September 8, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-5516-P
Electronically Submitted
1jz-8lol-xbgz

RE: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services (LEJR), (CMS5516-P)

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed rule, “Comprehensive Care for Joint Replacement Payment (CCJR) Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement (LEJR) Services.” Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

Medicare Rights serves over two million beneficiaries, family caregivers, and professionals through its national helpline and educational programming annually. If you have questions about our comments or require additional information, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202-637-0961 and Casey Schwarz, Policy and Client Services Counsel, at cschwarz@medicarerights.org or 212-204-6271.

We applaud CMS’ efforts to implement reforms to diminish wasteful spending and to transform our health care system from one that rewards high-volume care to one that rewards high-value care. We continue to support CMS’ use of its authority to test delivery system reforms designed to enhance health care quality while simultaneously driving down the cost of care.

In general, we support the CCJR program’s effort to coordinate care for Medicare beneficiaries, improve the quality of care, and improve the possibility of a safe, secure, and timely transition home. We have some concerns, however, about the effect of the proposed model on beneficiaries. We are concerned the breadth of the program could have unintended consequences that might be avoided by a somewhat slower approach to bundling.
We appreciate that CMS identified several potential problems that may arise from this program for beneficiaries and outlined proposals to address them. Our comments expand on these potential problems and offer suggestions for mitigating risk to Medicare beneficiaries. In sum, we recommend that CMS:

- Reconsider mandatory participation and replace with a phased approach, allowing for testing and monitoring;
- Provide an opportunity for participants of the Medicare Acute Care Episode (ACE) program to participate in an expanded version of ACE involving post-acute care providers;
- Transform the proposed notification aspect of the CCJR program into a detailed, concrete, and well-developed shared decision making strategic plan with detailed shared decision making guidelines;
- Include a measure to evaluate post-replacement change in function in the included quality metrics;
- Consider a reward for hospitals that achieve better outcomes for their patients at the same cost;
- Implement accurate risk adjustment for the post-acute components of the episode; and
- Carefully monitor implementation to ensure minimal impact on beneficiary access and choice.

**Evaluate Whether a Mandatory Program is Necessary**

CMS has conducted previous bundling projects, including the Medicare Acute Care Episode (ACE) and the Bundled Payments for Care Improvement (BPCI) demonstrations. ACE was evaluated and demonstrated hopeful improvements in care and cost containment.\(^1\) And the BPCI has now attracted hundreds of volunteers.

In general, we encourage CMS to release more detailed results from these demonstrations to assist in evaluating next steps and the roll out of the proposed CCJR model. ACE evaluations have been published, but we understand that, as yet, there are no quality and outcome evaluations for BPCI. As such, we are concerned that the roll out of the mandatory aspect of the proposed CCJR program is somewhat premature. We suggest that CMS consider a phased roll out, namely to allow time to incorporate lessons learned from both the ACE and BPCI demonstrations.

**Draw on Lessons from the Medicare Acute Care Episode (ACE) Demonstration:** Under Medicare’s ACE demonstration, which began in 2009, Medicare paid the 5 participating organizations a global budget for high-margin procedures, including cardiac valve surgery, coronary artery bypass grafts, defibrillator implantation, cardiac pacemaker placement, and knee and hip replacements.\(^2\)

The ACE demonstration saved Medicare $319 per episode of care for a total of approximately $4 million in net savings for 12,501 episodes of care. The mean savings of $585 per episode from the combined Medicare Part A and B expected payments were offset, in part, by increases in the cost of post–acute care services, particularly for patients undergoing percutaneous coronary interventions.

According to one analysis of the demonstration, the savings were modest, however, compared with the overall costs to Medicare of the cardiac and orthopedic procedures and varied by procedure and hospital. The largest aggregate savings were for orthopedic procedures, and the smallest savings per episode were for percutaneous coronary interventions (cost savings of $71). Hospitals also saved money, although the amount varied by hospital and episode of care. These savings largely resulted from negotiating lower prices for medical devices.

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\(^1\) See CMS discussion at 80 Fed. Reg. 41198 at 41202; Also see, Maura Calsyn, JD and Ezekiel J. Emanuel, PhD, “Controlling Costs by Expanding the Medicare Acute Care Episode Demonstration,” *JAMA Internal Medicine*, September 2014, Volume 174, Number 9.

