September 8, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–5516-P
P.O. Box 8013
Baltimore, MD 21244–1850

Submitted electronically via www.regulations.gov (RIN–0938–AS64)

Re: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

To Whom It May Concern:

The American Orthotic and Prosthetic Association (AOPA) would like to take this opportunity to offer comments on the proposed rule regarding the Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services (CMS-5516-P) which was published in the July 14, 2015 Federal Register.

AOPA is the leading national trade association for patient care facilities that provide artificial limbs and orthopedic braces to patients with limb loss or orthopedic and/or neurologic problems. Its membership consists of approximately 2,000 patient care facilities throughout the United States.

The proposed rule, as published in the Federal Register, establishes "a new Medicare Part A and Part B payment model under section 1115 A of the Social Security Act in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedures will be included in this episode of care." While AOPA understands the stated goal of CMS to move toward a payment system that is based on quality of care and improved patient outcomes, we are concerned that the inclusion of the provision of orthopedic braces in any post acute care bundled payment proposal will decrease Medicare beneficiaries' access to medically necessary orthoses that are designed to support and stabilize the joint that has been surgically replaced. This concern is specifically relevant to the provision of post

operative hip orthoses that are typically medically necessary to prevent hip dislocation during the rehabilitation process. These orthoses are rarely provided during the inpatient stay but are typically prescribed and provided after discharge from the acute hospital. In order to provide adequate support and stabilization during the post discharge rehabilitation period, these orthoses must be fit by an individual with specific education, training, and expertise in fitting orthoses such as a certified orthotist. Including post operative hip orthoses in a bundled payment model may create an incentive for hospitals to discourage the use of these medically necessary orthoses in order to achieve incentive payments for maintaining costs associated with the surgical procedure.

Post acute care bundled payments are poorly suited for the delivery of orthotic and prosthetic (O&P) care because the devices and related clinical expertise required to properly fabricate and fit them represent a relatively high cost, low utilization category of service that, if included as part of a bundled payment, may represent an unusual financial hardship to the inpatient facility responsible for providing care during the acute inpatient stay as well as the post acute follow up period. Precedence for exclusion of O&P services from existing bundled payment systems was established with passage of the Balanced Budget Refinement Act of 1999 (BBRA), which provided a specific exclusion of customized prosthetic devices from the bundled prospective payment to skilled nursing facilities. Through this legislation, Congress clearly signaled its intent that inpatient facilities could not be reasonably expected to absorb the cost of providing orthotic and prosthetic services to patients, and therefore provided a pathway by which O&P providers could provide quality services to Medicare beneficiaries at a reasonable reimbursement rate.

While the proposed rule makes no specific reference to the inclusion of prosthetic services in the proposed bundled payment model, the July 16, 2015 announcement by the Food and Drug Administration (FDA) regarding the approval of the first osseo-integrated above knee prosthesis, the Osseoanchored Prosthesis for the Rehabilitation of Amputees (OPRA), creates a significant “blurring” of the line between orthotic and prosthetic care. As prosthetic technology advances as evidenced by the FDA recognition of this new technology, AOPA is concerned that the post acute care bundled payment model in the proposed rule may be unintentionally expanded into treatment areas that were not part of the original proposal.

Congress Has Not Provided CMS with Legislative Authority to Institute Post Acute Care Bundling as to Medicare Beneficiary Care

There are currently two bills that have been introduced in the House of Representatives that create a legislative requirement for post acute care bundled payments. Representative McKinley, of the House Ways & Means Committee introduced H.R. 1458 on March 19, 2015 and Representative Black, a member of the House Energy and Commerce Committee introduced H.R. 2502 on May 21, 2015. Both of these bills, drafted independently, contain specific exclusions for orthotic and prosthetic devices from post acute care bundling provisions.

