November 7, 2023

Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–5540–NC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Dear Administrator Brooks-LaSure:

On behalf of over 39,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we are pleased to share additional feedback on the Request for Information; Episode-Based Payment Model (CMS-5540-NC). AAOS has been a steadfast and supportive partner in the transition to value-based care.

We urge the Centers for Medicare & Medicaid Services (CMS) to consider the profound impact that interoperability, multi-payer alignment of measures, and administrative burden have on the ability for physicians to successfully participate in alternative payment models. It is incumbent upon CMS to ensure that these perennial barriers are resolved in any future model. Likewise, AAOS strongly encourages CMS to only consider voluntary models that have incentives for participation. Mandatory models have historically been unsuccessful in engaging physicians who are otherwise eager to lead in the shift to value-based care. As in our earlier comments on the Comprehensive Care for Joint Replacement (CJR) Model and subsequent extension, a mandate to include all episodes, physicians, and facilities in a designated Metropolitan Statistical Area severely disadvantaged those surgeons, non-physician providers, and facilities that either did not have the proper infrastructure to optimize patient care under episodes-of-care payment models and/or lacked adequate patient volumes to create sufficient economies of scale. A voluntary program that allows surgeons, facilities, and non-surgical providers to tailor their episode-of-care models to their unique patient population would lead to far better patient outcomes as well as more accurate and efficient payments.

Instead, CMS should create incentives for interested participants that would reward innovation and high-value patient care. We believe the program should be voluntary and on a nationwide basis for any set of surgeons, facilities, and providers who seek to collaborate in innovative ways to bring higher quality, improved care coordination, and to lower costs for musculoskeletal care and who have the infrastructure necessary to carry out an episode of care approach to payment and delivery. A key component of this is ensuring that any payment structure used is one that accounts for inflation and other changes that have a direct impact on the financial viability of physician practices.

With this in mind, please find our response below:

1. How can CMS structure episodes of care to increase specialty and primary care integration and improve patient experience and clinical outcomes?

This question pinpoints the fundamental issues with operationalizing value-based approaches to care delivery and payment for the nation. CMS has taken the initiative to create and support Accountable Care Organization (ACO) models, which is a significant step in moving the United States toward a population health approach to care. Ultimately, we all want to create and participate in a model that helps patients achieve good health outcomes and enable us to sustainably care for our rapidly growing Medicare population. However, the current models are designed to place the risk and cost management aspects of value-based payments solely in the realm of primary care practitioners while keeping the specialists and their teams in the fee-for-service world. This is based on the premise that ACOs will be able to identify and refer patients to high value specialists while providing most of the care themselves.

Given the proportion of Medicare dollars spent on specialty care and the prevalence of conditions that are treated by specialists, this is a recipe for failure. **The AAOS strongly recommends an approach that allows risk sharing downstream with the specialists who provide care for these conditions.** Providing efficient, evidence-based treatments for musculoskeletal conditions with an eye toward preventive care and improving overall health can only be accomplished with deep and expansive expertise in the most prevalent health conditions. To achieve the shared savings that CMS aims for, it mandates that the experts who work directly with patients on key decision making are incentivized toward value. The most promising model to facilitate ACO/Specialist collaboration is a condition-based payment mechanism as described in the attached white paper developed by AAOS volunteers and staff. **Thus, AAOS urges the Center for Medicare and Medicaid Innovation (CMMI) to explore and immediately pilot a program for the management of chronic, prevalent conditions such as osteoarthritis of the knee, as delineated, with plans to expand into other conditions as the reconciliation, monitoring, and payment mechanisms are refined from this initial experience.**

The current total cost of care ACO model clearly lacks an appropriate and functional mechanism to manage the incredible knowledge and improvements that have been realized in the delivery of specialty care over the past 30-40 years. In the musculoskeletal health arena, these changes have dramatically improved quality of life, maintenance of function, and freedom from pain for the large population of Americans who suffer from chronic musculoskeletal conditions such as arthritis and low back pain. At the same time, orthopaedic surgeons have worked closely with CMS to adopt and implement alternative payment models to continuously improve the quality and efficiency of care. Helping our aging population live independent and active lives is crucial to the sustainability of the Medicare program going forward. To imagine a world where patients have neglected hip and knee arthritis to the point that they can no longer care for themselves would require massive increases in long term care expenditure, which would place a substantial burden on the Medicare program.

In full transparency, there is a reality that must be acknowledged and examined with ACO programs that are focused on primary care without value-based care incentives to be shared downstream with specialists. Fifty years ago, it might have been somewhat reasonable to expect our primary care colleagues to help manage a large spectrum of conditions in each of their patients with appropriate knowledge of the evidence and guidelines. However, those days are long gone. At that time, most of the knowledge a specialist needed to provide high value care to their patients could be found in a textbook. In the modern age, it is impossible for any physician, primary care or specialist, to keep abreast of the ever changing and increasing body of knowledge related to the prevention, diagnosis, and treatment of any disease. The increase in the knowledge of human disease and treatments has been staggering and forces modern physicians to subspecialize.

