



By electronic mail to: CodingComments@cms.hhs.gov

July 9, 2015

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on the Proposed Changes to Coding and Payment to Miscellaneous Codes

Dear Sir or Madam:

We are responding to your request for comments on a proposal to create six new HCPCS codes and fee schedule pricing for miscellaneous durable medical equipment (DME) currently billed under HCPCS E1399 and K0108. These two codes identify DME or wheelchair replacement parts and components or accessories that are “not otherwise classified” under another HCPCS code. CMS proposes the following new codes and payment amounts:

1. KXXX1 Durable Medical Equipment, Miscellaneous, the Purchase Price Does Not Exceed \$150

Based on the average reasonable charges for items that could be included in this code, CMS calculates that the 2015 fee schedule amount would be \$97.94; this amount will be updated by the 2016 covered item update.

2. KXXX2 Durable Medical Equipment, Miscellaneous, the Purchase Price Exceeds 150

Based on the average reasonable charges for all items covered by this code, CMS determines that the 2015 capped rental fee schedule amounts would be \$80.60 for rental months 1 thru 3 and \$60.45 for months 4 thru 13; these amounts will be updated by the 2016 covered item update.

3. KXXX3 Wheelchair Component or Accessory, Miscellaneous, the Purchase Price Does not Exceed \$150 –

The 2015 fee schedule amount generated based on CMS calculations would be \$72.56; this amount will be updated by the 2016 covered item update.

4. KXXX4 Wheelchair Component or Accessory, Miscellaneous, the Purchase Price Exceeds \$150

CMS calculates that the 2015 fee schedule amounts for items in this code would be \$53.41 for months 1 thru 3 and \$40.06 for months 4 thru 13; these amounts will be updated by the 2016 covered item update.

5. KXXX5 Repair Part For Use With Beneficiary Owned Durable Medical Equipment, Other Than Wheelchair, Not Covered Under Supplier Or Manufacturer Warranty, Not Otherwise Specified

Payment will be made on a lump sum purchase basis, per the contractor's individual consideration of the item.

6. KXXX6 Repair Part For Use With Beneficiary Owned Wheelchair, Not Covered Under Supplier Or Manufacturer Warranty, Not Otherwise Specified

Payment will be made on a lump sum purchase basis, per the contractor's individual consideration of the item.¹

CMS announced its intent to establish the new codes and pricing *via* a notice on its HCPCS coding *General Information* web page, the same page the Agency used to announce an internal coding action for E0463 and E0464 ventilators.² CMS is moving forward with changes to E1399 and K0108 devices using the same premise it used to justify revisions to payment and coding for ventilators. The Agency primarily asserts that it is requesting public comment on internal coding decisions as part of a limited demonstration to increase participation in coding actions that would not otherwise be open to comments, but the Agency nonetheless reserves the right to make internal coding changes as without notice as necessary.

We have the same concerns with this proposal that we did with the last one. First, CMS did not give the public sufficient notice of the Agency's plan to adopt new codes for miscellaneous items, and more importantly, assign new payment amounts to those items. Second, CMS plans to depart from the coding methodology the Agency established over 25 years of practice and proposes to substitute new HCPCS coding logic for E1399 and K0108 devices that fundamentally contradicts the coding rules CMS applies to all other DME.

And CMS plans to use a payment methodology that does not follow the structure Congress established for the DME fee schedules under the Social Security Act (SSA) which are founded on the premise that Medicare will pay comparable amounts for similar items. This is evident by the terms of the new code "descriptors" that group dissimilar items according to questionable payment thresholds because they do not have any design, technical or clinical functions in common. CMS' choice of pricing levels for code descriptors also results in arbitrary payment amounts. To this extent, the Agency's proposal lacks grounding in logic and common sense and would result in gross under or overpayment of certain DME items.

AAHomecare believes the approach CMS has suggested is misguided. Miscellaneous codes describe items that are unique or used infrequently and that generally do not warrant their own codes. By definition these items are "miscellaneous" and incomparable with any other item. They are fundamentally different from other DME and from each other and cannot be grouped together under one code and descriptor. CMS' rules for assigning HCPCS codes state clearly that the Agency assigns products to codes based on

¹ <http://cms.hhs.gov/Medicare/Coding/MedHCPCSGenInfo/>

² *Ibid.*

their similarity in function or therapeutic effectiveness, among other criteria.³ And the code descriptor captures the functionality or salient features of products in the code, establishing a coherent HCPCS coding methodology that has been in place for as long as Medicare has been processing DME claims.

CMS' decision to designate HCPCS code descriptors based on price thresholds for DME products rather than their clinical function or the salient features of the technology, is arbitrary and undermines the central premise that similar products will be reimbursed at comparable rates that underlies the fee schedules. This premise was almost certainly influenced by the HCPCS coding system for classifying comparable DME CMS had established.⁴

AAHomecare recommends that CMS withdraw the proposal to create new codes for miscellaneous DME based on the item's price. We recommend that the Agency retain the current miscellaneous codes and pricing methodology based on the contractor's individual consideration for the item. We describe our recommendations in more detail below.

