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

August 15, 2017

VIA ELECTRONIC MAIL

The Honorable Tom Price
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Regulatory Relief for Health Care Providers, Suppliers and Manufacturers: Recommendations for HCPCS Level II Coding Process Improvements

Dear Secretary Price and Administrator Verma:

We are writing to alert you to a Medicare policy issue that, we believe, is ripe for the application of regulatory relief: reform of the process used by the Centers for Medicare and Medicaid Services (CMS) to assign new Healthcare Common Procedure Coding System (HCPCS) Level II billing codes to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The undersigned are members of the Alliance for HCPCS II Coding Reform and other interested stakeholders who share the goal of improving, streamlining, and making the HCPCS Level II code set maintenance process more accountable and transparent.

We have worked with CMS officials responsible for the HCPCS code set over the past decade to improve this process. Unfortunately, to date only incremental changes have been made that do not address the more significant deficiencies with the process. The need to make these improvements stems from a longstanding history of concerns with the HCPCS Level II coding process. The process restricts patient access to certain devices, products, and technologies, stifles innovation, and fails to keep current with important technological developments. The failure to issue a code can also impact products which are used outside of a Medicare population because of the influence of CMS's coding decisions on other payers. As a result, patients have restricted access to medically necessary products designed to treat specific medical conditions. As the May 1998 GAO study "Need to Overhaul Costly Payment System for Medical Equipment and Supplies" summarized, "the current process results in codes that are so broad as to render CMS unable to identify what products Medicare contractors are reimbursing when they process claims." (see GAO/HEHS-98-102 Medicare DME Payments).

Despite repeated discussions with CMS staff over the years, our concerns with the HCPCS Level II coding process persist—leaving providers, manufacturers, payers and most importantly,

patients, with a coding system that inadequately describes the products that are being provided and billed.

In prior discussions with senior CMS officials, we were asked to develop a prioritized list of recommendations that we would like CMS to consider in making improvements. In response, we developed the attached set of consensus priority recommendations. Additional detail is provided in the attachments, but on a high level, we recommend that CMS:

1. Increase transparency of coding decisions and adopt procedural protections to enable stakeholders to participate in the coding decision process, including a mechanism for stakeholders to respond to coding decisions. We further recommend the creation of a HCPCS Level II Coding Advisory Committee to assist the HCPCS Coding Workgroup;

2. Clearly separate the criteria used to establish a new HCPCS code (or verify use of an existing code) from criteria used to establish a coverage policy for the product(s) described by that code. Coverage criteria should never be considered when making coding decisions;

3. Establish a transparent appeals process to provide an independent review or reconsideration of coding decisions; and

4. Improve the coding verification process used by the Medicare Pricing, Data Analysis and Coding contractor (the "PDAC"), as well as the CMS-initiated code revision process (e.g., for internal or modifying code descriptor).

We believe these recommendations will ultimately help improve patient access to medically necessary products and should therefore be embraced by HHS and CMS and adopted as expeditiously as possible.

We would welcome an opportunity to meet with both of you and your staffs to discuss our recommendations in more detail and to answer any questions you may have.

Thank you, in advance, for your consideration of our request.

Sincerely,

Academy of Spinal Cord Injury Professionals
ACCSES
Acelity, Amy Law
Advanced Medical Technology Association (AdvaMed)
Alliance of Wound Care Stakeholders, Marcia Nusgart
American Academy of Orthotists and Prosthetists
American Academy of Physical Medicine and Rehabilitation
American Association for Homecare, Kim Brummett
American Association on Health and Disability
American Board for Certification in Orthotics, Prosthetics, and Pedorthics
American Cochlear Implant Alliance
American Congress of Rehabilitation Medicine

