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Memorandum

To: Ken Van Pool, Vice President of Government Affairs
National Home Infusion Association

From: Crowell & Moring, LLP

Date: July 6, 2018

Re: Summary: CMS Proposed Rule Implementing Home Infusion Therapy Services Temporary Transitional Payment and Permanent Payment

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On Monday, July 2, 2018, CMS made available for public inspection a proposed rule[1] that, among other things, proposes payment for home infusion therapy services, both on a temporary transitional basis, for calendar years 2019 and 2020, and permanently for 2021 and future years. The proposed rule takes positions that we believe raise significant concerns for NHIA and its members.

The two areas of immediate and obvious concern we identified in the proposed rule are:

- Definition of "Infusion Drug Administration Calendar Day" – CMS defined an "infusion drug administration calendar day" in a way that would significantly limit home infusion suppliers' opportunities for reimbursement. The definition requires that a nurse be physically present at the patient's home on the day the code is billed, and does not provide for separate billing for the not-in-person services associated with home infusion. (See preamble discussion beginning at p. 400 and corresponding text at § 486.505 at pp. 568-69.)

- Evidence that Proposed Rule was Rushed – As a general matter, the proposed rule seems to evidence a lack of attention on CMS's part to the implementation of the home infusion benefit. A combination of typos and the inconsistent structure of the home infusion section suggests that CMS may have rushed the home infusion portion of the larger role, rushed its analysis or otherwise failed to devote sufficient resources to policy development.

The relevant portions of the regulation with regard to NHIA and the services payment are summarized below. Some parts of CMS's proposal do not appear in regulatory text, specifically the discussion of CMS's proposal for the temporary transitional payment. Therefore, the summary below is organized by reference to the preamble text with discussion of the proposed regulatory text where apposite. The main sections are health and safety standards, approval and oversight of accrediting

[1] The for-inspection version of the regulation is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14443.pdf. The formal Notice of Proposed Rulemaking (NPRM) is scheduled to be published in the Federal Register on July 12, 2018.

organizations, and payment. In the appendices to this document, we briefly summarize the statutory authority for the proposed rule and CMS's information requests.

I. Proposed Health and Safety Standards for Home Infusion Therapy (Proposed Part 486,[2] Subpart I, 42 C.F.R. §§ 486.500, *et seq*.)

There are a number of important provisions contained in this section, including the following:

- CMS Focus – Three Things – CMS proposes to focus on three main areas in the rule, which include (1) outlining home infusion therapy supplier requirements, (2) providing a framework for CMS to approve home infusion therapy accreditation organizations; and (3) including in that framework for accreditation organizations the authority to approve Medicare certification for home infusion therapy suppliers.

- Definitions (§ 486.505) – For the definitions of the terms "applicable provider," "home infusion drug," and "qualified home infusion therapy supplier," CMS adopted or closely tracked statutory definitions.

- Focus on "Plan of Care" (§ 486.520) – CMS focuses in on some details related to a Plan of Care and home infusion therapy suppliers, including the following:

    - Content of the Plan of Care – As required by statute, CMS proposed that patients be under the care of an applicable provider with a "plan of care" established by a physician. The rule states that the plan of care should outline and include:
        1. The type of treatment, amount, and duration of home infusion therapy services for the patient.
        2. The specific medication, the prescribed dosage and frequency as well as the professional services to be utilized for treatment of the patient.
        3. A description of the specific care and services necessary to meet the patient-specific needs.

    - Review of the Plan of Care – CMS proposes that the Plan of Care be "periodically reviewed" by the physician. But all of the details are not clear. For example, in this section CMS says the following:

[2] In some places, the preamble text instead cites Part 485, Subpart I, but the regulatory text contains no content for Part 485. Part 485 sets forth "Conditions of Participation: Specialized Providers," and Part 486 sets forth "Conditions for Coverage of Specialized Services Furnished by Suppliers." CMS's intention with the structure of these requirements is unclear.

1. Time Frame for Review of Plan of Care Requirements by Physician - CMS establishes no specific time frame for review requirements by physicians, but does require physician review.
2. Details or Metrics to Judge Physician Role in Plan of Care – CMS says that the expectation is that the physician will be active in the patient's care and should make appropriate decisions related to the course of therapy, but provides no further details, guidance or metrics.
3. Request for Comments on the Plan of Care – this section is a good indicator that CMS put out the rule as much to solicit input as to set regulatory policy. CMS invites comments, specifically as to whether it should include specific review timeframes for the plan of care.

- Required Services (§ 486.525) -CMS proposes to echo the statutory definition of items and services, which recognizes the following as necessary home infusion services on a 24-hour-a-day and 7-day-a-week basis:

1. The provision of professional services, including nursing services, furnished in accordance with the plan of care; and
2. The provision of patient training and education not otherwise paid for as durable medical equipment;
3. The provision of remote monitoring and monitoring services for the provision of home infusion therapy services.

