ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments: American Advanced Medical Technology Association
March 28, 2016

The Clinical Episode Payment (CEP) Work Group
Health Care Payment Learning & Action Network

Re: Comments on draft white paper, Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement

Clinical Episode Payment Work Group, HCP-LAN:

The Advanced Medical Technology Association (AdvaMed) is pleased to offer comments on LAN’s recommendations contained in the February 26th draft white paper, Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement. AdvaMed has been a strong supporter of delivery reform models, such as bundled payments and episode based payments since their inception in the Affordable Care Act. We recognize the importance of the goals of these payment models for improving both the efficiency and quality of health care through enhanced care coordination, greater provider investment in infrastructure and redesigned care processes for higher quality care, and incentives to provide higher value care across the acute and post-acute care continuum of services covered by Medicare.

Our members’ technologies play a critical role in assisting providers to achieve each of these goals—especially in the context of the broad spectrum of services related to elective joint replacement. Our member companies’ products and services improve patient care quality and outcomes and many improve efficiency by reducing the lengths of stay of patients in health care facilities, enhancing perioperative productivity and reducing costs, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

Total joint replacement is one of the major success stories of American medicine. Total joint replacement procedures have been shown to restore mobility, relieve pain, and help patients with osteoarthritis return to normal lives and functioning. Medicare patients receiving total hip and knee replacement show nearly half the risk of death after seven years compared to osteoarthritis patients not receiving total joint replacement.1 In addition, total knee replacement has been found


Bringing innovation to patient care worldwide
to be cost saving. One study has found that total knee replacement surgery generates a net societal savings of approximately $19,000 per patient lifetime, due to reduced disability costs and improved productivity.\(^2\) This study found that in 2009 alone, savings in the U.S. were an estimated $12 billion.

We have organized our comments for the CEP Work Group’s recommendations in the order in which they appear in the draft paper.

1. **Episode Definition**

**Elective:** Many providers participating in the Bundled Payment for Care Improvement (BPCI) initiative implemented by the Center for Medicare & Medicaid Innovation (Innovation Center) and the Comprehensive Care for Joint Replacement (CJR) bundled payment model already use or will be using Medicare DRGs for defining their bundles. AdvaMed recommends that future episode payment models for elective joint replacement also be based on DRGs, in order to simplify administration for providers. This would mean, however, creating additional target prices for fractures, as was done for the CJR, since these procedures have higher costs.

**Appropriate:** The white paper recommends that an ideal episode payment model for elective joint replacement should support appropriateness of the episode and optimal quality, and should have a set price that supports high quality care delivery.

We urge the CEP Work Group to consider that high quality care delivery should encompass evaluation of patient access to the full range of devices appropriate for a specific individual’s medical conditions and life-style. One of our overarching concerns with episode-based payments is their focus on short-term costs incurred during a relatively short period of time that can lead to stinting on care. Stinting in this instance can take the form of selecting only lower utility devices without proven track records of safety and durability. It can also mean compromised patient access to innovative technologies when these are more expensive than previous generations of devices. The Work Group should also consider how to structure policy options that would encourage use of joint implants associated with reduced revision rates. Lower joint replacement revision rates significantly lower Medicare spending outside the 90-day episode of care window, and translate to fewer beneficiaries undergoing costly and invasive revision surgery. Too much emphasis on short-term savings could compromise patient access to technologies that perhaps cost slightly more in the short term, but save much more long-term by reducing the need for revision surgeries.

Many medical devices and technologies provide benefits over a period of time spanning multiple years. The financial incentives in delivery reform models with short episode windows, together with their promise of an additional stream of income for providers, can be too compelling for providers, especially when the long-term value of more expensive care or technologies is not

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factored in. As a result, savings on short-term costs could translate into higher costs over the long term, for example, through higher revision rates for joint replacement procedures as a result of patients not having access to devices more appropriate for their needs and lifestyles. We also note the challenges in sustaining savings, year after year, that are generated by spending reductions year after year and how the pressure to do so can challenge a provider’s decision process in particular when the realization of these risks could take several years before they are expressed in a way that requires further utilization. We discuss this last point in greater detail below.

We offer a real world example of how financial incentives in delivery reform models can lead to what may be compromised patient access to appropriate devices for joint replacement. Some of our orthopedic company members have learned that certain providers participating in the Innovation Center’s BPCI initiative have radically changed the type of hip and knee implants that they buy and implant in patients.

In the past, these hospitals had purchased a range of device implants—including some implants that are more basic, without newer features and with varying levels of performance characteristics that improve range of motion or impact durability (e.g., lower utility implants). Providers made implant selection decisions that corresponded to the particular lifestyle needs of patients, including life expectancy, level of activity, and medical conditions. This process is called demand matching and is an effective method in managing utilization without limiting access to technologies that best meet individual patient needs. With participation in BPCI, these providers now purchase almost exclusively lower utility implants without respect to patient needs. Matching the utility of a device to a particular patient’s need is critical to ensuring a positive outcome for the patient and long-term effectiveness of the procedure. For example, an active, tennis-playing 65-year old requires a hip or knee of higher utility and performance characteristics than one that is appropriate for a sedentary 85-year old.

While it is possible that the patient mix of Medicare beneficiaries treated by the providers has changed since participation in BPCI began, it should be pointed out that lower utility devices are also initially less expensive than the higher utility devices, leading to potentially higher internal savings that can be shared in the short term. The longer term impact of using almost exclusively lower utility devices, when they may not be appropriate for the lifestyle and medical needs of individual patients, may not be known for several years, when active beneficiaries may require earlier than expected revision procedures or experience other negative outcomes. If the choice of a hip or knee device were made solely on the basis of patients’ relative health, lifestyle and life expectancy, patients would be provided a device that appropriately demand matched to their unique needs with cost not being a leading driver of this decision so as to ensure the best possible outcomes and longevity.

In order to protect beneficiaries from these potential consequences of the financial incentives inherent to certain delivery reform models and to ensure that decisions about a patient’s care are made solely on medical grounds, AdvaMed first recommends that participating providers be required to make available to the public on Hospital Compare or via other reporting:
(1) whether or not the providers have participated in gainsharing, and the amount of gainsharing rewards that physicians and other providers receive from internal savings initiatives of the hospital, and (2) savings they earn from reconciliation payments made for a performance year.

With this information, Medicare beneficiaries will be able to ask questions about how rewards and savings will affect their care and health care outcomes and also for making decisions with their providers about the most appropriate device for their particular health and lifestyle.

Furthermore, we strongly oppose any gainsharing programs that reward providers for using products simply because they are less expensive and not appropriate for patients’ needs. Internal gainsharing programs that focus on medical device savings simply drive providers to use devices because they are less expensive, even if it means higher Medicare spending in the long-run due to more frequent revision procedures in the future.

Toward that end, we oppose gainsharing that is exclusively tied to use of lower-utility medical devices not appropriately matched to patient needs. Instead, we believe that shared savings opportunities should be based on incentives that encourage providers to deliver high quality care more efficiently. In this way, higher quality and reductions in adverse patient events become the central organizing principles of care redesign, rather than incentives that lead providers to use the cheapest product to maximize a short-term gainsharing arrangement.

In addition, AdvaMed urges that episode payments be accompanied by controls that protect patients against wholesale changes in device offerings of providers participating in the payment model and to consider prohibiting gainsharing altogether when tied to the use of less expensive and lower-utility devices. We further recommend that care in participating hospitals be carefully monitored for the appropriateness of device choice for individual patients and surgeons.

**Functional Assessment Tool.** The white paper also recommends that providers use a standardized, validated functional status assessment tool to determine that the patient is an appropriate candidate for a surgical procedure. AdvaMed supports this recommendation as a safeguard for patient access to joint replacement procedures, especially in the context of persons receiving care through an ACO delivery model. The financial incentives in ACOs, with their emphasis on spending reductions without accompanying robust quality measures, could lead to delay in patient access to appropriate joint replacement as a response to the cost of the replacement procedures being significantly higher than alternative treatments, such as medication therapy. As a result, joint replacement procedures will have a much greater impact on an ACO’s year-end spending total than medication therapy and when compared to the ACO’s benchmark could result in lower shared savings available to providers in the ACO. A standardized, validated functional assessment tool will help protect patients against this form of stinting.

**Decision Aids.** AdvaMed strongly supports the use of decision aids as additional tools for safeguarding patients against stinting that may occur in delivery reform models. Further we recommend that the use of decision aids as part of shared decision making by patients and
providers be incorporated into a quality measure that would be required for joint replacement procedures. As discussed above, AdvaMed is concerned that some providers participating in BPCI may be shifting almost exclusively to using lower utility devices. A requirement that providers and beneficiaries share in decision-making about the particular device to be used for a procedure will help protect patients from financial incentives that may lead to less than optimal device choices.

We also believe that shared decision-making will be most effective for patients if they understand the financial incentives underpinning delivery reform models and also have available specific levels of financial rewards received by providers participating delivery reform models.

2. Episode Timing

So long as services that would be included in a look-back period of 30 days prior to surgery are related to the elective procedure, AdvaMed supports that starting point for the episode. We also support an end point of 90 days post-discharge, by which time most spending would have occurred for most patients. We also concur with the recommendation that quality measurement should include data up to 12 months post-discharge, even though the episode payment period ends 90 days post-charge. While we remain concerned with the impact financial incentives in short-term episodes can have on patient access to all appropriate treatment options and innovative technologies, we believe that tracking quality data for an entire year following discharge will counteract some of the delivery models’ underlying incentives that could lead to stinting. Possible areas for 12 month post-discharge measurement include patient-reported outcomes that capture return to activities of daily living, restoration of mobility resembling pre-surgical movement, and revision rates.

3. Patient Population

AdvaMed supports the white paper’s recommendation that the patient population to which the episode payment would apply should be broad and payments should be based on risk and severity adjustments to account for age and complexity. However, as we discussed in detail above, additional protections and strong monitoring programs also need to be put in place to protect patients from excessive standardization of hip and knee technologies and to ensure that they receive devices that most appropriately correspond to their lifestyles and medical conditions.

4. Services

AdvaMed agrees that the episode payment should include delivery of all services billed in the defined time period that are related to the joint replacement procedure, including physician services, skilled nursing or other rehabilitation services, home health, therapy service, etc.

We also recommend that payments cover telehealth services that are essential for maximizing the opportunity to improve the quality and efficiency of care provided under the episode payment. Given the variety of sites to which a patient can be referred following discharge from the hospital
setting and the desire for most patients to return to their homes as soon as possible, telehealth is ideally suited for allowing patients to return to the least restrictive setting for follow-up care and for monitoring their recovery and progress in regaining function. In order to incentivize the use of telehealth technologies, the episode payment for joint replacement procedures must recognize the need for coverage of services beyond restrictions and limitations that exist in public programs (see Medicare and expanded coverage for telehealth under BPCI and CJR) or private payer programs. Calculation of benchmarks and actual spending totals should not penalize providers for their desire to use these technologies, which are particularly central for these procedures to realize improvements in efficiency and quality of care.

5. Patient Engagement

As discussed above, AdvaMed strongly supports the development and deployment of rigorous decision-making tools for joint replacement procedures and we support including in these tools information enumerated in the specific recommendations of the white paper. However, we caution that shared decision-making may involve a cost to physicians not reflected in fee-for–service payments for their services and not included in benchmark calculation. We agree especially with the recommendation that patients and their family caregivers need information on how providers are being reimbursed in an episode payment model. We argue that this information should necessarily include a discussion of gainsharing rewards that a provider will receive as a result of services provided during the episode--and specifically how those rewards might affect a physician’s decision about device selection for the patient. From this discussion, patients should understand that devices have a broad range of functional features designed to address individual patients’ lifestyles and medical conditions, and how physician recommendations have changed over time, particularly in the context of participating in bundled payment programs. These discussions will protect patients as well as deter providers from less than optimal device choices for joint replacement procedures.

6. Accountable Entity

The white paper argues that the accountable entity for managing the episode should be chosen based on its ability to engineer change in the way care is delivered to the patient and its ability to accept risk for the episode. While CMS and the Innovation Center have opted to this point for hospitals to take on that role in bundled payment models, it is conceivable that certain physician practices may be able to meet both tests. AdvaMed agrees with the work group’s assessment that either type of entity may be able to meet the criteria, just as both types of entities now participate in the Medicare Shared Savings Program. What will be critical is an assessment by payers of an entity’s readiness to manage care across the entire continuum of settings where patients may receive care during the episode and the entity’s ability to promote collaboration and coordination among multiple providers. It is also critical that the entity be able to manage gainsharing programs, to the extent they are used to foster collaboration, so that they do not result in forms of stinting discussed in detail above.
7. Payment Flow

AdvaMed supports the white paper’s recommendation to use, at least for the immediate future, a retrospective reconciliation episode payment with upfront payments flowing through a fee-for-service mechanism. Given the major changes that will accompany episode payments for joint replacement and potential disruption to patient care that might occur in non-integrated systems, retrospective reconciliation based on fee-for-service payments has the advantage of being used in current episode initiatives and allowing providers to track more easily resources used in the episode—experience and information central to any transition to episodes based on prospective payments.

8. Episode Pricing

AdvaMed supports the white paper’s recommendation to establish an episode price based on regional and provider-specific data, but questions have to be resolved about what is an appropriately sized region and what is the optimal blend and transition from entity specific costs to regional costs. Our concern is with any methodology for establishing price that results in ever greater pressure on efficient providers to continue to achieve savings that would pose risks to patients in the form of stunting on care and compromised patient access to appropriate treatment options and innovative technologies—risks already inherent to episode payment models. Episode payments require rigorous monitoring of patient care outcomes, including evaluation of types of devices being used by providers participating in the episode model and determination of whether incentives in the model has led to excessive standardization of devices at the expense of quality patient care.

9. Type and Level of Risk

In general, AdvaMed supports both upside and downside risk, with physicians allowed to share risk. The white paper recommends that transition periods and risk mitigation strategies should be used to encourage broader provider participation. AdvaMed argues that both of these mechanisms are needed for another purpose: to ensure that patients receive high quality care during the episode and over the long term. As noted above, the financial incentives in relatively short episode windows and the promise of gainsharing rewards that would accompany reductions in costs of care could have the effect of compromising patient access to all appropriate treatment options, especially when some of those options are more expensive than others. In many cases, providers participating in the episode payment model would not experience the consequences of inappropriate device selection since they may not become apparent until several years after the conclusion of the episode. Transition periods and risk mitigation strategies could mitigate some of negative consequences of underlying incentives in the episode payment model.

10. Quality Metrics

AdvaMed strongly supports the development of patient-reported outcomes and functional status measures for joint replacement procedures, but believe that stakeholders should agree on meaningful and measurable standard quality metrics. Today too few measures exist for joint
replacement procedures to support an assessment of quality of care received during an episode of care or meaningfully inform patients about quality they can expect from specific providers prior to a decision to undergo an elective procedure. With patient-report outcome and functional status measures, quality measurement can and should continue beyond the defined episode period and should include data up to 12 months after discharge.

11. Role and Perspectives of Stakeholders

The Work Group’s white paper states that it is important to consider all stakeholder voices in the design and operation of episode payments—mentioning payers, providers, patients and consumers, and employers and purchasers—but not including manufacturers of the hip and knees technologies used in joint replacement procedures. Our member companies are, of course, expert in assisting with decision-making for matching particular design features of devices with the lifestyles of patients. In addition, they are currently developing capacities for helping providers with managing costs for the entire episode of care through services that will enhance both efficiency and quality. Manufacturers are stakeholders which should not be left out of the equation for maximizing improvements in care outcomes and controlling spending growth.

We would be pleased to answer any questions regarding these comments. Please contact Richard Price, Senior Vice President, Payment and Health Care Delivery Policy, at (202) 434-7227, if we can be of further assistance.

Sincerely,

/s/

Don May
Executive Vice President,
Payment and Health Care Delivery
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
Ambulatory Surgery Center Association
March 28, 2016

COMMENTS REGARDING THE DRAFT WHITE PAPER - ACCELERATING AND ALIGNING CLINICAL EPISODE PAYMENT MODELS: ELECTIVE JOINT REPLACEMENT

Via online submission at https://hcp-lan.org/groups/cep/elective-joint-replacement/ejr-comments/

Members of the Clinical Episode Payment Work Group:

The Ambulatory Surgery Center Association (ASCA) submits these comments in response to the Health Care Payment Learning and Action Network’s (LAN) Draft White Paper (Draft), “Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement.” The episode-payment framework set out in this Draft, while it does not explicitly exclude the ambulatory surgery center (ASC) setting, appears to focus solely on elective joint replacements performed in inpatient hospitals. Advancements in technology and surgical technique enable many surgeons to perform total joint replacements safely and effectively on a routine basis in the ASC setting. ASCA is encouraged by LAN’s collaborative spirit and mission to ensure high-quality outcomes and patient satisfaction, but concerned that ASCs are only mentioned once on page 14 of the Draft and generally all other references to site of service throughout the Draft seem to refer to inpatient hospitals. ASCA recommends that LAN include language in the Draft that specifically states and promotes that ASCs are an appropriate and viable treatment setting for some patients being treated for elective joint replacement. We welcome the opportunity to work with members of the Clinical Episode Payment Work Group (Work Group) to discuss the points raised in these comments.

