ALLIANCE FOR
HCPCS II CODING REFORM
creating a transparent, fair and predictable system

March 12, 2015

VIA ELECTRONIC MAIL

Chairman Fred Upton
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

RE: Comments to 21st Century Cures Act: Suggested HCPCS Coding Process Reforms

Dear Chairman Upton and Ranking Member Pallone,

The current Healthcare Common Procedure Coding System (HCPCS) coding process for Level II alpha-numeric codes used by Medicare, Medicaid, and private health plans (particularly for durable medical equipment, orthotics, prosthetics and supplies [DMEPOS]) is not transparent, understandable or predictable. Over many years, this has created strong barriers to appropriate coverage and reimbursement for new technologies and products. The current process has a chilling effect on innovation that drives researchers and R&D investments away from DMEPOS, ultimately compromising access to quality care for millions of Medicare beneficiaries and other individuals. Although this process is administered by the Centers for Medicare and Medicaid Services, this badly flawed process impacts Medicare and all payers using the uniform code set. Reform is needed to ensure the goals of a meaningful code set are met, namely, uniformity in billing, appropriate coverage and reimbursement policies, and patient access to quality care.

Included below are recommendations for your consideration to be included in the 21st Century Cures Act when it is introduced in final form. Given the overall purpose of that proposed legislation, these recommendations for HCPCS Level II coding reform fit well within the confines of that proposed legislation. The members of the Alliance would be pleased to speak with you at your convenience about our concerns regarding the HCPCS coding process as well as about our recommendations.

The Alliance for HCPCS II Coding Reform ("Alliance") was formed in May 2008 to seek improvements to the HCPCS coding process so that it is fair, transparent, predictable, accurate, understandable, timely, accountable, efficient and independent of any individual payer's coverage and payment considerations. An improved HCPCS Level II coding process would allow meaningful consumer access to technology, regardless of payer. The Alliance is comprised of key law firms, lobbying firms, associations, coalitions, medical device companies and

reimbursement consulting companies with expertise in HCPCS coding who recognize the need to take action to reform the HCPCS coding system.

We have met over the years with the Centers for Medicare and Medicaid Services (CMS) senior staff; unfortunately, they have been reluctant to make the significant changes that would be meaningful to the process. This is why we believe that it is imperative to have legislative action on this important issue.

The fundamental problems we have identified with the current HCPCS decision process are as follows:

1. The current HCPCS Level II code set includes broadly defined codes that are ambiguous and imprecise, resulting in dissimilar technologies being lumped into the same code. This challenges coverage policy development and creates barriers to comparative effectiveness research that could provide evidence to inform improvements to coverage and policy decisions. In addition, it leads to improper payment determinations that oftentimes create barriers to access of medically necessary devices and technologies.

2. The coding process is not transparent, predictable, or timely. The criteria used to justify issuing or modifying codes are often undefined, have never been subject to public notice and comment, and seem to be applied inconsistently from year to year. In addition, there is no assurance that coding decisions give appropriate weight to scientific and clinical trial evidence that may distinguish an item or service from existing items or services with HCPCS codes. The composition of the HCPCS Workgroup at CMS has never been disclosed publicly, and the Workgroup has never included stakeholders in the decision-making process. CMS also does not allow for advance notice and stakeholder feedback when it decides unilaterally to delete or modify certain existing HCPCS codes outside the external application process. Finally, there is no reconsideration/appeal process other than resubmission of the application in the next annual coding cycle; this insulates the process from any form of accountability and causes delays of at least one year in patient access to these products.

3. The coding process improperly commingles Medicare coverage decisions with coding decisions. The factors involved in justifying creation of a new billing code are separate and distinct from the factors involved in justifying coverage of a particular device or technology to meet the needs of a specific payer's enrollees. In fact, this distinction is well-recognized in the laws and precedents that apply to the Medicare program. Nevertheless, the current process results in CMS making coverage decisions for all payers and often overlooks non-government-supported health plans that have coverage and payment policies that may be different from Medicare and serve different patient populations.