II. Approval and Oversight of Accrediting Organizations for Home Infusion Therapy Suppliers[3] (Proposed Part 488, Subpart L, 42 C.F.R. §§ 488.1000-1050)

There are a number of important provisions contained in this section, including the following:

- Focus on Accrediting Organizations (AOs) – The rule and CMS spend considerable time focusing on the issue of accrediting organizations for home infusion therapy suppliers.

- Definition of "Qualified Home Infusion Therapy Supplier" – The regulatory text at proposed § 486.505 includes a definition of "qualified home infusion therapy supplier." Among other things, that definition includes a requirement that the supplier be "accredited by an organization designated by the Secretary . . . ."

- Designation of AOs by the Secretary of Health and Human Services – The Act requires the Secretary to designate AOs by 2021.

[3] This section is designated as VI.C. in the preamble text, but as VI.D. in the preamble table of contents. The following section on payment is also labeled VI.C. in the preamble text, but it follows the approval and oversight content.

- Solicitation for AOs to Apply to be Designated a Home Infusion Therapy AO – CMS says it will issue a solicitation in the Federal Register to invite national Accreditation Organizations (AOs) to apply.

- Distinction between AOs – CMS says that accreditation for a home infusion therapy supplier by an AO would be distinct from the AO's home health accreditation program (if it has one), and must be at least as stringent as its health and safety standards (as discussed above).

- The Process for Approving AOs for Home Infusion Therapy Suppliers – CMS sets forth processes and procedures for approval of AOs. These processes and procedures include:

    a) Application and reapplication procedures for AOs;
    b) Resubmission procedures for denied/withdrawn applications;
    c) Public notice and comment regarding each applicant AO;
    d) Release of accreditation surveys from AO to CMS;
    e) Ongoing review of AOs;
    f) Ongoing responsibilities of AOs;
    g) Onsite reviews by CMS of AOs;
    h) Termination of AO status; and
    i) Reconsideration of CMS determinations.

- Current AOs for Home Infusion Therapy Suppliers – In the preamble, CMS notes that six organizations currently offer accreditation for home infusion therapy suppliers, but proposes to require those organizations to apply and be certified as AOs to confer with their accreditations the ability of the accredited supplier to bill Medicare for home infusion therapy services.

III. Payment for Home Infusion Therapy Services

This section focuses in on the services payment as follows:

A. Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020

- What Does the Home Infusion Services Payment Cover? – As required by Section 50401 of The Bipartisan Budget Act of 2018 (BBA of 2018), a temporary transitional payment would cover payment for home infusion items and services (as defined in section 1861(iii)(2)(A) and (B) of the Act). The temporary transitional payment would be available from January 1, 2019 to January 1, 2021 when the permanent payment becomes available.[4]

- Definition of "Transitional Home Infusion Drug" – CMS's proposed definition of "transitional home infusion drug" closely tracks the statute.

- Definition of "Infusion Drug Administration Calendar Day" – In its definition of "infusion drug administration calendar day," CMS proposes to limit payment to a calendar day on which a nurse is in the patient's home when an infusion drug is administered.

[4] The text of the BBA of 2018 is available at https://www.congress.gov/bill/115th-congress/house-bill/1892/text#toc-HFDE57FDDC9714574BFEEF9BF935EF488.

- Impact of Requiring a Nurse – This would limit payment in two significant ways:
  a) **A nurse must be present**—not a tech, assistant, or person with another designation.
  b) The professional **must be in the patient's home on the day infusion occurs**, **rather than remotely available** or otherwise providing services in connection with the patient's home infusion.

- Payment for Days Nurse Present Designed to Cover All Services Over Multiple Days When Nurse Not Present – To the second point, CMS acknowledges that services may occur on other days, but states that the one payment (equal to 4 hours of physician's office infusion services) is designed to compensate for services on those additional days.

- Skilled Services Must be Complex – In addition, CMS adds a requirement that the skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

- Congressional Intent – We believe this interpretation would frustrate Congress's intent in providing for the transitional payment.

- Definition of Eligible Home Infusion Suppliers Who Can Receive the Transitional Payment – For the transitional payment, eligible home infusion suppliers are defined as suppliers (1) that are enrolled in Medicare as pharmacies (maintaining state licensure requirements); (2) that provide external infusion pumps; and (3) that provide external infusion pump supplies. This means that existing DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program's supplier standards and quality standards to become accredited for furnishing external infusion pumps and supplies.

- Billing and Payment – CMS notes that the following will be the billing and payment code regime per the statute and CMS:

  - Payment Categories – J-codes – The statute calls for payment under three separate payment categories, with each category corresponding to a set of J-codes.

  - Payment Categories – Three New Codes – CMS will create three new HCPCS G-codes for each of the three payment categories for eligible home infusion suppliers to bill for home infusion therapy services. These G-codes could be billed separately from or on the same claim as the DME, supplies, and infusion drug; and would be processed through the DME MACs.

  - One Supplier Must Provide the Professional Services – The supplier furnishing the DME, pump, the infusion drug, and other supplies must also provide the professional services under the home infusion therapy benefit during the temporary transitional payment period.

  - Payment Guidance – Payment guidance would be issued via Change Request.