Work Group members were charged with creating a set of recommendations that can facilitate the adoption of clinical episode-based payment models for elective joint replacement, also known as joint replacements to the lower extremities. ASCA believes ASCs can be an important part of this response. ASCs epitomize the value, quality, cost effectiveness and patient engagement that this Draft promotes. For example, an analysis by researchers at the University of California-Berkeley found that ASCs saved the Medicare program and its beneficiaries $7.5 billion during the four-year period from 2008 to 2011.1 The Berkeley researchers project that ASCs have the potential to save Medicare an additional $57.6 billion over the next decade. The federal government confirmed that substantial savings can be achieved when procedures are performed in ASCs. According to a report from the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG), from CYs 2007 through 2011, ASCs saved Medicare almost $7 billion, saved beneficiaries an additional $2 billion and have the

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1 University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, Medicare Cost Savings Tied to Ambulatory Surgery Centers, September 2013.
potential to provide the federal government and its beneficiaries even greater savings in the future.\textsuperscript{2}

More importantly, patients who receive treatment in ASCs benefit from high quality care that results in better outcomes. A study published in \textit{Health Affairs} in 2015 compared the quality of care provided in ASCs and hospital outpatient departments (HOPDs), and found that treatment in an ASC is associated with better patient outcomes, even when patient risk severity is held constant.\textsuperscript{3} This study analyzed inpatient admissions and ER visits up to thirty days following outpatient procedures, quality metrics similar those currently captured by the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. Beneficiaries and payors benefit when they work with ASCs and encourage migration of procedures to this setting.

\textit{ASCA's Episode Payment Model}

Enhancing the quality and cost-effectiveness of lower joint surgery in the ASC setting has been a priority for ASCA. To that end, we have done some significant thinking and research on this topic. In August 2013, ASCA developed and submitted a proposal to the Center for Medicare & Medicaid Innovation (CMS Innovation Center) entitled, “Medicare Beneficiary-Centered Surgical Care and Post-Acute Care Management for Hip, Knee and Spine Surgery in the Ambulatory Surgery Center Model (Model).” This proposal, a bundled payment model for hip, knee and spine surgeries performed in the ASC setting, introduced a new surgical care management initiative using an innovative clinical decision protocol tool to identify appropriate patients who may receive hip, knee, and spinal procedures in lower-cost, high-quality ASCs. It also included a quality component to ensure Medicare beneficiaries receive evidence-based, high quality care throughout the episode of care.

Although ASCA was not awarded a grant from the Innovation Center, the design elements of our Model focus on the outpatient setting and provide evidence of appropriateness of including elective joint surgeries performed in an ASC setting in this bundle. An elective joint bundle that includes the option of the ASC setting would improve the overall health status of patients while creating surgical efficiencies that reduce healthcare costs. Explicitly including ASCs in your recommendations for elective procedures would provide a means for LAN and other stakeholders to evaluate, test and develop an appropriate payment bundle for all of the settings where patients receive these procedures. Through such an approach LAN would be using the clinical process of care to guide the development of an appropriate reimbursement methodology versus a siloed approach that is just focused on one setting.

\textit{The Importance of Clinician Leadership}

The Draft references the importance of clinician leadership and the ways clinicians can have the greatest impact on care redesign. ASCA wholeheartedly agrees that physicians play a critical role


in the clinical and financial management of an episode of care. For such initiatives to be successful, there must be buy-in from physicians and their support is necessary to create a system-wide culture focused on high quality, patient-centered care. We also agree that while leadership will come from the physicians, it is critical that all providers that are part of the bundle share in both risks and rewards.

Clinician leadership is essential to identify care and redesign opportunities across the care continuum. The ASC environment provides an ideal example of how physician leadership can enhance the quality and cost effectiveness of care. Patients served in ASCs benefit from this type of clinician-led care team that extends beyond the walls of separate facilities. Physicians, surgical technicians, physician assistants, anesthesiologists, primary care physicians and therapists work as a seamless team when procedures are performed in ASCs. Non-clinical administrators play an important role in a patient’s care, but that role remains subordinate to the clinicians who lead care coordination, accountability and other components of meaningful care redesign.

The Importance of Patient, Family, and Caregiver Engagement

Patient, family and caregiver engagement is an important concern and recurring theme throughout the Draft’s design elements. A patient’s coping skills, emotional health and support system impact their ability to achieve better health outcomes post-surgery. These characteristics should be accounted for when the patient and provider consider not only the correct intervention, but the facilities where that intervention could take place. Differences in care settings are important factors for consideration by patients as they choose the optimal course of their care, and should be presented in shared decision-making and patient engagement tools.

Care provided in ASCs is a key element in this holistic approach. An integral part of the care provided in ASCs involves keeping patients, family members and caregivers connected and supported throughout the spectrum of care, from deciding if surgery is appropriate all the way through discharge home or to a post-acute setting. This is accomplished through the use of shared decision-making tools, thorough pre-surgery education, structured follow-up post discharge and communication and coordination among care team members.

We appreciate LAN’s continued effort to engage stakeholders in developing and promoting patient-center healthcare reform. Please contact Steven Selde at sselde@ascassociation.org or (703) 836-8808 if you have any questions or need additional information.

Sincerely,

William Prentice
Chief Executive Officer
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments: American Association of Hip and Knee Surgeons (AAHKS)
March 28, 2016

VIA ELECTRONIC SUBMISSION

Lewis Sandy, MD
Chair
Clinical Episode Payment Work Group
Health Care Payment Learning & Action Network

RE:  Comments on Elective Joint Replacement – Draft White Paper

Dear Dr. Sandy:

On behalf of the 2,710 members of the American Association of Hip and Knee Surgeons (“AAHKS”), thank you for the opportunity to comment and offer suggestions on the Health Care Payment Learning & Action Network’s (“LAN’s”) draft white paper, Elective Joint Replacement (“White Paper”).

AAHKS is the foremost national specialty organization of physicians with expertise in total joint arthroplasty (“TJA”) procedures. Many of our members conduct research in this area and are expert on the evidence based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is also closely engaged in the design and operational questions facing the various Medicare bundled payment initiatives.

AAHKS offers comments on this White Paper, prepared by the LAN Clinical Episode Payment Workgroup (“CEP”), to ensure the LAN benefits from our more broad experience in TJA procedures and bundled payments. Our comments below correspond to the sequence of design elements discussed in the White Paper.

1. **Episode Definition**

“The episode is defined as an elective and appropriate total hip or total knee replacement due to osteoarthritis.”

AAHKS accepts, in principle, the White Paper’s recommendations that the episode be limited to elective TJAs due to osteoarthritis. This is an improvement over the episode offered in the Medicare Comprehensive Care for Joint Replacement Model (“CJR”) commencing shortly. By excluding fractures, the White Paper properly recognizes that elective procedures are a
comparatively controlled clinical event, more subject to provider influence and care, unlike fracture cases. It should also, however, make an effort to exclude TJA for tumors, metastatic cancer, avascular necrosis, inflammatory arthridities such as rheumatoid arthritis and other diagnoses not addressed in the CJR.

The White Paper also recommends that in addition to a routine clinical assessment, a provider use a “standardized, validated functional status assessment tool” to ensure the patient is an appropriate candidate for the procedure. At this point in time, those tools have been used as outcome measure and are validated for measuring the change in status from before and after such episodes. They are not well validated as tools to decide who needs surgery.

We agree with the measuring of outcomes, but are concerned about cost and administrative burden. Functional status assessment tools must be brief and easy to incorporate into existing practice. The more than 40 questions of the HOOS and KOOS assessments become burdensome and unwieldy for routine use in a clinical setting. We appreciate that during the March 22, 2016 LAN webinar discussing the episode, multiple members of the CEP emphasized the need to develop short-form functional status assessments that “get to same good answers with fewer questions” and are therefore realistic for the patient encounter.

We ask the CEP to acknowledge that additional patient exclusion may be necessary as a component of defining the episode. Patient exclusion should occur when the rules and assumptions of the system of care at the heart of the episode cannot be expected to effectively manage the risk associated with their unique set of conditions. If these conditions are defined as modifiable, then their exclusion may be temporary and efforts can be made to correct medical conditions prior to the beginning of the bundle. Such exclusion would be consistent with the White Paper’s principle for limiting the episode to THAs for osteoarthritis, but more explicit definition of such exclusions is needed. Any method of selecting patients for inclusion in the bundle will have wide-ranging impacts, and care must be taken to ensure that adverse selection of at-risk patients does not result in care denial, if such care is medically necessary.

2. **Episode Timing**

“For purposes of payment, the starting point for this episode is 30 days pre-procedure, and the stopping point is 90 days post-discharge. Accountability for functional improvement may go beyond the 90 days.”

We do not agree with the White Paper recommendation to frame the episode as beginning 30 days prior to surgery, although we can accept the episode ending 90 days following discharge. This is an appropriate post-discharge window in which to capture most significant complications, after which the ability to impact quality and outcomes is diminished. As the White Paper notes, the appropriateness of the time frame for any episode is determined by which providers and services are included in the episode. An episode with narrowly defined services and fewer participating providers will logically correspond to a shorter timeframe. The
30 days window before surgery is too long and will attribute to the surgeons/hospitals work-up costs that were not in the control of the treating surgeons.

3. Patient Population

“The episode should apply to the broadest-possible pool of patients, using risk and severity adjustment to account for age and complexity.”

We agree with and embrace the White Paper’s assertion that “ Appropriately specified risk and severity adjustment algorithms applied to the episode price are critical.” AAHKS believes that inadequate or non-existent risk adjustment is the most significant possible deficiency in an episode or bundled payment design.

If an episode fails to reward hospitals and surgeons who treat high-risk patients at the same level of quality as those treating low risk patients, providers will be driven to treat only low-risk patients. Those treating a greater number of high-risk patients will face perverse financial penalties for taking on the most difficult cases.

For example, the White Paper does not address the differences between primary and revision TJA procedures. AAHKS has found that compared to primary total hip arthroplasty (“THA”) for osteoarthritis, conversion THA is associated with significantly more complications, a longer length of stay, and more likely discharge to continued inpatient care, implying greater resource utilization for these patients versus primary THA. Therefore, conversion THA appears to be one procedure for which risk-adjustment is appropriate.

The CEP should acknowledge that multiple methods are available to account for patient variation. Episodes may include risk stratification, exclusion, and other methods depending on what is most appropriate within the entire episode. Development of risk adjustment methods must be done with close consideration of minimizing additional data collection steps for providers. Many important risk factors for adverse patient outcomes currently are either not measurable using available data (e.g., preoperative functional status) or are not consistently reported (e.g., obesity).

4. Services

“All services needed by the patient that are related to the joint replacement procedure should be covered by the episode price.”

The White Paper recommends that episode payment should include delivery of all services billed in the time period that are related to the elective joint replacement procedure. The White Paper further notes this may be accomplished through enumerating specific included or excluded services. Such excluded services need to be broad enough to protect the providers from the actuarial risk in the post-operative period of events occurring that are unrelated to the TJA and out of the control of the providers.
AAHKS commends the White Paper for highlighting the challenge of creating such enumerations when considering patients with multiple complex, chronic conditions. Risk adjustment may not completely account for the magnitude of this variation and therefore episodes should also appropriately assign accountability to the provider or entity best able to manage or treat an underlying chronic condition.

5. **Patient Engagement**

“Require use of shared decision-making and patient engagement tools and transparency of the payment model in patient-facing materials to maximize opportunities to engage patients and families in advancing high-value care.”

AAHKS agrees that patient engagement is key and supports the White Paper recommendation that providers incorporate shared care planning. The White Paper specifically discusses setting goals prior to the surgery and ensuring that patient, provider, and appropriate family or care givers are included in that discussion. It is helpful that the role of primary caregiver is discussed as a necessary participant in care planning for patients with chronic diseases.

Proper patient engagement includes reviewing the social support and psychological wellbeing of the patient, along with ensuring a home environment conducive to optimal recovery. Providers need to stress the elective timing of surgery and the dramatic impact that modifying risk factors can have on avoiding adverse events or delayed recovery. Modifiable risk factors such as smoking, anemia, diabetes management, and malnutrition should be addressed as inherent risks on the surgical outcome. Finally, delaying surgery, though inconvenient and unsatisfactory, should be considered prudent and preferable to operating on a patient with poorly managed chronic conditions whose risk profile can be altered by appropriate interventions.

The White Paper additionally recommends that prior to surgery, patients be provided with information about the quality and procedure complication rates of possible surgeons and possible acute-care facilities. It is suggested that “such help should be available through clearly designated personnel without conflicts of interest.” It is not clear how this recommendation would be operationalized. It seems that the most likely personnel to deliver such information concerning surgeons would be the patient’s primary care provider, and that the most likely source of information concerning post-acute care facilities may be the orthopaedic surgeon. The White Paper should be clear if other “designated personnel” are intended and who they may be.

It is not clear that there is an appropriate shared decision making tool that has had been proven to have psychometric validity. It should be noted that the most recent version of the Healthwise tool as provided in 2015 had grossly incorrect information regarding survivorship of modern implants that was based on older literature.
Additional clarity is also needed around the definition of “conflict of interest” that the designated personnel would be free from. While patients may be ultimately free to choose providers, it should be acknowledged that primary care providers, surgeons, hospitals, and post-acute care facilities are increasingly likely to be operating jointly as accountable care organizations or collaborative care networks. Entities within these shared savings arrangements naturally will be incentivized to recommend participating providers with the highest quality and best efficiency, but will such arrangements be considered a conflict of interest?

6. **Accountable Entity**

“The accountable entity should be chosen based on its ability to engineer change in the way care is delivered to the patient and its ability to accept risk for an episode of care.”

AAHKS agrees with the suggestion that clinicians, particularly the orthopaedic surgeons or practice, may be most able to effect change in a joint replacement episode. Many hospitals will not have the capability of managing the episode without substantial additional guidance from surgeons, and could be placed at significant downside financial risk if they fail to turn clinical management over the provider most able to effect change in a joint replacement.

The White Paper also suggests that some physician practices lack the financial resources to assume downside risk as the primary accountable entity under an episode. This is true in some cases and therefore hospitals and physicians should be free to make their own arrangements as to the degree of upside or downside risk to be assumed by either under the episode. It would not be appropriate for a payer to unilaterally make the decision for all parties by, for example, barring orthopaedic surgeons from being in any way the accountable entity.

7. **Payment Flow**

“Use retrospective reconciliation with upfront payments flowing through an FFS mechanism (APM Framework Category 3).”

The White Paper discusses the alternative benefits and risks of prospective or retrospective fee for service payments in the episode. Regardless, AAHKS supports retrospective payment reconciliation for the episode to determine the actual costs.

8. **Episode Price**

“Data used to establish the episode price should reflect two years of historical costs and strike a balance between regional- and provider-specific data. The price should acknowledge efficiencies already gained by previous programs and incentivize more efficient levels of practice.”
The White Paper succeeds in articulating the interconnected challenges in setting a target episode price through a combination of provider- and regional-specific cost data. If provider-specific costs alone are used, institutions that have already achieved significant efficiencies will be challenged to achieve further savings required under the episode. Similarly, if regional cost data alone is used, those regions that are comparatively efficient as a whole will have a greater number of institutions that are challenged to achieve measureable additional savings in comparison to providers in other regions.

The White Paper proposes a mix of the two types of data, noting that “over time, as performance becomes less variable, it may be useful to lessen the proportion of the episode look-back period that is based on the organization’s specific experience.” This is very similar to AAHKS’ comments on the CMS CJR Proposed Rule, which also commences with a blend of regional- and provider-specific cost data for its episode price. We requested that CMS allow participating hospitals to opt in to regional-only pricing on a more accelerated timeframe lest efficient hospitals be penalized – through lack of payment – for their early efficiency.

We appreciate that the White Paper notes “risk adjustment will also be needed during this process to adjust for the unique characteristics of the population the provider serves.” As discussed earlier, proper risk adjustment is essential to account for the real differences in patient population that would not otherwise be appropriately or fairly reflected in regional- or population-specific cost data.

9. **Type and Level of Risk**

“The goal should be to utilize both upside and downside risk. Transition periods and risk mitigation strategies should be used to encourage broader provider participation.”

AAHKS embraces the White Paper recommendation to incorporate both upside and downside risk. We agree with the included qualification that some small providers, such as physician practices, face challenges in taking on downside risk and transitional “phase-in” periods may be necessary.

We appreciate that the White Paper again notes the importance of mechanisms for limiting risk, such as “risk adjusting the episode price, based on the severity within the population.” A variety of risk limiting methods are discussed, but what is most important to the success of the episode is that *some adjustment occurs* to limit risk to account for the health status of patients and account for the fact that care is provided by multiple providers across the episode.

10. **Quality Metrics**

“1) Prioritize use of patient-reported outcome and functional status measures; 2) Use quality scorecards to track performance on quality and inform decisions related to payment; and 3) Use quality information to communicate with and engage patients.”
Patient-Reported Outcomes - AAHKS agrees that it is critical to measure the outcomes and patient experience of care to determine whether quality improvements are achieved. We also agree that some metrics, such as patient experience surveys of a hospital experience, and may not be designed to capture key attributes of the patient experience specific to joint replacement. For example, CMS intends to use the HCAHPS survey as one of the measurements to determine a hospital’s eligibility for reconciliation payments under the CJR. However, the HCAHPS survey is given to a random sampling of all hospital patients. Therefore, the results that would be reported under the CJR Model would relate to all hospital patients, rather than those whose treatment is subject to the CJR Model. In addition HCAHPS only assesses the patient inpatient experience which does not reflect on the whole 90 day episode of care.

The White Paper notes that the Core Quality Measures Collaborative has released “consensus” orthopaedic measures and is also working towards Patient Reported Outcome and Patient Experience measures. We believe that payers’ attention should also be turned to consensus patient-reported outcomes measures suitable for TJA performance measures as developed by AAHKS, the American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, and American Joint Replacement Registry. Specialty Societies should be viewed as a resource with the appropriate experience and expertise to identify patient-reported outcomes that can be integrated into practice and that are reflective of quality. We appreciate the CEP members on the March 22, 2016 webinar discussing how patient reported outcomes measures have value as a process measure for orthopaedic surgeons but that they do not measure provider performance or outcomes.

