



Via Electronic Submission to: <https://www.regulations.gov>

August 7, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1674-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS Request for Information; Reducing Administrative Burden to put Patients over Paperwork (84 Fed. Reg. 27070, June 11, 2019, CMS-6082-NC, RIN-0938-ZB54)

To Whom It May Concern:

The American Association for Homecare (AAHomecare) is pleased to have the opportunity to submit comments on the above captioned Request for Information. AAHomecare is the national organization for the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) industry, representing suppliers, manufacturers, and other stakeholders in the homecare community. Members provide medical equipment and supplies for patients outside of the hospital setting to continue to improve the management of patients with chronic conditions. Due to our unique position, we have a vested interest in improving policies and processes for the DMEPOS benefit under Medicare and Medicaid.

In line with Center for Medicare and Medicaid Services' (CMS') effort to reduce administrative burden and improve patient care, we would like to take this opportunity to strongly encourage CMS to endorse e-prescribing to the extent of making it mandatory. To help referring prescribers meet all of the Medicare documentation requirements, CMS should move towards requiring all electronic health record (EHR) systems to meet all of CMS' documentation requirements for DMEPOS. In addition, documentation requirements specific to DMEPOS should be required to ensure hospitals, clinics and physician practices are incorporating these requirements into their daily practices. If properly implemented, EHRs can improve compliance, reduce burden, and enhance communication between all parties. The Clinical Data Elements (CDE) templates developed by CMS contain all of the data elements that should be required to

qualify a patient for specific DMEPOS. All other documentation requirements, such as face-to-face physician's evaluations, laboratory results and CMNs should be eliminated. In developing additional templates for the EHRs, AAHomecare recommends that CMS collaborate with industry stakeholders. An effective EHR implementation can have a significant effect on reducing administrative burden and improving healthcare delivery.

Below are several suggestions that CMS should consider that will reduce administrative burden. In this letter, we provided a summary of each issue, the related statute/regulation (as appropriate), and proposed solutions.

PART 1: MEDICARE ISSUES

1. Clinical Inference

Improve Medicare policies and procedures by restoring contractors' ability to use clinical inference.

Summary:

There are a number of documentation requirements that are burdensome and ineffective. Due to the prescriptive language of the regulations for DMEPOS equipment and supplies, auditing and processing contractors often overlook the intention of the regulation. Clinical inference is a term used to describe a practice that allows medical reviewers to use their expert medical knowledge to make judgments about medical necessity using information other than the records a provider or supplier submits to support a claim.¹ Using clinical inference, medical professionals apply their training, experience and judgment to confirm medical necessity as they consider a beneficiary's diagnosis, condition, history and other information like his or her Medicare claims history.² The ban on the use of clinical inference during complex medical review has failed cost containment strategies, threatened the operational stability of

¹ *As a practical matter, medical reviewers, like all medical professionals, always make use of their training to make judgments about the documentation they review. But as Medicare medical review strategies, the use of clinical inference and clinical judgment refer to the ability for reviewers to draw inferences and make judgments from sources of information other than the documentation submitted by the provider or supplier to support the claim under review. Generally, in this paper we use the terms "clinical inference" and "clinical judgment" as terms of art unless the context indicates otherwise.*

² *An admittedly oversimplified example would be that of a contractor's review of a claim for an immunosuppressive drug where all of the necessary elements for coverage have been documented in the submitted medical records, except evidence of a transplant surgery within a year of the prescription (a pre-Medicare Part D requirement). Allowing clinical inference and clinical judgment under this scenario would permit the reviewer to rely on the beneficiary's Medicare claims history to confirm that the transplant surgery occurred within the window identified under Medicare policy.*

**Medicare generally distinguishes between institutional "providers" under Part A and Part B "suppliers," including suppliers of durable medical equipment prosthetics, orthotics, and supplies (DMEPOS). We use these terms interchangeably in this paper, unless the context indicates otherwise.*

many providers and suppliers, and placed the Medicare program at odds with beneficiaries and their physicians.

This strategy has proved an ineffective use of Medicare's administrative resources and appears to be unfairly shifting the cost of paying for Medicare covered items to providers, suppliers and beneficiaries. Having had nearly ten years of experience with the ban on clinical inference, we now know that it has contributed to an unprecedented backlog in the Medicare appeals process.

Related Statute/Regulation/Policy:

- OIG Report, "Independent Contractor's Review of Fiscal Intermediary and Carrier Claims From the Fiscal Year 2008 Comprehensive Error Rate Testing Program," (Sept. 2009, A-01-09-00511)
- Medicare Program Integrity Manual, Chapters 3 and 5 (Section 5.7)

Proposed Solution:

CMS should restore the use of clinical inference in the complex medical claims review process.

2. Remove Burdensome Documentation Requirements and Allow for Beneficiary Choice

Remove prescriptive documentation requirements that are ineffective in providing quality healthcare service to beneficiaries.

