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June 16, 2020

Via Electronic Submission

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30329

RE: Management of Acute and Chronic Pain: Request for Comment, Docket No. CDC–2020–0029

Dear Director Redfield:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to respond to the Centers for Disease Control and Prevention's (CDC's) request for comment on Management of Acute and Chronic Pain (Docket No. CDC–2020–0029). SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. Our members serve 850,000 residents daily in skilled nursing facilities and assisted living communities across the country. Given the distinct characteristics of the LTC patient population and the enhanced clinical responsibilities of LTC pharmacies, we offer unique perspectives on the use of opioids and the distinct nature of patient needs in the long-term care sector.

We share CDC's concern about the threat prescription drug abuse poses to our nation and agree there is a real need to ensure Americans do not abuse opioids and other prescription medications. Our comments will focus on how CDC can best balance the need to control access to addictive medications and ensure appropriate use within unique healthcare settings like LTC facilities, which includes skilled nursing facilities (SNFs), Nursing Facilities (NFs), and assisted living facilities (ALFs). We specifically request that, in the next modification of the CDC's Opioid Guidelines, the CDC include a specific statement that ***any recommended opioid limits do not apply to patients in long-term care facilities, including skilled nursing facilities, nursing facilities, and assisted living facilities.***

General Background on the LTC Setting and LTC Pharmacy

LTC pharmacies serve patients in skilled nursing facilities, assisted living facilities (ALFs), and other group and residential settings. LTC pharmacies differ substantially from the general retail environment addressed in the current CDC Opioid Guidelines in three 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. The average resident in a skilled nursing facility (SNF) is a woman in her mid-80s suffering from multiple chronic conditions and co-morbidities with mild to moderate dementia who takes 12-13 prescription medications each month. In assisted living facilities (ALFs), the average number of prescriptions per patient is 11-12 per month. [1] This patient population has a higher incidence of pain requiring drug treatment, more conditions contraindicating alternatives to opioids for pain management and higher incidence of breakthrough pain requiring larger doses of pain management medication. 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. Pharmacists employed by LTC pharmacies become part of each patient's care planning team, and must discharge specific clinical responsibilities at least monthly, including:

    A. **Medication reconciliation for opioids/controlled substances.** At least daily, and in some cases for each medication administration (or "med pass") within a facility, LTC pharmacies reconcile dispensing and administration of opioids and other controlled substances;
    B. **Drug utilization review (DUR).** At least monthly and usually more frequently, LTC pharmacies review every patient chart to assure prescription, dispensing and administration of medications appropriate to each patient's clinical conditions and pharmacological needs;
    C. **Medication therapy management (MTM).** LTC pharmacies manage each patient's medication management continuously; and

[1] Analysis of data from SCPC member pharmacies May 2020.

D. **Transition management.** LTC pharmacies manage patient transitions between each care settings to ensure medication continuity between sites of care.[2]

LTC pharmacies conduct opioid reconciliation at least daily, and in some cases on a shift-by-shift basis. This substantially minimizes the risk of misuse or diversion.

3. **LTC pharmacies must satisfy strict packaging and delivery requirements.** LTC pharmacies must dispense prescriptions in specialized, patient-specific, "single unit dose" packages, unlike retail and mail order pharmacies which typically distribute medications in pill bottles. LTC pharmacies also must standardize packaging of prescriptions to assure consistency across all patients in a LTC facility. With oral solids constituting more than 90% of all prescriptions dispense, this often is a technologically driven process, and may include use of remote dispensing technology for commonly prescribed drugs. LTC pharmacies also must pre-position emergency kits (e-kits) in nursing homes and other care facilities. To the extent e-kits contain opioids, most LTC pharmacies exchange e-kits daily to minimize the risk of misuse or diversion. Unlike retail or mail order pharmacies, federal and state laws require that LTC pharmacies dispense and deliver prescription drugs 24-hours a day, 7 days a week, 365 days per year.

Consequently, patient considerations and LTC pharmacy legal obligations and practice protocols warrant separate consideration and different guidelines and recommendations for the LTC patient population in LTC facilities.

Risk of Opioid Abuse in the LTC Patient Population. 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. Indeed, given the patient profile, there is virtually no possibility that these patients could "doctor shop" or "pharmacy shop" to support either addiction or diversion. Taken together, these factors warrant different policies and guidelines for patients in LTC facilities.