At the same time, due to exponential growth in knowledge and evidence in many other organ systems, training on musculoskeletal care and other conditions treated primarily by specialists has been squeezed out of medical school curricula. As might be expected, this has created an environment where our primary care colleagues are unable to deliver basic musculoskeletal care efficiently. This is no fault of theirs but requires that CMS and other payers' approach musculoskeletal and other specialty care differently than primary care. This requires development of a condition-based payment mechanism to appropriately incentivize entities that can provide the full spectrum of evidence-based treatments. If the convener who chooses to engage in this program can measure their care in terms of patient reported measures of pain/function, appropriate condition-focused quality indicators, and avoid the traps of inappropriate over- or under-utilization of evidence-based specialty care paradigms, then the program would be open to a variety of practice settings and clinicians who are involved in the management of musculoskeletal disease. This could include teams of Orthopaedic Surgeons, Physiatrists, Rheumatologists, Physical Therapists, and others.

The financial risk and potential rewards of providing high value specialty care must be shared downstream with such teams to incentivize high value behavior. Conversely, if the entire bundle of risk and potential reward is siloed with the ACOs and primary care, then their only "lever" to reducing musculoskeletal health care costs will be to avoid referring patients to specialists, leading to inappropriate rationing, lost patient function/independence, high levels of dissatisfaction, and in some cases overutilization of inappropriate care, such as advanced diagnostic imaging for patients with osteoarthritis of the hip and knee. Without the knowledge and training needed to deliver the full spectrum of evidence-based care, our primary care colleagues will continue a cycle of non-value-added interventions, unnecessary advanced imaging, and CMS will lose the potential benefits of functional preservation and independence for our Medicare patients. Hence, this opportunity to appropriately create shared risk models or sub capitation relationships between ACOs and musculoskeletal specialty teams must not be missed.

3. How can CMS ensure patient choice and rights will not be compromised as they transition between health care settings and providers?

Until now, CMS has successfully driven essential care delivery changes to transform how patients transition between hospitals and post-acute care providers. The goal of the next model proposed by CMS should be to build on these care improvements to strengthen communication, collaboration, and coordination across providers at all points of a patient's journey through the health care system. The most important aspect of this model should be to keep the patient's experience at the center. It will be critically important to provide patients with easy-to-understand information to educate them on the care pathway and with health care choices within their networks. In previous health care delivery interactions that included capitation, patients believed that providers were withholding care to save or generate money. In today's environment of easily dispersed misinformation on the internet, any confusion or lack of clarity in patient choice would easily produce an unnecessary backlash. Patient-centered care with shared decision making at its core is critical to the success of any future model.

We need to empower patients to make informed decisions that are concordant with their preferences and values. To achieve this goal, there must be clear information shared by all clinicians along the patient's healthcare journey. There also needs to be adequate transparency to ensure that patients know that they have access to other physicians and specialists within their network. Communication is key to facilitating these healthcare transitions. We need to maintain continuity of care while respecting the patient's wishes throughout the process and clearly identifying treatment options. Patient empowerment will also necessitate that they know they can clearly state their preferences and goals and that there is a clear avenue to express their concerns if they feel that they are not being heard. Patient, physician, and network education is the main stay of continuity of care. Maintaining clear communication and transparency throughout the process will not only empower patients but will build trust with all stakeholders significantly increasing the likelihood of this model succeeding and ensuring optimum health care outcomes at individual patient and population levels.

4. How can CMS promote person-centered care in episodes, which includes mental health, behavioral health, and non-medical social determinants of health?

CMS can promote patient centered care in the musculoskeletal space by supporting payment for care navigators (including nurse navigators) with training on resources available in diverse communities. Cultural competence is key to engaging patients and their families in shared decision making. CMS can support this ideal with funding to incentivize recruiting and training of diverse applicants in this space.[1]

Toward this end, it is essential that episode lengths are long enough to capture the full breadth of work that is required to optimize a patient's surgical and nonsurgical care. We respectfully request that CMS not reduce APM episodes to 30 days. Such truncated episode lengths eliminate the ability to optimize care and achieve positive clinical outcomes.

[1] https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559#tab-contributors

5. For population-based entities currently engaging specialists in episodic care management, what are the key factors driving improvements in cost, quality, and outcomes?

Population health entities are aimed at improving the overall health of a specific population while reducing healthcare costs. This focuses on preventive measures, early intervention and promoting healthier lifestyles. Addressing the health care needs of a community can lead to long term savings by reducing high-cost medical treatments, hospitalizations, and emergency room visits. Collaboration between primary care providers and specialists within population-based health entities is essential for delivering targeted care, early intervention and preventive measures that ensure optimal outcomes while controlling costs.