Summary:

Medicare's overly burdensome documentation requirements have contributed to the congested audit and appeals system. For example, proof of delivery (POD) is one of the top denial reasons for DMEPOS claims. In many instances, the reason for the denial is because the POD is signed the day before the date of service that was billed on the claim, or the relationship of the person signing the delivery ticket is not listed. The intention of the POD is to establish the fact that the patient has received the equipment or supplies and many times auditing contractors deny a claim or uphold an appeal because of the prescriptive requirements in Local Coverage Determinations (LCDs), articles, and the Program Integrity Manual.

Additionally, CMS should allow suppliers to submit other types of proof with an audit that demonstrates the beneficiary has received the goods or services. To assist with determining documentation requirements that need to be evaluated, CMS should track the volume and types of technical denials that are overturned at the Qualified Independent Contractor and Administrative Law Judge.

The 2018 CERT Supplemental Improper Payments Data states that 78.1% of the DME error rate is due to insufficient documentation.³ Overall, only 2.5% of improper payments for DMEPOS were due to medical necessity, which means the majority of improper payments are due to the documentation requirements, not because patients are receiving equipment or supplies that are not medically necessary.⁴ The report provided examples of insufficient documentation including: face-to-face, POD, and physician signature on orders. Although CMS has not yet published the 2018 CERT Improper Payments Report, in the 2016 report that stated similar figures to 2018, CERT acknowledged that meeting all of the detailed documentation requirements is a challenge due to the involvement of multiple parties.⁵ For the top three product categories with the highest improper payment rate, the majority of the improper payments were due to the ordering physician not meeting the documentation requirements.⁶ Because suppliers are fully dependent on the ordering physician to properly complete the written order and clinical documentation to meet Medicare's requirements, Medicare should hold the ordering physician accountable rather than the supplier.

The industry also sees that burdensome documentation requirements and the prescriptive nature of the regulations have limited patient choice. For example, many prescribing physicians choose to list two types of CPAP masks on an order to allow the beneficiary to have an opportunity to choose their preferred mask when they are fitted by the supplier. The decision on what CPAP mask will best fit a beneficiary is made at the time of setup with a supplier and patient. However, MACs have denied the entirety of audited claims for all PAP supplies when an order has more than one mask listed. Many times, the physician will write a dispensing order that states: "fit mask to comfort." When a beneficiary chooses between a full-face mask and a nasal mask it is based on the comfort of the patient and their breathing patterns. For a patient to become compliant, it is critical that the supplier works with the beneficiary to make sure the mask they are using is most comfortable. This way the beneficiary will be more compliant with their therapy and prevent complications that could result from non-compliance. Furthermore, the supplier only submits one mask for payment. They are not seeking payment for two masks and therefore, there is no financial loss for the government. Requiring the patient to go to the physician each time there is a mask/supply change has caused delays in patient care, created additional paperwork, and has been an ineffective utilization of physicians' time.

Related Statute/Regulation:

- 42 C.F.R. §424.57(c)(12), Medicare Program Integrity Manual (PIM) Section 5.8

Proposed Solution:

AAHomecare recommends that CMS evaluate policies that disproportionately contribute to the appeals backlog and adjust the language to meet the intent of the requirement by allowing for some flexibility.

³ U.S. Department of Health and Human Services. 2018 Medicare Fee-for-Service Supplemental Improper Payment Data.

⁴ *Id.*

⁵ U.S. Department of Health and Human Services. Medicare Fee-for-Service 2016 Improper Payments Report.

⁶ *Id.*

In the case of POD, which is intended to prove a beneficiary has received equipment or supplies, CMS should allow the date of service to be flexible, so long as the date of service falls on or after the delivery date. CMS should also allow multiple accessories on a single order that is generated by a prescriber specific to CPAP and RAD.

3. Advance Beneficiary Notices - ABNs

Beneficiaries should be allowed to upgrade a piece of equipment or quantities of medical supplies using ABNs. The ABN should be extended to 13-months to mirror the capped rental period.

Summary:

Over the years, CMS has issued a series of guidances that has eroded beneficiaries' access to items that have features or benefits beyond the "standard" item that meets the beneficiary's medical need. When Congress passed the Balanced Budget Act of 1997, it was intended to allow beneficiaries to have access to upgraded items, but Medicare has eliminated any practical application of this law. As a result, suppliers who accept assignment must either restrict choice by limiting available products or they must stop accepting assignment on products altogether. Congress' Conference Report accompanying the legislative language of the Balanced Budget Act of 1997, section 4551(c) clearly contemplated that an upgrade item would have "deluxe features" which the beneficiary would like "for added convenience or other purposes." When CMS eliminated the ABN upgrade application within the same HCPCS for "premium quality services" as was intended by Congress, the original premise of the regulation was removed.

For rental items, a single ABN is only valid for 12-months. This creates an administrative burden when ABNs are used for capped rental items. Capped rental has a 13-month rental period and because an ABN is valid for only 12-months, this results in suppliers needing to request an additional ABN for the last month of the rental. Not only is this burdensome to the supplier, but it is also burdensome to the beneficiary who has to understand and sign additional paperwork. To help remove this additional documentation requirement on suppliers and beneficiaries, CMS should extend the ABN to be valid for 13 months.

