

August 15th, 2018

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AAHKS RESPONSE TO HEALTH CARE INNOVATION CAUCUS RFI

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to respond to the Health Care Innovation Caucus request for information regarding value-based provider payment reform, value-based arrangements and technology and health IT.

AAHKS is the foremost national specialty organization of more than 3,400 physicians with expertise in total joint arthroplasty (TJA) procedures. Many of our members conduct research in this area and are experts in using evidence-based medicine to better define the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS appreciates its ongoing close collaboration with the Administration and Congress to advance payment reform to best serve beneficiary access and outcomes.

AAHKS members have been the tip of the spear for value-based care. We have been involved in the development, testing and refinement of two CMMI APMs and are developing our own APM for total hip and knee replacement. We hope our experience working on innovative models of care will provide perspective to the Caucus as you consider policy options for future health reform.

VALUE-BASED PROVIDER PAYMENT REFORM

- **Please describe any value-based payment models that you participate in by payer – Medicare, Medicaid, employer coverage?**

Bundled Payments for Care Improvement (BPCI) – BPCI is a voluntary bundled payment model that links physician, hospital and post-acute care reimbursement to cost and quality. There are 3 reimbursement models within BPCI covering 48 specified clinical episodes (models 2-4, ending in September 2018) and one model covering all DRGs (model 1, which concluded in 2016). “Major joint replacement of the lower extremity” is one of the specified clinical episodes for BPCI, in which many of our members are

participants in BPCI Model 2. In BPCI model 2 is a retrospective bundled payment that covers the 90 day episode of care from inpatient procedure to post-operative recovery. The total cost of the episode of care is reconciled against a target price, and the awardee/convener either shares in the savings or CMS recoups the excess cost. BPCI offers flexibility in the awardee/convener who manages the episode of care and bears financial risk, allowing physician groups to manage the episode of care.

The next version of BPCI, BPCI Advanced (BPCI-A), has been announced for October 2018. It is a single voluntary model with one risk track for a 90 day clinical episode. It is most similar to the BPCI Model-2 track. There are 29 inpatient bundles that cover 105 different DRGs, and 3 outpatient bundles attached to 30 HCPCS codes. The bundle will include hip and knee replacement and AAHKS anticipates many of its members will participate.

Comprehensive Care for Joint Replacement (CJR) – CJR is the first mandatory bundled payment model implemented by CMMI that counts as an Advanced APM under the Quality Payment Program. There are 34 Metropolitan Statistical Areas (MSAs) that are required to participate in the model, with 33 additional MSAs which can voluntarily participate. Rural and low-volume hospitals are exempted from mandatory participation. CJR is also a retrospective bundle with price targets that are initially based on a hospital's historic costs, and then shifts to regionalized price targets. One of the fundamental differences between CJR and BPCI is that awardees/conveners are limited to just the hospital; physicians cannot be the risk-bearing entity responsible for coordinating care during the 90 day episode of care.

- **Which have been most successful at reducing costs and improving quality and access?**

The data from BPCI has shown significant savings for lower extremity joint replacement (LEJR); particularly for physician-led episodes of care. In an analysis of the largest physician group practice participating in BPCI, Medicare realized a savings of \$3,214 per episode of care¹; a 15% reduction.

The results from physician-led bundles are nearly three times better than those realized in hospital-led bundles. In an analysis by the Lewin Group², evaluating exclusively hospital-led bundles, data shows that Medicare saved \$1,105 per episode of care for LEJR in BPCI Model 2. While both physician-led and hospital-led bundles realized cost savings under BPCI, the physician led bundles fared better.

The entire TJA patient population benefits in improved outcomes and cost effectiveness when the discipline to successfully adopt a value-based care (VBC) initiative is introduced by a health care system. Cost ends up being the best quality metric. Poorly performing sites cost more than well performing sites. The other quality metrics such as poor outcomes on PROM's, readmissions, and other proxies are translated to increased cost by poorly performing institutions. The best run VBC initiatives are physician led. Hospitals are not very good at managing these episodes without physician buy in and Technology can replace many of the FTE's needed in an institution without the resources to hire and maintain a larger complement.

¹ <https://catalyst.nejm.org/physician-group-practices-succeeding-bpci-bundled-payments/>

² <https://downloads.cms.gov/files/cmmi/bpci-models2-4yr3evalrpt.pdf>

One of the critical lessons learned is that there were significant savings in the post-acute period that would not alter quality. The variation started high and quickly became more standardized.

There is no one size fits all way to do VBC and it needs to be customized to the practice environment, however, following several basic tenets can be helpful. Care management/patient education, standardized opioid sparing pain management, perioperative patient selection and optimization, blood management, standardized protocols, alignment, gainsharing, and transparent real time quality and cost data are the main components of success. How we divide the proceeds in an ACO or population management environment is even more complicated and unresolved especially in the case of subspecialty care.

The bottom line is when surgeons are allowed to participate in and share cost savings they can improve outcomes and cost effectiveness and they are much more effective than hospital or payer driven initiatives. It's all about alignment and eliminating perverse incentives to create a successful VBC initiative.

