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NEUROLOGICAL SURGEONS

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September 8, 2015

Mr. Andy Slavitt
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Patrick Conway, M.D., MSc
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Re: Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule [CMS-5516-P]

Dear Mr. Slavitt and Dr. Conway:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing over 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on CMS' newly proposed Comprehensive Care for Joint Replacement (CCJR) payment model. The CCJR would establish bundled payments for total hip and knee replacements, covering hospitalizations, professional fees, and all clinically related Medicare Part A and B services for 90 days after discharge, including skilled nursing facility care, home care, and hospital readmissions. At the end of each year, hospitals that spend less than the target price and achieve threshold performance on three quality measures would receive a bonus payment, up to a specified cap. Hospitals that spend more than the target payment would be responsible for repaying Medicare for the difference, up to a specified cap. This five-year, **mandatory** program would be implemented in 75 metropolitan statistical areas (MSAs) with approximately 750 hospitals beginning January 1, 2016.

Although the CCJR would not directly impact our membership at this time, this pilot could set the foundation for future bundled payment models that target other procedures that are relevant to our membership. Therefore, we appreciate the opportunity to express our overarching concerns with the proposal and to highlight questions and other issues that we believe must be addressed before CMS implements this particular model and potentially applies it to other procedures in the future.

The AANS and CNS recognize the positive impact that bundled payments may have on controlling healthcare costs, but these benefits can only be realized if the model focuses on appropriate and properly constructed episodes of care and is implemented in a manner that generates trust and buy-in from all providers affected by the model.

Mandatory Participation

Organized neurosurgery has closely tracked the Center for Medicare and Medicaid Innovation's (CMMI) Bundled Payments for Care Initiative (BCPI), which includes episode-based models that focus on musculoskeletal conditions, and some of our members have been integrally involved in the development and evaluation of episode of care payments for both Medicare and private payers. However, the models tested to date were all voluntary. The CCJR announcement is significant because it represents the first

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time that CMS is using its waiver authority under the Innovation Center statute to **mandate** hospital participation in one of its demonstrations. The hospitals in the regions randomly selected to be subject to this model would be **required to participate in this model** and would not have the opportunity to test other more innovative models.

The AANS and CNS strongly oppose CMS' proposal to make participation in this program compulsory. It is critical that CMS maintain voluntary participation models that allow hospitals and surgeons to tailor bundled and other innovative payment reforms to their specific patient populations, practice settings, administrative capabilities and resources. This is especially important as physicians transition to a new Medicare payment system in which substantial annual Medicare updates may be tied to participation in these models.

The proposed mandatory nature of this model unfairly targets providers who might not have participated in the BPCI or tested other bundled payments to date for legitimate reasons. These providers, many of whom are smaller hospitals or systems, face real challenges, such as a lack of resources to better coordinate care (including a lack of access to interoperable EHRs), insufficient patient volumes, and/or a lack of negotiating power in their community. These challenges will not be resolved, and will only be exacerbated, by forcing providers in different settings and with different resources into the same box. What these providers need most is more flexibility, better support and guidance, and stronger incentives — not a restrictive mandate. It is simply erroneous, and even dangerous, to assume that all providers and their patients, across the nation, would fit into and benefit from the same payment model.

Timeline

CMS proposes to begin the CCJR program on Jan. 1, 2016, with full scale implementation of the final rule within 60 days of its release. The AANS and CNS believe that this timeline is unreasonable, overly aggressive and impractical, especially considering the proposed mandatory nature of this program. As noted, many hospitals in the 75 selected MSAs do not have experience participating in bundled payment or other risk-based models and will simply not have the infrastructure in place to be ready to comply with this proposal's complex requirements by the start date. It is also extremely presumptuous to assume that any hospital — even those with experience and resources — has the capacity to understand and comply with the multiple requirements of this program in the short span between the release of the final rule this fall and the start of the first program year.

CMS' timeline completely ignores the wide range of administrative, organizational and legal activities that must take place before a hospital and associated professionals can adopt such a model, as well as the multiple competing mandates that hospitals and physicians currently face (e.g., ICD-10, EHR Meaningful Use and other quality-related programs). It is also inappropriate to roll out this model *before* it has completed and fully evaluated the BPCI. If CMS adopts such an unrealistic timeline, it will seriously disrupt care patterns, put patient access and quality at serious risk, and minimize the legitimacy of a potentially valuable payment model.