Related Statute/Regulation:

- Section 1834(a)(19) of the Social Security Act, Medicare Claims Processing Manual, Chapter 30, section 50.8

Proposed Solution:

Allow for ABNs to be used to upgrade items within the same HCPCS code. Extend the ABN from 12 months to 13 months to mirror the capped rental period.

4. Payment Authorization

Add flexibility to the payment authorization policy requirement for monthly, non-assigned DME rentals.

Summary:

CMS amended the assignment of benefits (AOB) rules in 2005, clarifying that signed AOB forms are unnecessary for services furnished under mandatory assignment.⁷ But the Agency did not make corresponding amendments to rules requiring suppliers and providers to have signed payment authorizations before they bill Medicare. Suppliers and providers must obtain signed authorizations even for services that require mandatory assignment, losing efficiencies CMS intended to create.

A signed payment authorization “in a supplier’s record” can be “effective indefinitely,” except for DME claims.⁸ For DME furnished and billed assigned, suppliers can get a “one-time” authorization that is good only for the rental period or sale of a specific DME item. The supplier still needs a new signed authorization whenever it furnishes another item to the beneficiary. In addition, suppliers submitting unassigned DME rental claims, must have a new signed authorization for every claim (each month of rental).

Requiring suppliers to obtain more than one signed payment authorization for all the DME claims they submit for a beneficiary, whether billed assigned or unassigned, does not enhance program integrity. This extra step is a costly strain on suppliers’ efficiencies. Deliveries are suppliers’ largest cost center, including fleet costs, fuel and personnel.^{9,10} The requirement to get a new signed authorization every time they deliver another DME item to a beneficiary, or with every unassigned claim submission,

⁷ 42 C.F.R. §424.55(c).

⁸ 42 C.F.R. §424.40(c)

⁹ See *Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population Measuring the Impact of Competitive Bidding*, Dobson DaVanzo & Associates, LLC for AAHomecare (2016).

¹⁰ The rules also burden beneficiaries who must sign redundant paperwork especially with respect to unassigned claims.

stretches out the home visit (or requires another trip back for unassigned claims), increasing suppliers' costs.^{11,12,13}

Related Statute/Regulation/Policy:

- Medicare Claims Processing Manual, Chapter 1

Proposed Solution:

Amend the payment authorization requirement for non-assigned claims to mirror that of assigned claims; requiring a one-time payment authorization.

5. Modify Payment Categories

Modify how items are categorized as inexpensive and routinely purchased and evaluate current HCPCS in the capped rental category that would be better suited to inexpensive and routinely purchased.

Summary:

There are several inconsistencies with the items included in Medicare's DMEPOS "capped rental" category versus the "inexpensive and routinely purchased" category. More specifically, there are several

¹¹ CMS recently responded to AAHomecare's questions about suppliers' recourse when a beneficiary refuses to sign a payment authorization but wants to keep equipment he received. The Agency said suppliers should obtain a "statement" from the beneficiary to that effect then bill the beneficiary directly. We respectfully challenge the assumption that a procedure requiring suppliers to obtain statements from beneficiaries saying they wish to keep the equipment but will not authorize claim submission is any less burdensome than requiring suppliers to obtain signed authorizations in the first place. As we noted, requiring beneficiaries to sign a new payment authorization for every unassigned claim the supplier submits for a beneficiary, is also time consuming and burdensome for beneficiaries. Asking the beneficiary to sign a "statement" as CMS has suggested is no less burdensome for beneficiaries as well.

¹² The Agency's suggestion that obtaining a signed statement like the one described above overrides the need to have a signed authorization also calls into question the Agency's program safeguard rationale for the rules. The availability of such a procedure undermines CMS' argument that a beneficiary's signature on a payment authorization for a DME claims protects Medicare from improper billing. Billing the beneficiary directly does not cure what would otherwise be improper billing.

¹³ Consider also that CB reduces the pool of suppliers who serve beneficiaries in a CBA. Contract suppliers that offer more than one product line will likely provide several different DME items to the same beneficiary over the contract term. So, it makes sense for contract suppliers to have a one-time authorization from a beneficiary that is valid indefinitely. Note also that contract suppliers must accept assignment for all CB items they furnish in CBAs. Allowing a one-time signed authorization for billing all DME items a beneficiary receives lets contract suppliers realize the administrative efficiencies CMS intended to create under the AOB rules.

HCPCS codes that are included in the capped rental category, despite the fact that they qualify under the inexpensive/routinely purchased category of DME. These HCPCS codes meet the statutory definition for purchased DME because in all current Medicare fee schedules, the payment rate is less than \$150, the threshold for the “inexpensive” prong of the purchased equipment category.¹⁴ As an example, CMS originally placed nebulizers in the inexpensive and routinely purchase category and then, many years ago, moved the HCPCS code to capped rental. However, reimbursement for nebulizers dropped sharply under the competitive bidding program (CBP). The average rental rates are \$5.62, or roughly a \$56.15 purchase price of the equipment.¹⁵ Billing for these small amounts over a 13-month rental cycle raises suppliers’ costs unnecessarily. In addition, almost all commercial payers and Medicare Advantage plans purchase nebulizers on initial issue to a patient.

