



NATIONAL ASSOCIATION OF
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December 28, 2020

The Honorable Alex Azar
Secretary
United States Department of Health and Human Services
Hubert H. Humphrey Building, Room 713F
200 Independence Ave, SW
Washington DC 20201

BY ELECTRONIC DELIVERY

RE: Regulatory Relief to Support Economic Recovery; Request for Information (RFI)

Dear Secretary Azar:

The National Association of Specialty Pharmacy (NASP) is pleased to provide comments in response to the Health and Human Services (HHS) Request for Information (RFI) on Regulatory Relief to Support Economic Recovery (85 Fed. Reg. 75720 et seq). NASP understands that the intent of the RFI is to consider which regulations and guidance implemented during the COVID-19 public health emergency merit reconsideration, continuance, or adjustments going forward and at the conclusion of the public health emergency.

NASP's members are committed to the practice of specialty pharmacy and to serving specialty patients to ensure better clinical outcomes and reduced overall healthcare costs.

NASP defines a specialty pharmacy as:

- Multi-state licensed and registered pharmacy that is accredited by an independent, third-party accreditor AND
- Solely or largely provides medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies.

NASP represents the entire spectrum of the specialty pharmacy industry, including the nation's leading independent specialty pharmacies and practicing pharmacists; small and mid-size pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. NASP is the unified voice of specialty pharmacy in the United States.

We support all efforts to ensure patients continue to have quality care and access to needed medications during the public health emergency. With these goals in mind, we offer the following comments on specific regulations and flexibilities that were implemented during the pandemic and provide suggestions on which should be maintained during the course of the public health emergency, permanently remain, or made permanent with modifications.

Relaxing Maximum Day Prescription Supply and Refill Too Soon Requirements

The ongoing coronavirus pandemic has highlighted the need to preserve uninterrupted accessibility to medications for those who are most vulnerable. NASP believes the Centers for Medicare and Medicaid Services' (CMS) flexibility that has allowed patients to receive extended supplies of maintenance and specialty prescriptions has supported medication access and adherence during the pandemic. This has been critically important for specialty patients who are more at risk of contracting COVID-19 given their complex medical conditions. However, NASP is also concerned about ensuring that decisions around which drugs should have extended days' supply is one made by the prescriber and in coordination with the pharmacy, particularly for specialty therapies. Specialty treatment regimens for complex conditions like cancer and cystic fibrosis can be frequently adjusted, particularly when a patient is just starting a new therapy and the treating provider needs to determine patient response and any necessary adjustments. A decision to provide advance supplies and refills needs to be in the best interest of the patient's treatment, to minimize the possibility of costly stockpiling and waste, and to ensure against any potential shortages in the supply of specialty medications.

Recommendation: NASP is supportive of the continuation of relaxed guidance on refilling prescriptions too soon, or for extended days' supply for the duration of the public health emergency provided the decision to extend the supply medications used to treat specialty conditions is made in consultation with the prescriber and pharmacist.

Removing Restrictions on Access to Home or Mail Delivery of Prescription Drugs

Many specialty pharmacy patients are at increased risk for COVID-19, including those with immunosuppressed conditions, making options for receiving prescriptions remotely even more important during the pandemic. Delivering medications via the mail or courier ensures patient safety during the pandemic and supports patient adherence to prescribed drug regimens.

Furthermore, as specialty pharmacy has so adeptly demonstrated, home delivery is useful outside of a global pandemic, particularly for specialty pharmacy patients who might not otherwise be able to easily access their life-saving medications due to their physical conditions or geographic limitations. The specialty supply chain is set up to address temperature control issues and other challenges in complex medication management to ensure safe, effective, home and mail delivery of specialty prescriptions to ensure timely patient access.

Prior to the pandemic, it was not uncommon to have prohibitive clauses in contracts between specialty pharmacies and plans/PBMs prohibiting or providing restrictions on home delivery. Guidance from the Department of Health was necessary to ensure there were no unnecessary

restrictions through the contract process or threats to pharmacies being in non-compliance with their contracts. These contractual requirements have sometimes been utilized in the past to subvert patient choice of pharmacy and to steer patients to a plan/PBM-owned mail order or specialty pharmacy. NASP strongly recommends that restrictions on home medication delivery should be prohibited even after the public health emergency in order to protect a beneficiary's ease of accessing needed medications and their right to use the pharmacy of their choice.