B. Permanent Payment for Home Infusion Therapy Services

- Permanent Payment Requirements – CMS separately proposes requirements for the permanent payment for home infusion therapy services for CY 2021 & subsequent years.

- Definition of "Infusion Drug Calendar Day" – The proposed definition of "infusion drug calendar day" for the permanent benefit is the same as CMS's unfavorable definition discussed above under the transitional payment.

- Submitting Claims Through A/B MACs – Although not required by law, CMS proposes that a Part B qualified home infusion therapy supplier could potentially submit a claim for home infusion therapy services on a Part B practitioner claim and processed through the A/B MACs, rather than the DME MACs. CMS is soliciting comment on its approach, particularly in the context of the types of entities that may meet the definition of qualified home infusion therapy supplier.

- Interaction Between Home Infusion Therapy Services and Home Health Services – CMS solicits comments regarding the interaction between home infusion therapy services and home health services.

- Services Payment Separate From DME Benefit – There is no separate Medicare Part B DME payment for professional services associated with the administration of home infusion drugs, including nursing services, or for training and education, monitoring, and remote monitoring services. Therefore, CMS considers the home infusion therapy benefit principally to be a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the home infusion therapy services.

- Medicare Enrollment Requirements for Home Infusion Therapy Services – CMS clarifies that, to provide both home infusion and DME services, a supplier would need to enroll in Medicare both as a Part B Home Infusion Therapy supplier and as a DME supplier.

- Coverage of the Benefit – The items and services covered under the home infusion therapy benefit are:
    - (1) Professional services, including nursing services, furnished in accordance with the plan;
    - (2) Training and education (not otherwise paid for as DME); and
    - (3) Remote monitoring and monitoring services for the provision of home infusion drugs furnished by a qualified home infusion therapy supplier.

Appendix A: Statutory Basis for the Proposed Rule

- Statutory Requirement for Accreditation – According to Section 5012 of the Cures Act, which established requirements for a home infusion therapy supplier to receive payment under the Medicare home infusion therapy benefit, the home infusion therapy supplier must select a CMS-approved accreditation organization (AO) and undergo an accreditation review process to demonstrate that the home infusion therapy supplier meets the AO's standards.
- Statutory Requirements for Home Infusion Therapy – Section 1861(iii) of the Act, as added by section 5012 of the Cures Act, establishes four elements for home infusion therapy in the following areas:
    1. Requiring that the patient be under the care of a physician, nurse practitioner, or physician assistant;
    2. Requiring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient specific needs;
    3. Providing patients with education and training on the effective use of medications and equipment in the home (not otherwise paid for as durable medical equipment); and
    4. Providing monitoring and remote monitoring services associated with administering infusion drugs in a patient's home.
- Standards for AOs – CMS, through the Home Health Rule, establishes basic universal standards for AOs and Medicare-participating qualified home infusion suppliers.
- Health and Safety Standard – CMS asserts that a private sector framework, already in existence, may suffice in establishing a basic health and safety standard.
- Request for Comment on Health and Safety Standards – CMS, still however requests stakeholder feedback on the determination, asking, "Are the standards sufficient for Medicare beneficiaries, should CMS consider additional standards and would additional standards impose additional burden?"
- Documents Reviewed by CMS in Preparing Rule – In developing and determining these standards, CMS reviewed the following documents:
    1. Requirements established under Section 5012 of the Cures Act
    2. Standards from the six AOs that accredit home infusion suppliers:
        a. The Joint Commission
        b. Accreditation Commission for Health Care
        c. Compliance Team,
        d. Community Health Accreditation Partner, Healthcare Quality Association on Accreditation
        e. National Association of Boards of Pharmacy
    3. Documents related to coverage:
        a. Government Accountability Office-10-426 report
        b. Medicare and Home Infusion white paper written by the National Home Infusion Association (NHIA)

c. American Society of Health System Pharmacists Guidelines on Home Infusion Pharmacy Services
d. MA-PD, Medicare FFS, and Private Health insurance requirements

Appendix B: Information Collection Requests

ICRs Regarding Home Infusion Therapy

Home infusion therapy suppliers are already required by accrediting organizations to provide care in accordance with a plan of care, thus this proposed requirement would not impose a burden upon accredited agencies.

ICRs Regarding the Approval and Oversight of Accrediting Organizations for Home Infusion Therapy

The rule articulates a New Set of Regulations for approval and oversight of accrediting organizations.

This burden would include, but is not limited to the time and costs associated with the following activities:

1. Preparation and filing of an initial application seeking CMS approval of the AOs home infusion therapy accreditation program;
2. Participation in the application review process (that is, meetings, provide additional information and materials that may be required, participate in a site visit, etc.);
3. Seeking new accreditation clients;
4. Performing on-site surveys, off-site survey audits or the performance of other types of survey activities;
5. Participation in CMS ongoing accreditation program review activities;
6. Performance of periodic re-accreditation activities;
7. Investigation of complaints and performing complaint surveys;
8. Administration of the appeals process for providers that have been denied accreditation;
9. Staff training, in-services and continuing education; and
10. Ensuring that surveyor staff have the proper education, training, and credentials.