Furthermore, there are inconsistencies with wheelchair accessories that have caused significant confusion for suppliers. As an example, there are two types of base wheelchairs: standard and complex. Standard wheelchairs are considered under the capped rental category while complex are not. However, accessories for these items are not categorized in the same category as the base and as a result, a beneficiary may be required to have parts of their wheelchair purchased and parts of their wheelchair rented. These differing payment rules for the paired accessories have caused a great burden on both suppliers and beneficiaries. To improve beneficiary access to needed wheelchair accessories, CMS should correct the payment rules for the accessories to follow the payment rule for the base wheelchair. Such adjustments will not only be beneficial for patients, but it will also simplify documentation requirements for prescribers and suppliers.

Related Statute/Regulation:

- 42 USC §1395m(a)

Proposed Solution:

CMS should update the financial threshold for inexpensive and routinely purchased and assign nebulizers to inexpensive and routinely purchased product category. CMS should simplify and correct the rules for capped rental. A thorough evaluation of the capped rental category should be conducted and appropriate HCPCS should be moved to the inexpensive and routinely purchased category.

6. CMNs and DIFs

Eliminate Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs) as they are no longer used to document medical necessity.

¹⁴ 42 USC §1395m(a).

¹⁵ National Contiguous United States Non-Rural January 2019 Fee Schedule Average for E0570

Summary:

The CMN and DIF, which were developed as tools to document medical necessity, have been reduced to merely another administrative hurdle to claims payment. The time and resources necessary to obtain a properly completed CMN are significant because of the limitations placed on the completion of the documents. A supplier is prohibited by statute from completing Part B of the CMN, the section pertaining to medical necessity. Any supplier who completes a CMN or alters the CMN after the physician has signed it is subject to civil monetary penalties. The DIF is prepared by the supplier but since supplier-prepared records are not considered part of the medical record, the DIF does not support medical necessity and serves no other purpose.

Not only is this process burdensome on the supplier and the physician, it ultimately affects beneficiary access to DMEPOS items as suppliers use time and resources to obtain paperwork that would otherwise be spent servicing beneficiaries. If the supplier does not produce additional documentation from the patient's file, the MACs will deny the claim for lack of medical necessity and deny or recoup payment, even though the equipment has already been provided to the beneficiary pursuant to the order of the treating physician and the signed CMN.

Related Statute/Regulation/Policy:

- The Medicare National Coverage Determination 240.2 mentions the CMN, but there is no Medicare regulation requiring CMNs directly
- Medicare Program Integrity Manual, 5.3.1—Completing a CMN or DIF
- Medicare Claims Processing Manual, Chapter 20, Section 100.2 (CMNs)
- CMN form (CMN CMS-484), (OMB approval #0938-0679).

Proposed Solution:

CMS should eliminate all CMNs and DIFs as they no longer serve the purpose for which they were created. Currently CMNs and DIFs are considered claims processing tools. CMS should alter claims processing requirements to eliminate them as they have done in the past with CPAP and hospital bed CMNs.

7. Targeted Probe and Education (TPE)

CMS should improve the transparency, consistency, and other program requirements in the TPE process.

Summary:

Overall, the TPE audit program has improved the supplier experience by allowing a two-way communication between the supplier and DME MAC nurse reviewer. The program's focus on communication and education has had a significant impact on the administrative burden. However, since the inception of the program in 2017, the industry continues to see areas for improvement in regard to transparency of the program, consistency of the reviews across the MACs, and other program operations. Below is a comprehensive list of areas of improvement to be considered related to DMEPOS specifically.

- a) Suppliers should not receive audits for multiple accessories used with the same device or for medical supplies in the same LCD. TPE audit should include all accessories within an LCD and claims with multiple items in the same LCD should be audited simultaneously.
- b) TPE audits on claims that have technical denials, such as same or similar and patient in part A stay should be removed from the audit sample and replaced with other submitted claims.
- c) Error rate calculations on TPE audits that include secondary claims should be based on estimated copay portion of the allowable that Medicare would have paid. An option might be to remove secondary claims from the audit and replace with other submitted claims that are primary.
- d) The DME MACs should provide more transparency on how the process works from initial call, letter and claim review. We have received many examples of letters suppliers have received where some claims are pulled in a TPE, but not the total 10. These audits remain open for many months and are still not closed or resolved.
- e) All suppliers should be audited under TPE. Currently, the same suppliers are being audited repeatedly, while there are many suppliers that have never received a TPE audit. Compliant suppliers who have passed a TPE audit and have had a year reprieve are immediately caught back up in the TPE cycle. TPE audits should occur in geographical areas so all suppliers that provide a certain HCPCS or group of HCPCS are audited at the same time.
- f) Now that CMS has data on providers and suppliers that have failed round 3, CMS should publish examples of what has happened to those that have failed round 3.
- g) CMS has indicated the nurse reviewer is to review claim by claim through the audit results to ensure the supplier is aware of all of the issues. However, supplier experience has shown a wide variance in what the DME MACs are doing.
- h) Suppliers have indicated that nurse reviewers are interpreting beyond the requirements of the LCD, policy articles, and PIM. The reviewers are making suggestions that do not exist under current requirements, and nurse reviewers at different DME MACs are interpreting the same requirements differently.
- i) Overturned appeals should be factored into the error rate. Appeals overturned at a minimum at the redetermination stage should require a recalculation of a suppliers' TPE error rate.
- j) CMS should provide guidance to the DME MACs on curable errors. DME MACs are inconsistent in what is categorized as a curable error and inconsistently allowing 5 calendar days to respond to curable error requests. Industry recommends 10 business days to respond.
- k) There is inconsistency regarding Process Improvement Plans (PIPs). One DME MAC requires a PIP when a supplier passes a round of TPE. A PIP should only be required when a supplier fails a TPE round.

