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June 21, 2022

Via Electronic Submission (www.regulations.gov)
Via USPS

Dr. Robert Califf, Commissioner
United States Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Providing Mail-Back Envelopes and Education on Safe Disposal with Opioid Analgesics Dispensed in an Outpatient Setting, FDA-2022-N-0165

Dear Commissioner Califf:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the U.S. Food and Drug Administration's proposed Public Docket and Request for Comments on Providing Mail Back Envelopes and Education on Safe Disposal with Opioid Analgesic Dispensed in an Outpatient Setting.[1] SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 80% of all independent LTC pharmacies. Our members serve one million residents daily in skilled nursing facilities (SNFs), nursing facilities (NFs), Intermediate Care Facilities (ICFs), and assisted living facilities (ALFs) across the country.[2] Given the distinct characteristics of the LTC patient population and the LTC facilities in which they reside, it is important that the FDA understand the impact this proposal would have on LTC facility residents who need LTC and the independent LTC pharmacies that serve them.

We generally support the FDA's objective of reducing diversion of unused prescription opioids by affording the general public an additional avenue for distribution of abuse. LTC pharmacies have been required, both by professional standards and by Medicare and Medicaid regulations and guidance, to implement rigorous measures to avoid opioid diversion, particularly in SNFs and NFs. We are committed to protocols designed to minimize diversion in all LTC facilities and related settings. While the FDA's concept regarding mail-back envelopes may create a valuable option for the general public who receive prescription opioids through retail community and mail-order

[1] FDA-2022-N-1065, published at 87 Fed. Reg. 23869 (April 21, 2022).
[2] Federal law defines SNFs as facilities that meet various requirements of participation, including pharmacy services requirements, to provide skilled nursing care to Medicare beneficiaries who qualify for such services, 42 U.S.C. § 1395i-3, Federal law defines NFs and ICFs as facilities that meet various requirements of participation, including pharmacy services requirements, to provide institutional long-term care to Medicaid beneficiaries who qualify for such services, 42 U.S.C. § 1396(r)(4)(a)(iii). Based on these statutory requirements, the Centers for Medicare and Medicaid Service (CMS) has promulgated extensive regulations detailing the requirements of participation for SNFs, NFs, and ICFs, 42 C.F.R.§§ 483.1-483.95. ALFs are not regulated under federal law, but may qualify as Medicaid providers under federal waivers.

pharmacies, such a standard would be problematic at best and counterproductive at worst if applied to residents in LTC facilities.

Background

SCPC's comments are based on the distinct characteristics of the patient population in LTC facilities and the clinical and specialized services LTC pharmacies provide to residents in such facilities. LTC pharmacies primarily serve patients in SNFs, NFs, ICFs, and ALFs. LTC pharmacies differ substantially from the general retail environment addressed in the FDA's proposal in two important ways:

1. **LTC patients are much more medically complex, take significantly more prescription medications, and have distinct pain management needs.** The complexity of LTC patient conditions distinguishes LTC pharmacy from retail pharmacy and underscores the value LTC pharmacies deliver through their services to patients. Fifty-nine percent of residents in LTC facilities suffer from four or more chronic conditions, and 75% suffer from cognitive impairments. The average resident takes 12 prescriptions per month.[3] As a result, pharmacy services – not simply dispensing medications – are crucial to the quality of care for patients and increasingly important in preventing adverse events like re-hospitalizations, patient falls, polypharmacy complications, medication-induced dementia, and other adverse drug reactions. LTC pharmacy provides specialized pharmacy services, thereby improving the quality of care and reducing Medicare expenditures.

2. **LTC pharmacies have extensive and extended clinical responsibilities to patients.** LTC pharmacies have extensive and ongoing clinical responsibilities well beyond those of retail or mail order pharmacies. These responsibilities begin when the pharmacy receives a prescription and continue through the patient's transition from a LTC facility to home or another setting. The Medicare Prescription Drug Benefit Manual (the Part D Manual) describes ten service criteria LTC pharmacies must meet.[4] Pharmacists employed by LTC pharmacies become part of each patient's care planning team, and must discharge specific clinical responsibilities at least monthly, including:

    - Direct and ongoing consultation with residents and their families.
    - Participation in resident care management teams, including direct interactions with and recommendations to the facility medical director, nursing staff, and administration. This engagement requires familiarity with the resident's medical records and complete prescription drug profile.
    - Drug utilization review to prevent over- or under-utilization of prescription drugs and to improve outcomes and reduce costs when medically appropriate.
    - Medication therapy management for Part D Plans, including comprehensive medication reviews and targeted medication reviews for all LTC beneficiaries.

