



December 22, 2011

Marilyn B. Tavenner, R.N.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-9070-P)

Dear Administrator Tavenner:

The National Home Infusion Association (NHIA), a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings, submits these comments in response to the proposed rule entitled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-9070-P).”

NHIA applauds the Department of Health and Human Services’ pursuit of reforms aimed at streamlining requirements and reducing excessive burdens on health care providers. There are several existing administrative processes that we believe are unreasonably onerous for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). These policies do not contribute to better outcomes for patients or to the efficient administration of the Medicare program. We believe that the following reforms are consistent with HHS’ goals of improving the quality of existing regulations, streamlining procedures for businesses to enter and operate in the marketplace, maximizing net benefits, and reducing costs and other burdens on businesses to comply with regulations:

- For parenteral nutrition (PEN), enteral nutrition (EN), intravenous immune globulin (IVIG) and DME-covered external infusion pumps and related drugs and supplies, CMS should require that regardless of setting the beginning date of service for the month is the date the beneficiary begins to use the product or service; and
- CMS should require that the DME MACs issue uniform policies on the information needed to justify the ongoing medical necessity of an item or service. Likewise, CMS should require physicians to respond fully and promptly to suppliers’ requests for information from patients’ medical records that are necessary to justify the continuing need for DMEPOS products and services.

Discussion

The date of service for claims for PEN, EN, IVIG and DME-covered external infusion pumps and related drugs and supplies should be the date that the beneficiary begins to use the product or service.

The current date of service requirements for claims submitted for certain items of DMEPOS are onerous and wasteful - not only to the DMEPOS suppliers but to the Medicare program as well. We believe that CMS could improve the accuracy of claims, reduce waste in the Medicare program and streamline existing burdens for DMEPOS suppliers by requiring suppliers to use the date that a beneficiary begins using PEN, EN, IVIG and other drugs and supplies associated with external infusion pumps as the initial date of service on a claim.

CMS only recognizes two possible dates of service that may be used on a claim for DMEPOS. If a supplier delivers an item directly to a beneficiary or designee, the supplier is required to use the date that the beneficiary receives the item as the date of service.¹ If a supplier uses a shipping service or mail order to deliver the item, the supplier is required to use the shipping date as the date of service.²

The use of the receipt or shipping date as the date of service is particularly confusing for claims submitted for PEN, EN, IVIG, and external infusion pumps. This approach virtually guarantees that there will be overlapping dates of service for DMEPOS claims, since the shipping date for the second month will occur before the end of the first 30 days. In addition, overlapping dates of service may occur because a beneficiary does not exhaust all of the supplies delivered due to an event such as death, having a change in medical needs, or being transferred from one health care setting to another (such as being discharged home from a nursing facility or being re-hospitalized during the month). Importantly, overlapping dates of service often result in denials from state Medicaid programs and private insurers for related claims, since those payers will not pay for what they perceive to be double-billing.

We do not understand the basis for the use of the receipt or shipping date as the date of service. We believe that claims reflecting the actual usage period for PEN, EN, IVIG and external infusion pumps would be more accurate and would avoid the confusion that results from overlapping claims. Therefore, we urge CMS to allow suppliers to use the date that a beneficiary begins using PEN, EN, IVIG and other drugs and supplies used with external infusion pumps as the date of service.

¹ Program Integrity Manual (Pub. 100-08), Chapter 4, Section 4.26.1 (Rev. 389: Issued: 09-30-11; Effective/Implementation Dates: 10-31-11).

² Program Integrity Manual (Pub. 100-08), Chapter 4, Section 4.26.1 (Rev. 389: Issued: 09-30-11; Effective/Implementation Dates: 10-31-11).

CMS should require the DME MACs to issue consistent policies on the information needed to justify the ongoing medical necessity of an item or service. CMS also should require physicians to respond in a timely manner to suppliers' requests for information from patients' medical records to support claims for the continuing need of DMEPOS.

We urge CMS to require the DME MACs to issue uniform policies on what documentation is needed to justify the ongoing medical necessity of an item or service for a patient. CMS contractors inconsistently interpret the requirements related to (1) how often medical necessity must be re-established, and (2) the documentation necessary to establish continuing need for the particular therapy. Suppliers devote considerable time and resources attempting to clarify what information the various DME MACs require to support the continuing need for DMEPOS products and services.

Likewise, CMS should require physicians to respond fully and promptly to suppliers' requests for documentation from patients' medical records that are necessary to justify claims for the continuing need of DMEPOS. The absence of such instructions is problematic because suppliers currently cannot routinely obtain such information from patients' medical records, but yet they are held accountable during an audit if health care providers do not provide them with adequate documentation in a timely manner.

CMS requires patients' medical records to contain sufficient information "to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable)."³ However, physicians are not required to regularly furnish suppliers with information from a patient's medical record that supports a Durable Medical Equipment Information Form (DIF) or Certificate of Medical Necessity (CMN). Nonetheless, when a supplier is audited, it must obtain sufficient information to justify medical necessity from a patient's medical record under significant time constraints. According to the Program Integrity Manual, "the DME MACs, DME PSCs, or ZPICs may request this information in selected cases. If the DME MACs, DME PSCs, or ZPICs do not receive the information when requested or if the information in the patient's medical record does not adequately support the medical necessity for the item, then for assigned claims the supplier is liable for the dollar amount involved unless a properly executed advance beneficiary notice of possible denial has been obtained."⁴

³ CMS Pub. 100-08 § 5.7 (rev. 242, Issued: 02-22-08; Effective/Implementation Dates: 03-01-08).

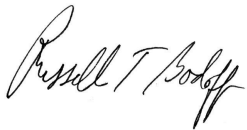
⁴ CMS Pub. 100-08 § 5.7 (rev. 242, Issued: 02-22-08; Effective/Implementation Dates: 03-01-08).

Physicians generally furnish suppliers with adequate documentation for the initial DIF or CMN, but they often are not sufficiently responsive to requests for information justifying a patient's continuing need for an item or service. We believe that it is unreasonable to hold suppliers responsible for documentation that they do not possess. Instead, once a supplier requests documentation justifying the medical necessity for the continuing use of an item or supply from a health care provider, CMS should require the physician to promptly give the supplier sufficient documentation from the patient's medical record.

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NHIA appreciates the opportunity to comment on reforms that will streamline requirements and reduce burdens on health care providers. If you have any questions or need additional information, please contact me at russell.bodoff@nhia.org or (703) 838-2678.

Sincerely,

A handwritten signature in black ink that reads "Russell T Bodoff". The signature is written in a cursive style with a large initial "R".

Russell T Bodoff
CEO/President