

Please Provide Responses to the Fields Below Electronically to be Accepted

Medicare Red Tape Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017

Name of Submitting Organization: National Home Infusion Association (NHIA)

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Statutory **Regulatory**

Please describe the submitting organization's interaction with the Medicare program:

The National Home Infusion Association (NHIA), based in Alexandria, Virginia, represents and advances the interests of providers and suppliers of infusion and specialized pharmacy products and services to home-based patients. Members of NHIA primarily interact with the Medicare Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) program and the Medicare Part D prescription drug program. A limited set of home infusion therapies are covered under the DMEPOS program and drugs not covered as part of the DMEPOS program are covered in the Part D program. Varying degrees of coverage for clinical services, devices, drugs and supplies exists in the Medicare program.

NHIA's recommendations are on the attached pages.

Short Description

Medicare Part B Durable Medical Equipment (DME) Delivery Prior to Discharge

Summary

When a patient is anticipated to be discharged home from a hospital or skilled nursing facility on enteral nutrition, parenteral nutrition or infused drug(s) the patient education process often starts prior to discharge. Medicare Part B DME allows for equipment to be delivered to the facility two days before the day the facility discharges the beneficiary. The general rule is that the date of service is equal to the date of delivery. However, pre-discharge delivery of items intended for use upon discharge is considered provided on the date of discharge. In this case, the date of service on the claim should be the date of discharge. This pre-discharge delivery rule applies to items of durable medical equipment (DME) only, and not the related supplies. The related supplies are integral to educating patients on the proper use of the DME, in this case infusion pumps, parental nutrition pumps and enteral nutrition pumps.

Furthermore, patients are not always discharged on the anticipated date, which can put suppliers outside of the two day prior to discharge rule.

Related Statute/Regulation

Medicare Program Integrity Manual – Publication # 100-08, Chapter 5,
Section 5.13 “Incurred Expenses for DME and Orthotic and Prosthetic Devices”

Proposed Solution

Allow supplier to deliver pre-discharge supplies, along with related equipment. Increase the pre-discharge delivery allowance to five days to encourage early identification of a patient that can transition home, allow for more patient education, and account for potential delays in discharge. The bill date would remain the discharge date. This would not cost Medicare, but would allow more flexibility.

Short Description

Medicare Part B Detailed Written Order (DWO) Quantity to be Dispensed Requirement

Summary

The Medicare Part B DME DWO requires documentation of quantity to be dispensed. The DME MAC's have interpreted the quantity to be dispense requirement to apply to each shipment. The quantity dispensed for home infusion drugs and related supplies can vary from shipment to shipment for a number of reasons including, but not limited to:

- Beneficiary has a scheduled appointment with physician which may cause the drug order to change. Supplier may ship only up to the appointment to minimize potential waste.
- Patient has scheduled blood work/labs that may change prescription. Supplier may ship only up to the lab draw date to minimize potential waste.
- Patient is traveling.
- Holiday schedules.
- In preparation for weather events (snow, ice, storms, etc.).

While many DME items are a one-time shipment, enteral and parenteral formulations, and infusion drugs require ongoing shipments that include several components which are altered frequently due to patient condition.

Related Statute/Regulation

Medicare Program Integrity Manual – Publication # 100-08, Chapter 5,
Section 5.2.3 “Detailed Written Orders”

Proposed Solution

Allow for quantity to be dispensed per day, verses per shipment. This would allow the supplier flexibility to manage the patients supply while minimizing waste.

Short Description

Medicare Part B Durable Medical Equipment (DME) Information Form (DIF)

Summary

A DME Information Form (DIF) form is required to help document the medical necessity and other coverage criteria for selected DMEPOS items. This form is onerous and unnecessary. The detailed written order contains the documentation necessary to establish medical necessity and other coverage criteria.

Related Statute/Regulation

Medicare Program Integrity Manual – Publication # 100-08, Chapter 5,
Section 5.3 “Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)”

DME Form 09.03, CMS Form 10125 “External Infusion Pumps”

DME Form 10.03, CMS Form 10126 “Enteral and Parenteral Nutrition”

Proposed Solution

Eliminate the DIF for external infusion pumps and enteral and parenteral nutrition. Instead the Medicare program can rely on the detailed written order (DWO) to validate medical necessity.

Short Description

Medicare Part B Durable Medical Equipment (DME) Delivery Documentation Requirements

Summary

The Part B DME proof of delivery (POD) requirements currently have three “methods” of delivery.

1. Delivery direct to the beneficiary or authorized representative
2. Delivery via shipping or delivery service
3. Delivery of items to a nursing facility on behalf of the beneficiary

Medicare places delivery documentation requirements on home infusion drugs and enteral therapy formulations which require frequent and ongoing deliveries to the Medicare beneficiary. Medicare has the most administratively cumbersome proof of delivery requirements as compared with other payers.