Before CMS fully implements the CCJR, CMS should test the system. At the very least, **the AANS and CNS recommend that implementation should be delayed until Jan. 1, 2017, at the earliest.**

The Role of the Physician

No bundled payment model can achieve success without hospital/physician alignment. While the hospital might be in the best position to manage certain aspects of a bundled payment model, physicians play an integral role in efforts to redesign care delivery in a way that can yield efficiencies, while protecting the needs of the patient. For acute care models, in particular, physicians make the critical decisions that can result in the success (or failure) of a bundle. Therefore, it is critical that physicians and other relevant clinical experts have a leading role in defining episodes, appropriate risk adjustment and attribution methodologies, and fair mechanisms for distributing payments under bundled models.

Under the CCJR, hospitals would be exclusively responsible for the bundled-payment program and would control any financial surpluses. Although CMS anticipates that hospitals will seek to enter into financial arrangements with providers and suppliers caring for patients in the episode, there is no explicit language that addresses the role of the physician in this model. This is problematic for multiple reasons. For one, it gives hospitals unfettered authority to restrict services and other care decisions made by physicians in order to mitigate risk under the CCJR model. We question what protections CMS would offer to maintain a physician's freedom to determine the best course of treatment or medical services for each individual patient. Also, what is the incentive for a physician to demonstrate superior efficiencies if all of the incentives go directly to the hospital? In acute care episodes, in particular, physicians bear a significant portion of the risk and typically have the most insight into the best pathways for improving patient care quality and efficiency.

Physicians must not be divorced from opportunities to contribute thoughtfully to decisions that could contribute to better care under these models. **We recommend that CMS adopt a mechanism to ensure that clinically relevant physicians play a leading role in these models.** This could be accomplished by ensuring they are integrated into the leadership and/or governance that oversees efforts to redesign care to ensure that the most clinically appropriate care is not sacrificed in an effort to achieve cost savings. These models also should preserve the opportunity for physicians to control the bundle in terms of directing the care and receiving and/or distributing payments if they so choose.

The CCJR model also incentivizes hospitals to acquire post-acute care facilities and surgery practices, while precluding independent practices from performing surgeries at the hospital. We question how CMS plans to guard against hospital-driven vertical integration or other forms of market consolidation that could lead to higher costs and limit physician autonomy and patient access to care. Similarly, we urge CMS to adopt a policy that prohibits hospitals from coercing physician participation in the CCJR or any other hospital-directed model. For example, hospitals should not be allowed to use provider restrictions or provider credentialing to limit the ability of physicians to perform services covered under these model if they are not willing to sign a participation agreement with the hospital. These protections are needed to preserve physician autonomy, but more importantly, to ensure that Medicare beneficiaries maintain a choice of provider.

In the proposed rule, CMS states that the Secretary is allowed to waive certain fraud and abuse laws for purposes of testing payment models. However, CMS believes that it must wait to finalize this proposed rule before it can articulate the need for or scope of any such waivers. We urge CMS and the Office of the Inspector General (OIG) to rapidly promulgate necessary waivers to fraud and abuse laws that currently pose impediments to the financial arrangements that support the coordination of care under these models. One aspect that may need to be addressed involves current regulations related to gainsharing.

With regard to gainsharing, CMS proposes to cap gainsharing payments for a calendar year paid to a physician who is a CCJR Collaborator at 50 percent of the total Medicare approved amounts for services furnished by that physician. **The AANS and CNS believe that this cap is arbitrary and may not reflect the efforts that the physician undertook to meet required quality metrics and reduce total payments.** Rather than setting this arbitrary limit, CMS should allow the providers to determine the distribution — provided, however, that the physicians have equal input into this distribution methodology. Alternatively, CMS could establish guidelines that require the distribution percentage to reflect the relative contributions made by the providers included in the bundle.

Also, if a gainsharing payment is made to a CCJR Collaborator that is a physician group, CMS is proposing that the payment “must be shared only with the physician or non-physician practitioners that furnished a service to a CCJR beneficiary during an episode of care.” **The AANS and CNS do not support this limitation and we urge CMS to remove it. The physician group practice should have**

the ability to determine the most appropriate method of distributing gainsharing payments, and that this added requirement is not necessary to prevent program abuse.

Risk Adjustments and Attribution Methodologies

In the CCJR model, CMS would calculate episode target prices for each specified MS-DRG and each hospital separately on the basis of 3 years of historical data. However, no adjustments would be made for patient-specific characteristics, such as coexisting conditions, since CMS has not yet identified a suitable risk-adjustment methodology.