CMS developed through statements of policy and consistent application over a 25 year period a coherent HCPCS coding system for classifying similar DME devices according to common features like their design, technology, clinical function or effectiveness.

CMS cannot depart from its longstanding rules for assigning HCPCS codes to DME items without publishing a notice in the Federal Register with a 60 day public comment period.

AAHomecare understands CMS' argument that the changes the Agency is proposing are only internal coding requests that do not otherwise trigger public notice. But the proposal CMS announced last week goes beyond a simple coding change. CMS plans to terminate rules for billing and payment of miscellaneous DME that have been in place for nearly 25 years and replace them with new rules that depart radically from the coding rules CMS established through policy statements and long standing practice.

CMS began using HCPCS codes in 1978 to create a standard system for billing items and services used in the delivery of health care.⁵ Through longstanding practice and Agency statements of policy, CMS developed a coherent coding methodology with an inherent logic for assigning codes. As CMS noted in the most recent policy statement available on the Agency's website:

The *HCPCS* level II coding system is a comprehensive and standardized system that *classifies similar products* that are medical in nature *into categories* for the purpose of efficient claims processing. For *each* alphanumeric *HCPCS code*, there is *descriptive terminology* that *identifies a category of like items*.⁶

³ HCPCS Level II Coding Process & Criteria, available at:

<http://cms.hhs.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html>; *HCPCS Decision Tree and Definitions for External Requests to Add or Revise Codes*, (October 16, 2006), available at: *Ibid.*

⁴The Medicare HCPCS coding system preceded the fee schedule legislation by just over ten years. See *e.g.*, *NEW CMS CODING CHANGES WILL HELP BENEFICIARIES IMPROVEMENTS WILL SPEED USE OF TECHNOLOGY*, (October 6, 2004), available at: <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html>, stating:

The Healthcare Common Procedure Coding System (HCPCS) was established in 1978 to provide a standardized coding system for describing the specific items and services provided in the delivery of health care.

⁵ *Ibid.*

⁶ HCPCS Level II Coding Process & Criteria, available at:

<http://cms.hhs.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html>

HCPCS are comprised of a single letter that typically identifies the type of product in a code, like a supply item or DME, followed by a series of numbers. Each HCPCS code also has a descriptor that identifies and defines the items in the code. The descriptors reinforce the coding logic that underlies the HCPCS system because, in the Agency's words, "The descriptors of the codes identify a category of like items or services . . . [.]"⁷

So, over a period of 25 years, CMS created a coding methodology from the rules the Agency established for the HCPCS coding system and the coding logic inherent in its practice of assigning codes and descriptors. Congress recognized the HCPCS code set as a coherent, comprehensive system governed by internal logic when it designated the HCPCS coding system as a standard code set for reporting health care transactions under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. CMS is the designated maintenance organization for the code set under HIPAA.

We recognize that CMS has latitude in making coding determinations. But its discretionary authority applies to coding decisions only when those decisions conform to the Agency's own rules. In this case, CMS is proposing coding actions that radically depart from the Agency's rules. The Agency wants to establish codes for dissimilar products by using pricing thresholds as descriptors. CMS' rules for assigning HCPCS codes state clearly that the Agency assigns products to codes based on their similarity in function or therapeutic effectiveness, among other criteria. And the code descriptor captures the functionality or salient features of products in the code.

The Agency's longstanding instruction has been that DME items "not otherwise specified" by a HCPCS code must be billed using E1399, or K0108 if the item is used with a wheelchair, and contractors must process these claims using individual consideration (IC).⁸ Now, after giving suppliers just a little over a week's notice, the Agency is proposing to create six new miscellaneous codes to describe thousands of disparate items based on ill-fitting payment categories and to adopt new fee schedule amounts for items CMS has always paid under IC.

When an agency engages in a longstanding policy or practice, as CMS has in this case, the policy becomes engrained as an interpretation of the agency's rules and the agency must use public notice and comment if it intends to depart from the practice.⁹ CMS cannot suddenly change this practice without broadly disseminating a notice of the proposed changes in the Federal Register with a 60 day public comment period. So, at a minimum, we believe that CMS must withdraw the proposal for new miscellaneous codes and fee schedule amounts and start over with a notice in the Federal Register and a new 60 day comment period to initiate formal rulemaking proceedings. This is essential, especially in light of the short notice AAHomecare and others have had to respond the Agency's request for comments.

⁷ *Ibid.*

⁸ See e.g., *The Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Repairs and Replacements*, available at:

https://www.cms.gov/.../DME_Repair_Replacement_Factsheet_ICN905283, stating in part:

Miscellaneous parts that are not identified by a specific HCPCS code are billed using HCPCS code K0108 if they are for a wheelchair or E1399 if they are for other items and paid based on the contractor's individual consideration of each claim.

⁹ *Mercy Med. Skilled Nursing Facility v. Thompson*, 2004 WL 3541332, at 1 (D D.C. May 14, 2004), citing, *Alaska Professional Hunters Association, Inc. v. FAA*, 177 F. 3d 1030 (D.C. Cir. 1999) (holding that departures from longstanding agency practice must occur through rulemaking).