Quality Scorecards - Any quality scorecards that are used should incorporate adequate risk adjustment to reflect the population served by a provider. AAHKS members have historically been assessed on readmission, re-operations, cost, and length-of-stay, but these measures often inadequately account for the wide variation among patients and therefore lose their comparative value. Whatever measures are developed or adopted, or quality assessments are used, they must be risk-adjusted for factors such as health status, stage of disease, genetic factors, local demographics and socioeconomic factors. These factors represent real variations in patient need and the costs of care. The lack of adequate risk adjustment would also limit the value of data generated by the episode to inform providers of optimal interventions.

11. Additional Operational Considerations

We support the White Paper statement that well-designed payment models must consider the perspectives of payers, providers, and patients, “well as support reliable delivery of care that is provided at the right time in the right setting.” Further, regarding the regulatory environment, we believe that federal and state law makers and regulators can do more to modernize existing regulatory frameworks to account for industry-wide progression towards more bundled payments.
AAHKS appreciates your consideration of our comments. You can reach me at mzarski@aahks.org, or you may contact Joshua Kerr at jkerr@aahks.org.

Sincerely,

Michael J. Zarski, JD
Executive Director
AAHKS
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:
Elective Joint Replacement
White Paper

Comments:
American Association of Nurse Anesthetists (AANA)
March 28, 2016

Submitted via https://hcp-lan.org/groups/cep/elective-joint-replacement/ejr-comments/

Clinical Episode Payment Work Group


To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on this white paper entitled “Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement.” The AANA makes the following comments and requests in the following areas:

- Role of anesthesia and anesthesia providers like CRNAs are missing from the major design elements and must be emphasized in the final white paper
- Recommendations on design elements should encourage cost efficient anesthesia delivery models
- The white paper should discourage the use of policies that drive up healthcare costs
- The role of APRNs should be emphasized and the white paper should treat APRNs, such as CRNAs, and physicians equally
- S-CAHPS should not be used to measure patient experience of care, particularly its problematic section on anesthesia services

OPERATIONAL CONSIDERATIONS SECTION

- The white paper should acknowledge and eliminate barriers to the use of APRNs and CRNAs in the regulatory environment

Background of the AANA and CRNAs

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists, and AANA membership includes more than 49,000 CRNAs and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 40 million anesthetics to patients each year in the United States.
have provided anesthesia in the United States for 150 years, and high-quality, cost-effective CRNA services continue to be in high demand. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the physician fee schedule amount for services.

CRNA services include providing a pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. According to a May/June 2010 study published in the journal of *Nursing Economic*$, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.\(^1\) Furthermore, an August 2010 study published in *Health Affairs* shows no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.\(^2\) Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration.\(^3\)

According to a 2007 Government Accountability Office (GAO) study, CRNAs are the principal anesthesia provider where there are more Medicare beneficiaries and where the gap between

\(^1\) Paul F. Hogan et. al, “Cost Effectiveness Analysis of Anesthesia Providers.” *Nursing Economic*$, 2010; 28:159-169.


Medicare and private pay is less. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Forces. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

**AANA Request: Role of Anesthesia and Anesthesia Providers like CRNAs are Missing From the Major Design Elements and Must Be Emphasized**

The AANA is concerned that the essential roles of anesthesia and that of anesthesia professionals, such as CRNAs, are missing from the draft white paper – even though the strategic management of anesthesia services is clearly crucial to patient access to safe and cost-effective joint replacement procedures. For instance, anesthesia and anesthesia providers, such as CRNAs, are missing from Figure 6 of the Joint Replacement Care Team Example on page 17 even though all anesthesia providers provide care in all three phases of the joint replacement continuum of care. In addition, CRNAs are not included in the payment flow diagrams on pages 18, 19, and 20. Every episode of care for hip and knee replacement involves the use of anesthesia services, and the diagrams should reflect that reality.

As CRNAs personally administer more than 40 million anesthetics to patients each year in the United States, including anesthesia for hip and knee procedures, CRNAs’ services are crucial to the successful development and implementation of the elective joint replacement payment model. Anesthesia professionals, such as CRNAs, play an integral role in these episodes of care as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and ultimately in cost savings. Conversely, research shows that suboptimal care in the preoperative, intraoperative, or postoperative phases of surgery

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may compromise care, resulting in poor patient outcomes and unnecessarily higher healthcare costs.\textsuperscript{6} Anesthesia is a portion of the variable costs associated with elective joint replacement procedures. We urge that the white paper emphasize the strategic consideration of the role of anesthesia delivery that is safe and cost-efficient and include the use of techniques such as Enhanced Recovery After Surgery (ERAS) programs, which help reduce costs and improve patient outcomes.\textsuperscript{7}

**AANA Request: Recommendations on Design Elements Should Encourage Cost Efficient Anesthesia Delivery Models**

Hip and knee procedures require anesthesia services. Therefore, the Clinical Episode Payment (CEP) Work Group has an interest in patient safety and access to anesthesia care as well as its cost-efficient delivery. While all models of anesthesia delivery are equally safe according to extensive published research, the most cost-effective anesthesia care delivery model is the CRNA non-medically directed model.\textsuperscript{8} Therefore, the white paper should encourage the adoption of safe and cost-efficient anesthesia delivery models for the reasons outlined below.

In demonstrating the costs of various modes of anesthesia delivery, suppose that there are four identical cases: (a) has anesthesia delivered by a non-medically directed CRNA; (b) has anesthesia delivered by an anesthesia care team where a CRNA medically directed at a 4:1 ratio by a physician overseeing four simultaneous cases and attesting fulfillment of the seven conditions of medical direction in each; (c) has anesthesia delivered by an anesthesia care team where CRNA medically directed at a 2:1 ratio; and (d) has anesthesia delivered by a physician personally performing the anesthesia service. (There are instances where more than one


\textsuperscript{8} Paul F. Hogan et. al, op cit.
anesthesia professional is warranted; however, neither patient acuity nor case complexity is a part of the regulatory determination for medically directed services. The literature demonstrates that the quality of medically directed vs. non-medically directed CRNA services is indistinguishable in terms of patient outcomes, quality and safety.) Further suppose that the annual pay of the anesthesia professionals approximate national market conditions, $170,000 for the CRNA\(^9\) and $540,314 for the anesthesiologist\(^10\). Under the Medicare program, practice modalities (a), (b), (c) and (d) are reimbursed the same. Moreover, the literature indicates the quality of medically directed vs. non-medically directed CRNA services is indistinguishable. However, the annualized labor costs (excluding benefits) for each modality vary widely. The annualized cost of practice modality (a) equals $170,000 per year. For case (b), it is ($170,000 + (0.25 x $540,314) or $305,079 per year. For case (c) it is ($170,000 + (0.50 x $540,314) or $440,157 per year. Finally, for case (d), the annualized cost equals $540,314 per year.

<table>
<thead>
<tr>
<th>Anesthesia Payment Model</th>
<th>FTEs / Case</th>
<th>Clinician costs per year / FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) CRNA Nonmedically Directed</td>
<td>1.00</td>
<td>$170,000</td>
</tr>
<tr>
<td>(b) Medical Direction 1:4</td>
<td>1.25</td>
<td>$305,079</td>
</tr>
<tr>
<td>(c) Medical Direction 1:2</td>
<td>1.50</td>
<td>$440,157</td>
</tr>
<tr>
<td>(d) Anesthesiologist Only</td>
<td>1.00</td>
<td>$540,314</td>
</tr>
</tbody>
</table>

Anesthesiologist mean annual pay $540,314 MGMA, 2014
CRNA mean annual pay $170,000 AANA, 2014

Under the more costly anesthesia models, hospitals and other facilities are bearing the additional costs. Hospitals and other facilities should be able to choose how much cost they are willing to incur with respect to how they provide their anesthesia care.

Therefore, we recommend that the white paper promote safe and cost-efficient anesthesia delivery models, such as non-medically directed CRNA services. Furthermore, we recommend that the development clinical episode payment models not include any policy or requirement in

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\(^9\) AANA member survey, 2014

this payment model that would result in different payment for the anesthesia service when furnished by a CRNA, an anesthesiologist, or both working together, except in the instance of medical necessity for more than one anesthesia professional in a case.

**AANA Request: The White Paper Should Discourage the Use of Policies that Drive Up Healthcare Costs**

While the AANA emphasizes the important role of anesthesia in elective joint replacement, the white paper should discourage the use of policies promoting anesthesia delivery models that drive up healthcare costs to a facility and to patients while also decreasing access to safe, high-quality anesthesia providers, such as CRNAs. For instance, the use of certain large group practices, such as those comprised solely of anesthesiologists, promotes higher cost models of anesthesia delivery and may not demonstrate sufficient patient-centeredness.

Evidence indicates that such large group practices have engaged in anticompetitive practices that decrease patient choice and increase both prices and patient out-of-pocket costs. Holding substantial market power, large anesthesiologist-only group practices have entered into exclusive single source contract service agreements with health systems, facilities and surgeons where the group practice’s market power increases costs, limits choice of anesthesia provider, and imposes opportunity costs that deprive resources from delivery of other critical healthcare services. Such enterprises may use their market power to maximize their income without relation to the actual costs of performing the procedure. For example, according to the New York Times, a patient was billed $8,675 for anesthesia during cardiac surgery. The anesthesia group accepted $6,970 from United Healthcare, $5,208.01 from Blue Cross and Blue Shield, $1,605.29 from Medicare and $797.50 from Medicaid. Providing large anesthesiologist-only single-source anesthesia services groups with too much leverage drives up healthcare costs and puts additional economic

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12 Ibid.
strain on consumers without improving healthcare quality. This white paper should discourage such arrangements.

**AANA Request: The Role of APRNs Should be Emphasized and the White Paper Should Treat APRNs, Such as CRNAs, and Physicians Equally**

Throughout this white paper, the CEP Work Group prominently emphasizes the role of the physician, only using the term “clinician” occasionally. We recommend that the white paper include advanced practice registered nurses (APRNs), including CRNAs, and prominently emphasize their roles in modern care delivery and payment models. The Institute of Medicine (IOM) recommends that government policy expand opportunities for nurses to lead collaborative healthcare improvement efforts, and prepare and enable nurses to lead changes that advance health.\(^{13}\) Increasingly, the healthcare industry is recognizing APRNs for their leadership role in clinical, educational, academic, executive, board, legislative, and regulatory domains. In addition to their roles as expert healthcare professionals, APRNs are CEOs of hospitals and health systems, chief nursing officers, chairs of regulatory bodies and advisory committees, and have taken many other positions with wide spans of responsibility. Furthermore, as the Centers for Medicare & Medicaid Services (CMS) acknowledges the role of all healthcare clinicians, which would include CRNAs and APRNs, as collaborators in the CMS Comprehensive Care for Joint Placement Payment Model final rule\(^{14}\), then we would recommend that this white paper also treat APRNs and physicians equally.

**AANA Request: S-CAHPS Should Not be Used to Measure Patient Experience of Care, Particularly its Problematic Section on Anesthesia Services**

We are concerned that white paper uses the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS) for quality measurement for patient experience of care as it


does not adequately capture the patient and caregiver experience with all types of anesthesia professionals. The S-CAHPS assesses patient experience for both surgeons and anesthesiologists -- and utterly fails to capture patient experience with all types of anesthesia professionals, including CRNAs, or with nurses of any kind whose care is critical to surgical patients. Anesthesiologists and CRNAs provide anesthesia services. Yet, the S-CAHPS recognizes only the care of anesthesiologists and not the care provided by CRNAs. CRNAs frequently administer anesthesia services without the participation or presence of an anesthesiologist, and the use of this survey for the purposes of measuring the patient’s care experience will not be an accurate reflection of care. We note that CMS omitted the use of the S-CAHPS survey in the final rule of the CMS Comprehensive Care for Joint Replacement Payment (CJR) because they did not believe the measure was appropriate to use for CJR program.\textsuperscript{15} Furthermore, the recent Institute of Medicine (IOM) study describes the critical contribution of APRNs to healthcare quality outcomes.\textsuperscript{16} APRNs, such as CRNAs, should be included in measure reporting. Use of the S-CAHPS’s findings will yield faulty data about patient experience with anesthesia care that should not be used to guide public policy decision making of any kind.

**OPERATIONAL CONSIDERATIONS SECTION**

**AANA Request: The White Paper Should Acknowledge and Eliminate Policy Barriers to the Use of APRNs and CRNAs**

We request that the white paper highlight the barriers to the use of APRNs, such as CRNAs, and include ways to eliminate these barriers in its discussion of the regulatory environment within the context of operational considerations for clinical episode payment. The need for access to APRN services is crucial, and all types of APRNs are the solution to developing improvements to quality, access, and cost-efficiency in healthcare. These barriers include burdensome physician supervision requirements; not credentialing APRNs in health plans, which results in APRNs being excluded from health plan networks; and not reimbursing for services that are  

\textsuperscript{15} 80 Fed. Reg. 73483, Nov. 24, 2015  
within an APRN’s state scope of practice. Waiving such burdensome barriers to the use of APRNs will enhance access to care, ensure quality healthcare delivery, and contribute to cost savings. This idea also corresponds with a recommendation from the Institute of Medicine’s report titled The Future of Nursing: Leading Change, Advancing Health, which outlines several paths by which patient access to care may be expanded, quality preserved or improved, and costs controlled through greater use of APRNs.17 The IOM report specifically recommends that, “advanced practice registered nurses should be able to practice to the full extent of their education and training.”18 Noting and addressing the barriers to the use of APRNs in the current regulatory environment will support the success of these new payment systems.

We thank you for the opportunity to comment on this draft white paper. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Frank Purcell, at 202.484.8400, fpurcell@aanadc.com.

Sincerely,

Juan F. Quintana, DNP, MHS, CRNA
AANA President

cc: Wanda O. Wilson, PhD, MSN, CRNA, AANA Executive Director
Frank J. Purcell, AANA Senior Director of Federal Government Affairs
Romy Gelb-Zimmer, MPP, AANA Associate Director Federal Regulatory and Payment Policy


18 IOM op. cit. p. 7-8.
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:
Elective Joint Replacement
White Paper

Comments:
Families USA
March 28, 2016

To: The Clinical Episode Payment (CEP) Working Group, Health Care Payment Learning & Action Network

RE: Families USA Comments on Elective Joint Replacement White Paper

Families USA appreciates the opportunity to offer comments on the Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement Draft White Paper. Families USA is a national non-profit, non-partisan consumer advocacy organization dedicated to the achievement of high quality, affordable health coverage and care for all people in this country.

We offer the following comments in response to this draft white paper. Broadly, we propose modifications to the final white paper that would put greater emphasis on documentation of shared care planning throughout the episode, the addition of protections against “cherry picking” of consumers for participation in episodic care, and the promotion of consumer engagement in developing quality measures.

We appreciate your consideration of these recommendations. If you have any questions, please contact Wes Rivers at wrivers@familiesusa.org or (202)628-3030.

Status Assessment and Decision Aid Requirement

We appreciate the working group recommendation that requires evidence of a standardized, validated status assessment tool and evidence that the patient or family caregiver has worked through a decision aid with the support of a coach or educator. Ensuring that joint replacement is appropriate based on the patient’s values, preferences, and health status will help the patient attain the best value and optimal clinical outcome.

A point of clarification on the timing and payment for the status assessment and decision aid requirement: The draft does not explicitly state that the episode should include the administration of the assessment and/or decision coaching/education for purposes of payment. Figure 5 (pg. 12) seems to indicate that they are included if both take place within the 30 days prior to surgery. However the draft never explicitly states if the assessment is included in the bundle should it take place before the 30 day window. We believe the assessment, any decision coaching or education, and any related doctor’s visits or tests, prior to the 30 day window be included in the episode and that this recommendation is clearly articulated in the draft.

We also believe that the model should require evidence of on-going goal setting and engagement through a documented individualized care plan. The draft recommends this as a form of patient engagement on page 16, but a requirement of documented evidence will ensure that patients are engaged in decision making through the entire decision making process. A requirement would also help the model achieve the stated goal that “the treatments the patients receive along the way reflect their wishes and cultural values.”
**Patient Population and Risk Adjustment**

We appreciate the Working Group’s recommendations to add risk and severity adjustments to episode price. As stated in the Patient Population section, to ensure that episode-based payment is effective in reducing costs and improving quality, models must reach high risk patients. Risk adjustment will remove barriers providers face in treating patients with more complex conditions and co-morbidities, and help to limit “cherry picking” of low-risk surgical candidates for an episode. Clear and robust accounting standards for an episode’s included services, as noted on page 15, will also help ease provider concerns and add clarity to payment for unforeseen procedures that patients with co-morbidities often need during an episode.

However, the risk of “cherry picking” is still a key concern for episode-based payment models, especially as these models are first implemented and provider experience is such that included services are still ill-defined. If inclusion standards are loose but the episode price does not fully reflect the scope of treatment needed for more complex patients, providers assume more risk and could avoid those patients.

First, we believe that there should be a clear accountability mechanism for patients at the offset of the episode. The draft mentions the possibility of incorporating an appeals process for patients found ineligible for an episode. We recommend that accountable entities be required to offer a right to appeal during the assessment and decision making process. This will help ensure some transparency on eligibility decisions and limit inappropriate steering away from an episode. Through the appeals process, the patient and/or family caregiver should have access to documentation used to make the eligibility decision, assessment results, and any other tests used.

Secondly, in an effort to promote health equity, the draft should be specific in recommending risk adjustments for payment for providers that serve a disproportionate share of high risk and lower-income patients, such as safety-net hospitals. Risk adjustment to episode price and other risk mitigation strategies will allow safety-net providers to take part in these important payment innovations. The draft discusses risk adjustment based on provider’s patient mix, but we believe it should be more explicit about populations served. Retrospective reconciliation will also allow for greater flexibility in downside risk sharing for these providers, as recommended by the model.