H.R. 1458 clearly recognizes that neither the government nor Medicare ought to engage in anything to abrogate the long-established patient-health care professional relationship, nor limit in any way the right of the patient to select the health care professionals who will be engaged in any long-term patient care relationship with patients. Therefore, H.R. 1458 provides for an exclusion from the bundle for a range of patient care providers including:

(i) physicians' services;

(ii) hospice care;

(iii) outpatient hospital services;

(iv) ambulance services;

(v) outpatient speech-language pathology services; and

(vi) the items and services described in section 1861(s)(9) which are defined as leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition.

H.R. 2502 contains a similar exclusion for items and services described in section 1861 (s) (9) from post acute care bundling. The recognition of O&P services as patient care services rather than commodity items in both of these bills establishes the grounds necessary to exclude them from bundle post acute care payment systems. To include orthotic and prosthetic services in an acute care bundling payment system would be a radical change to the Medicare system, and catastrophic for limb-impaired individuals, especially if adoption of post acute care bundling modified existing patient care relationships or denied Medicare beneficiaries the right to choose their prosthetist/orthotist.

Fortunately, Congress has previously addressed this issue very appropriately when, in 2003, Congress established that CMS' authority to apply competitive bidding in orthotics would be limited only to "off-the-shelf orthotics," which Congress further defined as devices which could be used by the patient with "minimal self-adjustment" and which do not require any expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. This congressional action, limiting the scope of competitive bidding to only the simplest of orthotic devices, further reinforces the importance of protecting patient choice and affirming the patient-provider relationship with their orthotist or prosthetist, as well as and on the same basis as in the other five patient care areas enumerated above.

Congress, through its action on the BBRA in 1999, its action on DMEPOS competitive bidding, and recently through the introduction of the two post acute care bundling bills discussed above clearly understands the value of the relationship between a patient and their orthotist or prosthetist as well as the fact that the cost of the provision of orthotics and prosthetics cannot be absorbed by the inpatient facility without creating a

serious and undue financial hardship on the facility and a threat to patient choice of those providing their care. Congress has not provided CMS with any legislative authority to institute post acute care bundling as to any aspects of beneficiary medical care. The proposed CCJR regulations go well beyond the ambit of the bills currently under consideration by the Congress and CMS must not implement any regulation relative to post acute care bundled payments until Congress enacts legislation that provides both regulatory authority to CMS and defines the appropriate boundaries of any implementation of such a concept. By prematurely publishing this proposed rule, CMS has reversed the necessary sequence—first Congress establishes and defines the authority, and only then can CMS move forward with proposed regulations to implement it.

While the current CCJR proposal is likely to have only limited impact on orthotic and prosthetic professionals, there are patients who require orthotic bracing services after joint replacement. Just as importantly, both pending Congressional bills (HR 1458 and HR 2502) include provisions to define the boundaries of post acute care bundling initiatives as they relate to health care professionals generally, as well as specific provisions establishing the limitations of any post acute care bundling programs as to orthotic and prosthetic care needed by Medicare beneficiaries. This CCJR proposal would leapfrog Congress, and eliminate entirely the legitimate boundaries that it appears likely that Congress will enact. CMS action here would set a bad precedent of moving ahead in an area still under consideration by Congress, and the nefariousness of such action is not diminished by CMS simply saying—"if and when Congress acts, of course we'll observe any parameters Congress sets." Stated differently, in this proposal, CMS sets the precedent of acting as if it has total authority over everything in the health care field, seeking to lead and even direct where Congress will go, unless and until Congress acts to limit CMS. Our system is based on the exact opposite principle—authority from Congress must come first, before CMS sets out in enacting new models of Medicare patient care.

In addition to AOPA's concern regarding the authority of CMS to promulgate regulations regarding post acute care bundled payments, AOPA has several concerns regarding the potential catastrophic consequences that such a program may have on Medicare beneficiaries. These concerns are addressed below.

CMS Cannot Implement an Overly Broad "Pilot Project", Creating a Non-Voluntary Change of National Scope

The CCJR proposed rule claims to create a pilot project under the innovation initiatives of CMS, but the facts belie that characterization. The proposed regulation outlines a program that would apply to virtually all hospitals in major areas of the U.S., covering all hip and knee replacement in those regions, and it goes well beyond being a hospital rule since it would impact all health care providers and all patients at all hospitals in

those regions. It is not voluntary or limited in any sense as a pilot project would be. Far from that, short of medical tourism, a patient who needs hip or knee replacement would be snared, with no choice but to have their surgery performed in this pilot, experimental framework. This essentially eliminates patient choice, which is a longstanding and highly publicized benefit of the traditional, fee for service based, Medicare program.