Related Statute/Regulation

Medicare Program Integrity Manual – Publication # 100-08, Chapter 5
Section 5.8 “Supplier Documentation”

Proposed Solutions

We recommend simplifying the POD requirements by changing the bill date for method 2, from ship date to delivery date. If the product is shipped or hand delivered to the patient, and the patient signs and dates the delivery ticket methods 1 and 2 could consistently use the delivery date as the bill date.

Another option would be to use the actual or anticipated usage date as the bill dates. Typically, other payors allow for drug or enteral formula usage dates on claims. If the from and to date requirements were consistent amongst payer it would greatly help benefit coordination with cross-over claims (Bill for Denial Claims) and secondary payer claims.

Short Description

Medicare Part B Durable Medical Equipment (DME) Audit and Appeal Process

Summary

While we realize the need to combat fraud and abuse, the current Medicare audit and appeals processes delays payment of legitimate claims an unreasonable amount of the time. This imposes a financial and administrative burden on suppliers. The volume of audit activity has increased from the various Medicare auditors including the Medicare Administrative Contractors (MACs), Zone Program Integrity Contractors (ZPICs), Recovery Audit Contractors (RACs), and Comprehensive Error Rate Testing (CERT). The appeals process has not been able to handle the increased volume of audits being appealed. The average time to obtain a hearing with the Administrative Law Judge (ALJ) at the third level of appeals in 2017 is over 1000 days. While a number of modifications and resolution processes have been initiated, it is not enough. While there is no one solution to this problem, we have proposed a number of solutions that we think would help.

Related Statute/Regulation

Medicare Claims Processing Manual, Chapter 29 - Appeals of Claims Decisions

Proposed Solutions

- a. Extend the Improvements to the Adjudication Process of Serial Claims MLN SE17010 initiative to all other product categories for DMEPOS claims.
- b. Permit a discussion period at every stage of the appeals process with the current entity prior to next appeal level.
- c. During any stage of the appeals process, if processing takes greater than 90 days that the appeal should default to a favorable outcome. This would not only ensure each appeal level is timely in processing appeals, but would remove any unnecessary hardship for Medicare beneficiaries.
- d. Extend the QIC Formal Telephone Discussion Demonstration to DME MAC Jurisdictions C (CGS) and D (Noridian).
- e. When medical necessity is not met during the appeal process, the responsibility should not fall solely on the DMEPOS supplier, but be either fully or partially shared with the authorized prescriber. Most instances it is the supplier that has to obtain medical documentation from physicians, this is unfair, especially when the prescriber must confirm and provide supporting records that affirms the patient's status. For example: Unfavorable denial letter(s) should include the prescriber, not just the supplier and the beneficiary, so that all parties are aware and involved with driving resolution and responsibility.

Short Description

Medicare Part B Durable Medical Equipment (DME) Parenteral Nutrition (PN) Coverage Criteria

Summary

The PN Local Coverage Determination is outdated and requires testing that is no longer considered best practice or effective in identifying medical necessity for PN. Examples of this include fecal fat testing and albumin levels when 10% weight loss is not met.

Related Statute/Regulation

National Coverage Determination (NCD): Enteral and Parenteral Nutritional Therapy (180.2)

Local Coverage Determination (LCD): Parenteral Nutrition (L33798)

Proposed Solutions

Revise the PN coverage criteria to be based upon current American Society for Parenteral and Enteral Nutrition (ASPEN) nutritional guidelines and in accordance with the PN National Coverage Determination for Enteral and Parenteral Nutritional Therapy 180.2.

Short Description

Medicare Part B Durable Medical Equipment (DME) Drug Waste Modifier

Summary

Beginning January 1, 2017, providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records.

This policy is administratively burdensome for DME suppliers of infused drugs.

Related Statute/Regulation

MLN Matters MM9603

Medicare Claims Processing Manual Chapter 17, section 40

Proposed Solutions

Remove the requirement to use the JW drug wastage modifier to identify waste.

Short Description

Medicare Part B Durable Medical Equipment (DME) Capped Rentals

Summary

Currently external infusion pumps (EIP) pumps cap and convert to purchase after 13 months. Parental nutrition (PN) and enteral nutrition pumps cap and convert to purchase after 15 months.

Related Statute/Regulation

Medicare Claims Processing, Chapter 20, Section 30.5.4 - Payments for Capped Rental Items During a Period of Continuous Use

Medicare Claims Processing, Chapter 20, Section 30.7.1 - Payment for Parenteral and Enteral Pumps

Proposed Solutions

Simplifying the capped pump rental policies for PN pumps, enteral pumps and EIP rental/purchase options, repair and maintenance to one matching policy.