Related Statute/Regulation:

- No statute or regulation currently defines/guides the TPE process; all sub-regulatory (see CMS [TPE web site](#))

Proposed Solution:

CMS should work with industry stakeholders to ensure improvements to the TPE process are made.

8. Prior Authorization

CMS should expand the prior authorization program and ensure that prior authorized DMEPOS cannot be audited for medical necessity.

Summary:

An affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity:

- of the item for the beneficiary;
- for all of the options, supplies, and accessories that may be used with the item;
- and for repairs to the item approved.

Although claims could be audited subsequently for technical issues such as POD, when a prior authorization is approved, suppliers should have the confidence that the medical necessity is met. Without such affirmation, the benefits of the prior authorization program to suppliers, providers, and beneficiaries are undermined. Prior authorizing a DMEPOS item requires an immense amount of paperwork upfront, and the benefit of this work is that all stakeholders have the confidence that the beneficiary's item meets coverage criteria under Medicare.

The prior authorization program should be expanded to include additional items of DMEPOS with the understanding that the time frame to issue authorization may need to be adjusted depending on medical need and the process must be electronic.

Related Statute/Regulation:

- 42 C.F.R. 414.234
- [CMS web site](#)
- CMS [Prior Authorization Operational Guide](#)

Proposed Solution:

CMS to issue guidance to the DME MACs to not review for medical necessity on prior authorized items. CMS should expand the program beyond the current Master List and make the process electronic to ensure efficiency.

9. HCPCS Improvements

Expand HCPCS coding to ensure it accurately and effectively categorizes items.

Summary:

The current Healthcare Common Procedure Coding System (HCPCS) code set for DMEPOS is inadequate. There appears to be an institutional unwillingness to expand the HCPCS code set. This has resulted in a myriad of problems including:

- Under-defined codes that contain too broad a range of products with a subjective code verification process.
- Products that receive payment rates that are too low, or too high.
- A disincentive to innovate.
- A lack of new/appropriate codes for innovative technologies and enhancements.

There are numerous HCPCS codes that do not represent a homogenous group of products but rather include a broad range of items from simple items to high-end complex items (such as HCPCS code E0955, a wheelchair headrest code which includes everything from “foam on a stick” to very complex head support systems and E0978, a positioning belt/safety belt/pelvic strap code which includes everything from very basic seat belts to complex pelvic support systems). The problem with grouping a wide range of technology under one code is that it fails to adequately recognize and reflect unique features, applications and benefits. Further, since the payment rate is established at the HCPCS code level, it inadequately compensates for more complex/costly items while potentially overcompensating simple/inexpensive items assigned to the same code.

The lack of specifications and unwillingness to routinely enhance coding and code descriptors discourages manufacturers from developing product improvements and new products that could benefit the user clinically and/or functionally. Typically, HCPCS codes include minimum product specifications that a product must meet in order to use the associated code for billing. However, in many cases these specifications are very minimal and only reflect the materials and technology that existed at the point the code was created. Any function and form requirements established by the Pricing, Data Analysis and Coding (PDAC) contractor that goes beyond the full HCPCS code descriptions are subjective and the PDAC does not publish decisions for stakeholder feedback.

CMS appears to display a strong aversion to expanding the HCPCS code set, as well as a concern about the impact additional HCPCS codes will have on the competitive bidding program. These concerns must be overcome and a more reasoned policy put in place that allows for more codes, along with more specifications in codes and coding that considers materials, durability, features and/or applications. There are many DME items that do not have a proper code. For example, Medicare has established

HCPCS codes for oversized/bariatric hospital beds, but no codes exist for bariatric sizes of full support surfaces that would be placed on such beds. CMS published an article reinforcing its unwillingness to recognize bariatric sized support surfaces, even though the design, materials, and costs associated with bariatric sized support surfaces would increase, just as it does for bed frames.¹⁶

These issues ultimately punish beneficiaries who would greatly benefit from these enhanced goods and services. Medicare's regulations encourage product offerings based on lowest cost rather than quality, durability, and effectiveness. As a result, Medicare beneficiaries may be less likely to receive advanced materials and technology. The broad grouping of HCPCS codes places premium products at a competitive disadvantage by assigning them to HCPCS codes that are inadequate and under reimbursed, while providing cheap products with a competitive advantage. CMS needs to expand HCPCS coding to ensure that each code represents a distinct, homogenous group of products and stop co-mingling disparate items.