Key factors that drive improvements in cost, quality and outcomes are communication, collaboration, and the use of high-quality data to inform clinical decision making. Successful population health organizations maintain services to patients aimed at providing as much on site and well-rounded care as possible. This may cost more upfront for organizations but eventually help to avoid costly acute and post-acute care. Such interventions will inevitably result in more value-based revenue and more importantly, better outcomes and happier patients. By utilizing high quality data and metrics, primary care practitioners and their teams can adopt referral patterns that correspond to population health and value-based care goals. They will be able to identify and work with high quality, high performing specialists. This will decrease stress and time for referral appointments for the primary care while enhancing the patient's experience and trust in the population-based organization.

Engaging specialists in episodic care management also reduces the stress and strain on primary care. No single physician can know and understand best practices for the management of every disease. By engaging specialists who are familiar with best practices for any given disease process, time and costly interventions can often be avoided. To share an example, it is quite common for a patient to have waited a lengthy period to be seen in an orthopaedic practice. They usually present in pain and frustrated with an MRI that is positive for meniscal tearing amid extensive osteoarthritis and their expectation is that arthroscopic surgery will heal their meniscal tear. In such a scenario, by engaging orthopaedic surgeons and other musculoskeletal specialists earlier in the process the patient would be more satisfied that their needs and fears were being addressed, the unnecessary MRI would be avoided, the patient would be reassured that arthroscopy is not indicated for meniscal tears in the setting of osteoarthritis and that by undergoing physical therapy and other non-operative measures they could potentially postpone or obviate the need for total knee arthroplasty. Thus, saving the system money and further enhancing the patient's experience with improved health outcomes.

6. How does the nature of the relationship (that is, employment, affiliation, etc.) between a population-based entity and a specialist influence integration?

Systems implementing population health care models will differ greatly based on the level of integration between the larger entity and smaller specialist groups. It is easier to align all parties in a relationship where the physicians and health care practitioners are in the same health system as an

employee or affiliate. This integration will be more challenging in decentralized areas (often rural) where there are more independent practices. CMS should keep this in mind and offer support to smaller practices and health care systems that want to develop and implement population-based health care models.[2]

Constraining relationships (e.g. narrow networks, monopoly/monopsony, consolidation) may be driven by profit rather than quality. Instead, setting value expectations open to "any willing provider" will deter the efforts to increase profit through marketing or steerage. All relationship types – including private practice – should have access to value-based patients. This may require more effort toward smaller entities, but the return on that investment is the limiting of runaway monopoly.

7. What should CMS consider in the design of this model to effectively incorporate health information technology (health IT) standards and functionality, including interoperability, to support the aims of the model?

Health IT should be agnostic. The differences between health IT systems should be on the user-sided front end, not the data-driven back end. As rural practices represent 20% of patients in the United States, they will need additional support due to poor IT infrastructure and resources. A minimum dataset should be developed which should be required as a component of health IT. The AAOS family of clinical registries is a good example of this.

Ideally, there would be clear diagnostic standards including ICD-10 and DRG definitions for when patients are or aren't included in the bundle. There should be simple and clear reporting standards to CMS, and the data reported should be easily accessible and transparent. Participating providers should be able to view not only their own data but compare their performance to other providers who can be used for benchmarking. Ideally, providers would be able to browse through deidentified data to look for patterns in the top performers that they could consider adopting in their practice.

8. We anticipate this next episode-based payment model would test a set of clinical episodes that is broader than CJR, but narrower than BPCI Advanced, with shorter episode lengths. We request feedback on the following clinical episode questions. 9. Which of the clinical episode categories, tested in either BPCI Advanced or CJR, should be considered for, or excluded, from, this next episode based payment model?

It is our belief that the goal of the next generation of APMs should be focused on broadening episode payments to clinical conditions. Therefore, we would not recommend narrowing the offerings based on BPCI-A or CJR episodes. Instead, we suggest that CMMI build on the broad model from BPCI-A that includes trauma and infection, upper and lower extremity total joints, and spine episodes. As the increase in outpatient episodes continues to trend upward, we recommend that CMMI increase the options for outpatient episodes for joints and non-fusion spine procedures.

[2] https://www.healthcatalyst.com/learn/white-papers/successful-population-health-entities-working-together

11. How many clinical episode categories or service line groupings should be tested?

CMS should indeed test new clinical episode categories. These categories should ideally represent conditions with high disease burden and those associated with high costs when considering corresponding procedural care. As aforementioned, traditional episodes in BPCI and CJR have focused on surgical episodes. However, many patients with musculoskeletal conditions are managed nonoperatively, and thus, additional episodes should reflect this. Therefore, our recommendation is to include, at the minimum, clinical episodes around knee osteoarthritis, hip osteoarthritis, and degenerative disc disease of the lumbar spine. Additional considerations could be made for meniscus tears as well as lumbago/low back pain.