**Inclusion of Drugs and Devices in Episode**

The working group recommends that episodes “should include delivery of all services billed in the defined time period that are related to the joint replacement procedure. Most initiatives (Appendix C) include all related services that occur within the defined time frame, including, but not limited to costs involving physicians, hospital/Ambulatory Surgical Centers, devices, labs, home health, skilled nursing facilities, physical therapy, and sometimes pharmaceuticals. Including pharmaceuticals and devices in the episode price and definition is important as they can be an expensive portion of the bundle.”
We believe that the recommendation should be more direct, including drugs and devices, so that payers, providers, and accountable entities have more direction in their decision making. As alluded to above, the use of more effective drugs and devices at lower costs within an episode has the potential to create large efficiencies. Example language: “episodes should include delivery of all services billed in the defined time period that are related to the joint replacement procedure, including, but not limited to costs involving physicians, hospital/Ambulatory Surgical Centers, devices, labs, home health, skilled nursing facilities, physical therapy, and pharmaceuticals.”

**Consumer Engagement in Quality Metrics**

We appreciate the Working Group’s prioritization of patient-reported outcomes and patient experience measures in measuring quality. We also appreciate the recommendation that quality information be readily available for patients to aid decision making throughout the episode.

One thing that would enhance the quality metrics recommendations is to advise accountable entities to engage with consumers when developing the metrics that will be used for their model. Interviewing patients to ensure that the quality metrics used in decision making adequately reflect/measure their experience will be crucial in promoting quality and patient values throughout the episode. Patient engagement through interviews and advisory groups may also help accountable entities to make quality data more accessible to those who need it, in terms of availability, presentation, and language.
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
Geisinger Health Systems
March 28, 2016

Re: Elective Joint Replacement whitepaper draft

Dear Healthcare Payment Learning and Action Network:

We thank you for the opportunity to offer feedback related to the ‘Elective Joint Replacement’ whitepaper draft. The following comments are being submitted on behalf of the Geisinger Health System for your consideration.

- **Episode** – The procedure code should be the trigger of the bundle payment episode as opposed to the final billing code (MSDRG) as application of specialized clinical pathways, regional anesthesia, and minimally invasive surgical techniques have allowed unicompartmental knee arthroplasty, total knee arthroplasty, and total hip arthroplasty to be performed in selected patients on an outpatient basis, proving a 3-day hospitalization is not always warranted.

- **Episode price** – Bundle payment participants who are already providing care at a local and regional low price point are unfairly penalized for their efficiencies and effectiveness of care by being benchmarked either against themselves alone (BPCI) or even a regional blend (CJR). Consideration should be given to additional blending at a state or even a national level – siphoning some of the wasted dollars that would otherwise be paid to very expensive providers to those that have already done the good work needed to provide optimal care at a reduced cost. A prospective payment model should be adopted as opposed to the retrospective payment model utilized under the BPCI and CJR programs. A prospective payment model will eliminate the many resources used under the current CJR and BPCI programs (as perpetuated via the true ups) to resolve the final payment. Furthermore, enticing groups to participate by offering them an internal gain sharing process is insufficient motivation, as long as their existing system is more profitable or beneficial or without other palpable disadvantages.

Eric Newman, MD  
Chief, Specialty Care Innovation & Integration  
Population Health Initiatives

Janet Comrey, RN  
Senior Consultant  
Population Health Initiatives

Geisinger Health System  
100 N. Academy Ave.  
Danville, PA 17822  
570-214-8724 Tel
• **Quality Metrics** – It is important to include not just functional status but also pain measurement pre- and post-procedure. The post-measurements for both functional status and pain should be distant enough from the procedure to represent the true benefit achieved. One approach would be measurement at 30 days prior to procedure (+/- 30 days) and again at 90 days (+/- 30 days) and 1 year (+/- 30 days). This would allow a pre-post comparison for the population to examine percent improvement across the 2 key measures that drive the patient to seek joint replacement to begin with (pain and dysfunction).

• **Patient population** – Currently, in BPCI, DRG assignment at time of discharge (469 versus 470) is the primary determinant of payment target – in our area approximately $40,000 per case versus $20,000 per case respectively. Unfortunately, these codes do not differentiate between cases of greater complexity or patients with greater morbidity – i.e. they don’t correlate with reasonable and defendable changes in cost of care.

• **Administrative burden** – An ideal program would make the administrative burden for participation minimal, and if at all possible, less burdensome than the traditional care model. Programs such as these often result in the funding insurance entity asking for the collection of additional burdensome information that does not add to quality of care but serves some internal payer need – this burden should not fall to the accountable participants. Additionally, existing burdensome administrative tasks (e.g. “pre-cert”) could be removed, again engaging groups to want to participate in this new care delivery model.
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
American Health Care Transformation Task Force
March 28, 2016

VIA ELECTRONIC MAIL

Lew Sandy, MD
Chair
Clinical Episode Payment Work Group
Health Care Payment Learning and Action Network

Re: Comments on Draft White Paper: Elective Joint Replacement

Dear Chair Sandy:

The Health Care Transformation Task Force ("HCTTF" or "Task Force")\(^1\) commends the work of the Health Care Payment Learning and Action Network’s ("LAN") Clinical Episode Payment Work Group ("Work Group") on its draft White Paper on Elective Joint Replacement (EJR) Framework ("White Paper" or "Framework"). The Task Force appreciates the opportunity to provide comments to the Work Group, and looks forward to collaborating with the LAN and all of its work groups to help facilitate widespread health care delivery transformation.

As a general consideration, we continue to advocate for full transparency in all matters related to bundled payment programs, including the specific methodology and data for setting target prices and the way issues such as attribution are handled. We also believe that bundled payments can promote greater transparency for patients in the evaluation and selection of health care providers. Transparency, in general, will lead to shorter cycle times to refine program designs while also creating greater confidence in the technical aspects of any bundled payment program.

\(^1\) The HCTTF is an emerging group of private sector stakeholders who are committed to accelerating the pace of delivery system transformation. Representing a diverse set of organizations from various segments of the industry—including patients/consumers, purchasers/employers, providers, and payers—we share a common commitment to transform our respective business and clinical models to deliver the triple aim of better health, better care, and reduced costs.

Our organizations aspire to put 75 percent of their business arrangements into value-based payment models, focusing on the Triple Aim goals, by 2020. We strive to provide private sector leadership through policy, operational, and technical support, and expertise that, when combined with the work being done by CMS and other public and private stakeholders, will increase the momentum of delivery system transformation.
We also reiterate our view that EJR is not a prototypical episode and aside from the high-volume nature, may not provide a suitable model for bundled payments associated with other conditions. Conversely, we view EJR as an especially appropriate episode for using an episode trigger related to diagnosis, rather than acute intervention.

Finally, we support options for prospective payment to “accountable entities” that can demonstrate reserve adequacy and the ability to administer claims payments consistent with that particular payer’s schedule for payments.

Our recommended refinements to the EJR Model design include:

**Patient Population and Transparency in Episode Creation**

As a general consideration, we continue to advocate for full transparency in all matters related to bundled payment programs, including the specific methodology for setting target prices for each hospital or participant. Data is key to fostering consensus and reaching agreement on appropriate structures to manage bundled payment programs. We believe greater transparency will lead to shorter cycle times to refine program designs while also creating greater trust in the technical aspects of any bundled payment program.

The LAN should consider and focus on the varied experience of patients who need joint replacement, including dual-eligible and disabled patients. The White Paper alludes to variation in costs due to variation in the acuity of patients, acknowledging that those conditions require and justify more intensive treatment and care and therefore higher costs, but only in the construction of the episode and inclusion/exclusion of these patients in an episode.

In order to ensure access to orthopedic surgery, we agree with the LAN’s support of the broadest possible patient population, with risk and severity adjustment to account for age, complexity and socioeconomic factors. We believe that should be acknowledged at the start, and should be considered by the LAN as a challenge to be addressed by constructing episodes that work for a broader set of patients.

**The Importance of an Accountable Entity**

We strongly support the sharing of risk among physicians, hospitals, and other health care providers. We believe that the “accountable entity” will be paramount in serving this function through the EJR model.

We believe that a wide range of provider and organization types should be encouraged to sponsor accountable entities in bundled payment programs. Adoption speed and quality of execution are often the main reasons commercial programs encourage “General Contractors” to form and develop risk-taking management service organizations. We therefore support the LAN’s agnostic view of the types of organizations that may sponsor an accountable entity; this is consistent with the structure of capitation arrangements and Accountable Care Organizations that can accept and pool the risk for participating providers.
Engaging Hospital-based Physicians

We believe that any capable organization should be able to sponsor an accountable entity. We further believe that the clinical model for the EJR episode should acknowledge the importance of hospital-based physicians.

The LAN identifies in Figure 6 the role of orthopedists, who are key physicians for engaging patients far upstream of an inpatient admission and are especially well positioned to set expectations and encourage appropriate next site of care decisions. For voluntary programs, we believe that the care model participants listed in Figure 6 should include hospitalists, who are well-positioned to serve as the principal accountable inpatient provider for high-risk inpatients, particularly those with comorbidities.

Given the current economic and financial pressures on community-based physicians, as well as the increased acuity and comorbidities of inpatients, we believe the LAN should support the designation, where appropriate, of a hospitalist as the principal inpatient accountable provider. The evidence demonstrates that hospitalist co-management of elective joint replacement inpatients, where appropriate, reduces time to surgery from admission, waiting time for specialists consultation and length of stay, and also results in fewer complications.²

In 2011, 11.3% of surgical Medicare DRGs listed a hospitalist as “the physician who has overall responsibility for the beneficiary’s care and treatment.”³ This percentage represented a 31.3% increase from that in 2009 despite the 8.0% decline in overall surgical DRGs.⁴ Moreover, orthopedists have increasingly relied on hospitalists for managing the comorbidities of their inpatients.⁵

This inclusion of hospitalists in the care model has been shown to improve the quality of care in studies of elective joint replacement. Successful outcomes were achieved for this cohort when the orthopedist designated the hospitalist as responsible for pre-anesthetic medical examination, daily patient evaluation during hospitalization, perioperative medical care, subspecialty medical consultation, and discharge planning.⁶

⁴ Ibid.
⁵ Kuo YF, et al., Growth in the Care of Older Patients by Hospitalists in the United States, 360 N. Engl. J. Med. 1102, 1106 (2009). In 2006, 37% of all orthopedic inpatients received care from a hospitalist, up from 5% in 1997.
⁶ Huddleston JM, et al., Hospitalist-Orthopedic Team Trial Investigators. Medical and surgical comanagement after elective hip and knee arthroplasty: a randomized, controlled trial, 141 ANN. INTERN. MED. 28, 30 (2004).
Therefore, we believe Figure 6 should include, in the “event” box, a reference to hospitalists, who often join the care team as either the attending provider for the admission (in co-management cases) or are consulted during the admission.

**Patient-Focused Quality Metrics**

The HCTTF supports the use of patient-reported outcome and functional status measures. However, we recommend that providers only be subject to performance in quality metrics that have been validated by sufficient data and accepted by institutions such as the National Quality Forum. In the CJR model, patient-reported outcome measures are not mandatory and providers are only being held accountable for the collection of the information, not the measures themselves. As these tools become widespread, the LAN should review and recommend which quality metrics show actual improvement in patient lives and have a dedicated group to continuously review quality metrics and ensure that they are aligned with other value-based arrangements.

**Seeking Fraud and Abuse Waivers to Enable Gainsharing**

The BPCI Initiative has demonstrated the importance of gainsharing in the design of successful bundled payment programs. While gainsharing helps to align care delivery incentives through financial benefits, gainsharing is often viewed under federal policy as inappropriate remuneration that raises fraud and abuse concerns. Waivers of these policies are key to forging the alignment between providers – hospital and physicians – necessary for success coordination under bundled payment programs. If providers continue to be subject to existing regulations, participants in an EJR model may need more than just waivers; new safe harbors from certain laws should be developed that eliminate potential liability due to the public policy benefits of better aligned care and cost reductions.

Please contact HCTTF Executive Director, Jeff Micklos, at jeff.micklos@leavittpartners.com or (202) 774-1415 with any questions about this communication.

Sincerely,

**Lee Sacks**
EVP Chief Medical Officer
Advocate Health Care

**Farzad Mostashari**
Founder & CEO
Aledade, Inc.

**Francis Soistman**
Executive Vice President and President of Government Services
Aetna

**Shawn Martin**
Senior Vice President, Advocacy, Practice Advancement and Policy
American Academy of Family Physicians
Peter Leibold  
Chief Advocacy Officer  
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Emily Brower  
Vice President, Population Health  
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Carlton Purvis  
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Wesley Curry  
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Martin Hickey
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Steve Wiggins
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Michael Slubowski
President and Chief Executive Officer
SCL Health

Bill Thompson
President and Chief Executive Officer
SSM Health Care

Rick Gilfillan
President and Chief Executive Officer
Trinity Health

Judy Rich
President and Chief Executive Officer
Tucson Medical Center Healthcare

Dorothy Teeter
Director
Washington State Health Care Authority
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:

Henry Ford Health System (HFHS)
March 28, 2016

Health Care Payment Learning & Action Networks (HCPLAN)
CMS Innovation Center
Centers for Medicare and Medicaid Services

Re: Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement

On behalf of the 23,000 employees of Henry Ford Health System (HFHS), I thank you for the opportunity to provide comments on the HCPLAN Draft White paper on bundled payment for elective joint replacement. HFHS agrees that this is an attractive and feasible area for true payment innovation, and we encourage HCPLAN to move forward as rapidly as possible to a set of recommendations that can be implemented by private and public payors.

HFHS is one of the nation’s leading vertically integrated health care systems and a Michigan non-profit corporation. HFHS provides a "seamless" array of services at all levels of care. Founded in 1915, Henry Ford is Michigan's sixth largest employer. HFHS is committed to improving the health and well-being of a diverse Michigan population. Care provided by HFHS includes 3.2 million outpatient visits, more than 88,000 surgical procedures and more than 104,000 hospital admissions. HFHS is a 2011 Malcolm Baldrige National Quality Award recipient.

HFHS is ready and able to implement true prospective bundled payment for elective joint replacement, since all of the required providers are part of an integrated system of care with shared clinical and administrative infrastructure. There are many other such systems in the country, so it should be feasible to move forward on prospective bundled payment with those systems capable of both coordinating care and managing the distribution of payments to providers within the system. HFHS encourages HCPLAN to consider and recommend this path forward, while recognizing that many providers are not yet sufficiently integrated to accept
prospective episode payment and may have to work with retrospective reconciliation for the foreseeable future.

Specific comments on the Draft White Paper

1. **Purpose of the White Paper, Page 5.** In the recommended retrospective reconciliation model for episode payment, individual providers ARE still paid on a traditional fee-for-service payment basis, and may be at no financial risk whatsoever for elements of cost and quality. An episode payment model designed in this way is not truly an “alternative payment model” according to the HCPLAN’s own stipulation here. At a minimum, an episode payment model must involve some element of payment linked in a meaningful way to both cost and quality for each and every provider involved in the episode for it to be considered a legitimate “alternative payment model.”

2. **Episode Definition, Page 11.** While assessment through a formal functional status tool may be an essential way to determine appropriateness of surgery, it is not necessarily the only way, nor is it sufficient. A simpler 0-10 pain rating scale could provide as much evidence of “need” as a functional status scale, and there should also be evidence of underlying etiology amendable to surgical treatment. There is no justification for joint replacement surgery if the pain or functional deficit will still be present after surgery. We also note that some of the scales listed here are not specific to joint problems (e.g., PROMIS, VR-12), and thus would not (without further specification) serve as a justification for surgery.

3. **Episode Timing, Pages 12-13.** The 30-day-before-surgery episode start point is problematic. Unscrupulous providers can easily game the system by scheduling surgery for more than 30 days after the pre-surgical workup. This is often done now in elective situations, and is actually more and more likely given the interest in surgical “pre-habilitation” programs to improve outcome. The episode period should include the essential pre-surgical workup services, whether or not they fall within a 30-day window prior to surgery.

4. **Patient Population, Page 13.** The analysis of risk factors and eventual development of risk adjustment models (for both payment and quality measurement) should include social and demographic risk factors, as recommended by the recent NQF Expert Panel on SES Adjustment. To the extent that patient- and community-level factors like poverty, illiteracy, lack of social support (e.g., living alone), and limited English proficiency bear on either episode costs or quality metrics like readmission, they should be included in risk adjustment models.
5. **Services, Page 15.** Documentation of complications is obviously problematic. While some inpatient complications may be reliably coded as complications, later events (AMI, infection, DVT) may not be either identified or coded as complications. Providers will have strong incentives to avoid coding these events as complications, both for quality measurement considerations and for episode payment considerations. Quality metrics and payment will both be better if these events are considered “outside” the episode. There will have to be clear and stringent rules written about when events like AMI or DVT should be considered to be post-surgical complications.

6. **Patient Engagement, Page 16.** A relatively easy and direct patient incentive would be the waiver or reduction of copays for use of “in-network” providers during the surgical episode. This feature may be easier to implement by private payors than by CMS, given the more common use of narrowly-defined networks in the context of commercial insurance. CMS could consider this feature as well, and a recommendation on this point from HCPLAN would be useful.

7. **Accountable Entity, Page 17.** The diagram here is extremely useful, and can serve as a model for how accountability can be defined for quality metrics linked to specific parts of a clinical episode. Rather than promoting some vague idea of “shared accountability”, the quality metrics (and associated links to payment) can be specified for individual providers at specific phases of the clinical episode.