Related Statute/Regulation/Policy:

- CMS Claims Processing Manual, IOM 100-4

Proposed Solution:

CMS needs to expand HCPCS coding to ensure that each code represents a distinct, homogenous group of products.

10. Gap Fill Methodology

Replace gap filling pricing methodology.

Summary:

Even if CMS were to act to address the problems that exist with the HCPCS coding system for DMEPOS, it cannot address the problems that exist unless the methodology for calculating payment rates (gap filling) is also reworked. The current gap fill method gives each product identified and assigned to a HCPCS code equal weight in the calculations. Each included product goes through the calculations to deflate its price back to 1987. Then the median price is identified amongst all of the included products. This single, median price is then re-inflated to calculate a current-year payment rate for the HCPCS code, and all products assigned to the code. The problems with this methodology include:

¹⁶ *Noridian Healthcare Solutions. Correct Coding- Bariatric Pressure Reducing Support Surfaces. July 27, 2017. Retrieved from: <https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/correct-coding-bariatric-pressure-reducing-support-surfaces>*

- Failure to recognize market demand and clinical preference in the calculations. For example, in considering the products assigned to a HCPCS code, one item may represent 30% of demand while another might not have any market demand. Yet, each is given an equal weight in identifying the median deflated price. To more fairly identify the median price, each item included should be weighted based on historic market demand.
- The current method of deflating current year pricing to 1987 and then re-inflating to present day is likely to calculate payment rates that are too low. Further, if the current method is extended too far into the future it will return payment rates of “\$0.00.” Since the gap fill methodology was adopted, CMS has applied deflation rate for each year back to 1987 but has omitted any inflation rate for years where DME payment rates were frozen (something not anticipated or considered when the method was created in the 1980s). In calculating current year payment rates for items that did not exist in 1987, it is inappropriate to apply a deflation rate for any year, unless an inflation rate for the same year is also applied.
- The gap fill methodology, in combination with under-defined coding, creates a competitive advantage for providing the cheapest products assigned to a code which could reduce beneficiaries’ access to the goods and services that they need.

CMS needs to replace the current gap filling methodology it utilizes to calculate the payment rate for new and updated HCPCS codes. The current methodology is out of date and insufficient. To develop a more robust reimbursement calculation procedure, CMS should collaborate with stakeholders to develop an alternative to this current methodology.

Related Statute/Regulation/Policy:

- Omnibus Budget Reconciliation Act of 1986 (PL 99-509)
- CMS Claim Processing Manual, IOM 100-4

Proposed Solution:

CMS needs to replace the current gap filling methodology it utilizes to calculate the payment rate for new and updated HCPCS codes. To develop a more robust reimbursement calculation procedure, CMS should collaborate with stakeholders that could provide input to the process.

11. Budget Neutrality

The budget neutrality requirement imposed on the oxygen product category is improperly applied and should be removed.

Summary:

As a result of CMS' interpretation of the "budget neutrality" requirement in 1834(a)(9)(D)(ii) of the Social Security Act, the rates for oxygen concentrators (E1390) in non-competitive bidding areas (non-CBAs) have been well below the regional competitive bidding rates from which they were derived. This outcome is inconsistent with the laws and regulations that govern Medicare reimbursement for oxygen and oxygen equipment.

CMS adopted this offset in 2006 as part of a decision to pay more for "oxygen generating portable equipment" (OGPE) than it would for traditional portable equipment. In turn, CMS decreased the payment for stationary oxygen equipment. CMS reasoned the offset was necessary to keep changes in overall oxygen payments budget neutral, consistent with the statute authorizing Medicare to pay for different categories of oxygen equipment. It was designed to account for higher expenditures for OGPEs as more beneficiaries used that technology.

By its terms, the regulation establishing the offset for E1390 concentrators applies to the unadjusted fee schedules under the fee schedule methodology mandated by Congress under §1834 (a) of the Social Security Act (SSA). In contrast, the 2017 fee schedules for concentrators in rural areas are based on information from CBPs under the methodology in 42 CFR § 414.210 (g). These two regulations, §414.226 and §414.210(g), describe different reimbursement methodologies that do not overlap. Section 414.226 applies to fee schedules based on suppliers' reasonable charges from 1986 to 1987. Section 414.210 (g) applies to fee schedules based on regional average SPAs from competitive bidding areas (CBAs).

In addition to the underlying different legal authorities, there is a strong policy rationale for making sure that payment rates in non-CBAs are higher than the SPAs, which are based on urban market dynamics that do not apply to non-CBAs. Any other result contradicts Congress' original exclusion of areas that are rural and not densely populated. Moreover, it defies any logic to have the resulting fee schedule amounts in non-CBAs to be lower than CBA rates. Congress' mandate in the 21st Century Cures law requiring CMS to consider the additional costs of serving beneficiaries in non-CBAs further underscores the notion that payment rates need to be higher in non-CBAs.