We believe this approach is extremely flawed and remind CMS about the serious unintended consequences that can result if quality and cost data are not properly adjusted for in accountability models. DRG categories, alone, will not sufficiently adjust for patient risk factors across an entire episode of care. The MS-DRG system is specifically designed to adjust for differences in inpatient hospital spending, not post-acute care spending. It also does not account for functional status, which could be as or more important than comorbidities in determining total amounts of Medicare spending and post-acute care needs following surgery. The CMS payment systems for post-acute care services delivered by skilled nursing facilities, inpatient rehabilitation facilities, and home health agencies all adjust payment amounts according to functional measures. If an episode is going to include post-acute services and outcomes, it must differentiate among patients based on their functional status.

We cannot overemphasize the importance of applying adequate risk adjustments under bundled payment models. Without them, providers will be disincentivized from treating patients that require more complex procedures, or those with multiple comorbidities, given the potentially high cost and high complication rate of taking on these patients. Risk adjustment is especially important when post-acute care costs are included in a bundle since patients with multiple chronic illnesses or comorbidities will generally require longer or more intense rehabilitation, which could contribute to overall spending.

If CMS needs more time to develop better risk adjustment methodologies, then it should at least, in the interim, provide additional financial protections for safety-net providers and those who treat riskier patients, in general, as well as those with fewer annual episodes (given random variation problems). It is essential that CMS incorporate safeguards into bundled payment models to ensure that patient access to care is not compromised. Bundled payment programs should be designed in a way that does not financially penalize providers for treating our most vulnerable patients.

In regards to attribution, we question how the CCJR model will account for situations when a patient chooses to follow-up for post-operative therapy or complications at another facility that is not a Collaborator with the index facility. How will these readmissions be captured? Even well executed discharge planning cannot prevent all readmissions, and not all readmissions will be at the index facility. The index facility would have little to no control over this scenario and should not be held accountable for it.

Quality Measures and Spending Targets

CMS must ensure that the metrics used to capture quality and cost are closely tied to the scope of the bundle and to each other so that they result in accurate assessments of value.

In terms of spending, CCJR prices would be calculated using a blend of hospital-specific and regional spending, versus BPCI episode prices, which are determined primarily by each hospital's historical spending. Initially, under the CCJR model, one-third of the price would be based on regional averages, but fully regional pricing would be used by year five. Organized neurosurgery is concerned that this could benefit low-cost providers, but present challenges for providers with high complication rates, excess use of post-acute care, or sicker-than-average patients.

Also, under CCJR's retrospective payment model, CMS would set annual target prices for each hospital,

but continue paying providers through a fee-for-service system. At the end of each year, CMS would reconcile payments with spending targets. Target prices would be updated annually and participants would be provided with target prices before each year began. The AANS and CNS believe it is important for CMS to provide spending data to participants in these models more frequently than is proposed under the CCJR model. Under the BPCI, for example, CMS recalculates target prices quarterly. More frequent updates to this data will make it easier for hospitals and their Collaborators to manage costs.

It is also important that CMS provide CCJR participants with baseline data in a timely manner. CMS proposes to provide baseline data no sooner than 60 days following the start of performance year one. However, in order to make well-informed decisions about efficient care delivery, participants will need this data *in advance* of the start of the performance year, rather than after the start of the program.

We are also concerned that the spending targets in this model provide few incentives to offer more innovative and potentially efficient services since CMS would base the episode spending target on the amount the group spent on services it billed for in the prior year, not on the actual costs incurred for services delivered. Spending targets used under these models should not stifle innovation or innovative practices. We question how this model will account for implanted devices and other innovative practices that might not provide immediate value, but still contribute to important innovation and effectiveness over time. We also question how super-specialized areas of medicine, such as neurosurgery, which frequently rely on devices and procedures that are costly, but effective, would be treated under this model. Furthermore, in situations where there is potentially excessive spending, we question how smaller hospitals with less bargaining power would have the leverage to hold down the cost of something like implants, versus a larger hospital with more of a market share. Finally, we question why this model does not reward the achievement of better outcomes at the same cost.

We also believe that CMS needs to better account for situations where alternatives to surgery might be more costly than the surgery itself. These models need to ensure that patients receive the most appropriate care. Cost effectiveness should be secondary, and should not be the impetus for care decisions.

The Role of the Patient

As mentioned throughout this comment letter, the policies proposed in this rule by CMS could seriously impact patient access to care, as well as the overall quality of care received. Under any model in which there is a financial incentive to reduce costs, there needs to be safeguards to prevent cherry-picking of lower risk patients and to prevent providers from otherwise skimping on care. We do not believe the current model offers adequate consumer protections on this front and question whether the quality measures accurately capture all instances where patient care might be adversely affected by these perverse incentives.

We also believe it is critical that consumer choice is maintained under any new payment model. What protections has CMS incorporated into the CCJR model to maintain a patient's freedom to choose their provider and their course of treatment?