4. Outside of the HCPCS coding process (where existing codes are modified and new codes are created), the coding verification process administered by the Pricing, Data Analysis, and Coding (PDAC) contractor is also in need of reform in order for manufacturers, suppliers, and providers to obtain clear guidance on accurate coding. This coding verification process also needs to separate coverage from coding criteria and to eliminate the problems associated with the reassignment of HCPCS codes which may immediately result in change of coverage of products and technologies.

To address these significant problems with the HCPCS Level II coding process, we offer the following recommendations:

1. Recommendation: Increase Transparency of Coding Decisions.

i. HCPCS Workgroup Responsibilities: There should be a mechanism in place for each representative on the HCPCS Workgroup to obtain comments regarding HCPCS coding needs and information on the submitted applications so as to represent their constituency. Representatives should have the explicit responsibility to listen to stakeholder groups and individuals who wish to inform them of facts and circumstances involving coding decisions.

ii. Public Accountability: CMS should publish the names, affiliations, and titles of the CMS HCPCS Workgroup members. The identities of the Workgroup members should be a matter of public record and CMS should explicitly permit direct contact between coding applicants and Workgroup members throughout the year.

iii. Robust Representation on the HCPCS Workgroup: A more robust representation of Medicaid, Veterans Health Administration (VA), and commercial payers should be involved in the coding process to meet the needs of diverse populations. CMS should meaningfully engage, *throughout the entire coding process*, Medicaid, VA, and commercial payers to a greater extent to obtain their opinions on current HCPCS code applications and determine their HCPCS coding needs. CMS should clarify and formalize the process for Medicaid and commercial payers to ensure that their coding needs or program operating needs are identified and given adequate consideration by the HCPCS Working Group.

iv. Detail Reasons for Denial: Reasons for denial currently used by CMS in this process should be explained with greater specificity. To be fair, CMS has made improvements in this area over the past several years. The reasons for denial form the basis for the changes to the applicant's revised coding application for the following cycle and as a result these reasons therefore need to be sufficiently detailed to provide clarity and avoid unnecessary waste of time and resources. If CMS denies an application for a new HCPCS code, the letter should specify both the rationale for the decision not to issue a new code and explain what information the applicant needs to provide in future applications to achieve a favorable code result.

v. One-on-One Consultation: CMS should provide applicants with an opportunity to meet in person with CMS Workgroup staff before a preliminary decision is made to ensure that the HCPCS Coding Workgroup fully understands the devices and technologies being considered, and so that applicants may advance their rationale for a new code or codes.

vi. Mechanism for Applicant to Withdraw HCPCS Code Application. CMS should work with stakeholders to develop a timeline, process and circumstances under which an applicant may withdraw an application for the current HCPCS coding year.

2. Recommendation: Clearly Separate the Criteria Used to Establish a New HCPCS Code from Criteria Used to Establish Coverage Policy.

i. Purge Coverage Criteria from Coding Decisions: Revise CMS's current *coding* "Decision Tree" to reflect that coding decisions are based on criteria that are separate and distinct from the criteria used to make *coverage* decisions for the same device or product. We recommend the following criteria to establish a new code. The device or product:

1. Performs a different function (does something clinically different for the patient) than a previously coded product; OR

2. Operates differently; OR

3. Is a distinct technology (e.g., components, materials of construction, structural features, size, mechanism of action are distinctly different from existing technology); OR

4. Meets a distinct patient or clinical need (e.g., there is a distinct patient population that benefits from the use of this device, or there are significant clinical indications or uses that are distinct from existing codes.)

ii. Conformity with New Coding Criteria: CMS should be required to revise its HCPCS Coding "Decision Tree" to conform with the criteria listed immediately above and the additional suggestions below:

1. Provide a clearer definition of what constitutes a "national program operating need" (in order to establish a new billing code) by commercial payers, Medicaid programs, as well as other payers and stakeholders by developing specific criteria to be met. We recommend revising the definition of the term "national program operating need" so that if one sector (defined as a payer, i.e., one Medicaid program, one commercial plan) supports the issuance of a new code, a national program operating need shall be recognized. To validate this request, the applicant would submit one letter from the one payer to CMS as part of the HCPCS application. In addition, the current requirement that an applicant demonstrate significant therapeutic distinction should be removed because it often comingles coverage with coding considerations; instead, the new decision tree criteria described above should be substituted.
2. Add additional objective data to support the sales volume criteria that would demonstrate significant product demand in the marketplace such as sales trend reports and product feasibility studies. (*See* new definition for sales volume criteria.).
3. Restrict the current practice of revising code descriptors to expand the scope of an existing code; this practice makes the coding system inaccurate and/or imprecise, leading to opportunities for abuse.