8. **Payment Flow, Page 20.** While we understand the HCPLAN rationale for recommendation retrospective reconciliation, we ask that HCPLAN make a more positive recommendation for true prospective bundled payment for those integrated systems and other providers capable of managing episodes under such a system. Retrospective models built on a FFS foundation provide very weak incentives for care coordination and efficiency, and are unlikely to create any significant changes in care patterns for elective joint replacement surgery. The initiative described here should focus more on true innovation in those organizations capable of working under prospective episode payment, and a secondary mention of retrospective reconciliation as a temporary model for those providers unable to work under prospective payment.

A big barrier in structuring a bundled payment arrangement, particularly for organizations that include major teaching hospitals, is the issue of pass-through payments (IME, bad debt, DSH). To be a low cost provider and participate in many bundled payment arrangements based on competitive pricing, such organizations would have to either forego those payments or participate with a payor willing to continue these payments in some sort of formula “outside” of the core bundled payment price.
9. **Type and Level of Risk, Page 23.** The point about downside risk is moot under true prospective episode payment. Again, we encourage HCPLAN to be stronger in its recommendations for prospective bundled payment. Retrospective reconciliation not only provides weak incentives for improvement, but it is administratively complex and uncertain. It should not be the “first-choice” model.

10. **Quality Metrics, Page 26.** We suggest a stronger positive statement about a link between improvement in Patient-Reported Outcomes (PROs) and payment. In elective joint replacement, improvement in pain and functional status is the main (or only) reason for surgery. If it is reasonable anywhere at all to consider the concept of “pay for outcome”, then elective joint replacement is the clinical setting for which it is appropriate.

11. **Data Infrastructure Issues, Page 30.** While we agree with the observations on the current claims-based data infrastructure, the White Paper could be stronger on moving forward with true prospective payment in those organizations who have developed, or will develop, the necessary clinical and financial infrastructure to manage clinical episodes. If this infrastructure is worth developing, then there is no point in delaying the development by designing episode payment initiatives on “old” data structures. If attractive episode payments models can be developed on a true prospective basis and offered to capable providers, then the necessary data infrastructure will get developed (or enhanced where it already exists).

12. **Regulatory Environment, Page 32.** We disagree with the point here that all stakeholders need full access to information about payments to providers. Under a true prospective payment system for episodes, there is no need for stakeholders to know what individual providers are being paid. It is important for patients and payors to know the full episode price, but not the details of negotiated payment rates between the accountable entity and individual providers. In fact, there may be no specific payments to know in situations where providers in an integrated system are paid on a salaried or capitated basis.

Thank you for the opportunity to share our concerns and recommendations. Please do not hesitate to contact me if you should have any questions.
Sincerely,

Mary Whitbread, Vice President
Reimbursement and Contracting
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
LAN Listening Session - States
States Listening Session Q&As 3/17

1. **What experience has Arkansas Blue Cross Blue Shield had with getting patients involved in accepting episode-based payments?**

Steven Spaulding: Because it is built on a fee for service chassis and because it is not a voluntary program, beneficiaries and patients really don’t realize that they are in part of an episodic inventive program. We pay claims the way we always have, so if a patient has any deductible or out-of-pocket it is the same as it has been in the past. When we reconcile the episodes, it isn’t considered a claims transaction so if there is any claw back or any incentive payment, it is Invisible to the patient. So there really hasn’t been a lot of outward engagement of patients, it is just that they receive better, more efficient care now from everyone who is providing services that are included in episodes.

2. **What kind of experience has Tennessee had with pushback or acceptance from providers?**

Brooks Daverman: The conversation over the past couple of years is so different from what it was a decade ago, because everybody is trying to figure out the best way to implement value-based payment. Nobody is really saying that “my patients are sicker, end of discussion, let’s just stick with fee for service.” At first there was a lot of conversion around whether these are the best approaches. Now, providers are generally on board with these approaches and they like that they do not have to completely change their business model to be a part of this. They don’t have to get bought by someone, or buy someone else, or change how they bill. Now providers are asking for more information. For example, they want to see quality measures for each episode, not just how they did overall for that quarter. It is a good problem to have when providers are asking for more information. We are really into the details at this point of making this better.

3. **For knee and hip replacements, do we have any problems with too many procedures? Or are we going through the appropriate number?**

Steven Spaulding: There is nothing in the traditional fee for service system that does a very good job of determining whether each and every one of the services rendered is totally appropriate for the patient. In Arkansas, we have a large employer that has begun to send joint replacements out of state to centers of excellence. Even though the procedures are more expensive when completed at the centers of excellence compared to being completed in the state, this employer believes that the centers of excellence do a better job of assessing the patient to determine whether there would be the appropriate improvement in quality of life for the patient if they had the procedure versus an alternative. Initially, my thinking was that an episode of care is effective when it has already been determined that a procedure needs to happen and the episode then creates an incentive that makes sure it happens at a very high quality and in a cost efficient manner. The discussions in the CEP Work Group have changed my opinion on that, because we think there probably should be an assessment included in the episode of care and there should be general consensus from the stakeholders on when you should try an alternative for a patient, such as having a patient lose weight, before they would
become eligible for a procedure. Another part of that is the coordination between the participants in the episode and the people who are in patient centered medical homes or the population managers to make sure that those medical homes understand that it is probably appropriate to do an assessment so that we can avoid the provision of marginally valuable services.

4. Can you provide more information about the initiative in TN?

Brooks Daverman: Visit www.tn.gov/HCFA and click on strategic planning. We have tried to put a lot of information online, including summaries and everything you need to have your own episodes program.

Steven Spaulding: Similarly there is a website for Arkansas, www.paymentinitiative.org. That will guide you to the Arkansas Health Care Payment Improvement Initiative.

5. For providers who operate inside financially integrated systems, is there any benchmark information available to help allocate savings to individual providers, such as the hospital, imaging center, or orthopedic surgeon?

Brooks Daverman: We used our own Tennessee Medicaid data to set the threshold for our Tennessee Medicaid providers, and we have some limited information of that public, but most of that is not public. I think your best bet is if you have access to a dataset of your own or buying a dataset and then applying your episodes approach to that dataset.

John Bertko: On the commercial side, you can buy datasets. The MarketScan dataset from Truven is pretty complete and there is a separate dataset from HCCI which aggregates three or four very large carriers. The problem is that while that is the right data, you need somebody to cruise through it pretty efficiently to get what you want.

Steven Spaulding: While the answer is probably yes, we don’t have any because we chose the one Principal Accountable Provider (PAP). Again, we hope to be able to get some change in law and policy to allow that PAP to share as he sees fit. If you are talking about how you parse a perspective bundled payment for an episode, the place to start is the historical proportion of the payment that each one gets and then determine whether that is fair in trying to accomplish your end result.
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
MPA Healthcare Solutions
Response to Solicitation for Comments  
Susan Nedza, M.D, M.B.A.  
March 28, 2016

On behalf of MPA Healthcare Solutions, please accept the following comments regarding the draft white paper, “Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement.”

The work group is to be commended for its thoughtful recommendations as well as the framework within which it was developed. The choice of Elective Joint Replacement as a priority area was important as it coincides with the launch of the Centers for Medicare and Medicaid Services, Comprehensive Care Joint Replacement (CJR) program.

Joint Replacement Episode Recommendations

1. Episode Definition
MPA agrees with the choice of elective and appropriate total hip or total knee replacement. We ask that the work group provide further clarification as to why procedures for conditions not due to osteoarthritis were excluded. Would this eliminate the inclusion of cases where surgery is appropriate for patients with other non-traumatic conditions that improve their lives and level of function?

2. Episode Timing- Start Point
MPA is concerned that the section outlining the rationale for the 30 day pre-procedure speaks only to inappropriate or unnecessary testing. We ask that the work group consider including language that explicitly supports appropriate testing and services that should be done during this period. In our experience reviewing electronic records of patients undergoing this care, we often identified pre-surgical history and physical examinations that were not comprehensive and did not fully reflect the condition of the patient and a comprehensive list of co-morbidities. In some cases we found focused orthopedic histories. We also request that language speaking to the inclusion of appropriate laboratory testing be included. For example, in the above cases we have identified that pre-operative testing did not routinely include tests linked to potentially preventable complications.

We would also like to suggest that a section regarding the use of pre-conditioning services be included.

Episode Timing- End Point
MPA strongly supports the decision to end the episode at 90 days post-discharge. MPA research (pending publication) focused on the joint replacement population found that over 44.6% of readmissions for patients undergoing total knee replacement...
replacement occurred between 31-90 days post discharge. These readmissions included cases related to technical/non-infectious surgical issues, cardiovascular/pulmonary issues, infections and gastrointestinal orders that were very likely linked to the index stay and procedure.

3. Patient Population
MPA supports the call for appropriately specified risk and severity adjustment to be applied across the episode. We strongly recommend that language be included that it is important that payers provide transparency into these methodologies for participants in order to build trust and to enable appropriate pricing. Any asymmetry with respect to risk and data utilized to capture it will impact the sustainability of these programs and potentially impact the viability providers who will not have the financial reserves to tolerate losses if potential financial and clinical risk isn’t fully recognized. The previous experience with capitation in the 1990’s should serve as a reminder that accurate knowledge of risk in a given population is in the best interest of all stakeholders.

4. Services- Patients with Multiple Chronic Conditions
MPA is concerned about the statement beginning “While some of those services may clearly be outside the scope of the knee or hip replacements others...may be less clear.” Robust risk-adjustment that is incorporated into the setting of payments should allow payers to develop episode prices that include the management of the chronic conditions that may occur immediately after or during the post-acute phase. Payers should be encouraged to develop and promulgate bundles that reward management of the entire person during the episode. This includes developing methodologies to manage bundled payments in a capitated patient population that rewards collaboration between the PCMH, hospital-based physicians and surgeons.

Rewarding co-management of these patients before, during and after the surgery is critical to alignment around long-term outcomes and hand-offs in care. We recommend that the work group specifically address co-management especially if performance metrics will extend beyond 90 days of care.

5. Patient Engagement
MPA recommends inserting language regarding the need to provide patient-focused materials at an appropriate reading level and that reflects the need for attention to serving patients and families with limited English proficiency.

6. Accountable Entity
MPA recommends expanding the list of the Joint Replacement Care Team to include emergency department physicians. In research pending publication we have identified that 10% of individuals undergoing TJR visit an emergency department within the 90-day post-discharge period. The emergency department physician has an impact on cost within the episode when making a decision to readmit a patient, admit them to observation as an alternative, or to diagnose and treat the patient prior to discharge home or back to a SNF. The inclusion of these physicians will help
to support developing of an infrastructure to better manage post-ED care that often
drives the admission decision.

7. Payment Flow
MPA would like to suggest that the workgroup be more direct in supporting a rapid
movement to prospective payment models. When CMS adopted the MS-DRG
payment system for IPPS hospitals in the 1980’s it did so in a deliberate and rapid
fashion. As a result, the need to build an infrastructure to support prospective
payments was embraced. We recommend that the workgroup consider removing
the box and shading from the section titled, “Future Considerations for Prospective
Payments” as a starting point.

8. Episode Price- Regional Costs
MPA recommends that the paper be more clear on its definition of “regional” and
seek to align with CMS on the choice of census area as it has in CJR. It is important
to define regional as being something that may vary by health plan or represent a
variant of prior benchmarks that have been used to determine “reasonable and
customary” fees.

9. Type and Level of Risk- Mechanisms for Limiting Risk
Section 3 of the draft paper, “Patient Population” strongly supports risk adjustment.
Section 9 seems somewhat out of sync with this recommendation as it seems to
make recommendations regarding potential alternatives. If this was not the intent
of the workgroup, we would suggest that the section be might be retitled to “Type
and Level of Financial Risk.”

We would suggest clarifying or dropping the example in the box. The line “This
method limits provider exposure, avoids the complexity of risk adjusting” seems to
be at odds with the statement in Section 3. If it is retained, it should be revised,
clarified and treated as a third option.

10. Quality Metrics
MPA strongly supports the language regarding driving quality and patient safety
improvement. Through its research, MPA has identified significant areas for
improvement across hospitals providing these surgeries.

We would also like to suggest that the working group move beyond the CQMC
Consensus Measure “hospital-level 30-day, all-cause risk-standardized readmission
rate following elective primary THA” and embrace a 90-metric that is in alignment
with the episode length.

Quality Score Cards
In a letter to CMS dated January 5, 2015, Medpac included the following statements
regarding an expanded list of proposed CMS measures for consideration:
• “The Commission has become increasingly concerned that Medicare’s
current quality measurement approach is becoming ‘over-built,’”
• “Depending on a large number of process measures...is overly burdensome on providers to report while yielding limited information to support clinical improvement or beneficiary choice,” and
• “The Commission has urged more focused attention on a small number of population-level outcome measures, such as potentially avoidable hospital admissions, emergency department visits, and readmissions.”

There is increasing concern within the provider community regarding the value and burden of quality reporting. MPA supports Medpac’s assertions regarding the need to seek simplicity and to move away from process measures. We suggest that any quality report cards be focused on a few population-level outcome measures. Setting complicated minimum thresholds for payment has been identified as problematic across ACO innovation projects where few facilities succeed in making the threshold and thus cease participating in these programs. If the healthcare system is to meet its goals regarding participation in APMs and the transition from volume to value, it is imperative that these minimum requirements are transparent, are agreed upon as important and enable providers to achieve sustainable targets that cover their cost of participation in an APM and most importantly, are linked to patient outcomes.

Thank you for the opportunity to participate in this critical work. We will be happy to share study data with the work group upon request.
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS: Elective Joint Replacement

White Paper

Comments:
National Bone Health Alliance (NBHA)
Thank you for the opportunity for the National Bone Health Alliance (NBHA, www.nbha.org) to provide feedback on the Health Care Payment Learning and Action Network’s draft white paper on Elective Joint Replacement. NBHA is a public-private partnership on bone health that includes 55 organizational participants (30 non-profit and specialty societies, 20 private sector companies and 5 government liaisons from CDC, CMS FDA, NASA and NIH) all working together to bring about a shared vision: to improve the overall health and quality of life of all Americans by enhancing their bone health.

NBHA and its members are aligned in driving awareness, diagnosis and treatment of osteoporosis, a prevalent chronic disease in the United States, with currently more than 2 million fractures caused by osteoporosis each year; over 300,000 of these bone breaks are fractures of the hip, which are the most costly and devastating, given a one-year mortality rate of 25 percent within a year after a hip fracture.

Per the most recent Centers for Disease Control and Prevention data from 2005-2010, 16.2% of Americans age 65 and above have osteoporosis and 48.3% have low bone mass. In aggregate, 64.5% of Americans age 65 and above are at increased risk to suffer from a fracture caused by osteoporosis due to reduction in bone strength that characterizes the disease.

Osteoporosis care currently costs the U.S. economy $17 billion per year (80 percent of these costs occur in patients age 65 and above) and is estimated to increase to over $25 million by the year 2025. Osteoporosis is also the tenth most prevalent major illness affecting the 5 percent highest cost Medicare beneficiaries. Effective treatments exist that can lower fracture risk and save health care dollars, as well as prevent the suffering experienced by older individuals with fractures.

Moreover, currently only 25 to 30 percent of older women who have suffered an osteoporosis-associated fracture receive any medical assessment for establishing a diagnosis of osteoporosis or for its treatment, a post-fracture care gap of between 70 and 80 percent.
To drive improvement in this post-fracture care gap, NBHA as well as the entire bone health field has aligned around a post-fracture care coordination model known as a "fracture liaison service" (FLS) which ensures that after a patient age 50 or above has sustained a fracture that he or she receives appropriate medical assessment and screening for low bone mass or osteoporosis and appropriate treatment if needed. There is over 15 years of international evidence this model drives better patient outcomes, improves quality and saves healthcare dollars. More information on the FLS model is available at the NBHA’s resource center on FLS programs, Fracture Prevention CENTRAL (www.FracturePreventionCENTRAL.org), which over 3,700 individuals have signed up to access since it launch in March 2013.

NBHA sees an opportunity for those institutions providing elective joint replacements through various bundled payment models who also have a FLS program (there are more than 300 programs nationwide) in place to utilize their FLS care coordination program given this program already works with a number of providers around post-fracture care.

Given that a number of these patients (especially those receiving hip replacements) may have suffered from previous fractures (or a fracture that may be the cause of needing an elective joint replacement), the FLS program could not only coordinate the care of their post-fracture care but also their post-joint replacement care. Further, osteoporosis and poor bone quality are both predictors of poorer patient outcomes and can make these procedures more difficult if the bone is deteriorated and therefore cannot support the weight of the implant and can also contribute to implant failure.

Given the more than 2 million fractures caused by osteoporosis or low bone mass that occur each year and the connection between poor bone quality/osteoporosis and poorer joint replacement outcomes, there is an opportunity to drive further patient outcome improvements in those patients with osteoporosis or low bone mass who receive either knee or hip replacement surgery through linking these two programs.

NBHA would welcome an opportunity to provide additional details, support or background in this regard upon request. For more information, contact David Lee, MPA, Executive Director, National Bone Health Alliance at david.lee@nbha.org or 703-647-3003. Thank you.
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
Next Wave
March 28, 2016

Comments: HCP-LAN Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement - Draft White Paper

1. The concept of "Complexity" in the Patient Population for risk and severity adjustment should explicitly recognize social complexity (health-related structural and social determinants of health) as episode-cost drivers to discourage providers from “cherry-picking.”
   - The National Quality Forum (NQF) is currently studying methods and appropriateness of risk adjusting for Socio-Economic Status (SES), however:
     o Most of the analysis is being performed on an age 65+ Medicare Fee for Service population, which constitutes less than half of the current volume of hip and knee replacements. Social complexity is less prevalent within this FFS study population than within “everyone else” (Medicare disabled, Medicaid only, Commercial insurance, and Medicare Advantage.)
     o Since the White Paper provides a framework for addressing all-payor episode payment, waiting for and extrapolating findings of this NQF analysis may not even provide the “trusted empirical data” desired for transparency.
   - While waiting for better methods to appropriately adjust for social complexity, we recommend reporting context of the population served along with prices and outcomes:
     o At minimum, transparently report core population characteristics (Neighborhood poverty, education levels, language, etc.) along with race/ethnicity at the plan and provider level.
   - This will allow all stakeholders to better assess whether plan and provider episode variation is likely due to value vs. simply more skilled cherry-picking. Without this context empirical data, it is not possible for stakeholders to fully trust findings.