American Foundation for the Blind
American Medical Rehabilitation Providers Association
American Orthotics and Prosthetics Association, Thomas F. Fise
American Physical Therapy Association, Kara Gainer
American Professional Wound Care Association, Steven J. Kavros, Jeffrey D. Lehrman
American Therapeutic Recreation Association
Amputee Coalition
Association for Education and Rehabilitation of the Blind and Visually Impaired (AER)
Association for the Advancement in Wound Care, Greg Bohn
Association of Assistive Technology Act Programs
Avalere Health, Abby Moorman
Board of Certification/Accreditation
Boston Biomedical, Randel Richner
Brain Injury Association of America
Christopher and Dana Reeve Foundation
Clinician Task Force
Coalition of Wound Care Manufacturers, Karen Ravitz
Epstein Becker and Green, Lynn Shapiro Snyder, Robert Wanerman
Institute for Matching Person & Technology, Inc.
J.D. Hutter and Associates LLC, Jennifer Hutter
J.D. Lymon, Jolayne Devers
Lakeshore Foundation
Latham & Watkins LLP, Eric Greig, Stuart S. Kurlander
Medical Device Manufacturers Association (MDMA)
National Association for the Advancement of Orthotics and Prosthetics
National Association for the Support of Long Term Care, Cynthia K. Morton
Paralyzed Veterans of America
Patient Access to Computerized Exoskeleton Coalition (Ekso Bionics, Parker Hannifin Corporation, and ReWalk).
Powers, Pyles, Sutter and Verville PC, Peter Thomas
Rees Smith LLP, Gail Daubert
ResMed, Christopher Salmen
RESNA, The Rehabilitation Engineering and Assistive Technology Society of North America
Smith & Nephew, Randall R. Carson
Sunrise Medical, Rita Stanley
The Myositis Association
The Simon Foundation for Continence
Unite 2 Fight Paralysis
United Spinal Association
Visiting Nurses Association of America, Joy Cameron
Wells Health Group, Debra Wells
Wound Zoom, Inc., Tom Whelan

cc: Kyle McGowan (Director, External Affairs, HHS)
Demetrios Kouzoukas (CMS Deputy Administrator and Director)
Carla DiBlasio (Senior Advisor, Office of the Administrator)

Background

Section 1173 of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requires the Secretary of Health and Human Services to select and establish uniform "code sets" for health care claims and payment, distribute these code sets for widespread and consistent use by all payers, and make modifications as necessary.

CMS established and operates the HCPCS Workgroup for the purpose of establishing Level II HCPCS codes as a uniform code set for medical devices, including durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"), as well as other drugs and biologics.

In implementing its functions, CMS routinely makes decisions involving this uniform code set based on factors that disproportionately impact Medicare beneficiaries, without seemingly sufficient consideration of the needs of individuals covered under the Medicaid or U.S. Department of Veterans Affairs (VA) programs or enrollees in private health plans. This must be corrected to perform the Secretary's congressionally intended role of developing and maintaining a uniform code set that all payers can use.

We believe the current HCPCS coding process is not sufficiently transparent, predictable or timely. The criteria used to issue new HCPCS Level II codes appears to be applied in an inconsistent manner. Additionally, the composition and operation mandates of the HCPCS Workgroup are not transparent. Improving the transparency of the process will allow persons applying for HCPCS Level II codes to have more predictability regarding the expected outcome of the process.

While Medicaid and commercial payer representatives participate on the HCPCS workgroup, the process by which they participate should be more transparent so that stakeholders are better able to understand how these representatives engage on behalf of their affected constituents.

Further, the current HCPCS coding process improperly applies criteria used to determine Medicare coverage decisions in making coding decisions.

The current HCPCS code set includes broadly defined codes that are often ambiguous and imprecise, resulting in dissimilar products and technologies being lumped into the same code. This creates potential program integrity concerns. The use of codes that are not sufficiently granular to describe the items and related services being provided leads to improper payments and creates barriers to access of medically necessary devices and technologies. Because HCPCS codes do not identify homogeneous items and services, it is difficult to measure clinical outcomes data at the code level. This impedes the ability of payers to effectively use claims data to inform improvements to coverage and payment decisions in the future.