[3] Analysis of data from SCPC member pharmacies May 2020; *see also* ATI Advisory, Understanding the Long-Term Care Needs of the Medicare Population, and the Role of Long-Term Care Pharmacies in Addressing this Need (July 2021), available at https://atiadvisory.com/wp-content/uploads/2021/07/Medicare-Beneficiary-LTC-Needs-and-Role-of-LTC-Pharmacies.pdf.
[4] Part D Manual at § 50.5.2.

- Medication reconciliation, including at least daily reconciliation for opioids.
- Direct and ongoing training and contact with facility nursing staff.
- Pharmacist availability to provide medication and patient care services 24/7/365.
- Direct placement of peripherally inserted central catheters and insertion of Midline and PICC lines.
- Antibiotic stewardship and infection control.
- Specialized packaging to improve adherence and reduce medication errors.
- Access to prescription medications at all times, pursuant to which residents must receive medications as soon as two hours after the pharmacy receives the prescription.

LTC pharmacies also provide broader specialized services, including patient-specific, unit-dose packaging to reduce medication errors, systematic packaging for entire facility, and 24/7/365 medication delivery.

Due to the closed nature of the distribution system in LTC facilities and the extensive clinical responsibilities and medication monitoring requirements imposed on LTC pharmacies, patients in LTC settings pose very low risk of abusing opioids or other prescription medications and the risk of opioid diversion is low. Residents in LTC facilities have a higher incidence of chronic pain requiring drug treatment, more conditions contraindicating alternatives to opioids for pain management, and a higher incidence of breakthrough pain requiring larger doses of pain management medication. Consequently, they are far less likely than the general population to have unused prescription opioids that require disposal.

Both LTC pharmacies and LTC facilities, moreover, have heightened responsibilities regarding opioids. For SNFs, NFs, and ICFs, opioids must be stored in a locked compartment within locked medication carts that facility nursing staff use to conduct medication passes (med passes) to administer medications to facility residents. Opioid reconciliation occurs at least daily, and in some cases on a shift-by-shift basis, specifically to minimize substantially the risk of misuse or diversion. LTC pharmacies also must comply with detailed protocols for disposing of unused opioids which are established and enforced under state law.

Congress has acknowledged this distinction in recent legislation. For example, the Comprehensive Addiction and Recovery Act's Part D lock-in provision included an exemption for beneficiaries residing in LTC facilities and gave the Secretary discretion to extend this exemption to other LTC care settings.[5] In creating this exemption – and several similar exemptions in the SUPPORT Act[6] - Congress recognized that residents in LTC facilities are a distinct patient population and the LTC pharmacies that serve them are distinct from retail or mail order pharmacies serving the general public such that public policy should be modified appropriately.

Comments

Outpatient Settings and LTC Facilities. The notice pertains to opioid analgesics dispensed in an outpatient setting. The notice does not define "outpatient setting," and various FDA regulations

[5] 42 U.S.C. § 1395w-10(c)(5)(C)(ii).
[6] Public Law No: 115-271 (10/24/2018).

suggest differing definitions of outpatient setting. It therefore is crucial that the FDA define outpatient setting for purposes of a mail-back policy and that LTC facilities be excluded from the definition of outpatient facilities.

As explained above, 75% of residents in LTC facilities suffer from cognitive impairments and both the facilities and the LTC pharmacies that serve them follow extensive protocols – often required by law – to minimize the risk of diversion. SNFs, NFs, and ICFs – which are federally defined LTC facilities – must also provide specialized services, including compliance packaging, and must comply with state laws concerning disposal of unused opioids. Similar requirements and protocols extend to ALFs, often pursuant to state law.