This model also lacks incentives and pathways for patients to be more actively involved in the care process. It also fails to account for independent decisions made by patients that may affect the ultimate quality and cost of care.

The Need for Better Data and Analytics

It is critical that entities participating in these models have access to enough historical and real-time data, from a variety of sources (claims, EHRs, clinical data registries) and spanning multiple settings of care (e.g., post-acute care data sources) to clearly understand their costs and outcomes and accurately

assess the risk they will be taking on under a bundled payment agreement. Unfortunately, multiple barriers continue to stand in the way of providers taking full advantage of this data.

For one, hospitals are not always fully transparent and, for proprietary or other reasons, do not necessarily “open their books” to all providers affected by a bundle. Current interoperability challenges among EHRs and between EHRs and clinical data registries also stand in the way of efforts to meaningfully share data across providers and settings and to achieve the level of coordinated care required to succeed in these models. There are also significant regulatory barriers that continue to impede the development, use, and effectiveness of clinical data registries. For instance, human subject protections have not kept up with our rapidly evolving quality data collection enterprise. As a result, the overlapping application of the Common Rule with the HIPAA privacy and security regulations to clinical data registries is highly confusing and often poses an unnecessary barrier to more robust data collection. To date, clinical data registries also have had limited access to Medicare data, which makes it difficult to track patients over time and accurately assess how practice patterns are tied to clinical outcomes and spending. Finally, despite large investments in measure development, quality remains poorly described and methods to continuously measure and report quality and safety in healthcare are underdeveloped. High-level evidence regarding the effectiveness of many diagnostic and therapeutic services is limited and optimal healthcare outcomes for many medical conditions remain undefined. Overall, “real world” care is still not well understood. Many specialties, including neurosurgery, need to first accumulate more data on procedures and outcomes before it can even consider cost.

Under the CCJR, CMS proposes to share data with participating hospitals to aid them in their care coordination and planning activities. However, CMS will only allow participating hospitals to request data regarding services furnished to beneficiaries under the model. The AANS and CNS strongly urge CMS to share this data with all CCJR Collaborators, including physicians, and not just the participating hospitals. Physicians, in particular, will be the drivers of care redesign under these models and have the clinical insight to ensure that care decisions are driven by patient needs and not the potential financial risk of the hospital.

Looking to the Future: Applicability of Bundled Payment Models Across Medicine

As CMS looks to expand bundled payment models in the future, we remind the agency of the limited generalizability of the CCJR model to other procedures. The CCJR focuses on a high-volume, relatively standardized elective procedure with moderate cost variation. It will be very challenging, if not impossible, to apply bundled payment models to procedures that are: non-elective; more nuanced in their approaches; include wider variation in regards to cost, outcomes and patient heterogeneity; and that have lower patient volumes. The bundled payment model can only succeed where care is being done in a relatively similar and predictable manner. If a bundle is too heterogeneous, or there is an insufficient number of patients who fall into the episode (and there is not sufficient risk adjustment to account for these factors), this could not only pose challenges for financial modeling, but could also lead to cherry picking of patients.

Even where bundled payments are appropriate, CMS cannot take a one-size-fits-all approach. Different procedures and patient populations will require different approaches. For example, CMS should not specify a single episode length that applies across all episodes. Instead, CMS should make this determination on a case-by-case basis. For some bundles, a 30-day episode may be appropriate, while others may require a 60-day, 90-day or even longer episode. The private sector, for example, is currently testing ways to break down bundles more specifically (e.g., patients with six comorbidities could have a different target price versus than one with three comorbidities, based on actuarial data).

We urge CMS to work closely with professional societies and their clinical experts, in a transparent manner, to not only refine current bundled payment models, but to determine which procedures are most appropriate candidates for this model. Many neurosurgical procedures are nuanced, have wide

variation, and simply do not meet this definition. CMS will need to work with relevant stakeholders to identify more appropriate payment models for procedures that do not fit this model. This work is especially critical as Medicare physician payment updates are based increasingly on physician participation in alternative payment models.

Concluding Remarks

Given the many problems identified with the proposed CCJR program, it is essential that CMS should make this a voluntary rather than mandatory program at this time. If the agency insists on mandating this new bundled payment system, it is critical that the agency delay implementation for at least a year to allow for additional testing and resolution of the numerous outstanding questions that we and others have raise.

The CCJR program, and other bundled payment programs modeled off of it, should be designed to enable teams of providers to redesign care in ways that reduce avoidable spending while ensuring that patients who need individualized care are still able to receive it. It is critically important that CMS engage clinical experts when developing these and other models.

Sincerely,



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