2. Criteria for people eligible and ineligible (i.e. exclusions) for episode pricing should be clearly and explicitly stated when implemented. Alignment of outcome metrics with these inclusions and exclusions should also be documented. This context will help assure that plan and provider comparisons are meaningful and avoid systematic bias. Some examples:
   - Elective Joint Replacements appropriately exclude patients with fractures, who almost always require more costly bed-based post-acute care.
     o The key outcome metrics for complications and readmissions also exclude fractures.
   - Patients already living in a nursing home prior to joint replacement are highly likely to return to their nursing home after discharge. Excluding them from episode payment is also appropriate.
     o The Surgical CAHPS measures surveyed 90-180 days post-surgery also exclude institutionalized persons.

Thank you for the opportunity to comment on this framework.

Sincerely,

John D. Shaw
President
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
Pacific Business Group on Health
March 28, 2016

Lew Sandy, MD  
Chair, Clinical Episode Payment Work Group  
Health Care Payment Learning and Action Network  
PaymentNetwork@MITRE.org  

Re: Comments on Draft Elective Joint Replacement White Paper

Dear Dr. Sandy:

Thank you for the opportunity to provide comments on the clinical episode payment (CEP) workgroup’s paper on elective joint replacement. The Pacific Business Group on Health (PBGH) is a non-profit organization that leverages the strength of its 65 members—who collectively spend $40 billion a year purchasing health care services for more than 10 million Americans—to drive improvements in quality and affordability across the U.S. health system.

Moving toward value-based payment methodologies like orthopedic bundles has long been a cornerstone of our members’ strategy for lowering health care spending while improving the quality of care their employees receive. As part of that effort, PBGH currently administers the Employers Centers of Excellence Network (ECEN), a nationwide travel surgery program for joint replacements that features episodic payments to hospitals, physicians, and post-acute care providers. To date, ECEN participants have paid four hospital systems more than $30 million in bundled payments for 1,120 hip and knee replacement surgeries.

PBGH also has several years of experience administering one of the first and most comprehensive joint replacement data registries in the country. Founded in 2009, the California Joint Replacement Registry (CJRR) serves as an important public resource for comparative effectiveness research and evidence-based decision-making. CJRR is a “Level 3” registry that includes patient-reported outcome data as well as payer, provider, clinical, surgical, laboratory, pharmacy, and device information. It has recently been incorporated into the nationwide American Joint Replacement Registry.

Both CJRR and ECEN—as well as other PBGH member initiatives—have generated significant insights in orthopedic bundle design, quality measurement, and patient experience that can be brought to bear on the LAN’s framework for joint replacement document. It is with these lessons in mind that PBGH and its members offer the following feedback:

1. **Appropriateness of Care.** The paper needs to more clearly define what constitutes “appropriate care” and ensure that this definition represents a suitable threshold. Our ECEN experience suggests that there are a number of cases where joint replacement is sought by a patient or referred by their treating physician that are determined to be inappropriate or in some cases not necessary. For Lowe’s, a participating ECEN employer, 15% of cases referred for surgery were told by a Center of Excellence that a joint replacement was not the appropriate course of treatment at that time. The Bree Collaborative cites additional components for determining appropriateness: 1) disability due to osteoarthritis despite conservative therapy, 2) documented
conservative therapy for at least three months, and 3) evidence of osteoarthritis according to standardized radiographic criteria.

2. **Prospective Bundled Payment vs. Retrospective Reconciliation.** The workgroup’s recommendation to pursue retrospective reconciliation through fee-for-service rather than prospective payment is not very aspirational. Hospitals and surgeons have more opportunity to innovate in how they deploy professional staff, choose technology, and engage with outpatient and home-based services when they have full flexibility within a budgeted payment amount. Prospective bundles are indeed spreading in the hip and knee replacement market; for instance, ECEN uses a pre-negotiated rate for DRG 469 and 470 that includes pre-op diagnostics, facility and professional fees, implants, post-op clearance, and initial physical therapy.

The LAN paper recognizes prospective bundled payment “may serve as a foundation for greater innovation in the quality and coordinated care delivery needed to make episode payment successful” but concurrently conveys a strong bias towards retrospective fee-for-service reconciliation. At the top of page 19, the report states that the prospective method “works most effectively when care is delivered via an integrated health system.” This is overly simplistic. The prospective method is undoubtedly easier to implement in integrated settings; however, its impact would be greater—and therefore more “effective”—in non-integrated systems by incentivizing collaboration and coordination across providers and care settings.

While the report concludes that retrospective payment is “the most practical approach at present,” there is value in the CEP workgroup advancing a stronger view about the importance of testing prospective models that change the underlying financial incentives to motivate care redesign. Many of the early Medicare BPCI adopters reported savings through reduced post-acute care utilization and steerage to providers with deeper contractual discounts. Prospectively negotiated bundles could lead to more targeted action to reduce care variation, optimize patient safety, and promote provider engagement.

3. **Patient-Reported Outcomes Measures and Quality Scorecards.** Requiring providers to report and achieve benchmark levels on patient-reported outcome and functional status measures (PROs) in order to receive payment under an orthopedic bundled payment scheme is prudent. We concur with the need to prioritize PROs and measure longitudinal patient outcomes. The Core Quality Measures Collaborative Orthopedic Measures do not go far enough in this regard. The paper states that the use of functional status tools is relatively new and that there may not be enough information on where quality thresholds should be set. In fact, the Hip disability and Osteoarthritis Outcome Score (HOOS) and Knee injury and Osteoarthritis Outcome Score (KOOS) have been widely used and validated. Each of the Employers Centers of Excellence hospitals collect patient-reported outcomes. Effective risk adjustment and comparative presentation of quality and outcome metrics is now widespread in other industrialized nations, including the United Kingdom, Sweden, Norway, and Australia. The California Joint Replacement Registry, now working with the American Joint Replacement Registry, published initial quality results in its 2014 Annual Report.

Not only is quality information needed to communicate and engage with patients, but better quality information to inform improvement activities and consumer choice of provider. We note the absence of any meaningful emphasis in the workgroup paper about improving quality information
and longitudinal measurement of functional outcomes. Rather than suggesting that quality measurement “may” include up to 12 months of data, it “should” include such measures. Encouraging broader participation in and reporting to clinical registries and embedding such data collection in current workflows are essential to improving care and reducing unwarranted variation.

4. **Patient Population and Risk Adjustment.** The paper states that appropriate risk and severity adjustment to price are “critical… if the episode is to be attractive to providers.” If attractiveness to the provider is the litmus test, the bundled payment is not likely to be much differentiated from fee-for-service. We note that this paper is focused on elective joint replacement and that aggressive appropriateness criteria should be applied at the outset. With screening criteria such as BMI levels already in place as well as use of optimal care guidelines pre- and post-surgery, there is already risk mitigation. Risk adjustment should not serve as a back door for insufficient patient safety management and avoidable complications. Alternatively, using a risk corridor or basic stop-loss mechanism may be more appropriate for managing undue insurance risk. Patient exclusion processes are equally likely to incent “reverse cherry-picking” that increases surgical volume and inclusion of low-risk patients in the bundle, a bundle that has been priced for the whole population at the outset.

5. **Alignment with Benefit Design.** We strongly recommend revisiting the workgroup’s decision not to endorse the importance of tying benefit changes to payment reforms. Employers (e.g., all of the ECEN participants, Boeing and Intel with their ACOs) rely on aligning payment with benefit design to make the APMs like CEP work.

6. **Fraud and Abuse Waivers.** It is important to acknowledge that fraud and abuse waivers are needed to enable gainsharing. The BPCI Initiative has demonstrated the importance of gainsharing in the design of successful bundled payment programs. While gainsharing helps to align care delivery incentives through financial benefits, it is often viewed under federal policy as inappropriate remuneration that raises fraud and abuse concerns. Waivers of these policies are key to forging the alignment between providers—hospital and physicians—necessary for successful coordination under bundled payment programs. If providers continue to be subject to existing regulations, participants in joint replacement models may need more than just waivers; new safe harbors from certain laws should be developed that eliminate potential liability due to the public policy benefits of better aligned care and cost reductions.

7. **Implementation Toolkit.** Many of the purchasers we spoke with reported that providing explicit language, talking points, or instructions for employers who want to encourage their carriers to adopt this type of prospectively negotiated, comprehensive joint replacement bundle could increase the uptake and impact of the CEP workgroup’s recommendations. A “gold standard” and set of metrics with which to evaluate the orthopedic bundles offered by carriers and TPAs would also be helpful. We strongly advise the group to develop a short implementation toolkit for commercial purchasers as part of the white paper.

To augment the listed resources in Appendix D, we also offer the following materials developed from our experience in implementing the joint registry:
Shared Decision-Making Tools: Impact of decision and communication aids on patient knowledge, efficiency of decision making, treatment choice, and patient and surgeon experience.

Patient Assessment Tools: The California Joint Replacement Registry Selecting a Tool for Evaluating Patient-Reported Outcomes. This report provides a literature review of the most commonly-used PRO questionnaires, as well as the use and performance criteria considered by CJRR in selecting an instrument. Additional information on implementation experience has also been published.

Thank you again for the opportunity to provide feedback to the CEP workgroup on this important framework document. We look forward to continuing to engage public and private purchasers in the workgroup's activities, and continue to strongly support the LAN’s broader effort to increase value across the U.S. health system.

Please contact me should you require any additional information or clarification.

Sincerely,

David Lansky, PhD
President and CEO
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
The American Medical Group (AMGA)
March 28, 2016

To: The Health Care Plan Learning and Action Committee (HCPLAN)

From: AMGA

Re: Comments in Response to HCPLAN's "Elective Joint Replacement" Draft White Paper

On behalf of AMGA, we appreciate the opportunity to comment on the Health Care Payment Learning and Action Network’s (HCPLAN) "Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement, Draft White Paper." AMGA, founded in 1950, represents more than 450 multi-specialty medical groups and integrated delivery systems representing about 177,000 physicians who care for one-in-three Americans. Our member medical groups participate in the Center for Medicare and Medicaid Services' Comprehensive Care for Joint Replacement (CJR), in the agency's Bundled Payments for Care Improvement (BPCI) demonstrations, and in various commercial bundled payment arrangements. AMGA has a strong interest in the success of both the Medicare program and private payers’ bundled payment initiatives.

AMGA's sees the same problems present in the HCPLAN's white paper draft outline of "the adoption of clinical episode-based payment models" "for elective joint replacement" (or for lower extremity joint replacement, or LEJR) as we saw in Medicare's CJR demonstration. Several substantive issues are either unaddressed or addressed inadequately. AMGA's comments are limited to five comparable issues or problems: underlying payment; overuse; care coordination; quality measurement or including the use of the Unique Device Identifier (UDI); and, profit sharing.

Underlying Payment
Like the Medicare CJR demonstration, the white paper does not address underlying payment reform. Under "episode price" the white paper simply states, "price should be based on the performance of the better performers in a particular market." As in Medicare's CJR demonstration, a finite list of reimbursements for LEJR-related services and procedures is assumed and simply bundled for the white paper's proposed 120 day LEJR episode. Paying providers exactly the same neither encourages, nor allows for, care innovation. As Harold Miller noted in his 2015 report, "Bundling Badly: The Problems with Medicare's Proposal for Comprehensive Care for Joint Replacement," "in a true episode payment system, the providers have the flexibility to deliver services that they could not bill for under the fee for service structure, knowing that they will ultimately be paid for those services when the reconciliation occurs." Providers are left unable to innovate by providing services that reduce costs, not just improve savings. Like the Medicare CJR demo, the white paper's design outline is simply another pay for performance effort.
Overuse

There is substantial LEJR overutilization, which is made evident by unwarranted variation. Researchers at Dartmouth's Institute for Health Policy and Clinical Practice have shown regional LEJR variation per 1,000 Medicare beneficiaries can range from two to seven episodes for hip replacement and from four to sixteen episodes for knee replacement. There also exists substantial variation within regions and by race. These problems are compounded by the fact that LEJR episodes account for the largest dollar amount ($25 billion) and highest percentage (6.3 percent) of annual 30-day-episode Medicare spending. Beyond the recommendation under "Episode Definition" that there needs to be evidence of a functional status assessment and the use of a shared decision aid to "support the appropriateness of the episode," AMGA recommends there needs to be demonstrated use of appropriate evidence-based clinical guidelines. We also recommend that payers carefully monitor utilization to better assure appropriate use. Absent these checks, LEJR episode expenditures could perversely decrease episode spending while at the same time increase aggregate spending.

Care Coordination

Care coordination is not one of the white paper's 10 "recommendation" subtopics. Care coordination is only mentioned within the context of the white paper's LEJR 120 care episode. This is disappointing since healthcare is already too fragmented. We also know that nearly 75 percent of seniors, who are most likely to receive a LEJR procedure, suffer from two or more chronic conditions and that nearly four in ten suffer from four or more chronic conditions. The white paper ignores the fact these patients are more likely than not co-morbid. This means these patients simultaneously have other, or additional, on-going care needs. The white paper final draft should include a discussion of how the joint replacement episode will be coordinated with other providers, such as Accountable Care Organization providers, to treat patients with simultaneous or ongoing chronic care needs. We also encourage the white paper work group and staff to consider the use of patient navigators throughout the entire 120-day episode, since many CMS Acute Care Episode (ACE) demonstration participants made product use of their services.

Quality Measurement

The use of implantable medical devices, particularly artificial hip and knee replacements can cause substantial iatrogenic harm. Causes of joint replacement failure include mechanical loosening, osteolysis, infection, instability, peri-prosthetic fracture, and implant failure. These can lead to, among other consequences, cerebral and nervous system impairment, bone deterioration and amputation. If a hip or knee implant fails, a second replacement has a higher failure rate than a primary replacement; these surgeries require more technical expertise, are significantly more expensive, and fewer surgeons have the ability to perform second or "revision" replacement surgeries, which limits access to these procedures in some regions.

AMGA strongly supports the use of the quality metrics identified in the paper. However, it is disappointing the white paper does not recommend the use of the FDA's Unique Device Identification (UDI) system, particularly because the CMS ACE demonstration providers used cheaper surgical implants, equipment and materials in both the orthopedic and cardiovascular DRGs to produce the greatest cost savings. The white paper should support Department of Health and Human Services Secretary Sylvia Burwell's advocacy for incorporating UDIs in support of the FDA's Sentinel Initiative. This effort also is supported by the American Joint Replacement Registry, HL7 (Health Level Seven International), AARP, Duke Medicine, Geisinger, Intermountain Healthcare, The Leapfrog Group, the Pacific Business Group on Health, The Pew Charitable Trusts, Premier, and numerous others.
Profit Sharing
Under "payment flow," the white paper discusses prospective versus retrospective payment and recommends, "at this point in time," the latter. Per our "underlying payment" comment above, providers should be given a choice in how they are reimbursed. Providers more able to accept risk and more willing to innovate to reduce costs should be given the opportunity to do so.

For several reasons, we also recommend that the white paper outline a protocol whereby profit sharing is achieved. There is no evidence to support the view that the "accountable entity" or "quarterback" will simply "opt" to profit or gain share. Most ACE demonstration providers did not do so. Profit sharing would enable the "accountable entity" to share risk with providers formally involved in the care episode, particularly post-acute providers where LEJR care costs most widely vary. Profit sharing should include non-episode providers in cases where the patient is receiving simultaneous or ongoing care. Profit sharing should also include the patient to incent self-activation. Profit sharing also avoids the perception, or reality, that in a world where providers are caring for the whole person and addressing population health needs, bundled payment arrangements fragment or silo care, are redundant, and competitive. Bundled payment arrangements should create synergy between and among providers.

Thank you for offering AMGA an opportunity to comment. We look forward to continuing to work with the HCPLAN to evolve further bundled payment arrangements. If you have any questions please do not hesitate to contact David Introcaso, Ph.D., Senior Director for Regulatory and Public Policy, at dintrocaso@amga.org.

Thank you.

Donald W. Fisher
President and CEO
ACCELERATING AND ALIGNING
POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
The American Medical Rehabilitation Providers Association
March 28, 2016

Lewis G. Sandy, M.D., F.A.C.P.
Chair, Clinical Episodes Payments (CEP) Work Group
Health Care Payment Learning and Action Network
7515 Colshire Drive
McLean, VA 22102

RE: Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement; Draft White Paper

Dear Dr. Sandy and members of the Work Group,

Thank you for the opportunity to provide comments on the draft white paper entitled Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement. This letter is submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA).

AMRPA is the national voluntary trade association representing more than 500 inpatient rehabilitation hospitals and units (which are referred to by Medicare as IRFs), hospital outpatient departments (HOPDs), and settings independent of the hospital, such as comprehensive outpatient rehabilitation facilities (CORFs), rehabilitation agencies, and skilled nursing facilities (SNFs). AMRPA members provide rehabilitation services across multiple health care settings to help patients maximize their health, functional skills, independence, and participation in society so they can return to home, work, or an active retirement.