12. Should CMS consider alternatives to a 30-day episode length? If so, include evidence to support this marker as the most appropriate transition point from the hospital to the primary care provider.

CMS should consider longer periods (>30 days) for episode length. Ideally, this would consist of a 6-month episode for the nonoperative treatment of these conditions. Evidence in support for this extension can be found at: http://www.aahks.org/wp-content/uploads/2020/02/OA-Condition-Based-Bundled-Payments.pdf.

Unlike surgical episodes, condition-based bundles must be long enough in time/scope to allow for adequate nonoperative treatment. This treatment should focus on not only exercise therapy but also on multidisciplinary care of the patient, including but not limited to assistance with nutrition/lifestyle management, pain coping, and concomitant mental health conditions.

13. Which clinical episodes are most appropriate for collaboration between episode-based model participants and ACOs?

Clinical episodes that are appropriate for this model include conditions, procedures or surgical interventions that require coordinated care over a specified period of time. The aim is for clinicians to collaborate on behalf of the patient to streamline the process, increase efficiencies throughout the system, thereby being cost effective and most importantly, improve patient outcomes and satisfaction. Obvious examples include certain surgical procedures such total joint replacement, spine surgery, cardiac surgery, and cholecystectomy. Each of these episodes require clear communication and collaboration between multiple health care providers within the system for preoperative assessment, para-operative care and treatment, and post-operative follow up and therapies to ensure the best possible outcomes while decreasing risks and complications. Less obvious examples would be the management of chronic disease states like osteoarthritis, low back pain, diabetes, COPD and hypertension that require long term care.

By employing collaboration between an episode based model and ACO, care teams can exchange high quality data and metrics between specialists teams and primary care teams within the organization to

ensure that patients receive continuity of care, that critical follow up is maintained, that long term medication use is managed appropriately, and that health, wellness, and lifestyle changes are made to further ensure optimal outcomes while decreasing the risks of expensive emergency room visits and hospitalizations. Obstetrical care is also quite conducive to this type of episode-based collaboration. This would include prenatal care, labor and delivery and postpartum care that would then seamlessly transition to preventive maternal and pediatric care that works very well within population health and ensuring the best possible outcomes under the value-based payment model.

The reality is that any and every chronic health care condition can be managed under this collaborative model including cancer treatment and mental health. The full spectrum of care—from wellness and preventive care to focusing on the non-medical determinants of health that impact outcomes—can be considered episodes of health care within this model.

14. Are there particular types of items or services that should be excluded from clinical episodes?

Every aspect of health care delivery, in theory, can be broken down into an episode-based care model. In a perfect world, each of these episodes would be able to be paid for within the system. The episode-based model would ostensibly deliver the best possible outcomes at the lowest possible cost for the population cohort that is being treated. Services that may be excluded would be primarily cosmetic and deemed not medically necessary after thorough review. Other services that could be excluded include treatments that are experimental, unproven, or not appropriately vetted within the medical community. Although many of these treatments may prove effective in the future, they should be excluded from current episode-based care until they have been effectively studied.

When discussing specific episodes, treatments that are outside of the defined episode's scope of care should be excluded from that clinical episode. This highlights the importance of defining each episode, communicating each episode clearly between care providers within the episode and collaborating efficiently. There will necessarily be a great deal of overlap in clinical episodes. If the responsibilities for each episode are not clearly defined, then there may be components of treatment that may not be addressed appropriately because it is not viewed as part of any given provider's care episode. This could easily lead to loss of coverage for necessary tests or treatments and patients being either denied treatment or surprised by unexpected, costly bills.

In earlier iterations of bundled or episodic care, components such as routine preventive care, long term maintenance medications and non-medical support services would have been excluded from considerations from the episode or "bundle." With the emergence of importance of population health and social determinants of health, these aspects have proven crucial to patient satisfaction, better health outcomes and lower systemic costs. Each of these components are, by necessity, episodes of care in and of themselves. It is essential to ensure that each clinician involved in the episode of care remains aligned with the intended outcomes for the patient, the population, the community, and the health of the health care system itself.

15. Aside from the episode selection, reducing the duration of an episode of care, and the types of services in an episode, what other ways can CMS prevent unnecessary overlap with ACO functions?

The methods listed in this question and discussed in the above responses are the most appropriate ways to prevent unnecessary ACO function overlap. Episode lengths greater than 30 days, ensuring inpatient and outpatient episodes for a large swath of clinical episodes and procedures are available, and ensuring that all necessary services are included in a given episode to facilitate appropriate use and reduce the patient time and clinician's administrative burden generated by unnecessary overlap.

16. For which clinical episodes are ACOs better positioned than episode-based payment model participants to efficiently manage care?