The grouping of heterogeneous products into a single HCPCS code has an additional negative impact on Medicare beneficiaries. The Advanced Beneficiary Notice (ABN) is a tool that allows suppliers and providers to notify beneficiaries of situations where Medicare payment will likely be denied. The ABN is also used when a beneficiary prefers to receive a technology that better meets their needs and the beneficiary is willing to pay out-of-pocket for the difference between the Medicare fee schedule for the medically necessary product and the out-of-pocket cost of the

deluxe featured product, otherwise known as a beneficiary upgrade. CMS does not allow an ABN to be used for beneficiary upgrades when both the product Medicare would pay for and the upgraded product are in the same HCPCS code. The CMS practice of grouping a wide array of product features and functions into a single HCPCS code prevents beneficiaries from applying their Medicare benefit towards the cost of the technology that provides them more value. The broad coding practice prohibits beneficiaries from making important decisions about the value of products used in their care and treatment.

The requirement that a HCPCS application submitted by a device manufacturer must provide 3 months of sales data is onerous and can hinder Medicare beneficiary access to necessary and innovative devices and technologies. We understand the need to consider potential utilization of a new HCPCS code in determining whether a unique code is required. However, depending on when a new product is launched, the sales data required by the HCPCS application may not be representative of actual/projected sales for an item. Additionally, the lack of a HCPCS code has a direct and negative impact on sales. The HCPCS code process should provide an alternative mechanism for substantiating product sales so as not to hinder code issuance and beneficiary access to necessary and innovative devices and technologies.

Perhaps the most troubling aspect of the process is the fact that there is no reconsideration/appeal process other than resubmission of the application in the next coding cycle, resulting in a minimum one-year delay of patient access to these products. The end result of this coding system is restricted patient access to new devices and technologies due to what appears to be a CMS bias against creating new codes.

Deficiencies with the process are underscored by decreases in the number of applications submitted and in the number of new DMEPOS codes that are granted each year. (See Attachment No. 1; Note: this information is based on the best available public information). In CY 2007, CMS received 171 HCPCS applications of which 35 requests were approved. In CY 2017, CMS received only 78 DMEPOS applications, reflecting 68 requests for new codes and 9 requests to revise existing codes. In the preliminary decisions issued by the HCPCS Workgroup only 7 new codes were approved and 5 code descriptors were revised. The decline in applications coupled with the low number of approvals illustrates a pattern of CMS not issuing new codes.

In almost all cases, the rationale for not creating a new code was that there was no national program operating need (28 times) or the product fits into an existing code (37 times). Although these were the preliminary decisions (and are subject to change), these numbers reflect the steady decline of applications being submitted and codes being issued. They also suggest that the HCPCS Workgroup's rationale for not issuing new codes is often not understood by applicants. This lack of transparency frequently extends to the final HCPCS decision letter to the applicant wherein the CMS HCPCS Workgroup does not provide a detailed rationale, if one is provided at all, for its decisions to not issue a new code. In instances where a decision is made to not issue a new or revised code it is important that the HCPCS panel/workgroup provide a detailed and understandable rationale for their determination. This is imperative since the reasons for denial form the basis for the changes to the applicant's revised coding application for the following cycle.

In summary, inadequate and inappropriate coding has a chilling effect on investment in research and innovation in the area of assistive devices, products, and technologies and curtails access to

these innovative products by the patients who need them. With these significant deficiencies in mind, we urge CMS to seriously consider and implement the following priority recommendations as expeditiously as possible.

HCPCS Level II Coding Reform Recommendations

1. Recommendation: Increase Transparency of Coding Decisions.

i. HCPCS Workgroup Responsibilities: There should be a mechanism in place, outside of the HCPCS meetings, for stakeholders to provide information to HCPCS workgroup members regarding their coding applications. Representatives should engage with stakeholder groups and individuals who wish to inform them of facts and circumstances involving coding decisions.