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. 42 U.S.C. 1395w-10(c)(5)(C)(ii). In creating this exemption, Congress recognized that in care settings where only one pharmacy is under contract to provide all medications there is no risk of multiple pharmacies dispensing opioids or other frequently abused drugs. Since the only source of medications is the single pharmacy under contract there is no option for the patient to "pharmacy shop."

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[2] These activities are listed in and required by the Medicare Prescription Drug Program Manual (the Part D Manual), Chapter 5, Section 50.5.2.

Dispensing Limits on Opioids. Because the LTC patient population differs substantially from the 65+ patient population in the community, opioid limits must be approached differently. Both regulatory requirements and clinical needs in LTC facilities and settings demand more timely opioid dispensing and consistently higher therapeutic doses of opioids and other pain control prescription medications. Also, in LTC settings patients are much more likely to be opioid-resistant.

First, LTC patients are more likely to have developed opioid tolerance. Opioid tolerance occurs when a patient no longer responds to a pain medication in the way that she or he did initially. It is common that LTC residents achieve some level of tolerance over the course of treatment. For example, there are bone cancer patients in LTC facilities that require 200 Morphine Milligram Equivalents (MMEs) per day to address their breakthrough cancer pain. We appreciate that the CDC has previously recommended[3] general MME limits but believe that approach is simply too blunt to be used in LTC settings. There is a significant difference between opioid tolerance and opioid abuse or addiction in community versus LTC settings, yet existing guidelines do not draw any relevant distinctions.

Second, there are fewer alternatives to opioids in the LTC patient population. Alternatives to opioids are more frequently contraindicated for a geriatric population suffering from multiple chronic conditions and co-morbidities, and the prevalence of such conditions is significantly higher among seniors in LTC facilities than among seniors living in the community. Once again, there is a substantial clinical difference for patients in LTC facilities.

CDC guidance does not differentiate the LTC patient population. For this patient population, per day limits will not reduce opioid abuse but will increase the likelihood that patients who disproportionally rely on opioids to manage severe pain will not receive timely, necessary, and clinically appropriate pain management.

We also recognize prior discussions concerning minimum dispensing limits. While we believe patients in LTC facilities should be exempted entirely from guidelines or recommendations relevant to the general population or the geriatric population living in the community, should the CDC conclude otherwise it is essential that minimum dispensing limits be no less than seven days. Any dispensing cycle less than seven days risks potential delays in therapy and adverse impact on patient care. Given the significant controls in place by LTC pharmacies and LTC facilities for any controlled substances, and especially opioids, the CDC should scrutinize the need for these dispensing limits in LTC facilities. They simply are not needed.

Opioid Potentiators

As mentioned above, the clinical needs of patients in LTC facilities differ substantially from patients living in the community. This is particularly relevant regarding limitations on use of "potentiator" medications, which CDC and others have considered in making recommendations

[3] Moreover, much as the Center has repeated that its Guidelines are not intended to be regulatory limits, the Center is well aware that the Guidelines have repeatedly been cited and its limits implemented in regulation by Medicare in the Prescription Drug Program.

designed to reduce opioid abuse. Due to the multiple co-morbidities of patients in LTC settings, use of pregabalin (Lyrica) or gabapentin (Neurontin) is more and more appropriately prevalent for patients in LTC facilities than for patients in the ambulatory and community settings. Common uses include treatment of post-herpetic neuralgia, fibromyalgia, epilepsy and other seizure disorders, and neuropathic pain, which arise much more frequently in the LTC population. Given the nature of LTC patients – elderly, suffering from multiple chronic conditions, in need of 12-13 prescription medications daily, significant impairments in activities of daily living and moderate cognitive impairment - these drugs simply are not opioid "potentiators."

Also, federal law requires LTC pharmacies conduct monthly medication reviews that flag the possibility that medications like gabapentin and pregabalin could "potentiate" a shift to opioids. These existing review requirements, and related and mandated medication reviews and opioid protocols, provide timely and effective oversight of potentiator use and risks. There is no need to add additional flags for opioid potentiators for patients in LTC settings. Therefore, we recommend that the CDC accommodate this unique characteristic of LTC settings in any guidance on opioids.

Conclusion

We urge CDC to recognize the distinct factors that impact appropriate use and dosage of opioids in the LTC patient population by revising existing Guidelines to explicitly exempt all LTC facilities – (SNFs, NFs, and ALFs). We also recommend that CDC recognize the distinct characteristics of the LTC patient population and the substantial protections against substance abuse that LTC pharmacies provide when considering future guidelines, recommendations, and policies.

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,

Alan G. Rosenbloom
President & CEO
Senior Care Pharmacy Coalition