April 8, 2020

Via Electronic Delivery (Email)

Ms. Amy Larrick
Director, Medicare Drug Benefit and C and D Data Group
Centers for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Long-Term Care Pharmacy Specific Part D Administrative Concerns in Response to COVID-19

Dear Amy,

On behalf of the American Society of Consultant Pharmacists (ASCP), the National Community Pharmacists Association (NCPA) and the Senior Care Pharmacy Coalition (SCPC), we thank you and your colleagues for your extraordinary efforts in response to the COVID-19 public health emergency. We are writing collectively to reinforce issues each organization has raised concerning the assistance LTC and community pharmacies need to assure their robust response to the crisis.

LTC pharmacies routinely navigate various PDP/PBM utilization management and administrative requirements on pharmacies participating in Part D networks that, in the current crisis, threaten beneficiary access to medications and increase the unnecessary risk of exposure to beneficiaries, patients in LTC facilities, facility staff and pharmacy personnel. We appreciate the actions CMS already has taken, as well as actions some PDPs/PBMs have taken in the marketplace, to help pharmacies focus on patient care. These measures include CMS guidance to PDPs/PBMs on refill-too-soon (RTS) point-of-sale edits and face-to-face signature requirements. Some PDPs/PBMs also have suspended both desk and field audits, but several appear to be continuing desk audits. **Unfortunately, issues of concern remain. Our organizations respectfully ask that CMS take the necessary steps to address the following concerns.**

Prior Authorization (PA):
PDPs/PBMs have not taken appropriate action to alleviate potential restrictions on Part D beneficiary access to medications created by extreme physician workload. Physicians practicing in long-term care facilities are overwhelmed by patient care and are unable to complete paperwork concerning prior authorizations and formulary interchanges. When LTC pharmacies do not receive PA approvals, they must reduce the amount of drug dispensed until they can get authorization. This is usually a three-day supply, which increases the amount of deliveries needed as well.
We believe CMS has the statutory and regulatory authority to relax PA requirements under § 1135 waiver authority (which extends to both Medicare and Medicaid), under the President's emergency declaration and Secretary Azar's declaration of a national health emergency and under § 3714 of the recently enacted Coronavirus Aid, Relief and Economic Security (CARES) Act. CMS has issued additional direction to states concerning Section 1135 waivers, specifically noting that state Medicaid programs have the flexibility to temporarily suspend prior authorization requirements. CMS also has waived its own prior authorization documentation requirements for PDPs themselves.

Therapeutic Interchange and Substitution:
In addition to existing authority, CMS should authorize pharmacists providing direct patient care to individual patients to conduct therapeutic interchange and substitution when product shortages arise. On medications within one of Medicare's six protected classes (anticonvulsants, antidepressants,

antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants), pharmacists, in consultation with the patient's prescriber, will continue to make therapeutic interchanges when necessary. When product shortages arise, plans should facilitate therapeutic interchange and substitution by pharmacists providing direct patient care to individual patients without prior authorization and with appropriate physician notification.

We respectfully request that CMS provide additional guidance to PDPs/PBMs to temporarily waive or override point-of-sale edits, specifically including but not limited to prior authorization and formulary interchange edits, for the duration of the COVID-19 crisis.

We recognize that PAs and FIs are an important utilization management tool, and do not request relaxation lightly. However, the current crisis demands relief in the interest of Part D beneficiaries, other patients in LTC facilities, and facility/pharmacy staff. We are confident CMS could craft a solution that affords appropriate relief to pharmacies without precipitating overuse of medications subject to PA requirements. We also believe that PDPs/PBMs easily could implement override codes that would address these concerns quickly, given that they have done so during previous natural disasters.

There are four other routine practices that also unnecessarily increase risk of exposure for nursing home patients and facility/pharmacy staff, or otherwise divert pharmacy staff from patient-focused activities:

- **Short-Cycle Dispensing.** Based on discussions, we understand you appreciate the ways in which the short-cycle requirement concerning Part D beneficiaries in LTC facilities presents potential risk to uninterrupted Part D beneficiary access and unduly greater risk of exposure. Easing the short-cycle limitation by allowing 30-day or even 60-day dispenses rather than a maximum 14-day dispense would not unduly increase waste or unnecessarily burden facilities, and therefore would properly balance the competing concerns.

  The best available anecdotal information demonstrates that at least 90% of these prescriptions are refilled. Another anecdotal report states that the average number of refills per short-cycle drug dispensed is 3.95, which translates roughly to a two-month supply. PDPs/PBMs seems inherently to understand these facts since they typically authorize refills for six months to a year for short-cycle drugs. Consequently, there is no appreciable risk that waiver of short-cycle dispensing will cause a significant increase in waste.