   1. Advisory Committee: CMS should establish an advisory committee, comprised of external stakeholders, in compliance with the Federal Advisory Committee Act (FACA) to advise the HCPCS Workgroup. This advisory committee would provide CMS with clinical, technical and regulatory expertise to assist in making informed coding decisions. The advisory committee should be comprised of representatives with DMEPOS expertise including pediatrics, people with disabilities and chronic conditions, beneficiary organizations, specialty physicians, rehabilitation and wound care professionals, orthotic and prosthetic clinicians, DME providers, and manufacturers. The advisory committee would review applications, make recommendations to the HCPCS workgroup, and collaborate with the HCPCS Workgroup to define the threshold for objective metrics when defining the national program operating need.

   2. 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 create a mechanism for facilitating contact between coding applicants and Workgroup members.

ii. Transparent Process for Obtaining Input from Medicaid, VA and Commercial Payers: While there are Medicaid and commercial payer representation on the HCPCS workgroup, there must be a formalized and fully transparent process to understand the mechanism by which these groups are engaged by the HCPCS Workgroup to obtain their opinions on current HCPCS code applications and to determine how their HCPCS coding or program operational needs are identified and given adequate consideration by the HCPCS Workgroup. It is also important to identify how they reach out to their constituents to obtain input for both their coding needs and for feedback on HCPCS coding applications that the payer needs to make decisions on for their role in the HCPCS Coding Workgroup.

iii. Timely Public Notice of Coding Decisions: CMS has posted the final coding decisions on its website since 2016 by updating the already existing HCPCS public

meeting agendas and summaries with the final decision. We would request that if the decision was changed or the coding request denied, that a detailed reason for the denial (see below) also be included and that the posting be at the same time when the coding decisions are made public. We would also request that these coding decisions remain on the CMS website for 5 years for historical memory.

iv. Detail Reasons for Denial: Reasons for denial currently used by CMS in this process should be explained with greater specificity (e.g., "no national program operating need") and defined in greater detail. While CMS has made improvements in this area over the past several years, these reasons for denial need to be sufficiently detailed since they form the basis for the changes to the applicant's revised coding application for the following cycle. The CMS coding letters to applicants must not only specify the rationale for the decision not to issue a new code, but also specify what information was lacking in the application that led to the unfavorable result and consequently, what information the applicant needs to provide in future applications to achieve a favorable coding result. Stakeholders have heard from CMS staff that there is opposition to having the agency post more detail regarding denied applications. We do not agree with this statement and assert that stakeholders are open to working with CMS staff to determine an appropriate level of information that can and should be posted regarding these denied requests.

v. Improvements to CMS Public Meetings: While it is important to have the primary speaker in-person at the meeting, we believe that CMS should allow the 5 minute speakers to give their testimonies via conference call. For some applicants, attending the HCPCS public meeting in-person involves significant travel cost and can be burdensome. Having the opportunity to participate via conference call would allow for broader participation. We also request that CMS provide at least 30 days between release of the HCPCS preliminary coding decisions and the deadlines for identifying primary speakers and submitting materials for the meetings. (In 2017, there were only 10 days between release of the preliminary coding decisions for the June 7-8 meetings and the deadline for submission of presentation materials [May 14 release and May 24th deadline for presentation materials]). These very constrained timelines to prepare for the HCPCS meeting do not allow adequate preparation by applicants and may compromise the quality of their presentations and the subsequent outcome of those presentations.

vi. One-on-One Consultation: CMS should provide applicants with an opportunity to engage (meeting or conference call) with CMS Workgroup members and staff under the following conditions:

    1. 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.
    2. After the preliminary coding decisions to discuss any questions related to the preliminary coding decision.
    3. Up to 30 days after the last HCPCS public meeting to discuss any additional information.