Given the numerous payment and delivery system reform initiatives, (e.g., Bundled Payments for Care Improvement (BPCI), Comprehensive Care for Joint Replacement (CJR), Medicare Shared Savings Program (MSSP)) underway or under consideration, we recognize that there is an intense interest in realigning payment for and delivery of health care services to ensure that resources are allocated efficiently and care quality is improved. AMRPA shares this commitment to achieving these overarching objectives. We are hopeful that organizations such as the Health Care Payment Learning and Action Network (HCPLAN), which have an opportunity to shape these reforms, continue to engage stakeholders to ensure these goals are achieved in a way that minimizes burden on providers and maintains access to health care services, specifically medical rehabilitation services, for patients.

AMRPA has considered many of the issues surrounding bundled payments and service redesign, which are discussed in our policy paper, American Medical Rehabilitation Providers Association
Position Paper on a National Pilot Program on Payment Bundling.\(^1\) We believe that any such program should adhere to a core set of guiding principles.

**AMRPA’s Guiding Principles for Bundled Payment Initiatives, including Episode Payment Models:**

- **Nondiscrimination:** Any program should assure that there is no discrimination in admission or treatment of vulnerable populations, particularly persons with disabilities.

- **Patients:** Any program should be patient-centered with a focus on restoring health; enhancing function; returning patients to their communities, jobs, and school; and maintaining access and quality. Hence, persons with functional loss must have access to medical rehabilitation. Any program must avoid incentives to withhold care or steer patients only to select providers. Furthermore, patients must be able to exercise informed choice regarding their course of care.

- **Providers:** Participating providers should be empowered to deliver services that are clinically appropriate for the patient based on clinical evidence and professional judgment.

- **Payers:** Cost-effective and cost-efficient care should be promoted. Payment must be equitable and thoroughly account for all payment, costs, and resources that reflect the characteristics of patients served, as well as costs not related to patient characteristics such as facility maintenance. The system should maximize administrative simplicity for providers and payers.

- **Quality:** High-quality care should be enhanced, sought, delivered, fairly reimbursed and maximize patient/family outcomes and satisfaction. Reimbursement and measures of success for providers should be risk adjusted to promote the care of those with the greatest need. Hence, care must be taken in the design of these programs to assure that any bias against caring for the most medically complex cases is removed and that there are no incentives to withhold on care or game the payment. Quality measures selected should promote positive outcomes, avoid potential adverse events, and demonstrate effectiveness and efficiency of care.

**General Comments**

In an ideal world, any real opportunity for advancements in joint replacement care would focus on eliminating the need for joint replacement procedures by using weight loss programs, rehabilitation techniques, optimizing pain management with more conservative medical care and less invasive procedures that would also improve mobility. Short of these approaches, AMPRA thinks the next best way to deal with elective joint replacements (EJRs) would be a comprehensive pre-planned package of care (pre-rehabilitation) that commences twelve weeks before a patient’s EJR and includes weight reduction and rehabilitation services, followed by surgery in an ambulatory surgical center (ASC) or hospital, and post-operative care in an IRF.

SNF, or best, in the home depending upon the patient’s clinical circumstances. A clinical episode payment (or bundled payments) model for EJR must recognize the complexity, medical co-morbidities, and complications of some patients.

As the Work Group formulates its final recommendations, AMRPA suggests it put more thought into creating counterbalancing measures of accountability to disincentivize payers and providers from stunting on or withholding medically necessary care, even if inadvertently. The metrics applied to the EJR clinical episode model should encourage the accountable entity, or bundle holder, to take a quality of care and outcomes perspective rather than just a utilization management approach. Too often, AMRPA members have seen business practices overriding clinical expertise and patient choice. One glaring example of patient steering under the guise of (strong-handed) cost-management strategies is Medicare Advantage (MA) plans’ substitution of proprietary post-acute care referral guidelines in place of physician judgment or Medicare coverage criteria.

We also suggest the Work Group recognize that the longer-term patient impacts of bundled payment models have yet to be satisfactorily realized. AMRPA believes fully in patient-centered and outcomes-driven care delivery innovation, but we caution against proceeding with such models when the quality framework and patient safety protections have not been proven to be sound enough to support them. As acknowledged in the paper’s Appendix C: Summary Review of Selected Joint Replacement Initiatives, the table of sixteen current models is qualified by the footnote “Results reported are based on studies of varying statistical rigor and extrapolated from publications.” For instance, the Centers for Medicare and Medicaid Services’ (CMS) BPCI models have yet to undergo a second evaluation and many results from the Year 1 evaluations were considered preliminary; some examined only one quarter of data. Perhaps most alarmingly, quality outcomes results from the Arkansas Health Care Improvement Initiative, seemingly the most comparable model to the Work Group’s draft white paper recommendations, demonstrated a 75 percent increase in patients’ post-operative complications. These results emphasize the need for outcomes-focused and comparative-effectiveness research on EJR bundled payment models. They also call for greater efforts in developing both provider- and patient-reported outcome measures for pain, ambulation, and functional improvement, rather than a more prevalent adoption of EJR bundled payment models.

Recognizing that certain model specifications and benefit designs are outside of the scope for the Work Group, we present the following comments on the Work Group’s ten design elements for EJR bundled payment models.

**Design Elements**

**Recommendation 1: Episode Definition**

“The episode is defined as an elective and appropriate total hip or total knee replacement due to osteoarthritis.”

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2 Results from the Arkansas Health Care Improvement Initiative show that post-operative complications increased from 8 percent to 14 percent. Please see *Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement; Draft White Paper*, pg. 43.
AMRPA supports the clinical definition of eligible procedures as elective and appropriate total hip or total knee replacement due to osteoarthritis. Elective total joint replacements, versus partial joint replacements or fractures, present a more controlled clinical event with a more homogenous patient population and thus more predictable costs and care trajectories. We also appreciate the Work Group’s considerations as to the appropriateness of the surgical procedure in the first place. This is reflected in its recommendation that EJR payment models incorporate a functional status assessment tool in the pre-operative surgical visit. IRFs are required to assess patients’ functional abilities with the inpatient rehabilitation facility patient assessment instrument (IRF PAI) at admission and discharge. This assessment underscores the importance of ensuring that functional ability is accounted for and post-operative gain in function is quantified and measuredly evaluated. In addition, we strongly support the recommendation to account for patients’ preferences as they relate to care options. This ensures the model remains patient-centric and also supports care innovation should less invasive treatments achieve similar or better outcomes at lower costs.

Recommendation 2: Episode Timing

“For purposes of payment, the starting point for this episode is 30 days pre-procedure, and the stopping point is 90 days post-discharge. Accountability for functional improvement may go beyond the 90 days.”

AMRPA supports the 30-day pre-procedure window during which shared decision making and appropriate clinical assessments can be performed to ensure that surgery is in a patient’s best interest. We support the pre-procedure window conceptually and in fact believe a twelve-week pre-surgery treatment approach would be ideal, as noted above. We recommend the duration of the pre-procedure window (for the purposes of payment) be flexible depending on the clinical care program the accountable entity is following, with a minimum duration of 30 days prior to surgery.

We disagree, however, with the Work Group’s proposal to make the episode duration 90-days post discharge from the surgical setting. After deliberating with members who currently participate in bundled payment initiatives for EJRs as well as a number who treat EJRs patients under the inpatient rehabilitation facility prospective payment system (IRF PPS), we believe the appropriate duration for financial responsibility is 60-days post-discharge.

AMRPA strongly supports the Work Group’s recommendation that an extended accountability period for functional improvement may go beyond the 90-day window for financial accountability. We recommend the Work Group consider extending the period of time for which bundle holders will be responsible for the quality outcomes of EJR patients to at least six months post-hospital discharge. We also echo the Work Group’s concern that there should be routine monitoring and analysis of usage patterns to ensure that patient care is not inappropriately impacted. We ask that the Work Group propose a financial discount or penalty against those providers found to be stinting or withholding medically necessary care.

Recommendation 3: Patient Population

“The episode should apply to the broadest-possible pool of patients, using risk and severity adjustment to account for age and complexity.”
We disagree with this statement and recommend the Work Group limit eligibility to a well-defined patient population with low risk and absent multiple comorbidities or chronic conditions. Certain comorbidities such as obesity or diabetes may unexpectedly influence or exacerbate the post-procedure recovery. Granted, a narrower definition of eligible patients would likely diminish the applicable patient volume and is therefore a critical factor for entities evaluating bundled payment initiatives. However, we believe a more homogenous patient population will support the HCPLAN’s goals of discouraging providers from “cherry-picking” the lowest-risk patients.

Additionally, AMRPA cautions the Work Group against placing too much faith in risk-adjustment methodologies when such methodologies may be insufficient at predicting costs and therefore poorly mitigate provider risk. For example, the draft paper cites the Medicare Payment Advisory Commission’s (MedPAC) 2014 risk-adjustment analysis as one of several resources for risk-adjustment models. Yet MedPAC’s critical finding was that CMS’s hierarchical condition classification (HCC) risk-adjustment model overpredicts costs of the least costly beneficiaries and underpredicts costs of the most costly beneficiaries.\(^3\) A more recent study of the HCC methodology by Avalere Health in January 2016 reinforced MedPAC’s conclusions. Furthermore, it identified osteoarthritis and rheumatoid arthritis as two chronic conditions for which the HCC model substantially under-predicted provider costs.\(^4\) With this in mind, we suggest the Work Group reevaluate the strength it places in current actuarial risk-adjustment methods for EJRs, especially when some methods have been found to inaccurately predict costs for osteoarthritis patients. Again, we recommend limiting the eligible patient population to low-risk EJR patients who do not present with multiple comorbidities. These patients have more straightforward and predictable care trajectories which translate to more accurate episode prices and therefore more controlled risk for involved payers and providers.

**Recommendation 4: Services**

“All services needed by the patient that are [billed in the defined time and] related to the joint replacement procedure should be covered by the episode price.”

We agree with the Work Group’s assessment that providers generally prefer a more narrowly defined episode because 1) the clinical pathways can be developed, and 2) there are fewer clinical variables in the population that may not easily be addressed. While AMRPA recognizes that the list of covered services is ultimately under the purview of the accountable entity and collaborators, we believe limiting the eligible patient population as suggested above would help better identify those services in or out of the scope of EJR care.

**Recommendation 5: Patient Engagement**

“Require use of shared decision-making and patient engagement tools and transparency of the payment model in patient-facing materials to maximize opportunities to engage patients and families in advance high-value care.”

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Consistent with previous recommendations AMRPA has made to CMS regarding the implementation of BPCI and CJR, we recommend the Work Group include the following patient protections for EJR bundled payment model:

1. Patient participation should be transparent and patients should not be automatically enrolled in the bundling model by virtue of being in a provider network or insurance plan. They must be informed that they have been and retain the right to opt out of receiving services from the accountable entity.

2. If patients choose to participate, they should retain the right to choose their providers within their healthcare or insurance network even if that provider is outside the specific EJR bundle network. Hence, if the discharge plan is to send patients to a SNF and they, their physician, or their family believe that an IRF or LTCH is more appropriate, patients should be able to make that choice.

3. Patients retain appeals rights regarding discharge from acute care hospitals, post-acute placement and all other providers per programmatic requirements (e.g. Medicare, qualified health plans, etc.). Patients should also retain appeals rights they otherwise have in their coverage. These appeal rights must be clearly stated.

4. The accountable entity should identify those providers included within its EJR model from those not participating in the list of providers furnished to potential EJR patients.

5. The accountable entity must inform potential EJR model patients of other providers within and near the same region that provide EJR services but are not participating in the model.

Recommendation 6: Accountable Entity

“The accountable entity should be chosen based on its ability to engineer change in the way care is delivered to the patient and its ability to accept risk for an episode of care.”

The accountable entity must be selected with great attention paid to its ability to recognize the value of all post-acute care providers, including IRFs. IRFs have extensive experience managing EJR cases across the post-acute care spectrum. AMRPA recommends the Work Group include IRFs in its recommendations of accountable entities. IRFs are hospital-level settings that satisfy the following criteria critical to being an effective accountable entity for EJR procedures for those providers who are able to assume the necessary levels of risk. These criteria include having the:

- Requisite clinical staff and expertise overall and for EJR cases;
- Experience and ability to coordinate and manage the upstream services of the acute care hospital or ASC;
- Demonstrated dedication of the hospital, physicians, nurses, therapists, and other clinical professionals’ time to the programs;
• Systems in place to include rehabilitation physicians and extenders early in the discharge planning process to help in identifying the proper trajectory of patients and their care;

• Ability to deliver, or contract for, the entire bundle of services to be rendered, including clear statements of the capacity to provide inpatient rehabilitation hospital/unit services;

• Clinical pathways and effective discharge planning capacities;

• Ability to manage transitions or handoffs from one setting to another when necessary (e.g. entry, transitions, and discharge);

• Capacity to monitor patient clinical status and coordinate medication management/reconciliation as patients progress across the acute and post-acute care settings;

• Ability to track quality indicators and patient outcomes across an array of services and settings;

• Capacity to manage medical complications and assume risk for readmissions;

• Ability to coordinate with other community services to foster the patient’s independence;

• Necessary financial systems to administer payment across multiple entities;

• Ability to tolerate financial risk and understand its own risk exposure;

• Minimum volume standards for overall patient care, in both acute and post-acute care, for EJR patients; and

• Demonstrated ability to care for all types of patients including intense medical rehabilitation patients and medically complex patients.

AMRPA has the following concerns about acute care entities’ (hospitals, physicians or physicians groups’) exclusive capacity to be effective accountable entities:

• Many, if not most, acute care providers currently do not provide adequate time and training for discharge planners to conduct a complete assessment of the post-acute care needs of acute care patients on discharge;

• Acute care providers’ discharge planners may not be fully aware of the differences among post-acute care settings;

• If any assessment tool is used, discharge planners in all settings would require extensive training on functional status assessments;
Acute care providers will have incentives to discharge post-acute care patients to the lower cost providers without providing adequate services for full functional and medical recovery in the long-term, beyond the proposed episode of care.

In either the commercial or public sector, payers should work with the accountable entity to promote collaborations to allow for multiple providers within a joint replacement care team to share the risk and reward.

**Recommendation 7: Payment Flow**

“Use retrospective reconciliation with upfront payments flowing through a fee-for-service mechanism.”

AMRPA agrees with the Work Group’s conclusion that, while a prospective payment structure would be ideal for episodic bundled payment models, retrospective payment with reconciliation is most feasible for the current operational environment. We have urged CMS to pursue prospective payment demonstration projects through additional BPCI models 4-8, and not to impose an untested payment system in any mandatory Medicare programs. We believe a more prudent first step to testing prospective episode payment would be a bundled payment pilot limited to post-acute care providers only. A post-acute care-only prospective episode payment initiative would allow predictable and reduced costs, yet keep the responsibility for serving the clinical needs of the beneficiary in the hands of providers who understand patients’ need for medical rehabilitation.

**Recommendation 8: Episode Price**

“Data used to establish price should reflect two years of historical costs and strike a balance between regional- and provider-specific data. The price should acknowledge and incentivize more efficient levels of practice.”

AMRPA recommends using three years of historical data in instances where there is an adequate volume of episodes. This would also parallel the episode price construction in the CJR and BPCI models. We also support a phased-in approach in moving from a provider-specific benchmark price to a regional-specific benchmark. However, we caution the Work Group against “incentivizing more efficient levels of practice” in its recommendation. There is a critical balance between encouraging provider efficiency and not endangering the quality of care and services furnished to the patient. Again, it is of utmost importance to build in enhanced checks and balances into the model’s accountability framework to ensure that the interests of payers and providers remain congruous with those of patients.

The Work Group’s white paper seeks to encourage EJR service delivery and care coordination. However, an element essential to enabling care innovation is granting providers the ability, via operational flexibility, to change the payments and costs generated by care delivery. IRFs have a wealth of experience in treating EJR patients and therefore, have significant advantages to offer accountable entities and bundled payment collaborators. For example, IRFs have considerably

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lower hospital readmission and complication rates than other post-acute care providers, particularly SNFs. Today, SNFs often serve as a surrogate for some of the less complex hospital days, but require a patient to be physically transferred from a hospital treatment team to more limited caregivers earlier in the recuperation process. This disruption is often compounded by limited communication regarding care planning, health status, and other pertinent clinical information, leading to greater fragmentation and duplicative testing.

Yet, for IRFs to be attractive as potential collaborators and viable providers in an EJR bundled payments model, accountable entities will need to consider granting IRFs the option of pricing flexibility. Using Medicare’s payment structure as an example, IRFs do not receive payments on a per diem (unlike SNFs) or on a fixed-length episode basis (unlike home health agencies). Furthermore, precedent to receiving a per-stay payment for each Medicare beneficiary, IRFs must comply with hospital-level regulatory requirements not characteristic of non-institutional post-acute care providers. IRFs must provide 24-hour physician supervision, as well as multiple weekly physician visits for each patient and IRF patients must also receive a minimum of three hours of intensive therapy five days a week (3-Hour Rule). The rigidities imposed by these regulatory requirements simply do not allow IRFs to be as flexible in adjusting their costs. Therefore, IRFs’ lack of price flexibility could cause EJR entities to steer patients from IRFs and towards other less costly but higher-risk providers. We recommend the Work Group more strongly consider these payment issues in its model design suggestions.

We also advise the Work Group reference the CJR model’s restrictions to gainsharing payments and propose them as advisable guidelines for upside and downside gainsharing. These limitations prevent an accountable entity from unloading undue financial risk onto its collaborators. Critically, they also serve to protect patients by discouraging inappropriate payer/provider behaviors that may not always align with the patient’s interests and well-being.

**Recommendation 9:** Type and Level of Risk

“The goal should be to utilize both upside and downside risk. Transition periods and risk mitigation strategies should be used to encourage broader provider participation.”

Implementing strategies to limit risk or transition (phase in) downside risk is fundamental to securing provider buy-in, particularly to a voluntary bundled payment model with target pricing. Such limits are critical considering that providers would most likely be accountable for care provided by several other providers across the episode. AMRPA supports utilizing transition periods and other options for limiting the level of risk such as stop-loss caps, again paralleling similar strategies in CJR.