The proposed coding action is inconsistent with the SSA which requires CMS to keep coding, coverage and pricing determinations separate.

CMS' proposed new payment determinations for miscellaneous DME lack any grounding in common sense.

Congress designed different procedural mechanisms for making coverage and payment determinations, and CMS is required to ensure that those processes remain separate.¹⁰ The same holds true for coding actions which Congress acknowledged under § 553 (b) BIPA are separate from coverage and payment determinations. CMS has itself reinforced these distinctions by way of frequent policy statements that coding, coverage and payment require separate determinations:

HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.¹¹

For DME, payment occurs under fee schedules derived from average reasonable charge data from the fee schedule base year 1986–1987. Our experience has been that CMS adheres to and applies a strict interpretation of the fee schedule statute and the requirement that DME items fall within the literal terms of that statute for reimbursement purposes. Recently for example, CMS changed the payment category for DME items that were “expensive” and not “routinely purchased at least 75% or more of the time” during the fee schedule base year to the “capped” payment category because the items did not exist between July 1, 1986 through June 30, 1987.¹² This is why we are surprised to see CMS propose such a radical departure from the DME fee schedule rules by way of a coding decision.

Information from notice does not support the Agency's assertion it will create fee schedules using the DME payment categories. Congress adopted the fee schedules on the premise that Medicare would pay comparable amounts for comparable items, relying at least in part on the HCPCS coding system CMS created. There are literally thousands of miscellaneous items that fall into any of the new codes, and CMS has not said how it will reconcile “charges” for these disparate items using the statutory formulas. And in some cases the statutory methodology may be incorrect altogether because CMS' payment policy requires the Agency to use gap-filling to set payment amounts for new technology that did not exist during the fee schedule base year

As it stands, CMS appears to have randomly assigned products to one of six codes based on the Agency's determination of the item's price. But that determination is itself arbitrary. How did the Agency decide what price to use – was it the MSRP, for example? Assuming, without conceding, that CMS could proceed in this direction, there is no transparency on what products were assigned to which codes, the criteria CMS used to establish cut-off points for the new code “descriptors,” or how CMS handled new technology that did not exist during the fee schedule base year.

¹⁰ See *e.g.*, *Hayes v. Sebelius*, 589 3d 1279(D. D.C. 2009) (holding that CMS could not use a least costly alternative policy in an LCD to by-pass the statutory reimbursement policy for brand name drugs Congress enacted under the Medicare Modernization Act of 2003).

¹¹ HCPCS Level II Coding Process & Criteria, available at:

<http://cms.hhs.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html>

¹² Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 78 FR 72156-01 (December 22, 2013)

The Agency has lumped together “not otherwise classified” DME and assigned new payment amounts to these dissimilar items ranging in price from less than \$1.00 to up to \$150.00. The resulting reimbursement is arbitrary and irrational: payment for some items will be grossly excessive while for others it will be grossly deficient. The same is true for rental items. Again, CMS will either grossly over pay or under pay for an item, removing any possible justification for the Agency’s proposal.

Equally important, as we stated above, we believe CMS cannot use payment thresholds as code descriptors under the HCPCS coding methodology CMS adopted and which now serves a standard code set for health care transactions under HIPAA. CMS has itself stated innumerable times that the code descriptors: “describe products with . . . [f]unctions similar to the item in the cod[e].”¹³ Assigning inherently dissimilar items to the same code using arbitrary payment amounts for code descriptors violates the Agency’s rules. And because all payers and providers must use the codes, CMS should not be able to unilaterally create codes that do not conform to the logic inherent in the code set.

CMS’ decision to depart from the coding methodology it created and instead designate HCPCS code descriptors based on the price of DME products rather than their clinical function or the salient features of the technology, is misguided and contradicts the basic structure and mandates of the fee schedules and the internal coding logic of the code set. AAHomecare recommends that CMS withdraw the miscellaneous coding proposal.

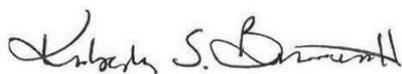
AAHomecare recommends that CMS withdraw the miscellaneous coding and payment proposal and retain instead the current miscellaneous codes and reimbursement based on IC.

In the alternative, if CMS decides to move ahead with this plan, CMS has to withdraw the proposal and proceed with a notice and comment rulemaking proceeding via the Federal Register.

AAHomecare recommends that CMS withdraw the proposal to create new codes for miscellaneous DME based on the item’s price. We recommend that the Agency retain the current miscellaneous codes and pricing methodology based on the contractor’s individual consideration for the item. If CMS moves forward with this proposal, then it must do so using formal notice and comment rulemaking by publishing a request for comments in the Federal Register.

Thank you for the opportunity to submit these comments.

Sincerely,



Kimberley S. Brummett, MBA
Vice President for Regulatory Affairs

¹³ HCPCS Level II Coding Process & Criteria, available at:
<http://cms.hhs.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html>