

March 24, 2020

The Honorable Seema Verma
Administrator
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma:

The Premier healthcare alliance plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Innovatix, a wholly-owned subsidiary of Premier, is one of the nation's largest non-acute care group purchasing organizations that delivers savings and value to long-term care pharmacies (LTCPs), skilled nursing facilities (SNFs), infusion pharmacies and other provider organizations.

Together, Premier and Innovatix serve more than 650 LTCPs, 6,525 SNFs, 4,800 home infusion locations, 4,000 hospitals and approximately 165,000 other providers. While we appreciate CMS' guidance for nursing homes, more action from CMS is needed to ensure non-acute providers can continue delivering high-quality care to patients given new and heightened pressure they are facing due to the COVID-19 outbreak.

Premier appreciates the chance to offer comments on behalf of our non-acute members. We request CMS take action on recommendations outlined in this letter which are designed to help reduce the spread of COVID-19, while supporting efforts by LTCPs and infusion pharmacies to be more efficient in providing services to their patients¹.

Long-term Care Pharmacies

CMS issued revised guidance to nursing homes to limit the spread of COVID-19 to its vulnerable residents on March 13, 2020², for the protection of both residents of nursing homes and providers of healthcare. Critical best practices include screening providers prior to entry to the nursing home, expanded use of Personal Protection Equipment (PPE), enhanced sanitizing of testing equipment, and up to 14-day quarantining of professionals who may have been in contact with a patient with COVID-19. While CMS is appropriately restricting access to this older, frailer patient population, more guidance is needed for the pharmacies that are responsible for providing medications and services to the facilities. Pharmacies that provide services to nursing home beneficiaries face significant challenges as their service model requires frequent visits that can include multiple visits in a single day. Most notably, pharmacies deliver medications, perform medication inventory services, and are required to conduct Drug Regimen Reviews (DRRs).

To ensure nursing home residents continue to receive high-quality services as well as timely access to medications from LTCPs, we request CMS take the following action, which should remain in place until

¹ CMS has the authority to act upon all of Premier's recommendations pursuant to President Trump's Executive Order and subsequent Waiver or Modification of Requirements Under Section 1135 of the Social Security Act issued by HHS Secretary Azar on March 13, 2020. Accessed at:

<https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>

² Centers for Medicare & Medicaid Services, QSO-20-14-NH, Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes. March 13, 2020. Accessed at: <https://www.cms.gov/files/document/3-13-2020-nursing-home-guidance-covid-19.pdf>

the agency issues a definitive update that COVID-19 outbreak is no longer a threat to the nursing home population:

1. As part of CMS' conditions of participation for long-term care facilities (LTCFs)³, the drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist and this review must include a review of the resident's medical chart. ***CMS should provide flexibilities concerning the DRR requirements so that pharmacists and pharmacy personnel may continue to provide these required services to residents. To accomplish this, CMS should provide guidance that there will be no enforcement of the conditions of participation related to medications while the COVID-19 pandemic persists.*** CMS should provide such guidance so that 1) pharmacists are permitted in facilities to perform the monthly chart review, or 2) pharmacists can perform their chart requirements via telehealth; or 3) the pharmacy and facility can develop an alternative approach that protects residents, facility staff, and pharmacists.