Those treatments which have been thoroughly studied and do not rely as much on clinical judgment or experience or preference are best managed by ACOs. One example is hip fractures. The more elective the clinical episode, the less likely ACOs can effectively manage. For those elective episodes, an ACO might be tempted to withhold care or severely cherry-pick patients.

17. *Given that some entities may be better positioned to assume financial risk, what considerations should CMS take into account about different types of potential participants, such as hospitals and PGPs?*

CMS should consider the size of the practice or facility (number of beds), location (rural versus urban as well as service area), affiliation with a larger institution (specifically, research institutions are a key source of support for new initiatives), and financial reserves. Patient payer source should also be included. AAOS recommends that CMS ensure surgeons and physician groups have the ability to be in charge of the bundle, or explicitly create a mechanism allowing the surgeon or group to participate with a facility or third party to manage the episode, collect payments, recoup overpayments, and return "shared savings" across the spectrum of care.

We also recommend that new models should begin with no risk and allow progression to risk-bearing as experience is accumulated. Special emphasis must be given to rural locales where large geographic areas must be covered to gain efficiency. This will require more effective use of telemedicine from physician-to-physician, and especially not telemedicine from physician to patient. Risk-bearing is challenging in a sparsely populated area as there is no option to distribute care elsewhere.

18. Should CMS consider flexibilities for PGPs to participate, such as a delayed start or a glide path to full financial risk?

See above. CMS cannot expect entities to assume risk-bearing at the entry point. That would encourage speculative third parties who are not invested long-term or significant consolidation. There must be a progression from no-risk to risk.

19. How can CMS ensure PGPs will remain engaged and accountable for their contributions to managing the episode of care?

Episodes of care require investments of both financial resources and time, as well as an ongoing commitment to quality care. This invariably means an investment in technology and staff to coordinate care. It is important that the burden of reporting does not outweigh the potential cost savings and that quality care is maintained. To remain engaged, PGP's need continued support, such as access to patient-reported outcomes measures (PROMs), and payment arrangements that ensure quality episodes of care can be done with minimal administrative burden. It is important that access to care not be negatively impacted, and that practices are supported in documentation and reporting of quality metrics.

20. What concerns are there with conveners not being formal participants in this model since CMS cannot require entities that do not participate in the Medicare program?

Formal participants may be more likely to adhere to quality standards and evidence-based practices for any given health care episode. Active participation in the model ensures that each health care provider is maintaining specific goals and outcomes that have been clearly defined. The goal of the episode-based care model is to enhance coordination and collaboration on the patient's behalf throughout the entire episode. If a convener is not a formal participant there is the possibility that this may be disrupted, leading to care that is more fragmented and could affect outcomes and patient satisfaction. A critical component of effective and successful episode-based health care delivery is communication, especially of sharing high quality patient data.

If conveners are not formally aligned with the model this may hinder fast access to important data not only for immediate patient care but also to be able to assess effectiveness of treatments and therapies. If conveners are not formally part of the program and not required to undergo the same oversight, there may be concerns of transparency that would affect either the perceived utility of the model or of the reported outcomes. There would also be an issue of conflict of interest for conveners who are dependent on fee-for-service. Conveners bring flexibility in health care access for every episode. It will be important to maintain oversight of standardized health care delivery to optimize outcomes and transparency to ensure success on all levels.

21. How should incentives be structured to promote shared accountability and ensure program integrity?

To encourage participation and shared accountability there needs to be both support for the resources required for successful implementation as well as the ability to have flexibility and independence when delivering care. A key component of this is ease of transmitting metrics to minimize administrative burdens. There needs to be both a financial reward, as well as clear, transparent, and reasonable penalty for metrics not met. The tools to measure outcome can be costly to implement, so support both in technical and financial support would be needed to encourage participation. The

startup cost of implementation may be too high of a burden for many healthcare providers and systems, so providing incentives up front with the financial support to implement change would likely be important to increase participation.

Shared accountability could come in the form of meeting certain quality metrics which were mutually decided in advance. Clinics and healthcare systems could submit proposals for funding projects or choose from a list of supported designed programs. There should be ease of communicating the outcome being measured to decrease administrative burden while ensuring metrics are being met, or trending towards the goal. There could be clearly defined goals that have a transparent and reasonable penalty if not met. The penalty could be repayment of the initial investment versus percent decrease in reimbursement.

22. What risk adjustments should be made to financial benchmarks to account for higher costs of traditionally underserved populations and safety net hospitals?

CMS should create a risk adjustment factor that considers the higher acuity of patients served at safety net hospitals and other facilities who support patients with high social and medical complexity. These factors include the prevalence of traditional comorbid conditions: cardiovascular disease, obesity, diabetes, and tobacco use. Additionally, non-medical determinants of health should also be considered with a focus on access to care. For example, consideration that a population has limited access to primary care practitioners and grocery stores (which are associated with poorer health). Risk adjustments must be made locally based on the health of the region or area. If these things are not done, no one will participate in the very areas where it is needed most. Patient self-reported health measurements must also be considered as part of risk adjustment.