In addition, applicants should receive notice when their applications are a part of the monthly HCPCS workgroup coding calls and should be allowed to participate and provide feedback.

vii. Due Process for Deletion of HCPCS Codes: In 2016, CMS conducted a limited demonstration for a web-based notice and comment mechanism allowing public input on requests to discontinue Level II HCPCS codes that are generated internally based on national program operating needs. Comments on the last code that was posted for consideration of discontinuation were due by July 21, 2016. We are supportive of efforts that make the process surrounding deletion or modification of HCPCS Level II codes more transparent and that provide opportunities for stakeholder feedback and would recommend that CMS continue with this project.

viii. Mechanism for Applicant or CMS to Withdraw HCPCS Code Application: CMS should work with stakeholders to develop a timeline, process and circumstances under which an applicant or CMS may withdraw an application for the current HCPCS coding year. Specifically, we request that the applicant be afforded the opportunity to withdraw an application if the Agency determines that the information in the application is not accurate.

2. Recommendation: Clearly Explain the Criteria Used to Establish a New HCPCS Code.

i. Coverage Criteria Should Not be Part of the Coding Decisions: On its face, the HCPCS Level II application and accompanying decision tree appear to lay out a readily understandable process for evaluating requests for new or revised HCPCS codes. However, CMS frequently denies applications for new and revised codes based on the applicant's failure to satisfy the criteria for "significant therapeutic distinctions compared to existing coded treatments or products". There is significant uncertainty regarding what is needed to meet this criterion. The definition included in the decision tree and applications suggest that CMS may be considering factors that are unreasonable when making these determinations including differences in item cost. CMS coding and coverage policy generally prohibits evaluation of a product based on cost impact. Therefore, it seems inappropriate to include this criterion.

Additionally, stakeholder experience suggests that the information submitted to support significantly improved medical outcome or significantly superior clinical outcomes are not being adequately evaluated. This is in part based on the frequent findings that a new code is not merited based on lack of program need or failure to demonstrate significant therapeutic distinction.

We recommend that CMS revise the 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 which is further defined in *Attachment 3- Proposed Revised Definitions and Clarifications for HCPCS Decision Tree.* 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 (mechanically); 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. HCPCS Coding Decision Tree Revisions: *Attachment 2- Alliance HCPCS Decision Tree Revisions and Attachment 3- Proposed Revised Definitions and Clarifications for HCPCS Decision Tree* reflect our recommendations on a revised Decision Tree document and definitions. We recommend the following changes to the criteria listed in the current Decision Tree and CMS adoption of the revised definitions listed in Attachment No. 3

1. Provide a clearer definition of what constitutes a "national program operating need" by developing specific criteria. We recommend revising the definition to show 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. CMS should also identify the payers that were contacted when determining the existence of a national program operating need. The national program operating need could be demonstrated by having the applicant submit one letter from the payer to CMS with the HCPCS application.

2. Remove the significant therapeutic distinction requirement (this criterion often comingles coverage with coding considerations) and add the new criteria stated above to the decision tree.

3. Eliminate the marketing and volume criteria for devices. Currently, CMS requires device manufacturers requesting a HCPCS Level II code to submit evidence of volume in the affected patient population-- as demonstrated by three months of marketing activity data. Drugs are exempted from this requirement. CMS has never offered an explanation for this artificial distinction in the treatment of drugs versus devices. Therefore, the requirements for marketing and volume data should be eliminated for devices.

4. Replace the indefinite use of miscellaneous codes with new and transparent guidelines on when products should transition to unique HCPCS codes

5. Issue more new/distinct codes in lieu of revising code descriptors to expand the scope of an existing code. The practice of repeatedly revising existing codes creates inaccuracies or imprecision in the coding system and may lead to opportunities for abuse.

iii. Coding Application: Recommended Changes to HCPCS Code Application:

1. Clarify 8A- *List any 3rd party payers that pay for this product*—how much information does the applicant need to prove that its product is being covered and paid for under other programs?

2. Eliminate 7c-*Claims of significant therapeutic distinction when compared to the use of other, similar items, must be described in detail.* Since we are recommending the elimination of this criterion in the Decision Tree, this concept should be eliminated in the application.