3. Recommendation: Establish an Appeals Process to Provide Independent Review/Reconsideration of Coding Decisions.

i. Establish the Right to Appeal Coding Decisions: HCPCS coding applicants who receive adverse coding decisions should have a right to appeal the decision to a HCPCS Coding Appeals Board. The applicant should be granted an informal, in-person hearing with the appeals board within the 90-day period and prior to a final decision being made, providing the applicant with an opportunity to discuss the application, answer any questions, and address CMS' previous decision rationale. The appeals board should be comprised of a representative sample of individuals who serve on the HCPCS Workgroup, including Medicaid, VA, and private insurance representation as well as either the Director or Deputy Director of the CMS Chronic Care Policy Group to provide historical context and expertise to the coding decision. The board should be required to solicit external physicians and other health care professionals and suppliers with expertise in the specific subject of the coding application at issue to assist the appeals board in rendering a final coding decision. If the coding decision is changed as a result of the appeal, the new or revised code and fee schedule would be implemented in the next HCPCS quarterly update.

4. Recommendation: PDAC Coding Verification Process Must be Improved

i. Proper Notice and Comment of All Coding Changes: All revisions, deletions, consolidations and changes to code criteria of HCPCS codes announced by the PDAC must first be published on the DME MAC websites and supplier publications in draft form with reasonable time for public comment before any HCPCS coding change becomes final and effective. This would not rise to the level of public notice and comment procedures under the Administrative Procedures Act.

ii. Greater Access to the PDAC: PDAC officials should meet with coding verification applicants to discuss the product(s) at issue. In addition, key PDAC decision makers should be required to keep periodic office hours at CMS central in Baltimore, Maryland in order to permit small businesses and manufacturers to more easily engage the PDAC in coding verification discussions.

iii. Pediatric Coding: CMS should develop a mechanism for coding verifications for pediatric products or otherwise work with Medicaid programs to eliminate the requirements for obtaining PDAC code verification. (For example, the PDAC currently declines to conduct coding verification for pediatric products.)

iv. Coverage Information Separate from Coding: Consistent with our recommended standard for separate consideration of coverage and coding for new and revised codes, the PDAC should never use coverage information in the code verification process**.**

v. Independent Reviewers for Reconsideration Appeals. Independent reviewers should be engaged during the appeals process. External physicians and other health care

professionals and suppliers with expertise in the specific subject of the coding re-verification could serve as advisors in rendering a final coding decision.

The Alliance for HCPCS II Coding Reform appreciates the opportunity to submit these comments to you for consideration of inclusion in the 21st Century Cures Act. We stand ready to meet with you to discuss these issue in more depth at your convenience. Thank you.

Sincerely,

Marcia Nusgart R.Ph.
Alliance for HCPCS Coding Reform Participants who include but are not limited to:*

John Broughton; Medela, Inc.
Grant Bagley; ADVI (formerly HillCo Health)
Kim Brummett; American Association for Homecare
Donald Clayback; National Coalition for Assistive and Rehab Technology
Jennifer Hutter; J.D. Hutter and Associates LLC
Seth Johnson; Pride Mobility Products Corp.
Stuart S. Kurlander; Latham & Watkins LLP
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Marcia Nusgart; Coalition of Wound Care Manufacturers
Lynn Shapiro Snyder; Robert Wanerman; Epstein Becker and Green
Rita Stanley; Sunrise Medical
Peter Thomas; Powers, Pyles, Sutter and Verville PC
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