**David Schwartz**
Head of Global Policy
Public Policy and Federal Government Affairs

August 21, 2020

701 Pennsylvania Avenue, NW
Suite 720
Washington, DC 20004
(202) 719-6499
David.Schwartz@Cigna.com

VIA ELECTRONIC SUBMISSION TO http://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1730-P
P.O. Box 8013
Baltimore, MD 21244-8013

**Re: CMS-1730-P; Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements**

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the Notice of Proposed Rulemaking (NPRM) for the CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements. We appreciate the ongoing work by the Department of Health and Human Services (HHS) to seek industry feedback on best practices and solutions that may help impact this critical public health challenge. Our experience as a commercial health insurance provider and administrator of integrated pharmacy benefit plans can be instructive as the Centers for Medicare & Medicaid Services (CMS) considers the issues raised in this NPRM.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as "Cigna"), is a global health service organization dedicated to helping people improve their health, well-being, and peace of mind. Our subsidiaries are major providers of medical, pharmacy, dental, disability, life and accident insurance, and related products and services, with over 180 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Worldwide, we offer peace of mind and a sense of security to our customers seeking protection for themselves and their families at critical points in their lives.

Within the U.S., Cigna provides medical coverage to approximately 14 million Americans in the commercial segment. We also provide coverage in the individual insurance segment in several states, both on- and off-Exchange, to about 280,000 people. Additionally, Cigna, together with our Express Scripts business unit, serves more than 4 million people through our Medicare Advantage, Medicare Prescription Drug Program and Medicare Supplemental products.

In addition to our comprehensive services as both an insurer and a pharmacy benefit manager, our subsidiary specialty pharmacy, Accredo®, serves patients with complex and chronic health conditions, including those

treatable with home infusion. It is in this context that we provide the following comments on these aspects of the NPRM.

*****

**1. General Comments**

Cigna would like additional clarity around the enrollment process and requirements for a "Pharmacy Supplier" using internal or contracted professional nursing services to meet billing requirements for the home infusion therapy (HIT) benefit.

Section 1861(iii)(3)(D)(i) of the Social Security Act (the Act) defines a "qualified home infusion therapy supplier" as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. The provision specifies that qualified HIT suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of HIT on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary of HHS; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for HIT established by Medicare Advantage plans under Part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements. Provider is defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant.

Currently, each of our Accredo® specialty pharmacy locations is enrolled as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Supplier under application CMS-855-S and has started or completed the process of enrollment under application CMS-855B. Under the proposed rule, "beginning January 1, 2021, a single payment will be made to a qualified home infusion therapy supplier for items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services)." 85 Fed. Reg. 39408, 39432 (June 30, 2020). We recommend that, with the implementation of the "home infusion therapy supplier" benefit in 2021, a "pharmacy supplier" be subject to only one enrollment as a "qualified home infusion therapy supplier" and be able to submit all claims for items (*e.g.*, drugs, durable medical equipment) and services provided to Medicare B beneficiaries to the A/B Medicare Administrative Contractor (MAC) for payment.

**2. CY 2021 Payments for Home Infusion Therapy Services**

HIT eligible drugs:
The proposed rule notes that Hizentra (HCPCS Code J1559), subcutaneous immune globulin (IG), is not included in the definition of home infusion drugs because it is listed on the self-administered drug (SAD) exclusion list by the MACs. Therefore, although HIT services related to the administration of Hizentra are covered under the temporary transitional payment, because it is on a SAD exclusion list, services related to the administration of this biological will not be covered under the benefit in 2021.

We provided feedback on Hizentra in our December 2019 comments. We again urge CMS to work with MACs and other interested parties to remove Hizentra from the SAD exclusion list. As with other IG products that are subcutaneously administered via durable medical equipment (DME) (*e.g.*, external infusion pump), Hizentra has been covered under the DME benefit and therefore has been eligible for HIT benefits. Cigna is concerned because it appears, however, that beginning in 2021, Hizentra will be excluded from the HIT benefit, because it is on the SAD exclusion list instead of under HIT covered drugs.

According to CMS, as cited and published by Noridian Healthcare Solutions, the reason for Hizentra's inclusion on the SAD exclusion list (since February 15, 2011) was "Apparent on its Face Presumption of Long-Term Non-Acute Administration.[1]" However, historically, CMS has stated that chronic disease treatment with DME-dependent SADs should be excluded from the SAD exclusion list; we note Hizentra fits that description and should therefore be included within the HIT benefit.

Related to covering subcutaneous IG drugs in category 2, we also recommend modifying the definition of "infusion drug administration calendar day" to include days on which HIT services are self-administered by a beneficiary regardless of whether a HIT supplier was physically present in the beneficiary's home.

**3. Comments on the Intravenous Immune Globulin (IVIG) Demonstration Project**

Cigna recognizes the success of the Medicare IVIG Demonstration project and its extension in 2017. Our specialty pharmacy, Accredo®, has served and will continue to serve beneficiaries enrolled in the project. However, the anticipated expiration on December 31 of this year will require several thousand beneficiaries, who currently receive their IVIG infusions in their homes, to move their site of infusion to an infusion center or a hospital outpatient facility.

We recommend extending again, or making permanent the home infusion benefits currently available to beneficiaries using IVIG. Due to the circumstances surrounding the COVID-19 global pandemic, beneficiaries may be unable to find a suitable alternate infusion site, which could interrupt therapy. Additionally, these beneficiaries are in a high-risk population due to both age and compromised immune status, meaning the exposure to an infusion setting may elevate their health risks. As an example, a study from 2017[2] showed that patients who receive IVIG at home had lower rates of pneumonia and bronchitis than those treated in a hospital outpatient infusion center.

The COVID-19 pandemic has also led to reduced plasma collections. According to the Plasma Protein Therapeutics Association , there have been fewer collections because of the pandemic and the uncertainty felt by plasma donors. IVIG is derived from plasma after a 9-12 month process from the date of collection, so any downward trends in plasma collections will impact IVIG supplies, as well as other plasma-derived therapies . Disruption in the site of service for an IVIG beneficiary may also lead to a disruption in IVIG availability. The chosen site may not have IVIG allocations to support the increased demand or may not have the brand of IVIG the beneficiary has found clinically stable. More information can be found here: https://primaryimmune.org/news/covid-19-and-threat-immunoglobulin-availability.

In addition to the health and safety concerns outlined above, removing the ability for patients to receive IVIG infusions in their homes can place other burdens on patients and their families. For example, personal cost, transportation, and time associated with having to travel to a new site are some of the significant burdens patients and their families will face. Additionally, alternative sites could be more costly. A study from 2016[3] noted that home infusion had the same or better quality, higher patient satisfaction, and lower costs as compared to medical setting infusion costs.

---

[1] https://med.noridianmedicare.com/web/jeb/policies/sads#sads10
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5325835/
[3] https://pubmed.ncbi.nlm.nih.gov/28668202/

Thank you in advance for your consideration of these comments. Cigna would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,

David Schwartz