\(^2\) The hospital sites were Baptist Health System in San Antonio, Texas; Oklahoma Heart Hospital and Hillcrest Medical Center in Tulsa; Lovelace Health System in Albuquerque, New Mexico; and Exempla Saint Joseph Hospital in Denver, Colorado.
The effect of the demonstration on quality of care, resource use, and case mix was evaluated by tracking 22 measures. There was “little evidence of a demonstration effect on most of the process and outcome measures,” and quality of care levels seemed to be maintained, suggesting that the savings did not come from skimping on care or taking other harmful shortcuts. Additionally, the evaluation found no evidence that hospitals were “deliberately” choosing “to provide services to healthier, less financially risky patients” and no evidence of increased transfers of patients or increased admissions to post–acute care settings. Evaluators also described a variety of quality improvement efforts by physicians and hospitals.

The ACE demonstration gives important but limited information for evaluating this model because it did not include post–acute care services. More than 70% of the variation in the costs of care under Medicare results from variation in the use of post–acute care services. Thus, one analysis recommended that CMS expand the ACE demonstration and consider evaluating an ACE demonstration wrap-around with additional components, inclusion of post-acute services, and a strong emphasis on shared decision making. The analysis did not overtly address mandatory versus voluntary but the thrust of the recommendation appeared to be preserving the voluntary nature of the program for the time being and assuring adequate hospital preparation for shared decision making.

**Draw on Lessons from the Bundled Payments for Care Improvement (BPCI) Initiative:** Since 2011, CMS has developed and tested four models of bundling under the BPCI initiative. Under this initiative, organizations can take responsibility for quality and financial performance for episodes of care. The initiative was designed to test whether bundled payment can reduce Medicare’s cost while maintaining or improving quality. CMS recently announced that over 2,100 acute care hospitals, skilled nursing facilities, physician group practices, long-term care hospitals, inpatient rehabilitation facilities, and home health agencies transitioned from a preparatory period to a risk-bearing implementation period in which they assumed financial risk for episodes of care.

According to the announcement, 360 organizations entered into agreements with CMS to participate in the BCPI initiative and an additional 1,755 providers partnered with those organizations. This announcement means several hundred providers—acute and post-acute—are advancing into a program that rewards them for increasing quality and reducing costs while also penalizing them if costs exceed a set amount. Despite this enthusiasm among health care providers for BPCI, CMS has proceeded to propose a mandatory program involving all hospitals in 75 Metropolitan Statistical Areas with implications—mostly unknown—for not only the hospitals, but in addition, the post-acute providers, and Medicare beneficiaries.

CMS explains that the proposed model would require the participation of hospitals in multiple geographic areas that “might not otherwise participate” in the testing of bundled payments for episodes of care for lower extremity joint replacement procedures. Like CMS, we recognize that there may be limitations to using only voluntary programs to test alternative payment. Analysts suggest that those who volunteer are not typical providers, and they may be providers who already engage in appropriate value-based care provision.

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3 Maura Calsyn, JD and Ezekiel J. Emanuel, PhD, “Controlling Costs by Expanding the Medicare Acute Care Episode Demonstration,” JAMA Internal Medicine, September 2014, Volume 174, Number 9.
4 Id.
8 Id.
10 See, e.g., Jackson Williams, A Milestone Is Reached As CMS Moves Beyond Voluntary Participation, Health Affairs Blog, August 2015, available at: [http://healthaffairs.org/blog/2015/08/14/a-milestone-is-reached-as-cms-moves-beyond-voluntary-participation](http://healthaffairs.org/blog/2015/08/14/a-milestone-is-reached-as-cms-moves-beyond-voluntary-participation)
Yet, we are concerned that there may be a gap between the idea of bundling and the mechanics of bundling, taking into account the clinical, operational, financial, and administrative demands on providers. The hospitals involved in ACE and the BPCI are well-prepared providers who have learned and now understand the demands of the bundling model and who have in place the administrative, social, and operational infrastructure to succeed for themselves and for their patients.

We suggest that CMS use these experienced participants of the ACE program to participate in an expanded version of ACE, involving post-acute care providers. Alternately, we encourage CMS to explore alternatives to a mandatory, universal, program—such as targeting states with high Medicare per beneficiary spending.11 If CMS decides to proceed with the CCJR mandatory model, it should greatly enhance and improve its plans for implementing and monitoring key components of the model as described further below.