23. Should episode-based payment models employ special adjustments or flexibilities for disproportionate share hospitals, providers servicing a greater proportion of dually eligible beneficiaries, and/or providers in regions identified with a high ADI, SVI, or SDI?

Yes. It is crucial that the adjustments be made to encourage the adoption of episode-based models.

24. What metrics should be used or monitored to adjust payment to assure health disparities are not worsened as an unintended consequence?

CMS should consider the demographics of the patients served when adjusting for and monitoring health disparities. Causes of racial health disparities are multifactorial and outcomes data (readmission rates and infection rates) should be included with patient factors including race, sex, Charlson comorbidity index, and zip code. Specifically, zip code tracking will offer additional information on non-medical determinants of health information and context.[3] Other social determinants of health such

[3] JBJS Open Access d 2021:e21.00004. http://dx.doi.org/10.2106/JBJS.OA.21.00004

as the ability to travel independently as well as access to internet and health technology have a significant impact on the success of treatment.

25. What data or metrics or both should we share with participants to ensure they are addressing gaps in clinical outcomes and access to appropriate procedural care and with what frequency?

The most important metric to ensure patient centered care values are being maintained is patient reported outcome measures as well as patient satisfaction surveys. This will give the most immediate and relevant information as to whether treatment, therapy, or procedures are having positive impacts and addressing clinical gaps. This is an area where we, as physicians, can also bring our influence to help to stem the opioid crisis. In the past, patient satisfaction measures such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) were used. The earlier surveys were weighted heavily to pain management from each member of the health care team. Our goal is always to decrease a patient's pain level, but we need to be cognizant of the outcomes measures and patient satisfaction measures that we use so that physicians do not feel that they are being evaluated solely on a patient's level of pain. It is also incumbent upon us to help to educate the patient so that they understand that health care providers are working very hard to control their pain, but that opioid addiction is a serious risk and concern. These measures will help to increase patient and caregiver satisfaction immeasurably.

Using outcome measures such as mortality rates, infection rates, readmission rates and other complication rates are also important to follow. If one of these measures were to increase over a short period of time for any institution, it would be extremely important to realize this as soon as possible and for all involved to take positive corrective action immediately. These are critically important for physicians, departments, hospitals, and healthcare systems for not only corrective but educational purposes. It would not be beneficial for this to be used for punitive measures in a payment model. If we are seeking to include all hospitals and asking smaller or rural hospitals to adapt to a new payment model we have to use reasonable incentives. If we are asking to decrease hospital stays for total joint arthroplasties and other procedures, smaller community hospitals may have initial upticks in readmissions or return to the emergency room which should be accounted for.

Measuring access to care is important to share among all participants. Many hospitals will be surprised to learn how difficult it is for patients to gain access to their health care providers. When measuring access, it will be important to ascertain whether we are measuring access to insurance, access to primary care, or access to specialty care. Some metrics may be patient wait times, and how often are the patients using the Emergency Room for issues that should be taken care of in a primary care clinic. By measuring access, we should also be able to address health care gaps and inequities as well. Rural settings are not the only areas where health care deserts exist. These areas are just as apparent and consequential in urban settings. Health outcomes should not be determined by a person's zip code. Furthermore, measuring the use and effectiveness of telehealth will also be an important aspect of increasing access to care and this should be shared as well.

It will be critically important to share quality improvement data. Even with the advent of the EMR, healthcare systems have not achieved success at sharing data. As much data as we can share, the quicker we can all learn and spread quality improvement initiatives that may be working incredibly well for certain institutions but not be well known across a broader spectrum. Sharing and communicating successful quality improvement initiatives is imperative.

The question of frequency can also be intimidating to prospective participants, especially for smaller hospitals, practices, or healthcare systems. We want to collect date that is relevant to patient outcomes in a timely fashion without increasing expense or work exorbitantly. Once instituted, collecting and sharing PROMs could be done on a semiannual basis. All measures should be shared on a minimum of a yearly basis.

26. What data or metrics or both should we share publicly to help inform beneficiaries of provider performance?

Number and general type cases performed along with readmission and infections rate should be shared publicly. This data should not be shared in isolation. For example, CMS should share the total number of knee arthroplasty cases with a surgical complexity score and patient complexity score. The surgical complexity score would look at the number of primary joints versus revision/conversion arthroplasties. The patient complexity score (or a surrogate like the Charlson comorbidity index) would account for the medical comorbidities of the patient population.

27. What provider-level initiatives or interventions, such as shared decision-making, could be considered to ensure equitable access to procedures and treatments for beneficiaries?

