Draft Advance Briefing Mini-Synopses on Agenda Topics for HHS Briefing, April 27

Regulation & Value Proposition for Replacement Limbs for Amputees & Bracing for the Mobility Impaired:

Issues History

1. August, 2011- CMS Treatment of Prosthetist/Orthotist Clinical Notes,- Prosthetist/orthotist did not alone have authority to prescribe, so a physician's sign-off to a detailed written order has always been required. CMS' DME MAC contractors released a "Dear Physician" letter theoretically responding to an OIG report that errantly attributed higher Medicare spend from 2005-10 to inappropriate payments rather than recognizing changes in technology as well as CPI statutorily required annual fee schedule increases. In this letter, the DME MAC contractors also asserted that the prosthetist/orthotist notes are NOT a legitimate part of the Medicare patient record..

Result: Physicians are expected to not only prescribe but also document in their records, without any scientific training for this, the medical necessity for the individual elements of the prosthetic treatment plan. According to the DME MACs the prosthetic clinical records cannot be used by Medicare contractors to support the medical necessity determination and are deemed to be not part of the medical record.

Impact: RAC and Prepay audit is rampant as new records requirement is applied retroactively to prosthetist claims. Timeliness of patient care is significantly delayed as providers—now dependent on the quality of physician documentation—are responsible for paperwork out of their control.
Surge in claim payment appeals by providers ultimately contributing to the current Administrative Law Judge backlog.

2. July, 2014—CMS proposed a rule that would recognize the essential role of certified orthotists in improved care and reducing costs to Medicare. CMS Definition of "Minimal Self-Adjustment" For purposes of competitive bidding, the only orthotic devices that qualify for inclusion in this program are off-the-shelf orthoses, which the agency defines as requiring minimal self-adjustment. However, CMS has defined this term as adjustment not only be the patient, but also other individuals such as a caregiver or the supplier. This has resulted in numerous orthotic devices being inappropriately classified as off-the-shelf, which poses a risk of harm to patients.

a. Grassley-Harkin Letter—In October 2014, Sens. Grassley and Harkin criticized CMS's violating the statute in Medicare's efforts to expand the "off-the-shelf orthotics" category and include many devices which do NOT meet the criteria Congress stated, namely, that the device could be used by the patient with **minimal self-adjustment** made solely by the patient (emphasis added).

b. Provisions of the Protecting Access Through Competitive-Pricing Transition (PACT) Act (H.R.4185)-- Then Rep. Tom Price (R-GA) included a provision correcting this in his bill, clarifying that the definition of minimal self-adjustment only includes adjustment by the patient and not a third party.

Result: After receiving thousands of comments favoring the proposal, CMS shut it down without conclusion.

Impact: Medicare continues to pay non-qualified providers.

3. July, 2015-- Draft LCD for Lower Limb Prostheses and Study by Interagency Task Force—This proposal, was released to change the existing local coverage determination (LCD) for lower extremity prosthetics, and was widely criticized as potentially denying amputees access to advanced prosthetic care, and because it was not transparent, was initiated without private sector/stakeholder input, and was not supported by any relevant evidence.

Patients and O&P health professionals agree that this policy effort should be scuttled. The RAND Corporation study provides evidence (see below) that makes clear that advanced prosthetics reduce falls, and deaths at a very reasonable cost to Medicare. AOPA urges that CMS rescind its draft; remove it from the CMS website, and follow the long-standing lower limb prosthetics LCD currently in place until such time as a scientifically meritorious new proposal is proposed in an APA rulemaking process directly managed by CMS to ensure transparency and broad stakeholder input.

Result: Interagency Task Force convened in October 2015 to study issue. Roster remains without private input, and as CMS has declined to reveal its composition, there is no assurance of O&P researcher input.

Impact: Implications of draft LCD adopted and remain in effect in commercial payor realm-patient access and care restricted as a result. High degree of concern prevails in provider community over lack of transparency of Interagency proceedings.

Legislation-Driven Initiatives

1. December, 2001- BIPA 427 Proposed Regs—Section 427 of the Medicare, Medicaid and SCHIP Improvements and Protections Act of 2000 (BIPA) instructed CMS to implement a final rule to assure protection of patients, and the recognition of the expertise of the small business certified health O&P professionals by assuring that Medicare only pays providers who were either licensed or certified in accordance with the recognized criteria/standards on long-standing accreditation bodies. No regulation was issued until January, 2017.