**Prevent Potential, Adverse Consequences for Beneficiaries:**

**Promote Beneficiary Choice:** Freedom of choice is foundational to the Medicare program.12 Steering has been anathema since the inception of Medicare, and prohibitions are in many CMS regulations. Hospitals, in particular, are required to provide fully independent information about post-inpatient care.13

In the proposed rule, however, CMS expresses the expectation that participant hospitals will identify key providers and suppliers for CCJR beneficiaries in their communities and then establish close partnerships with them to assist the hospital in redesigning care for lower extremity joint replacement episodes to improve quality and efficiency, coordinating and managing care for beneficiaries, monitoring episode performance, and refining care pathways. In short, CMS is encouraging participating hospitals to partner with community providers (CCJR collaborators) to jointly engage in care redesign and potentially share in any financial risk and/or reward.

CMS acknowledges that because the CCJR model is designed to promote efficiencies in the delivery of all care associated with lower extremity joint replacement procedures, providers may seek greater control over the continuum of care. Yet, CMS insists that the CCJR model does not limit the ability of a beneficiary to choose among Medicare providers or diminish the range of services available to the beneficiary.14 Medicare beneficiaries may continue to choose any Medicare participating provider with the same costs, coinsurance, and responsibilities as they have with other Medicare services. Under the proposed rule, hospitals may not restrict beneficiaries to any list of preferred or recommended providers that surpass any restrictions that already exist under Medicare rules.

CMS relies largely on beneficiary notification and engagement to counter any problem of choice limitation. We fully support enhancing beneficiaries' understanding of their care, improving their ability to share in the decision making, and ensuring that they have the opportunity to consider competing benefits even as they are presented with cost-saving recommendations. In particular, we support CMS’ requirement that appropriate beneficiary notification should accomplish the following:

- Explain the model and how it will or will not impact their care;
- Inform patients that they retain freedom of choice to choose providers and services;

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11 Maura Calsyn, JD and Ezekiel J. Emanuel, PhD, “Controlling Costs by Expanding the Medicare Acute Care Episode Demonstration,” JAMA Internal Medicine, September 2014, Volume 174, Number 9.
12 Social Security Act, SEC. 1802. [42 U.S.C. 1395a]
13 See 42 CFR 482.43 at Condition of participation: Discharge planning.
• Explain how patients can access care records and claims data through an available patient portal and through sharing access to their Blue Button® electronic health information with caregivers;
• Advise patients of both their clinical needs and their care delivery choices;
• Clearly specify that any non-hospital provider holding a risk-sharing agreement with the hospital should be identified to the beneficiary as a “financial partner of the hospital for the purposes of LEJR services”; and
• Advise patients that all standard Medicare beneficiary protections remain in place. These include the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1-800-MEDICARE.

CMS proposes that participating hospitals must require all providers and suppliers to provide notice (via materials to be developed or approved by CMS) that explains the proposed payment model to involved beneficiaries before ordering an admission for joint replacement. Depending on the given situation, the beneficiary notification must be provided by either the hospital or the providers or the suppliers.

We support CMS’ requirement that this notice, including the minimum elements outlined above, be provided to all beneficiaries. Going further, we encourage CMS to develop and promulgate concrete and well-developed shared decision making processes and record keeping related to the CCJR model. The proposed rule acknowledges that shared decision making prior to episode initiation can serve as an important tool to ensure appropriate care. CMS seeks feedback on the opportunity to capture quality data related to shared decision making between patients and providers, including the development of measures that evaluate a trial of conservative medical therapy prior to elective procedures and broader shared decision making. We fully support the development of such measures.

Establish Adequate Program Monitoring and Quality Measurement: The proposed rule acknowledges that hospitals could have an incentive to avoid complex, high-cost cases. CMS intends to monitor the claims data from participant hospitals—for example, to compare a hospital’s case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded.

CMS will publish these data as part of the model evaluation to promote transparency and an understanding of the model’s effects. The agency also proposes to continue to review and audit hospitals if CMS has reason to believe a given hospital is somehow compromising beneficiary access to care. For example, where claims analysis indicates an unusual pattern of referral to regional hospitals located outside of the model catchment area or a clinically unexplained increase or decrease in joint replacement surgery rates. We fully support these steps, but we encourage CMS to explore both the retrospective reviews outlined in the model and real-time monitoring.