Related Statute/Regulation:

- SSA 1834(a)(9)
- 42 C.F.R. §414.226(c)(6)

Proposed Solution:

Remove the budget neutrality offset applied to payment for oxygen items.

12. Competitive Bidding Prices Applied to Complex Rehabilitation Therapy (CRT) Accessories

CMS should not apply competitive bidding prices to accessories used with complex rehab (CR) manual wheelchairs.

Summary:

In 2008, Congress excluded CRT power wheelchairs and accessories used with them from the competitive bidding program.¹⁷ At the time, CMS had not yet included any manual wheelchairs in the CBP, as a result, the exclusion did not explicitly state the exclusion CRT manual wheelchairs. CMS, however, followed the spirit of Congress' exclusion mandate for CRT power wheelchairs and their accessories exclusion by not including CRT manual wheelchairs. On January 1, 2016, CMS began applying competitive bidding payment rates to accessories used with CRT manual wheelchairs when provided to beneficiaries residing in non-CBAs. In June 2017, CMS used its administrative authority to not apply CBP-derived payment rates to accessories used with CRT power wheelchairs, when provided to beneficiaries residing in non-CBAs. Applying bidding pricing to accessories used with CRT manual wheelchairs drastically reduces reimbursement for these items and we believe it is contrary to Congressional intent as understood by CMS in 2010. Most importantly, the reduced payment rates create significant access problems for Medicare beneficiaries and other people with disabilities.

Related Statute/Regulation:

- Medicare Improvements for Patients and Providers Act of 2008 (PL-110-275)
- 42 C.F.R. §414.210
- CMS June 23, 2017 [Frequently Asked Questions Frequently Asked Questions on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies \(DMEPOS\) 2015 Medicare Payment Final Rules \(CMS-1614-F\)](#)

Proposed Solution:

CMS can clarify under its current authority that the adjusted fee schedules do not apply to accessories used with CR wheelchairs.

13. Power Seat Elevation Coverage

Medicare should provide coverage for power seat elevation technology for beneficiaries with a medical need for a power wheelchair.

Summary:

Medicare does not cover power seat elevation technology on power wheelchairs because it has not believed the technology serves a "medical purpose." Power seat elevation, when used on power wheelchairs, enables some people with disabilities to more fully participate in their mobility related

¹⁷ Public Law No: 110-275 (07/15/2008)

activities of daily living (MRADLs), by which coverage for the base wheelchair is rendered. The current position prohibits Medicare beneficiaries from having access to this enabling technology, as a replacement for loss of function, that is considered for coverage and payment by other insurers, including the Veterans Administration (VA) and state Medicaid programs.

Medicare, through determinations made solely by its DME contractors, do not cover power seat elevation as a critical component to power wheelchairs because it does not fit within the DME benefit category because it is “not primarily used to serve a medical purpose” - one of the required prongs for coverage under the Medicare Part B DME benefit. As a result, Medicare beneficiaries do not have access to this medical technology even though it is assigned a HCPCS code (E2300). Seat elevation technology is considered for payment by other payers (e.g., state Medicaid programs, the VA, private insurance, etc.) who make their coverage decision based on a review of the medical documentation.

Related Statute/Regulation:

There is no regulation or statute that prohibits coverage of this critical component on a medically necessary power wheelchair. This is solely a Medicare/DME contractor interpretation issue.

Proposed Solution:

Medicare should provide coverage for power seat elevation technology when medically necessary for a beneficiary who meets the coverage requirements for a power wheelchair.

PART 2: DUAL ELIGIBLES/MEDICAID ISSUES

14. Inconsistencies with HCPCS Codes Amongst Payers

There are inconsistencies with HCPCS codes amongst the payers. All payer types should recognize all codes. Payers should be required to deny non-covered or ineligible service with accurate denial codes.

Summary:

There are HCPCS code inconsistencies between Medicare, Medicaid, and other third-party payers (S and T HCPCS codes as an example). All payer types should recognize all codes and if not covered, deny with correct denial codes from Medicare FFS, Medicare Part C, Medicaid FFS, Medicaid managed care and other third-party payers. For example, incontinence products with T HCPCS codes are not covered by Medicare and the HCPCS codes are not recognized, but they are covered by Medicaid. Suppliers must bill an A code that is recognized by Medicare which they must then manually cross-walk to a T code to bill Medicaid. If a supplier attempts to bill Medicare with a T HCPCS code, it will reject on the front end and never be processed by Medicare. In addition, Medicare must deny with an appropriate

code for the Medicaid programs to make payment; this means a patient responsibility (PR) denial as opposed to a contractual obligation (CO) denial. When a Medicaid program sees a CO denial, they assume there is no patient liability and will not process and pay for the covered services.

In many cases, Medicaid covers more equipment and supplies than Medicare. In this case Medicare does not recognize Medicaid covered codes. We believe all payers should acknowledge all HCPCS codes to allow other secondary payers to be able to process covered services for patients.