Short Description

Medicare Part B DME Competitive Bidding Program

Summary

The Competitive Bidding process for enteral nutrition causes disruption in the Medicare beneficiaries' care. The outcome of each round can be very disruptive to patients when they are forced to change providers. Many of these beneficiaries are receiving therapy long term and may be required to transfer to a new company with each new round of competitive bidding. This change in providers may require the beneficiary to learn the operation of a new pump, change some of the beneficiary's supply items and even their formula, i.e. Abbott or Nestle.

Additionally, the *21st Century Cures Act* barred competitive bidding of DME infused drugs. Drugs are considered a supply necessary to make the item of DME (the infusion pump) therapeutic. The drug, pump and supplies should be provided by the same supplier in order to best coordinate patient care.

Related Statute/Regulation

Section 1834(a) (42 U.S.C. 1395m(a)), Section 302 of the Medicare Modernization Act of 2003 (MMA)

Proposed Solution

Do not include External Infusion Pumps and Supplies (EIPS) or Enteral Nutrients, Equipment and Supplies (ENES) in future rounds the competitive bidding program.

These items have been bid in previous rounds and the Medicare Fee for Service rates have been adjusted downward significantly. Including EIP and/or ENES in future rounds of competitive bidding is unlikely to bring about additional savings and given the long-term nature of these patients it not worth the disruption in their care.

Short Description

Medicare Part D Prior Authorization Simplification

Summary

Many Part D plans require prior authorization for home infusion drugs. The prior authorization process often delays transition to the home. While prior authorization may be necessary, the process needs to be expedited for home infusion drugs. The Medicare Program Integrity Manual specifies that:

“In general, should prior authorization or other utilization management edits apply to any of these agents, CMS would expect that Part D sponsors handle these in an expedited manner in order to facilitate hospital discharge in appropriate time frames.”

This requirement is not being met by Medicare prescription drug plans.

Related Statute/Regulation

Medicare Program Integrity Manual – Publication # 100-18, Chapter 6, “Part D Drugs and Formulary Requirements”, Section 10.11 “Common Home Infusion Drugs”

Proposed Solution

Require Medicare Part D plans that utilize prior authorization for home infusion drugs to finalize the prior authorization on the day of patient discharge or referral.

Short Description

Medicare Part D Network Adequacy Requirements

Summary

Medicare Part D requires prescription drug plans have an adequate home infusion network. Chapter 5 Section 50.4 of the Medicare Program Integrity Manual states:

“In order to meet the requirements for adequate access to home infusion pharmacies, Part D sponsors must deliver home infusion drugs to enrollees within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. To ensure Part D sponsors can provide such access, as part of their initial pharmacy access submissions, and through Part D annual reporting requirements (Information Collection Requirements (ICF) OMB 0938-0992), each Part D sponsor must provide a list of all contracted home infusion pharmacies licensed/legally able to serve in all State(s) and/or territories in the service area under each CMS pending contract number.”

In some cases it appears that prescription drug plans are fulfilling this requirement by reporting retail pharmacies that do not meet the standards outlined in Chapter 5 Section 50.4 of the Medicare Program Integrity Manual.

Related Statute/Regulation

Medicare Program Integrity Manual – Publication # 100-18, Chapter 5, “Benefits and Beneficiary Protections”, Section 50.4 “Home Infusion Pharmacy Access”

Proposed Solution

Section 50.4 should be actively enforced and prescription drug plans should not be allowed to use retail pharmacy locations to fulfill this requirement.

Short Description

Medicare Part D Reference Pricing

Summary

Many Medicare Part D contract reimbursement rates for drugs are dependent on reference pricing metrics, such as Average Wholesale Price (AWP) or Average Sales Price (ASP). Medicare prescription drug plans often lag far behind in implementing published reference pricing. In many cases the lack of updating to published reference pricing metrics puts pharmacy's reimbursement below their acquisition cost for the drug.

Related Statute/Regulation

None

Proposed Solution

Require Medicare Part D prescription drug plans to update drug reference pricing monthly or quarterly.

Short Description

Medicare Part B Durable Medical Equipment (DME) Bill for Denial (BFD)

Summary

Stringent Medicare documentation requirements apply when billing for denial, in order to cross-over claims for services not covered by Medicare, but covered by another payer. Medicare policies often conflict with commercial payers making the billing process administratively burdensome. Examples: proof of delivery (POD), detailed written order (DWO), DME Information Form (DIF).

Related Statute/Regulation

Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)

Proposed Solutions

Exempt suppliers from having to meet some documentation requirements, DWO, DIF, POD, when billing for denial using the GA, GZ or GY modifier. The supplier should be able to meet the requirements of the payer responsible for paying the claims, not Medicare who is denying the claim.