- **Audits.** Pharmacies remain one of the few entities open to assist patients in their local communities. Our members need relief to stay open and help their patients. PDP/PBM audits of LTC pharmacies, whether field audits or desk audits, require substantial commitment of pharmacy time and resources. While some PDPs have suspended all audits, others have suspended field audits but have continued and, in some cases, increased desk audits. As a result, pharmacy staff, who already are overtaxed by COVID-19 demands and understaffed by COVID-19 protections (e.g., requiring non-essential personnel to work remotely), must divert even greater time and resources from patient care to audit responses. We ask that CMS provide clear guidance stating that Part D sponsors and PBMs are not able to audit pharmacies in the future for any alterations or waivers of Part D sponsor and PBM requirements. This includes patient signatures as proof of delivery for any medications, made during this emergency period. **We ask that CMS require Part D sponsors and Pharmacy Benefit Managers (PBMs) to temporarily suspend all pharmacy audits during the public health emergency.**

- **Face-to-Face Signature Requirements.** We greatly appreciate CMS' guidance dated March 20, 2020, "Minimizing Face-to-Face Contact for Medication Delivery or Dispensing," and we continue

to track how various PBMs are implementing this guidance. In this guidance, CMS stated the following: "We are making clear that HHS does not require and will not audit for patient signatures as proof of delivery for any medications, including for controlled substances." Despite this statement, PDPs/PBMs have imposed alternatives to face-to-face signatures, with protocols differing between plans. Since LTC pharmacies do not deliver medications to LTC facilities by payer, much less individual plan, LTC pharmacies are at risk of payment recoupment during post-emergency audits. LTC facilities, moreover, have established their own protocols consistent with CDC and state or local guidance that may differ from those adopted by a particular PDP/PBMs, adding another layer of complexity.

We understand that CMS appropriately is focused on immediate concerns related to patient care, however, we urge that CMS address this potential complication when considering the transition from emergency to normalcy. However, PBMs are still requiring pharmacies to document various aspects of proof of delivery, and each PBM's notice to pharmacies can vary greatly. Our concern is that Part D sponsors and PBMs may audit our members when the public emergency ends and penalize them for technicalities.

Therefore, we ask CMS to encourage Part D sponsors and PBMs to suspend proof of delivery audit requirements during the public health emergency and ask that CMS prohibit these entities from performing future proof of delivery audits relating to medications filled during this emergency period.

- **Window for claims resubmissions**. PDPs/PBMs require that pharmacies complete claims resubmissions within 90 days following coverage denials. Pharmacies understandably are focusing resources on patient care needs. It is not reasonable to expect LTC pharmacies to devote time and resources to managing claims resubmissions rather than concentrating on protecting staff and, for LTC pharmacies, protecting not only Part D beneficiaries but all LTC facility residents as well as facility and pharmacy personnel. Given these concerns, our organizations request that CMS direct PDPs/PBMs to increase the time allotted for resubmissions.

Finally, we would like to share additional concerns that could be relevant to post-crisis implications of CMS guidance already issued in response to the current pandemic.

Telehealth and Chronic Care Management:
We applaud CMS' recent expanded use of telehealth during this time of national, state, and local emergency. We ask that CMS review and include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit and create additional payment codes for those telehealth services that pharmacists provide to Medicare patients and their health care management teams. Pharmacists are a critical part of the health care management team. Telehealth enables pharmacists to connect with skilled nursing home nursing and management teams, as well as patients and caregivers, particularly when questions arise concerning laboratory orders, progress notes, medications prescribed or changes to medications. Medicare does not reimburse pharmacists for telehealth services currently. We urge CMS to expand reimbursement for telehealth services during this emergency to include services provided by pharmacists in skilled nursing facilities including medication management services (MMS)[1], chronic care management (e.g., diabetes, hypertension), medication reconciliation, and interpretation of diagnostic tests and results. In addition, some states have allowed for medication security, storage and destruction to be performed using telehealth.[2]

[1] "Medication Management Services (MMS) Definition and Key Points," Joint Commission of Pharmacy Practitioners, https://jcpp.net/wp-content/uploads/2018/05/Medication-Management-Services-Definition-and-Key-Points-Version-1.pdf
[2] Texas State Board of Pharmacy, https://www.pharmacy.texas.gov/files_pdf/destruction-of-drugs-ltc-facilities.pdf

Thank you for your consideration of these requests.

Sincerely,

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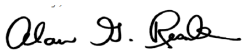

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