Shared decision-making is often a patient-level initiative with the primary goal of informing the patient of the potential risk and benefits of a procedure while taking their own preferences and values into account. These tools have the added benefit of being able to be set at the appropriate levels of reading and health literacy. Having goals at the physician level for providing such tools and documenting their use prior to major procedures can help to “level the playing field” for patients. At the physician-level, it is helpful to see abstracted reports on surgical rates and outcomes by region, so that one may compare their practices to peers and give appropriate data for use in quality improvement efforts.

28. What PRO measures should CMS consider including in this next episode based payment model?

AAOS has published a list of suggested PROMs for orthopaedic subspecialties. For knee conditions (Anterior Cruciate Ligament/Osteoarthritis) we recommend the International Knee Documentation Committee (IKDC) Subjective Keen Form (Pedi-IKDC), the MARX Activity Rating Scale, the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the Knee Injury and Osteoarthritis Outcome Score Jr (KOOS-Jr). For hip arthritis we recommend the Hip Disability and Osteoarthritis Outcomes Survey (HOOS) and the Hip Disability and Osteoarthritis Outcomes Survey Jr (HOOS Jr). For spine

conditions we recommend the Neck Disability Index (NDI) and for shoulder and shoulder instability we recommend the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), the Oxford Shoulder Score (OSS), and the Western Ontario Shoulder Instability Index (WOSI).

For additional PROMs and further recommendations from AAOS, please visit https://www.aaos.org/quality/research-resources/patient-reported-outcome-measures/performance-measures-by-orthopaedic-subspecialty/.

29. How can registries, electronic health records, and other quality reporting systems reduce reporting burden for participants?

AAOS is a strong proponent for the use of Qualified Clinical Data Registries (QCDRs) to collect and analyze a multitude of quality reporting measures. Specifically, we know the power of using patient-reported outcome measures (PROMs) to assess health outcomes and identify new opportunities for innovation. It is important to incentivize the creation and ease of managing of QCDRs as the U.S. population ages and the health care sector moves to more value-based investments. QCDRs help with improving population health outcomes, effectiveness of care pathways and surveillance of drugs and devices. To create a sustainable future for the Medicare program, policy makers must focus on ease of access and interoperability of Medicare data to aid in decision making and quality improvement. By incentivizing and streamlining the use of interoperable data collection and dissemination methods, any future model participants and patients will benefit from more time focused on patient care.

It is vital that there is alignment in reporting between registries and quality reporting systems in the future. The goal is to allow a high capture rate for patient outcomes without overburdening physicians and practices. For example, within each patient, standardized reporting with set PROMs and time points allows communication between quality reporting systems and registries. Within each electronic health record system there needs to be an ease to query and transfer data directly into registries and quality reporting systems without much overhead burden of the practice.

30. What approaches are providers currently utilizing that would create opportunities for payer alignment?

Many physicians and payers are currently using strategies to better align incentives with improving health outcomes and reducing the cost of health care. These include using bundled payments which cover a single episode of care, such as with total joint arthroplasty. A single payment covers multiple services related to the same episode of care. This method necessitates collaboration, cooperation, and communication to optimize outcomes while controlling costs.

In attempts to align physicians and hospitals that currently rely on fee-for-service for economic survival, shared savings models have been developed. This allows physicians and hospitals to share in cost savings that are achieved through increased use of quality metrics resulting in fewer higher cost

events like hospital readmission, use of ambulance for emergency room visits, and post operative risks including infection, wound issues, deep vein thromboses and pulmonary emboli. These savings can be shared at a decreased financial risk to participating physicians and hospitals.

Even if participants continue to operate in a fee-for-service structure, they are still capable of participating in value-based contracting in addition to their current fee-for-service contracts. These contracts include value-based incentives that encourage care coordination and use of evidence-based treatment protocols designed to optimize outcomes while being more cost effective. Value based contracting will allow physicians to become familiar with the model and its goals. The advent of ACOs is a significant development of approaches physicians are currently utilizing to align with payers. ACOs can help to develop alternative payment models which can blend fee-for-service with value-based payment models that provide opportunities for physicians to share savings while lessening financial risk, with the goal of delivering high value health care and improved health outcomes from which data can be obtained and shared. ACO care teams include health care navigators, social workers, and nurse practitioners in fee-for-service models because they address the complexities of the non-medical determinants of health. They help to ensure that patients can make appointments, that they are taking their prescribed medications, that they can afford those medications, and that they are following up with referrals. All of this enhances the probability of the patient achieving the best possible outcome with greatly decreased stress to an already overstressed clinic or health care system. This approach also incorporates wellness and preventive medicine which decreases costs and increases efficiency of the system. Use of telehealth and home monitoring also play very important roles in achieving the best possible outcomes at lower costs whether in a fee for service structure or value-based model.