The Hospital Bonus Payment Unnecessarily, and Improperly Involves Denial of Patient Access to Services Currently Being Provided

The economic features of the CCJR proposal don't make sense and are inconsistent with the attestations of the proposal itself. The proposal, on the one hand, states that hospitals will receive a bonus payment if the total patient costs for all treatments relating to hip and joint replacements are decreased, in a purported risk-sharing model. At the same time, the proposal states that all providers will continue to be paid the same amount for each service, without any reduction, in accordance with the current Medicare fee for service structure. Therefore, the only way that the objective of this CCJR proposal can be met is for the number of services provided to patients in conjunction with their surgery, hospital care, and treatment for hip and knee replacements to be reduced. The hospital could be very persuasive in limiting the number of services it permits health professionals to provide in their facility, or in the community after discharge in the pursuit of the bonus payment. This is tantamount to making each hospital a mini-HMO for purposes of all knee and hip replacements in which the pervasiveness of the rule's applicability to all hospitals in the region to force patients to have necessary services performed in this mini-HMO, denying patients the choice to select their preference among a true fee-for-service model, an HMO, or some hybrid care. The proposal amounts to a rationing program that, in limiting the number of services that can be provided to patients without economic-based constraints applied by the hospitals, compromises quality of care, and places patients/Medicare beneficiaries at greater risk.

The CCJR Proposal Is Premature, Excessive and Must Be Withdrawn

The CCJR proposal is totally premature and excessive in its scope of applying in a universal fashion to all hospitals and all hip and knee replacement patients in a region. CMS needs to withdraw this proposal. A true innovation pilot project would be voluntary, more limited in scope, and would assure that patients can make an informed choice as to whether to participate in this pilot, experimental approach to joint replacement care. CMS needs to wait until Congress enacts legislation that both provides authority to venture into post acute care bundling, and defines the appropriate boundaries of any implementation of such a concept. The Congress is currently considering this very type of legislation. CMS has reversed the necessary sequence—first Congress establishes and defines the authority, and only then can CMS move forward with proposed regulations to implement it.

In addition, data collection efforts regarding the effectiveness of post acute care bundling payment systems and their impact on patient outcomes have been extremely limited to date. With the passage of the *Improving Medicare Post Acute-Care Transformation (IMPACT) Act of 2014*, data collection is expected to improve significantly. AOPA believes that CMS will better serve its Medicare beneficiary population by not implementing any post acute care bundling regulations until it has had the chance to collect and analyze sufficient data regarding these programs. The premature release of post acute care bundling regulations will significantly impact the rehabilitation and recovery of Medicare beneficiaries by limiting their access to needed and medically necessary care.

CCJR "Sharing Arrangements" Creates Significant Concerns Regarding Anti-Kickback Statutes

While the proposed rule acknowledges the risk of potential violation of anti-kickback statutes as a result of "sharing arrangements" between acute care hospitals and their CCJR collaborators, and states that any sharing arrangements must be written to ensure full compliance with the law, AOPA remains seriously concerned that "sharing arrangements" will result in potential violations of anti-kickback statutes as the parties involved compete for an increased portion of any bonus payments made to the hospital. These sharing arrangements have the potential to result in decisions that are not in the best interest of patient care but rather are in the best interest of increased profit for the collaborators. This incentive based arrangement will inevitably lead to lower quality of care and restricted access to medically necessary services.

Conclusion

AOPA appreciates the opportunity to provide public comment on such an important issue and hereby requests that the publication of any final rule regarding Medicare post acute care bundled payment systems be suspended pending resolution of congressional action related to this process.

Sincerely,

Charles H. Dankmeyer, Jr., CPO
President
American Orthotic and Prosthetic Association