We appreciate that hospitals are held financially accountable for quality in the proposed model—in addition to rewarding cost savings. CMS proposes three quality measures: 30-day all-cause risk-standardized readmission rates, risk-standardized complication rates, and patient-experience scores on the Hospital Consumer Assessment of Healthcare Providers and Systems. Hospitals would have to score above the 30th percentile nationally on all measures in order to keep the savings they generate.15

We strongly encourage, at minimum, maintaining these measures and this threshold. Yet, we are concerned by the absence of post-acute care measures discussed or linkages provided between post-acute measures and the three hospital measures, and we encourage the development of such. Below we outline additional areas where measurement, standards, and monitoring are needed.

Develop a Functional Measure: In particular, we agree with the Medicare Payment Advisory Commission’s (MedPAC) call for a function outcome measure.\textsuperscript{16} The proposed set of measures do not gauge improvement in function, the primary reason beneficiaries undergo the procedures and subsequent rehabilitation.\textsuperscript{17} MedPAC recommends that hospitals collect the same information on function that is required of post-acute providers to comply with the requirements of the Improving Medicare Post-Acute care transformation (IMPACT) Act of 2014 H.R. 4994.

The IMPACT Act requires the implementation of quality measures that are standardized and interoperable using standardized patient assessment data. Gathering consistent information across hospitals and all settings would enable comparisons of costs, quality of care, and patient outcomes. In turn, those comparisons would allow assessment of the value of services furnished in each setting. The IMPACT Act will require providers to submit standardized data by 2019 to allow Medicare to compare quality across different post-acute care settings. We strongly encourage CMS to incorporate data from IMPACT Act reporting into the quality measures in this model as soon as they are available.

Explore a Reward for Higher Quality: The goals of “reduce[ing] spending without reducing the quality of care or improve[ing] the quality of patient care without increasing spending” drive the provision of the Affordable Care Act (ACA) that gives CMS the authority to issue the proposed CCJR regulations.\textsuperscript{18}

Yet, under the proposed program, there is no reward for a hospital that achieves better outcomes for its patients at the same cost, e.g., if its patients had less pain during the recovery period or less pain or discomfort with their new knee or hip after they completed rehabilitation. Under the proposed CCJR program, quality measurement only comes into play as a punitive measure. If spending is the same but quality is higher, there is no bonus. If spending is lower and quality decreases, but remains above the threshold, bonuses can be paid. We recommend that CMS resolve this imbalanced incentive by exploring paying bonuses to hospitals which improve quality while keeping costs stable.

Ensure Effective Care Coordination by Creating a Minimum Standard: We understand the theory behind episodic bundling—namely, that accountability for one fixed payment will encourage highly coordinated care. We are skeptical, however, that this financial incentive in and of itself is enough to transform care. Instead, we encourage CMS to establish basic requirements for care coordination and competencies that must be met, independent of payment and measurement. Certain functions, such as discharge planning, are so integral to care coordination that requiring them should be routine for entities that aspire to coordinate care well.

Specifically, participating hospitals should be required to have clearly document clinical care models, care and transition plans including shared decision making tools and coordination with community supports, and protocols for documenting discharge planning and post-acute care coordination and supports (including consultation with post-acute care experts). Without these components, the success of financial incentives and measurement outcomes will not tell a reliable story. We believe that managed care entities receiving capitated payments for care (which are theorized to promote care coordination incentives similar to episodic bundling) have an uneven record of truly improving care coordination, and the CCJR bundles will have some disadvantages relative to traditional capitated entities, such as less influence over post-acute providers.

\textsuperscript{16} MedPAC Letter to Andrew Slavitt, Acting Administrator, CMS, commenting on the CCJR Proposed Rule, August 19, 2015.

\textsuperscript{17} Id.

\textsuperscript{18} 42 U.S.C. 1315a.
**Implement Accurate Risk Adjustment to Ensure Appropriate Incentives:** Under the proposed regulations, CMS would not adjust the episode spending targets based on differences in the kinds of care Medicare beneficiaries needed after they left the hospital. Although CMS will have different spending targets for hip and knee surgeries, the current rules were designed to risk-adjust spending for care in the hospital, not to risk-adjust spending for both hospital and post-acute care.

We are concerned about the consequences of failing to adequately risk adjust for post-acute needs. The proposed rule acknowledges that differences in patient characteristics could affect episode spending to a greater degree than is accounted for, but decline to impose a risk adjustment system because of a lack of consensus regarding the substance of such a system.