With more patients seeking to access care and medication access at home, it merits a larger conversation as to the utility of expanding access to home delivery of medications by pharmacies that provide support services to monitor and guide patients with complex treatment protocols.

Recommendation: NASP urges CMS to engage pharmacy stakeholders to examine ongoing access to home or mail delivery of Medicare Part D medications. We stand strongly against PBM contracts that limit a pharmacy's ability to ship medication to a patient. We feel this contractual requirement subverts patient choice of pharmacy and can be used to steer patients to a mail order or specialty pharmacy owned by the PBM. We feel this restriction should be prohibited even after the public health emergency is declared over to maintain a beneficiary's right to use the pharmacy of their choice.

Waiving Medication Delivery Documentation and Signature Log Requirements

Over the course of the pandemic, prescription delivery by USPS, UPS, FedEx and local couriers has increased, and will most likely continue for the foreseeable future as patients become comfortable with receiving their prescriptions at home. As evidenced by the pandemic, requiring the documentation of delivery via signature logs will remain a challenge; however, eliminating delivery confirmation completely could increase the risk that a patient's medication could be stolen, delivered damaged or severely impacted by weather. Limiting weather impact is particularly crucial for specialty medications which are acutely affected by temperature changes. Delivery management companies that work in partnership with specialty pharmacies frequently utilize telephonic confirmation technology for specialty prescription delivery. Patients are able to verify if a package was received by pushing a specific number on their phone or responding back with a simple "yes" or "no." Recording this information telephonically can also streamline proof of delivery audits by storing data in an easily transferrable file.

Recommendation: NASP recommends that CMS work with stakeholders to receive recommendations on how to implement waived signature log requirements following the public health emergency with a modification that instead allows telephonic or electronic acknowledgement of package receipt.

Relaxing Prior Authorization Requirements

Allowing for the relaxing of prior authorization requirements for drugs that had previously been authorized has helped to support consistent patient access to medications and adherence to treatment protocols during this unprecedented time. The relaxing of these requirements has also supported treating physicians by avoiding time consuming and administratively burdensome efforts while physicians have been so overwhelmed during the public health emergency.

Recommendation: During the course of the public health emergency, NASP recommends that CMS maintain prior authorization flexibility that extends existing prior authorization to maintain continuity of care and reduces burden on the stressed healthcare network as it continues to respond to the pandemic.

Broadening the Homebound Definition

CMS issued regulations to broaden the definition of who can be considered “homebound” for home care services, including home infusion services. The revised definition allows a beneficiary to be eligible for home care services if it is medically contraindicated for the patient to leave the home due to a COVID diagnosis or the patient is more susceptible to contracting COVID-19. This flexibility has been particularly important for patients with complex specialty conditions like cancer and immunodeficiency disorders. Physician documentation is required to be considered homebound for these purposes. Efforts are needed to ensure that those most at risk of COVID-19 have safe access to remote medical services that can safely be provided in the home, including home-based infusions and injections.

Recommendation: NASP advises that CMS continue to allow for the expanded definition of homebound to support patient access to home infusions. This flexibility is necessary when a beneficiary would otherwise have limited or no access to their infusion, missing needed treatments, or access that requires them to only receive infusions in a hospital outpatient or physician office. Patients receiving infusion therapies are often those at highest risk of contracting COVID, and limiting their options to treatments could result in missed treatments or risky exposure to the virus in another setting. CMS is encouraged to engage the broader specialty and infusion stakeholder communities to discuss what flexibilities are needed to support home infusion access post-pandemic, and as the agency moves forward in 2021 with implementation of the new home infusion therapy services benefit.

NASP appreciates the opportunity to comment on HHS’ request for information. Please contact me at sarquette@naspnet.org, (703) 842-0122 or NASP’s Washington Representative Julie Allen at julie.allen@powerslaw.com, 202-494-4115 if there are any questions regarding our comments. Thank you for your attention to these important matters.

Respectfully submitted,



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