2. ***CMS should take action on point-of-sale edits under Medicare Part D to reduce barriers to medication access for those residing in LTCFs during the COVID-19 pandemic.*** Premier requests that CMS provide additional guidance to plans directing them to temporarily waive or override all point-of-sale edits. While we understand some plans have already taken some steps to alleviate these access barriers, it is imperative that CMS provide clear, uniform direction to all plans. Premier notes that during previous natural disasters, plans were easily able to implement override codes for these three point-of-sale edits in the affected geographic areas.
 - ***CMS should direct Part D plans (PDPs) to override prior authorization (PA) requirements they place on the prescriber and pharmacy before they will approve payment.*** Temporarily overriding PA requirements will alleviate the strain on prescribers and allow pharmacies to be more efficient and consolidate delivery of prescriptions to nursing homes. Of note, on March 22, CMS issued additional direction to states concerning Section 1135 waivers⁴ specifically noting that CMS has the flexibility to temporarily suspend prior authorization requirements. CMS should use its authority under Section 1135, which authorizes waivers of Medicare requirements as well as Medicaid requirements, to address Part D beneficiary access issues created by prior authorizations.
 - ***CMS should direct PDPs to override formulary interchange policies that require documented justification when a prescriber issues a prescription for a plan's non-preferred drug.*** Formulary interchange requirements are a frequent occurrence for LTCF beneficiaries and lead to the LTCP obtaining a form from the prescriber justifying the use of the non-preferred/non-covered drug before the patient can gain access to their medication. Like the PA requirement, temporarily overriding this edit will alleviate the strain on prescribers and pharmacies. Further, CMS could invoke Section 1135 to waive the formulary interchange policy.
 - ***CMS should direct PDPs to override refill-too-soon (RTS) edits and authorize 90-day supplies.*** Following CMS' March 10 guidance⁵ related to formulary adjustments necessary during the COVID-19 pandemic, many PDPs have provided override codes that allow LTCPs to refill prescriptions early. This is notable progress; however, we ask CMS to extend this policy further by issuing clarifying guidance that directs PDPs to allow RTS overrides that will serve as authorization for a 90-day supply of the medication to be dispensed.

³ Centers for Medicare & Medicaid Services, Conditions of Coverage, Long-term Care Facilities. Accessed at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/LTC>

⁴ Centers for Medicare & Medicaid Services, Section 1135 Waiver Flexibilities. Accessed at: <https://www.medicare.gov/state-resource-center/disaster-response-toolkit/cms-1135-waivers/index.html>

⁵ Centers for Medicare & Medicaid Services, "Information Related to Coronavirus Disease 2019 - COVID-19." Accessed at: <https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf>

3. The Part D requirement that brand name, solid oral drugs be dispensed in increments of no more than 14-day supplies creates more frequent deliveries to LTCF, which should be minimized during the COVID-19 pandemic. **Premier requests that CMS temporarily waive the short-cycle dispensing requirements and provide guidance to plans directing them to suspend any policies, practices or procedures that deny coverage based on short-cycle dispensing requirements.**

Infusion Pharmacies

For decades, home infusion has been recognized as a safe and effective method of delivering critical drugs to patients. With the recent outbreak of COVID-19, the need to minimize exposure for beneficiaries receiving infusion drugs is more urgent than ever. To increase access to home infusion and reduce administrative burdens during this pandemic, we request CMS take the following action:

1. **CMS should relax proof of delivery signature requirements** for all home infusion drugs, including Medicare Part B. We thank CMS for the March 20 guidance⁶ to PDPs that relaxes the signature requirement for drugs covered under Medicare Part D. We call on CMS to use this same authority to extend this policy further for the same purpose of reducing beneficiaries' exposure to those delivering medications.
2. **CMS should ensure full coverage for infusion therapy so that beneficiaries can receive treatment in their home.** CMS can do more to ensure home infusion providers can treat these vulnerable patients currently in their homes as well as patients in already-burdened institutional settings who can be transitioned home for infusion therapy. We urge CMS to:
 - **Allow home infusion therapy suppliers to bill for remote pharmacy services under the transitional home infusion therapy services benefit and provide reimbursement for each day an applicable drug is infused.**
 - **CMS should extend the Part B durable medical equipment (DME) transitional home infusion therapy service codes (G0068, G0069 and G0070) to Part D infused drugs to pay home infusion pharmacies for each day the drug is infused to beneficiaries in their homes.** Medicare Part D coverage of home infusion therapy is limited to the drug itself and does not cover the services, supplies and equipment needed to safely deliver therapy in the home, so CMS would incentivize beneficiaries who otherwise would travel to institutional settings to receive home infusion therapy services to receive treatment in their homes.

We underscore the need for clear guidance from the agency so that pharmacies can continue to treat the nation's oldest and sickest patients as seamlessly as possible during this national emergency. If you have any questions, please contact Shara Siegel, Director of Government Affairs at shara_siegel@premierinc.com or 212-901-1264.

Sincerely,



Blair Childs
Senior Vice President, Public Affairs
Premier Inc.

⁶ Centers for Medicare & Medicaid Services, Center for Program Integrity, Memo from Alec Alexander to all Part D Plan Sponsors, March 20, 2010. Subject: "Minimizing Face-to-Face Contact for Medication Delivery or Dispensing."