Related Statute/Regulation:

- Health Insurance Portability and Accountability Act (HIPAA, Pub. L. 104-191)

Proposed Solution:

Ensure all payers recognize all HCPCS codes so that coverage and denial codes can be consistent across the board.

15. Medicaid Excessive Documentation Requirements

State Medicaid programs should not require any additional documentation when Medicare is primary.

Summary:

State Medicaid programs should not require any additional documentation beyond what Medicare has required for dual eligible beneficiaries. Some state Medicaid programs require additional documentation beyond what Medicare requires when Medicare is the primary payer. Medicaid programs requiring additional documentation when they are secondary payers puts beneficiary access to timely service at risk. The Medicaid program should cover the secondary portion without requiring additional documentation or any specific forms.

Proposed Solution:

Encourage state Medicaid programs to be less restrictive in their documentation guidelines when they are the secondary payer to Medicare.

16. Medicaid to Medicare Transition

When Medicaid beneficiaries become eligible for Medicare, they should be grandfathered in based on the state Medicaid coverage criteria.

Summary:

When a patient formerly covered by Medicaid becomes Medicare primary, services covered under Medicaid should be grandfathered in as meeting coverage criteria under Medicare. The requirement for patients to be re-qualified for equipment or medical supplies after already qualifying under a state's Medicaid program is duplicative. Suppliers are forced to re-start the costly process of re-qualification even though the patient's equipment and supplies were already proven medically necessary. This process is not only burdensome to suppliers but may create access issues for beneficiaries transitioning from Medicaid primary to Medicare primary.

Proposed Solution:

Allow Medicaid covered items and services to be grandfathered under Medicare when the patient becomes Medicare eligible.

17. Medicaid Secondary Claims Processing

Medicaid as a secondary payer should accept and process all secondary claims for dual eligible beneficiaries in the same manner as Medicare.

Summary:

Several state Medicaid programs process rental claims as daily claims with spanned dates, whereas Medicare processes rental claims monthly without a date span. When Medicare claims are automatically crossed over to Medicaid, there are issues with how a state Medicaid program processes the secondary claim. This requires suppliers to manually manipulate secondary claims to accommodate the state claims processing requirements. This is a labor-intensive process that is not necessary if Medicare has already approved the primary payment. By requiring state Medicaid programs to process secondary claims for dual eligible beneficiaries as they are received from Medicare, CMS will be reducing supplier burden and ensuring dual eligible patients have the same access to care across all states.

Related Statute/Regulation/CMS Policy:

- Medicare Secondary Payor (MSP) Manual (Pub. 100-05)

Proposed Solution:

CMS should encourage state Medicaid programs to accept and process all secondary claims for dual eligible beneficiaries as Medicare has.

18. Medicaid/Medicare Modifiers

Medicaid programs must recognize all valid Medicare claim modifiers.

Summary:

Many Medicaid programs do not recognize Medicare required modifiers. This creates a problem for dual eligible patients when Medicare pays as primary and automatically crosses the secondary claim to Medicaid. For example, when a state Medicaid program does not recognize the KX modifier and Medicare processes a claim with the KX modifier, the Medicaid program may not process the secondary portion of the claim without manual manipulation of the claim by the supplier. This requires suppliers to manually manipulate secondary claims to accommodate the state claims processing requirements. This labor-intensive process is burdensome for suppliers and it can be eliminated by requiring state Medicaid programs to process secondary claims for dual eligible beneficiaries as they are received from Medicare. By doing this, CMS will be reducing supplier burden and ensuring dual eligible patients have the same access to care across all states.

Proposed Solution:

CMS should encourage state Medicaid programs to recognize all Medicare required modifiers and pay secondary claims appropriately.

19. Quantity Limitation

Dual eligible patients experience access to care issues when a state Medicaid program allows a higher quantity of an item than Medicare.

Summary:

When a Medicaid program has a higher quantity limitation for specific HCPCS codes than Medicare, it is important that Medicare deny the excess quantity of that HCPCS code to allow the Medicaid program to pay for the additional allowed quantities that a dually eligible patient needs. For example, when Medicare only covers one unit of a urological supply per month and Medicaid allows two, if the treating practitioner prescribes two per month, then there needs to be an efficient way for this claim to be processed and paid by Medicare for one unit and then allow Medicaid to receive the secondary claim

electronically and pay for the second unit not allowed by Medicare. This would ensure dual eligible patients maintain access to the appropriately prescribed quantities that Medicaid allows, even when Medicaid is the secondary payer.

Proposed Solution:

Require Medicare contractors to deny the over quantity amounts appropriately and recommend the state Medicaid programs process the claims for the additional quantity for dually eligible patients.

AAHomecare appreciates the opportunity to share the DMEPOS industry's concerns and recommendations to reduce administrative burden. There are many opportunities for CMS to improve policies and procedures and we look forward to continuing the conversation with the Agency on the issues above. Please feel free to contact me to discuss in more detail.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberley S. Brummett". The signature is fluid and cursive, with the first name being the most prominent.

Kimberley S. Brummett, MBA
Vice President for Regulatory Affairs