Value based models inherently align the interests of both providers and payers to provide high-quality, cost-effective healthcare. This is none more apparent than in the early adoption of value-based programs such as CJR and BPCI, which saved over 61 million dollars within the first three years of CJR initiation alone. At the heart of defining value is tracking patient performance and outcomes with PROMs which many orthopaedic surgeons and groups are already actively collecting as well as various registry participation such as the American Joint Replacement Registry, AAOS Shoulder and Elbow Registry, and others. Much of PROMs collection has been focused on patient factors that put them at risk for poor outcome or complication following orthopaedic surgery, which provide a unique environment for partnership between provider and payer in the form of preoperative optimization as well as make a better effort at risk adjustment that will allow at-risk patients continued access to healthcare without penalizing providers.

32. How should risk adjustment be factored into payment for episode-based payment models?

Clinicians who care for more medically complex patients should receive adjustment (either point or factor based) to account for increased risk of poor health outcomes in this more challenging patient group.

33. How can risk adjustment be designed to guard against preferential selection of healthier patients (that is, cherry picking)?

Risk adjustment needs to account for both medical comorbidity and surgical complexity, rather than just utilizing general comorbidity indices. This can be accomplished through appropriate separation of diagnoses (i.e. hip osteoarthritis vs. Osteonecrosis in THA, stable vs. unstable femoral neck fractures, rheumatoid arthritis vs. osteoarthritis for TKA patients), socioeconomic status, preoperative narcotic use, prior surgery to the same extremity, etc. The goal should be to reach the level of appropriate risk adjustment to remove the disincentive to care for complex patients. It will be worth the extra effort and "risk" because the reimbursement for that diagnostic or surgical category accounts for it. Surgical quality should also be measured with more appropriate risk adjustment in order to allow surgeons to apply their skills to broader populations who need their care. Finally, it should reflect the inability of rural and more severely ill patients to travel a certain distance. In other words, a risk-based entity separated from tertiary care should garner preferential risk adjustment (since they must treat the sickest patients, with decreased transfer ability). Registry data must capture enough patient information to demonstrate the true health status of patients, such as using Hierarchical Condition Categories (HCC).

37. How can CMS leverage this episode-based payment model to incentivize participants to join an ACO if not already a part of one?

CMS can offer higher reimbursement rates to physicians who join ACOs and participate in episode-based care. It may be difficult initially for CMS to justify paying higher rates for a program that is aimed at containing costs, but if they are successful in recruiting significant numbers of physicians then the cost savings in having those physicians practicing episode-based care within a value-based payment program will far outweigh those upfront costs. CMS could also help in transitioning physicians from their current practice to an ACO to decrease financial risk and decrease physician fear and anxiety of not being supported. Again, using a carrot over the stick, shared savings programs afford physicians who join an ACO the opportunity to share the financial benefits of improved outcomes while striving for cost reductions and efficient health care delivery. Additionally, allowing physicians who join ACOs the autonomy to create and control avenues within their episode-based model will be a significant incentive to participate. CMS and ACOs need to educate physicians that joining will enhance their influence within the episode and not detract from it. They need to market themselves in a positive light and demystify notions that ACOs and episode-based care are not cookie cutter programs that pigeonhole physicians. Their industry, passion, and creativity are needed and desired now more than ever. ACOs can help physicians obtain and process data quickly and allow physicians to access that data in real-time to fine tune therapies and treatments to further enhance positive outcomes and patient satisfaction.

38. How can CMS design this model to spur ACOs to engage specialty care providers for episodes of care that may not be included in this model?

ACOs should be proactively looking to involve all care providers and not just primary care providers or certain specialists. To ensure that episode-based care and value-based payment models succeed in full, all providers will need to be involved eventually. Even while working within the currently limited number of care episodes, specialists need to be incorporated to finalize treatment pathways that require their expertise and allow the best possible outcomes for the patients. ACOs need to not only be proactive with specialist involvement but also be flexible and creative in how to incorporate specialists into the episode. This is particularly true if that episode is being reimbursed in a bundle type payment structure.

To this end, ACOs in conjunction with the specialist's input, could create smaller, more distinct episodes within the larger episode specifically tailored for specialist involvement. ACOs should create a network of specialists that they work with as stakeholders sharing risks and benefits while maintaining the goal of optimizing outcomes while holding costs. It will be incumbent upon CMS to provide ACOs with technical support and education on best practices that involve specialists which the ACO may not be familiar with. This support would include how to align incentives of ACOs and participating specialists in a collaborative manner and not as a "necessary evil."

Thank you for your time and attention to the feedback of the American Association of Orthopaedic Surgeons (AAOS) on the important proposals made in the Request for Information; Episode-Based Payment Model. We respectfully request that CMS avert any plans to implement a mandatory model. Such an action would be in the disinterest of collaborative, patient-centered care. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,

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