

FDA REPACKAGING GUIDANCE MUST ACCOUNT FOR LONG TERM CARE PHARMACY

THE FDA DRAFT GUIDANCE

In February 2015 the Food and Drug Administration (“FDA”) issued a “Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities,” through which the FDA would fundamentally limit pharmacies’ ability to repackage and ship drugs in advance of a specific patient prescription. It appears that the FDA is focused on further limiting practices of large compounding pharmacies. Unfortunately, the draft Guidance did not account for important practices in long term care (“LTC”) pharmacies that are integral to patient safety, patient care and nursing home compliance.

WHAT IS LTC PHARMACY?

LTC pharmacy is a specialized, dedicated type of pharmacy that serves nursing home residents and other facilities that have residents with unique medication needs. For example, today’s nursing home residents have high medications needs (average 11-13 prescriptions per patient) and cannot leave the home to pick up their medications. In response, and to ensure that nursing homes comply with their federally-mandated Medicare and Medicaid Conditions of Participation, LTC pharmacies must dispense medications in specialized packaging designed to ensure safe and appropriate dispensing. Medications often are pre-positioned on the premises of LTC pharmacies to allow safer, more efficient and more timely dispensing when patient-specific prescriptions are received. These pre-positioned medications are packaged in so-called “bingo cards” or “blister packs,” and generally are packaged in 30-day supplies. Compliance with Medicare and Medicaid Conditions of Participation also require LTC pharmacies to pre-position emergency medications in the nursing home in case of emergency. In addition, driven in part by federal initiatives to spur greater use of technology in health care delivery, LTC pharmacies in some cases pre-position medications in remote dispensing machines for daily dispensing at the nursing home directly. These remote dispensing machines remain in the care, custody and control of the LTC pharmacy under DEA and state pharmacy laws. Traditionally, neither emergency kits nor remote dispensing technologies allow for pre-positioning medications in response to patient-specific prescriptions.

THE ISSUE

Unfortunately, the FDA Guidelines (which were developed without stakeholder input from the LTC community), if finalized, would prohibit many of these essential patient safety care practices. More specifically, the Guidance could:

1. Limit the ability of LTC pharmacies to prepackage pharmaceutical products, **including drugs that remain in the pharmacy**, without receipt of a patient-specific prescription/chart order. Under the Draft Guidance, LTC pharmacies could prepare blister/punch cards in advance of a prescription/order, prepackage products for use in emergency kits or carts, or stock automated dispensing machines **only if** the pharmacy (i) met an uncertain “14-preceding-day” patient-specific quantity limitation, or (ii) undertook



FDA-regulated “manufacturer” obligations applicable to commercial drug repackagers. This 14-day requirement is not workable for LTC pharmacy. As a result, LTC pharmacy practices would be significantly impacted in ways that could undermine patient safety;

2. Prevent **any** dispatch of prepackaged/repackaged pharmaceuticals, **packaged or sent from the pharmacy**, in advance of receiving patient-specific prescriptions or chart orders (this specifically impacts emergency kits and remote dispensing practices); and
3. **Impede pharmacy practice in a manner that would impact nursing home compliance with safety requirements** specified as part of the Medicare and Medicaid Conditions of Participation, Conditions for Coverage and Requirements for nursing homes.

THE SOLUTION

Currently the FDA permits LTC pharmacy repackaging practices in compliance with state pharmacy law. To allow LTC pharmacy to continue timely meeting the needs of nursing home residents, the Draft Guidance **must** be revised before it becomes final to continue the FDA’s existing practice of allowing current LTC pharmacy repackaging practices that meet state law requirements. By doing so, safe, efficient and appropriate dispensing of needed medications can continue, benefitting nursing homes and patients alike.

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