**Recommendation 10:** Quality Metrics

1) Prioritize use of patient-reported outcome and functional status measures;
2) Use quality scorecards to track performance on quality and inform decision related to payment; and

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6 In 2013, the rate of potentially avoidable rehospitalizations during the stay was 2.5 percent for IRFs and 11.1 percent for SNFs. Potentially avoidable rehospitalizations during the 30 days after IRF discharge was 4.5 percent and 5.5 percent in the 30 days after SNF discharge. See the Medicare Payment Advisory Commission’s *March 2015 Report to the Congress: Medicare Payment Policy*, pgs. 191 and 249.
3) Use quality information to communicate with and engage patients.

Incentives to reduce costs may create incentives to reduce medically necessary or beneficial services, so quality metrics must be used both to assess whether this is occurring and to protect patients. AMRPA strongly agrees that measuring the outcomes and patient experience of care to determine improvement to the quality of care. We appreciate the Work Group’s acknowledgement that many quality measurement metrics are designed for measuring the quality of care in a single setting of care but not for observing quality over multiple settings.

According to our members’ clinicians, patients are concerned about elimination of pain via surgery and subsequent pain management. Second, they seek to be able to ambulate independently for functional distances and speeds, and without the use of assistive devices. Third, they wish to avoid any complications such as an infection, and avoid a return to the hospital. Hence, AMRPA recommends that the quality measure set additionally include pain experience and management measures, and ambulation functional measures. The ambulation measures should specifically focus on the ability to walk in a meaningful and measurable way.

In the CJR model, participant hospitals are required to report on the Hospital-level 30-day all-cause RSRR following elective primary THA and/or TKA (NQF #1551), Hospital-level RSCR following elective primary THA and/or TKA (NQF # 1550), and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #1661). While AMRPA supports the intent of these measures, we find them to be insufficient metrics to assess beneficiaries’ health care outcomes and to protect against incentivizing payers or providers to delay or withhold medically necessary patient care or provide substandard care. Like the Work Group, we believe it is critically important that more work be done to develop pain and function outcomes measures. Any measures applied to a bundled payment initiative must ensure that they respond to the patient’s concerns and goals, while also ensuring that any withholding of care can be adequately identified for all patients and, in particular, for any complex patients who are medically and/or functionally compromised.

Operationally, we believe measures should be collected at intervals more immediately post-surgery and more routinely afterward throughout the six-month post-discharge duration as part of accountable entities responsibility for patient functional outcomes and improvements. For example, pain relief and pain management should be assessed at least three times in the episode of care: 72 hours after the EJR surgery, six weeks after, and six months after. Lastly, we strongly support the recommendation that all outcomes measures used to determine payment or reported to or by patients be accurately risk adjusted to account for the effects of patient case mix.

**Stakeholder Perspectives**

1. **Data Infrastructure Issues**

   According to a recent study in *Health Affairs*, IRFs and LTCHs had, on average, significantly lower rates of EHR adoption than acute care hospitals which were eligible for incentive payments. This is not at all to say that IRFs should be precluded from

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7 CMS’s meaningful-use incentive program aims to promote the adoption and use of electronic health records (EHR) throughout health care settings; however, IRFs and long-term care hospitals (LTCHs) were among some providers
being accountable entities. Those inpatient rehabilitation providers with sophisticated data infrastructures capable of assuming the upstream (acute care) and downstream (subsequent post-acute care) management, and related data analysis, should be enabled to do so. Rather, as various entities – private and public, payers and providers – evaluate the feasibility of a patient-centric bundled payments models spanning the continuum of care, it would behoove them to be cognizant of the realities and potential operational obstacles of the post-acute care arena where EHR adoption is less prevalent. AMRPA recommends the Work Group encourage entities to be aware of factors such as time or capital investment in order to achieve EHR alignment. However, we must emphasize that they should not be seen as hindrances to innovative collaboration across silos. Post-acute care providers are a critical component of the episode of care and many are eager to participate in care redesign models. As the study notes, connecting “ineligible providers with acute care providers linked through both payment and information exchange could contribute to more patient-centered health care within systems.”

Conclusion
Thank you for the opportunity to provide our recommendations for improving the draft white paper on designing clinical episode payment models for elective joint replacement. AMRPA stands ready to assist the Work Group and the HCPLAN in its work. If you have any questions regarding our recommendations please contact Carolyn Zollar (czollar@amrpa.org) or Mimi Zhang (mzhang@amrpa.org) at 202-223-1920.

Sincerely,

Bruce M. Gans, MD
Chair, AMRPA Board of Directors
Executive Vice President and Chief Medical Officer, Kessler Institute for Rehabilitation
National Medical Director for Rehabilitation, Select Medical

Douglas M. Baer, CPA
Chair, AMRPA Bundled Payments Work Group
Chief Executive Officer, Brooks Rehabilitation Hospital

ineligible for incentive payments. Please see “Meaningful Use Of EHRs Among Hospitals Ineligible For Incentives Lags Behind That Of Other Hospitals, 2009–13,” HealthAffairs March 2016 vol. 35 no. 3495-501.
ACCELERATING AND ALIGNING POPULATION-BASED PAYMENT MODELS:

Elective Joint Replacement

White Paper

Comments:
American Occupational Therapy Association
Via online submission to https://hcp-lan.org

March 25, 2016


Dear Clinical Episodes Payment Work Group:

The American Occupational Therapy Association (AOTA) is the national professional association representing the interests of more than 213,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. The science-driven, evidence-based practice of occupational therapy enables people of all ages to live life to its fullest by promoting health and minimizing the functional effects of illness, injury, and disability. Occupational therapy practitioners serve beneficiaries in all inpatient and outpatient settings, including but not limited to inpatient acute care hospitals, home health agencies, skilled nursing facilities (SNF), long-term care hospitals, inpatient rehabilitation facilities (IRF), hospice, outpatient hospitals, and independent occupational therapy private practices. For the purposes of this comment, we find it important to note that occupational therapy practitioners have an especially significant role in the post-discharge phase of an elective joint replacement procedure and as a result, the significant value of having an occupational therapy practitioner working in collaboration with the acute and post-acute care (PAC) team should be recognized. We appreciate the opportunity to comment on the Clinical Episodes Payment (CEP) Work Group’s Elective Joint Replacement draft White Paper.

The Health Care Payment Learning & Action Network (LAN) is proposing 10 recommendations that consist of both design elements and operational considerations based on the experience and the analysis of existing episode payment initiatives. The occupational therapy profession has an important stake with regard to recognition in recommendations 1, 4, 5, 6, and 10¹, and thus the focus of this comment will be on those particular recommendations with the ultimate goals of providing both evidence asserting that occupational therapy practitioners should be included as part of the team in the post-discharge phase of the episode model, and illustrating the significant impact the services OTs provide in order to move and keep post-discharge individuals well-functioning and out of acute and post-acute care facilities so they can successfully integrate back into the community.

1. Inclusion of an Occupational Therapy Practitioner in the Elective Joint Replacement Model

   The CEP Work Group notes that a significant component of an “accountable entity” is the ability it has to engineer change and that, while it is important that one entity be the primary accountable party, it is also important that care is provided using a team-based approach.

¹“Episode Definition”, “Services,” “Patient Engagement,” “Accountable Entity,” and “Quality Metrics”
AOTA believes that the provider responsible for the episode of care should have appropriate knowledge of the clinical needs of beneficiaries who require outpatient rehabilitation and PAC services. They should understand the differences among PAC settings or risk jeopardizing beneficiary access to the right care in the right setting at the right time.

AOTA believes that the provider responsible for the episode of care:

- Must have the necessary clinical staff, including occupational therapy practitioners, with appropriate expertise in a range of patient needs depending on condition and medical complexity;
- Must include rehabilitation staff, like occupational therapy practitioners, in discharge planning to ensure patients are discharged to the most appropriate setting;
- Must be able to monitor patient status and track quality indicators and patient outcomes; and
- Must coordinate with other settings and providers to focus on patient-centered care that promotes the patient’s independence.

AOTA asserts that explicit recognition of how the profession of occupational therapy interacts with other disciplines involved in care (e.g., physicians, nurses, physical therapists, speech-language pathologists, social workers) is necessary in the White Paper to facilitate better collaboration and thus more coordinated care. This consideration is especially significant for patients who, although they may be appropriate for the model, may also come with complex rehabilitation needs and/or multiple chronic conditions requiring more intensive occupational therapy to develop their activities of daily living and other skills for a full return to the community/home setting.

Further, the patient-centered focus of the care plan and discharge planning processes discussed in the White Paper are part of the foundation of occupational therapy practice and how occupational therapists assess, treat, and consider discharge and transitions as part of the assessment of a patient’s functional and cognitive status on an ongoing basis. AOTA strongly supports the involvement of the patient in determining their goals of care and discharge planning, as well as taking into account realistic caregiver support after discharge. We believe this recommended step would result in appropriate and more informed choices that meet the patient’s needs. In this instance, the presence of an occupational therapy practitioner is not only suggested, but should be deemed necessary in the White Paper to fully achieve the most optimal patient outcome.

II. Episode Definition – Functional Status Assessment Tools and “Episode end point”

In defining whether an episode is “appropriate” for the purposes of this Model, the Work Group recommends that “in addition to a clinical assessment, a provider used a standardized, validated functional status assessment tool to determine that the patient is an appropriate candidate for surgical procedure, as opposed to being a candidate for less invasive care.”

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AOTA recommends that the following tools that apply to occupational therapy and other therapy disciplines be utilized in the assessment for determining whether an episode is “appropriate” for the purposes of the Model. We feel that the following assessment instruments3 more fully reflect the scope of a patient’s severity level and functional status prior to an elective procedure, and reflect the needs of the full range of providers who could be performing this assessment:

- Activity Measure for Post-Acute Care (AM-PAC): Daily Activity and Basic Mobility sections
- Activity Daily Living Index
- Berg Balance Scale
- Assessment Motor and Process Skills (AMPS)
- Functional Assessment Scale
- Performance Assessment of Self-Care Skills (PASS)

These assessments are standardized, validated functional status measures of variables that focus on mobility, activities of daily living (ADLs), cognitive status; static and dynamic balance abilities using functional tasks commonly performed in everyday life; various motor and process skills; self-care function for institutionalized individuals and; ADL function in the clinic or at home.

With regard to the “episode end point,” AOTA supports the principle that the episode design should be patient-centered, and acknowledge the challenges patients experience in the recovery period post-operatively. The Work Group proposes the episode should end 90 days post-discharge and while that may seem like a reasonable timeline following an elective procedure, the discussion does not actually go into further detail on what should be taken into consideration when assessing whether the Model actually delivers on its ultimate purpose by the end of the episode.

Existing evidence strongly emphasizes that appropriate and effective discharge planning should help reduce readmissions and address a patient’s functional and cognitive status needs so he or she can reside as independently as possible. Of note with respect to potentially preventable readmissions and a patient’s occupational therapy needs, several recent studies consider whether returning to the community from a recent hospitalization with unmet ADL need was associated with probability of readmission. The findings from these studies indicate that unmet ADL needs is indeed a considerable risk factor.

The studies reveal that many older patients are discharged from the hospital with ADL disability. Those who report unmet need for new ADL disabilities after they return home from the hospital are particularly vulnerable to readmission. This area is not typically addressed in a thorough manner through current discharge practices. This needs to change. Patients' functional needs after

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3 Selected Assessment Tools for Occupational Therapy Reporting of Outpatient Functional Data (G-Codes and Modifiers) to the Medicare Program. [http://www.aota.org/-/media/corporate/files/advocacy/reimb/coding/g%20codes/aota_g-codechart_2015%20review.pdf](http://www.aota.org/-/media/corporate/files/advocacy/reimb/coding/g%20codes/aota_g-codechart_2015%20review.pdf)
discharge should be carefully evaluated and addressed. Factors such as enabling self-management and ensuring appropriate medication management and ADLs, such as cooking and eating are addressed, can have a direct effect on readmissions. Self-management is a key element in successful post-acute care, and occupational therapists are experts in motivation, task analysis, and psychosocial contexts, which all contribute to enabling positive outcomes.

With that in mind, AOTA poses the question of whether 90 days is enough time to sincerely conclude whether the patient was actually better off after the episode of elective joint replacement – i.e. are they functioning adequately in the community, and does his/her outcome match or come close to the goals they set prior to the episode’s commencement? Furthermore, who is monitoring the patient’s status after the 90 days is complete to see if the discharge plan was completed and additionally, adequately followed-up? Ultimately, how do we a measure a threshold or standard to say whether the episode was a success upon the Model’s intended “end point”? AOTA requests that the Work Group consider each of the above questions and concerns when developing language in the White Paper to address the episode timeline/definition and the long-term functional status needs of recipients of elective joint replacement to assure the most appropriate and high quality services are provided under this Model to keep patients functioning as independently as possible post-surgery and rehabilitation. This would likely need to be a concern of the accountable entity.

III. Services

AOTA believes that the Work Group’s recommendation that “all services needed by the patient that are related to (emphasis added) the joint replacement procedure should be covered by the episode price,” is too broad and may exclude important and medically necessary services depending on who is interpreting the phrase “related to.” Additionally, the Work Group directs readers to Appendix C, however from those initiatives, it is still not entirely clear on what services are “related to” the joint replacement procedure. Considering the complexity of certain patients, an excluded services list would likely run into issues if it did not take into consideration the patients with complex rehabilitation needs or those with multiple chronic conditions. AOTA supports the idea of an included services list as being a more effective alternative to an excluded services list. An included services list would be easier to manage without being overly broad or overly restrictive, and would be better suited for patients with conditions that may be reasonably tied to an elective joint procedure that may not have been identified at the onset of the episode. Finally, AOTA respectfully requests that occupational therapy services be added to that included services list.

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IV. Patient Engagement

AOTA supports and applauds the Work Group’s strong recommendation on the required use of shared decision-making and patient engagement tools in order to maximize opportunities to engage patients and families in advancing high-value care. The experience of a patient and his or her caregiver/family following a procedure such as elective joint replacement that spans over a course of an episode is undoubtedly impacted by a variety of factors, both having to do with the intensive therapy provided in the phase following the event, as well as the health care team’s involvement in the patient’s personal treatment aims from the beginning of the intervention until discharge. Supported care planning should not be something taken halfheartedly.

AOTA believes that occupational therapy’s “client-centered” approach to treating patients directly aligns with the overarching purpose of the recommendation of supported care planning and ultimately seeks to get to the core of what is important and meaningful to the individual patient. Using a client-centered approach, the practitioner gathers information to understand what is currently important and meaningful to the client (i.e., what he or she wants to do) and to identify past experiences and interests that may assist in the current understanding of current issues and problems. During the process of collecting this information, the client, with the assistance of the occupational therapy practitioner, identifies priorities and desired target outcomes that will lead to the client’s engagement in occupations that support participation in life. Only clients can identify the occupations that give meaning to their lives and select the goals and priorities that are important to them. By valuing and respecting clients’ input, practitioners, help foster their involvement and can more efficiently guide interventions.

Moreover, coordination and collaboration on the patient’s medical and functional goals of care are critical since many patients have both a personal and rehabilitation goal of returning to their home or a community-based setting. It is part of the AOTA Practice Framework’s teachings to consider what the patient wants to achieve from rehabilitation to ultimately achieve his or her long term living objectives. Aspects of patient-centeredness, such as acknowledging the importance of the patient’s perspectives in treatment planning have been present in occupational therapy practice values since the very beginning of the profession.

V. Accountable Entity and Quality Metrics

AOTA believes that these recommendations leave a lot of considerations unanswered, making it difficult to take a fully informed position. The Work Group provides an example in the form of a “Joint Replacement Care Team” that divides the phases of the episode into pre-procedure, event, and post-discharge. Those phases then include within them, a minimum of two providers. One concern that we would raise would pertain to what is an appropriate way to measure the quality of the entire model’s outcome when the quality and inclusiveness within the care team may vary in and of itself? This next raises a concern from AOTA about quality measurement

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7 Accountable Entity, supra., n. 2, p. 17
once the patient reaches the end of an episode. The Work Group must consider and address in the White Paper which professional service will be measured and the issue of attribution, i.e., how any one profession can be assessed in affecting patient outcomes when the joint replacement model, by its very nature, requires bundling of discrete services to best treat patients. If accountability is delegated to each provider who essentially touches the patient at one phase or another during the episode, is it the amount of time spent with that provider that goes into consideration when factoring out risk and reward? Or, rather, will the quality of the services delivered within the bundle as a whole be measured for quality? If so, how will that quality measure be developed?

AOTA would further suggest that measures be developed to take into consideration the events following the end of the post-discharge phase of the episode that are critical yet often ignored, when patients are trying to integrate back into the community. These considerations would include but are not limited to follow-up that may be required given the patient’s age, socioeconomic status, mental health, family/caregiver support, and outside persistent health problems. With regard to these considerations, AOTA believes there needs to be some level of clarity on how the “accountable entity” would be responsible for the risks or rewards associated with the outcomes, both long and short term, if those were added considerations to the model’s overall effectiveness.

AOTA finds that there is a lack of clarity of what the quality metrics in this Model actually signify. For OT, quality measurement at the conclusion of the episode, or even at a later point after that time, would not truly encapsulate the value of what OTs strive for with regard to helping patients achieve their goals related to functioning in occupations that give their lives meaning.

* * *

Thank you for the opportunity to comment on the Elective Joint Replacement draft White Paper. AOTA looks forward to a continuing dialogue with the Health Care Payment Learning & Action Network on the prospective future of payment policies that may affect the ability of occupational therapy practitioners to provide quality care to beneficiaries in settings that implement these models.

Sincerely,

Ashley Delosh, JD
Regulatory Analyst