Opting not to risk adjust for post-acute needs risks two effects. First, it may become more difficult for beneficiaries to find a hospital to perform surgery if the patient would likely need higher levels of post-acute care after surgery, because the hospital could be penalized if those higher-need patients cause the hospital’s average episode spending to increase. Examples of beneficiaries who may require more intensive care include: those who are particularly frail, those with fewer resources available to them in their homes and communities, and those whose homes are less appropriate for post surgical recovery—e.g. multi-story walkup apartments.

Furthermore, since the hospital would, potentially, be accountable not just for services and care related to the surgery, but for chronic disease care, it might also be more difficult for patients with chronic conditions to receive surgery from a hospital. In addition, it may be more difficult for a patient to obtain care from a hospital if the patient’s other physicians are not affiliated with that hospital, because the hospital is less able to control post-acute costs, impacting access to care as well as patient choice.

Second, we are concerned that CCJR could create an incentive to encourage younger, healthier patients to undergo surgery—even if the beneficiaries could have managed with non-invasive treatments, such as physical therapy, medications, and exercise. These patients are likely to need less post-acute care, and they could reduce a hospital’s overall average spending per episode.

The proposed regulation does not penalize a hospital for performing surgeries that could have been avoided by using other services, but does for spending more than average on surgeries performed. The net result could be more surgeries and higher total spending, even though the average spending per surgery episode would be lower. As such, we encourage CMS to develop risk-adjustment measures that include the appropriateness of the surgeries performed, including by evaluating the use of pre-election shared decision making tools.

**Develop Objective, Accurate Notices:** We strongly commend CMS for the inclusion of beneficiary notice requirements. More specifically, we strongly support all of the required elements outlined, including that it be a written notice, with a detailed explanation, notification of freedom of choice, notice of beneficiary protections, and is applicable to CCJR partners. We recommend that CMS retain all of these elements in the final regulation.

In addition, we suggest the following to ensure accurate, timely notice for beneficiaries. First, we recommend that the notices be developed by CMS, essentially creating a notice template for use by hospitals. Allowing hospitals, that ultimately stand to profit from the model, to describe the “model and how it might be expected to affect the beneficiary’s care” may not result in objective information for consumers. We believe CMS is better positioned to create a standardized, customizable notice for use by hospitals.
Second, while we support a requirement on notice timing, we believe the proposed standard (upon admission) is unnecessarily late in most circumstances. At admission, a patient is in no reasonable position to understand, much less evaluate and act on, the CCJR information. Most candidates for CCJR bundling will have extensive contact with providers “at least one week prior to admission, or the earliest contact thereafter,” and that is the better standard for timing of notice.

We are concerned that hospitals may steer patients away from needed services or preferred providers that are more expensive. Hospitals may only inform patients of the less expensive treatment options or provide biased information about treatment options, even when a more intensive treatment is needed. As such, we encourage CMS to develop clear requirements for hospital and partners about providing full information about treatment options and providers. Hospitals should be required to document conversations with patients about all treatment options, and the patient and unbiased care team members should all be on record. CMS should also implement a “second opinion” process whereby a concerned consumer can seek an independent medical opinion concerning a post-acute care plan.

**Monitor Participating Providers:** CMS must develop a plan to identify where and when stinting on care occurs. We commend CMS for articulating this concern, but we believe a clear and specific monitoring and enforcement plan is needed to ensure beneficiary choice is protected and to ensure that consumers receive the most appropriate care, in the most appropriate setting, at the right time. The general enforcement authority referenced in the proposed rule should be strengthened to include a financial penalty for stinting on care. This penalty should be sizable enough to act as a disincentive for hospitals and other providers that might consider stinting as potentially profitable.

In addition, we strongly encourage CMS to develop training for 1-800-MEDICARE call center staff to identify and flag potential care reductions or inappropriate steering in this model. CMS should also ensure that the State Health Insurance Assistance Programs (SHIPs) are appropriately trained and engaged as the final model is implemented.

Lastly, we urge CMS to consider establishing an independent ombudsman program for the purposes of monitoring and assisting beneficiaries in all demonstration programs underway at the Centers for Medicare & Medicaid Innovation (CMMI), including the proposed CCJR program. Ombudsman programs are being successfully used in the Financial Alignment Initiative for Medicare-Medicaid Enrollees as well as to monitor the Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding program authorized by Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

These independent entities are responsible for monitoring beneficiary access to care, in addition to limiting beneficiary confusion and promoting enhanced understanding. With an increasing number of delivery and payment system models ongoing at CMMI, we believe a dedicated ombudsman is warranted.