



NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY

300 New Jersey Ave., Suite 900
Washington, DC 20001
www.naspnet.org

June 1, 2020

Ms. Seema Verma, MPH
Administrator
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

RE: CMS-1744-IFC

Dear Administrator Verma:

The National Association of Specialty Pharmacy (NASP) is pleased for the opportunity to provide comments on the Interim Final Rule “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC).” NASP appreciates CMS’s efforts to address needed regulatory adjustments to respond to the COVID-19 emergency, support health care provider efforts, and help patients access health care services during the pandemic, especially in the home. Home access to health care services, medications, and infusion treatment is especially critical for patients with chronic and complex “specialty” conditions who are at highest risk of contracting the coronavirus.

NASP’s members are committed to the practice of specialty pharmacy and to serving specialty patients to ensure better clinical outcomes. NASP defines a specialty pharmacy as a state-licensed and registered pharmacy that:

- Is accredited by, or in the process of specialty pharmacy accreditation 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, from the nation’s leading independent specialty pharmacies and practicing pharmacists to 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. With over 120 corporate members and 1,800 individual members, NASP is the unified voice of specialty pharmacy in the United States.

Access to Home Infusion Therapy

Many specialty pharmacies provide home infusion medications and services to support patient access to medications needed to manage their complex health conditions. Home infusion is often a needed option for those patients with geographic challenges to accessing therapy in another care setting. For vulnerable patients with chronic and life-threatening health conditions, home infusion can be a safer alternative to receiving treatment in a hospital or physician office setting, particularly during the COVID-19 pandemic. Home infusion as an option for patients also safely frees up capacity within hospital settings at a time when hospitals are otherwise occupied by treating patients with the coronavirus.

In the Interim Final Rule, CMS includes many policy adjustments to support patient access to remote health care services in the home setting. The rule makes multiple amendments to current regulations to support the use of telehealth services to ensure patients continue to receive their medical services without having to visit health care facilities. Unfortunately, the rule does not make needed policy adjustments that would fully support access to home infused medication therapy for patients who need this benefit to best manage significant clinical conditions like cancer, immune disease, and congestive heart failure.

Physical Presence Requirement

Specialty pharmacies remotely provide a number of health care services to support patients receiving home infusion therapy. These services include therapy consultation and management, drug preparation, therapy assessment to advise on adjustments given the patient's condition, patient monitoring to ensure adherence and address concerns, and 24/7 access to patient calls for support. Current CMS policy does not recognize or reimburse pharmacists for the remote services they provide to home infusion patients. When addressing home infusion medication therapy, the rule implies that a health care professional would need to be present through telemedicine audio and/or video technology in order to bill and receive payment for home infusion therapy. NASP asks that CMS revisit this policy by acknowledging the services that are provided by specialty pharmacies to support home infusion therapy management and allowing pharmacists to bill for these services.

Direct Supervision Requirement

Telehealth visits are an essential alternative to physician- or hospital-based visits for patients, especially those patients with conditions that make them the most vulnerable to coronavirus transmission, including those receiving infusion therapy. In making policy reforms in the interim final rule, CMS requires that many services, including infused drug services, be provided incident-to a physician service. Unfortunately, for home infusion services, this requirement

presents significant challenges for the health care process and does not recognize the unique way in which home infusion services are provided today. For home infusion, the prescribing physician typically directs the home infusion care rather than coordinating the services needed to provide and oversee each infusion. Such coordination by a physician is not necessary and is managed instead by pharmacists and nurses who have the expertise for providing infusion services. In subsequent Interim Final Rules, CMS has acknowledged and allowed non-physician supervision of health care services during the COVID-19 crisis (e.g., diagnostic testing services). NASP urges CMS to amend this rule and allow physicians to delegate the coordination of home infusion therapy to home infusion pharmacists and nurses specially trained to manage these therapies in the home setting. Amending this policy would allow the policy to mirror commercial insurance and the Medicare Part B home infusion benefit.

Application of Certain National Coverage Determination (NCD) and Local Coverage Determination (LCD) Requirements

In the interim final rule, CMS relaxes the clinical indications for coverage across respiratory, home anticoagulation management, and infusion pump NCDs and LCDs during the public health emergency. NASP supports this decision to allow patient access to covered drugs under the Medicare Part B Durable Medical Equipment (DME) benefit. For patients that receive home infusion services during the pandemic as a result of this policy change, NASP asks that these services be permitted to continue once CMS begins to enforce clinical indication requirements.

Medicare Part D-Covered Infusion Drugs

Infusion drugs administered at home using non-mechanical devices are billed to Medicare Part D. Unlike in the commercial insurance sector, however, Medicare Part D does not provide coverage of supplies and professional services. Part D beneficiaries must pay out of pocket, receive their services outside the home, or skip treatments. These limits put patients at significant health and financial risk, especially during the pandemic. Ensuring these patients have full access to home infusion treatments and services is critically important to addressing patient health and well-being, especially at this sensitive time. NASP joins other stakeholders in requesting that CMS follow the commercial sector model and consider making payment for Part B home infusion therapy professional services available to providers of Medicare Part D drugs for at least the duration of the public health emergency.

NASP greatly appreciates the opportunity to comment on the Interim Final Rule “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC).” We want to ensure that policies are enacted to support home access to infusion medications and related services to support patient needs, especially during the pandemic. NASP looks forward to continuing to work with CMS on the issues addressed in

our letter. Please contact Julie Allen at 202-494-4115 or Julie.allen@powerslaw.com if you have any questions regarding our comments or if we can provide additional information.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sheila Arquette", with a large, stylized flourish at the end.

Sheila M. Arquette, R.Ph.
Executive Director