Providing mail-back envelopes in the context of residents in LTC facilities, therefore, will not reduce the risk of diversion. In SNFs, NFs, and ICFs residents do not receive their prescriptions directly. Rather, LTC pharmacies deliver medications to these facilities using packaging systems designed to streamline medication administration by facility nursing staff. It simply makes no sense to provide mail-back envelopes to patients who do not handle or manage their prescription drugs directly.

In ALFs, residents may, but are not obligated, to obtain prescription drugs from LTC pharmacies. However, many residents do so, and protocols similar to those used in federally defined LTC facilities are used in ALFs. Whether from ALF staff or LTC pharmacies, ALF residents have some degree of medication management and assistance in proper disposal of unused medications, including opioids. More importantly, with 75% of ALF residents suffering from cognitive impairments, it seems unlikely that providing them with mail-back envelopes for one of on average the twelve prescriptions they take each day is more likely to create confusion that will reduce medication adherence and undermine quality of care than to substantially reduce the risk of opioid diversion.

Unfortunately, the FDA has no clear definition of outpatient setting, such that the policy described in the notice arguably could be applied to all LTC facilities. Perhaps the most relevant FDA commentary may be found in Questions and Answers on Guidance for Industry: Medication Guides - Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS). In this document, the FDA includes SNFs among a list of inpatient settings, while including ALFs among a list of outpatient settings if a drug is dispensed directly to a patient or caregiver.

This is an inadequate basis on which to base a mail-back policy. First, the examples ignore NFs and ICFs, both of which are federally defined LTC facilities, both of which must comply with pharmacy services requirements of participation in Medicaid that are substantially similar to the pharmacy services requirements in Medicare with which SNFs must comply, and both of which, in many cases, are the same buildings, rooms, and beds as the buildings, rooms, and beds that also may be characterized as SNFs depending on whether the resident qualifies for Medicare skilled nursing coverage or Medicaid nursing coverage. Second, for many ALF residents, drugs are not dispensed directly to them or, in any meaningful sense, to the caregiver. Rather, the LTC pharmacy with which the ALF has a relationship dispenses drugs, including opioids, using processes and in compliance with protocols similar to those used in SNFs, NFs, and ICFs. It therefore is essential

that the FDA clearly define outpatient settings for purposes of a mail-back policy, and that all LTC facilities – including SNFs, NFs, ICFs, and ALFs – be excluded from the definition of outpatient setting or exempted from any mail-back requirement.

Mail-Back Cost. We appreciate that the notice would impose the cost of mail-back envelopes on manufacturers. This must remain an essential component of any policy proposal. SCPC members estimate that appropriate secure mail-back envelopes currently cost roughly $1,100 for 250 envelopes. Given the number of outpatient opioid prescriptions dispensed each year, the cost of providing mail-back envelopes could be substantial.

The cost of the envelopes is only a portion of the costs pharmacies would incur under a mail-back policy. There will be administrative costs and compliance costs, which likely would be greater for LTC pharmacies than for retail or mail order pharmacies, given the additional regulatory obligations which LTC pharmacies must fulfill. Medicare Part D Plans (which account for roughly 75% of LTC pharmacy revenues) are unlikely to reimburse LTC pharmacies for these additional costs. Other payers similarly have no incentive to compensate LTC pharmacies for added costs associated with a mail-back policy.

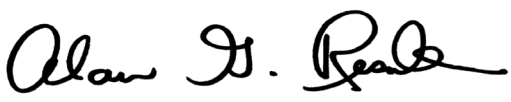
Requiring manufacturers to cover all costs – both mail-back envelopes and related administrative and compliance costs – could well increase the cost of prescription drugs. Manufacturers likely will recoup such costs by raising drug prices, primarily to the determent of patients.

Conclusion

We therefore urge the FDA to define "outpatient setting" in any proposal to implement a mail-back policy, and to exclude all LTC facility types – SNFs, NFs, ICFs, and ALFs – from such definition or otherwise exempt residents in such facilities and the LTC pharmacies that serve them from any mail-back policy. We also urge the FDA to assure that, should the agency implement a mail-back policy, neither LTC pharmacies nor patients bear the costs of implementation.

We thank you for your consideration of these comments and welcome any questions or follow up that you may have. If we can provide any additional information, please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org.

Sincerely,



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