote and rural populations where it might otherwise take days to get life-saving medication to patients;
- hospice providers who dispense necessary pain medication. Without access to proper medications, this population is at risk of readmission to a hospital or other acute care facility. Furthermore, hospice providers must also report quality data to the Centers for Medicare & Medicaid Services about their ability to treat pain in a timely fashion, so restrictions on emergency kits and remote dispensing are counter to those expectations; and
- correctional facilities must have access to certain detoxification medications that otherwise could harm a patient or put the public at risk when a patient is being transferred to a hospital.

Innovatix believes the language in the FDA draft guidance would eliminate the permissibility of emergency kits and remote dispensing. We urge the FDA to create an exemption for emergency supplies and remote dispensing units in an updated guidance document so that patients are ensured access to medically necessary medications. LTCFs will not be able meet the requirements or demand for adequate care without these longstanding, already regulated processes for ensuring timely patient

access to needed medications. Furthermore, with current Medicare and Medicaid policies aimed at reducing hospital readmissions, effectively managing pain, and ensuring timely patient access to needed medications, limiting or eliminating emergency kits and remote dispensing technology would be a significant barrier to achieving these goals.

Limits on Repackaging

Innovatix has particular concerns about lines 157–168 of the draft guidance (the discussion of a 14-day period for repackaged drug products), which would impact a pharmacy's ability to prepackage medications. Based on the language in the draft guidance, there is general confusion among stakeholders about how the FDA would structure, implement, and enforce limitations on pharmacies repackaging medications. The draft guidance suggests placing limitations on repackaging based on a rolling calculation of the repackaging done by the pharmacy during the previous 14-day consecutive period. The process suggested in the draft guidance would use an inordinate number of resources to continually calculate the historic use of medications and does not take into consideration the fact that the number of medications a pharmacy can repackage or prepackage varies from day to day.

First, we urge the FDA to facilitate a meeting of stakeholders prior to finalizing a policy to limit repackaging, so they can gain a clear understanding of the FDA's goal for this policy. We also believe a stakeholder meeting would benefit FDA staff, so they can hear from stakeholders firsthand how a policy limiting repackaging might be implemented without compromising patient care. We stress that any prepackaging limitation needs to be transparent and easily understood by stakeholders.

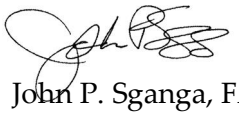
Our second concern regards placing repackaging limitations on pharmacies that dispense medications to residents in long-term care settings. Prepackaging is an integral practice for these pharmacies, in order to ensure optimal patient care and timely medication delivery. Many of our members reported that placing prepackaging limitations would result in a steep reduction in the number of deliveries the pharmacy would be able to make to each LTCF. This policy would create unneeded administrative hurdles for pharmacies that use prepackaging to streamline medication delivery, which is essential to secure timely access for patients and for overall medication management in LTCFs. Limiting pharmacies to an arbitrary 14-day algorithm, and presuming that pharmacy operators will understand how this works and have the capacity to manage the process described in the draft guidance, is not pragmatic (or possible). It will lead to additional costs for patients and for Medicare/Medicaid. In addition to convening a stakeholder meeting to discuss alternative ways for the FDA to have oversight of repackaging, we urge the agency to exempt pharmacies that serve beneficiaries in long-term care settings from prepackaging limitations.

In conclusion, Innovatix applauds the FDA's aim to make drug repackaging practices safer for all those who rely on such medications. However, we urge the FDA to remove the established and already regulated practices of pharmacies that dispense medications to patients in long-term care settings from the draft guidance. We stress that this is particularly important because these pharmacies must provide needed emergency medications and remote dispensing to their patients. We also ask the FDA to

reconsider the current language that will make prepackaging medications impossible. The FDA should convene a stakeholder meeting to discuss alternative processes for achieving its goals regarding oversight of repackaging.

Thank you in advance for considering these important issues.

Sincerely,



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