Status: The proposed regulation is not detrimental to health professional businesses or patients and should be finalized. The proposed rule did receive a number of comments concerning some technical issues and some refinements are needed to the proposed rule. However, it remains critically important that the proposal be advanced expeditiously to a final regulation and amputees should not have to wait any longer for the quality of care protection that Section 427 intended when it was passed 17 years ago.

Impact: Medicare continues to pay non-qualified providers.

2. April, 2016 The Medicare Orthotics and Prosthetics Improvements Act (S.829/H.R. 1530)—This legislation, championed in the 114th Congress by Sen. Grassley (R-IA) in the Senate, and Rep. G. Thompson (R-PA) in the House would accomplish the needed improvements to make Medicare work much better for limb loss/mobility impaired Medicare beneficiaries as well as health professionals like the AOPA members who are life-long care providers to these patients. It would re-enforce the commitment that only qualified providers serving Medicare patients will be paid by Medicare, separating the lifelong care provided by O&P professionals from the delivery of usually one-time durable medical equipment (DME) devices, legitimatizing the orthotist/prosthetist notes as part of the medical record (see #1 above), and reiterating and clarifying that Medicare recognizes the statutory provisions on "minimal self-adjustment" solely by the patient in defining off-the-shelf orthotics.

Status: Significant bi-partisan support from leadership in Senate Finance and House Ways and Means Committees as well as a "zero "cost score from CBO, however there was no legislative vehicle to attach this to at the conclusion of the 114th Congress. Plan to re-introduce in 115th Congress.

Data and Evidence Research Initiatives

1. Oct 2011-Current- What Does Medicare's Data Say About Cost Effective Care--Dobson-DaVanzo ! & !!—Medicare claims data for 2007-10 establishes that patients who receive timely orthotic and prosthetic care save lives and money, whereas untreated patients have greater co-morbidities and higher costs. Yet, for a number of factors, including some delays and barriers set by Medicare policy, fewer than half of amputees ever receive prosthetic care. Medicare needs to work smarter, and that includes advancing, not deterring timely, quality care that can actually reduce total health care costs.

2. February 2016-RAND Corporation Study on Comprehensive Economic Value of Prosthetic Care—Systematic Literature Review and HECON model-RAND Corporation has been working to complete a comprehensive, independent, validated study to establish the comprehensive economic value proposition for prosthetic services to amputees, which focuses on advanced prosthetics. RAND's work is strictly evidence-based, relying on peer-reviewed medical literature, and is expected to result in a 10-year simulation model of all costs and benefit analysis. The RAND Corp evidence makes clear that these advanced prosthetics reduce falls, and deaths and offer "excellent value" for the cost to Medicare.

3. *June 2016- Prosthetic Patient Registry, In Conjunction with American. Joint Replacement Registry*—Patient outcomes data is critically important, and nowhere more so than in restoring patient mobility through O&P interventions. Recently, both NIH and DoD have called for investment into a long-term prosthetic patient registry. The Secretary doubtless is familiar with the excellent work in the orthopedic surgery profession in creating the American Joint Replacement Registry (AJRR), which now has roughly 1,000 hospitals providing data. AOPA has

developed a working model and partnership with AJRR that will permit all patients and payers to know patient outcomes and integrate it into priorities for patient care decisions.

Industry Growth Concerns

1. Prior Authorization & Competitive Bidding—CMS has implemented Prior Authorization (which unlike the private sector does not include any commitment to payment) and Competitive Bidding. These are bad concepts for O&P mobility impaired patients, and if either were enacted for O&P it would almost certainly delay access to care and reduce range of options and sources/patient access to care on a local basis—in short harming both patients and those small business health care professionals who provide their ongoing care year after year. AOPA favors the sounder approaches—separation of O&P from DME (where both concepts are currently operating), and revisions of options aligned with concepts stated in H.R. 4085 in the last Congress

2. Labor/HHS Approps Language—How to Encourage Technological Advancement-"Innovation in Prosthetic Technology and Access to Prosthetic Care – New technological advances in prosthetics technology benefitting Medicare enrollees, Veterans and active duty military is dependent on a reliable approach to coding that promotes innovation by evaluating devices for their functional performance characteristics. The Committee affirms its belief that CMS policies impacting seniors, active duty military, and veterans with limb loss should continue to facilitate patients' ability to receive the prosthetic devices medically indicated to restore them to their greatest functional potential. The Committee advises CMS and other government payors to work proactively to avert disruptions or interruptions in access to prosthetic care, and facilitate timely access to appropriate advanced prosthetics for patients with disabilities without new delays, impediments, or reductions in access to care

."

.