3. Eliminate question in 11b regarding the reason the product should not be in same code as the predicate device—there are different standards and categories for FDA and CMS. CMS should not use FDA's predicate device standard as a *de facto* coding decision for a unique HCPCS code.

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.

ii. Timeframe to Apply for an Appeal: The applicant would have 30 days following receipt of written notice from CMS denying their code application to request review of the decision and to provide supplemental information addressing the basis for the denial.

iii. CMS Response to Appeal Request: CMS would be required to send a letter to the applicant acknowledging their appeal request within 10 days of receipt. CMS would have 90 days to issue a written decision to the applicant regarding the disposition of their appeal request.

iv. Opportunity to Present Before the Appeals Board: The applicant should be granted an 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.

v. Composition of the Appeals Board: 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 solicit external input from

medical and clinical associations or societies, 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.

vi. Implementation of 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.

vii. Right to Pursue New Application and Appeal Simultaneously: An applicant's decision to appeal a coding decision shall not prevent the applicant from simultaneously resubmitting an application to the HCPCS Coding Workgroup. This will permit the applicant to continue working with CMS to appropriately code the product in the most expeditious manner possible.

viii. Right to Withdraw a Coding Application Appeal: An applicant should have the right to withdraw, without prejudice, a coding application appeal at any time prior to the issuance of a final, written decision.

4. Recommendation: Improvements to the PDAC Coding Verification Process are Needed

i. Proper Notice and Comment of All Coding Changes: All revisions, deletions, consolidations and changes to code criteria for HCPCS codes announced by the PDAC must be published on the DME MAC websites and supplier publications in draft form, with reasonable time for public comment, before being finalized.

ii. Coding Errors: Applicants who identify a coding error should notify the PDAC in writing. If the existence of an error is agreed upon by the applicant and the PDAC said error must be corrected within 30 days of receipt of the applicant's initial written notice to the PDAC. This would include PDAC mailing a corrected letter to the applicant, correcting the coding error on the website, and alerting other payers to this issue. Corrections of coding errors and statutorily-directed revisions should be exempt from the notice and comment provisions recommended above.

iii. Greater Access to the PDAC: PDAC officials should meet with coding verification applicants to discuss the product(s) at issue on a monthly rather than quarterly basis. In addition, key PDAC decision makers should be required to keep periodic office hours at CMS central in Baltimore, Maryland or in locations convenient to the contractor (e.g., Columbia, South Carolina) to allow small businesses and manufacturers to more easily engage the PDAC in coding verification discussions. A coding verification application should not be a prerequisite for a meeting with PDAC officials.

iv. Establish PDAC Advisory Committee. The PDAC should also establish an outside advisory committee, similar to the one established for the HCPCS Workgroup, to obtain external clinical, technological, and regulatory expertise needed to make informed coding decisions. The advisory committee should be comprised of experts

from the key constituencies involved in DMEPOS (e.g., pediatrics, people with disabilities and chronic conditions, beneficiary organizations, specialty physicians, rehabilitation and wound care professionals, orthotic and prosthetic clinicians, DME providers, and product manufacturers). The advisory committee would review applications and make recommendations to the HCPCS workgroup.

v. Coverage Information Separate from Coding: The PDAC should not use coverage information in the code verification process**.**

vi. PDAC website: Non-Medicare payers have the flexibility to classify specific products into HCPCS Level II code categories and to establish their own coding instructions in accordance with their policies and program operating needs. The PDAC should clarify that the information posted on its website is intended for use in the Medicare program and is not binding on other health plans.

vii. Development of HCPCS Code Requirements and Criterion. The PDAC, with the assistance of the recommended Advisory Committee, should have the ability to develop and establish code requirements and criterion.

viii. Coding Criteria Changes: Coding criteria changes in an article (e.g., coding or policy) linked to an LCD may not go into effect until the LCD is finalized.