- **What changes were made in practice management or care delivery as a result of these value based arrangements?**
- **What effect did you observe on patient outcomes?**

Below are a examples of practice management and care delivery changes and subsequent outcomes:

SCMCPs

Standardized care management and clinical pathways (SCMCP) serve as a framework for the total episode of care (EOC) for a patient from the time of diagnosis through the post-acute care period. With the help of a multidisciplinary team of nurse practitioners (NP), clinical care coordinators (CCC), physical therapists, nurses, care managers, social workers, and attending orthopaedic surgeons, SCMCPs can be developed to guide patients throughout their EOC.

Patient education is a major component of the SCMCP, and standardized patient classes were instituted with the goals of:

- 1) Guaranteeing that the patient education is consistent and without variability in message
- 2) Reduction of patient and family anxiety regarding processes, pain control, and post-operative care
- 3) Making clear that home discharge has no difference in outcome compared with skilled nursing facilities (SNFs) and/or rehabilitation hospitals
- 4) Creation of an expectation of home as the first-choice goal
- 5) Explanation of what human and physical resources might be needed for discharge to home
- 6) Allowing for an opportunity allay anxiety and discover possible barriers to a smooth discharge that might be better met with a delay of surgery

- 7) Fully explaining that there were resources 24/7 to reach for questions or concerns and that urgent office returns (shy of critical medical events) were preferable to ER visits
- 8) Introduction of the care navigators that would be available to assist in the process.

The implementation of SCMCPs improves communication between the patient, the care management team and the provider, ensured follow-up in the post-discharge period, and helped enhance patient outcomes, led to a more-ready acceptance of home discharge, earlier, safer and more smoothly in the hospital course, while reducing utilization of SNF and RHs.

The creation of standardized care management and clinical pathways (SCMCP) for each episode of care (EOC) has been shown to reduce length of stay (LOS) and costs without sacrificing complication rates, patient reported outcomes, or patient satisfaction.

Additionally, they can improve patient reported outcomes and decrease the utilization of costly post-acute care facilities by establishing appropriate expectations as well as engaging and educating patients and their families in the discharge process. Coordination of care has historically aligned value-based care goals, and has been shown to reduce LOS, readmission, and cost without sacrificing outcomes.

Increased oversight over implant costs and waste can lead to a substantial reduction in implant and hospital costs associated with historical spend for the EOC. Coordination among anesthesia, preadmission testing, and medical clearance teams can help reduce cancellations, eliminate unnecessary tests, and optimize patient safety while emphasizing cost-effectiveness. These improvements result in a reduced mean LOS, a decrease in discharge to inpatient facilities, and a decrease in costs to Medicare during reconciliation in 2016.

VTED risk stratification and blood management optimization:

Optimization of venous thromboembolic disease (VTED) prophylaxis is crucial to the success of VBC as pulmonary embolisms (PE) are one of the most common causes of 30-day readmissions. Finding the optimal balance of VTE and bleeding prevention can minimize the risk of costly complications such as wound hematomas, periprosthetic joint infections, and need for readmission/reoperation. Deciding on a suitable prophylactic therapy to achieve both efficacy and safety necessitates an individualized evaluation of the patient's risk profile.

In one example, an institution implemented a risk-stratification VTED prophylaxis protocol for patients undergoing TJA in an effort to reduce or maintain VTED rates, while minimizing the complications of aggressive prophylaxis. 2611 patients were separated into two cohorts. Cohort 1 received anticoagulation irrespective of their risk factor profile as per standard of care at that time (Warfarin, Enoxaparin, Rivaroxabin), and cohort 2 received anticoagulation based on their individualized VTED risk profile. The risk-stratified cohort had a lower incidence of VTED, decreased 30-day readmission rate, less adverse events, and lower rate

of infection when compared to the non-risk stratified cohort. These results, however, failed to reach statistical significance due to the underpowered size of the study. More importantly, within the risk-stratified cohort, standard-risk patients receiving ASA and PCD's had an 18.15% lower cost per EOC with no difference in VTED rate when compared to high-risk patients ($p < 0.001$).

In addition to VTED risk-stratification, the institution was able to safely reduce blood loss and postoperative transfusions with the implementation of a standardized tranexamic acid (TXA) protocol. TJA patients received 1 gram of intravenous TXA after anesthesia induction. THA patients then received 1 gram of TXA before wound closure, and TKA patients received 1 gram prior to tourniquet release. When compared to a cohort of patients that did not receive TXA, transfusion rate reductions of 10.8% and 12.4% were reported in THA and TKA patients, respectively. In line with our VBC goals, there was a \$3,083 and \$2,852 cost reduction for THA and TKA patients, respectively per hospital episode. The TXA cohort had a lower rate of VTED, and comparable rates of intra-/post-operative myocardial infarction and stroke.

By implementing VTED risk-stratification and TXA protocols, the institution has successfully delivered value without sacrificing safety, throughout the EOC.

Minimization of post-acute facility and resource utilization

A significant portion of costs (35%) for a single EOC is attributable to post-acute care (PAC) and discharge disposition.^{30,31} With wide variation among PAC practices and no significant difference in outcomes, a cost-conscious approach to this portion of an EOC can result in appreciable savings and value creation. In addition to higher costs, patients discharged to facilities are at an increased risk for complications, are less satisfied, and have higher reoperation and readmission rates when compared to patients discharged home. At an example institution, patients discharged to facilities have a 11.6% higher 90-readmission rate than those that are discharged home.

In an effort to capitalize on potential PAC savings, the institution began to limit the use of inpatient facilities. This led to an overall 40% average decrease in inpatient facility utilization and a savings of approximately \$4,777 per EOC. Additionally, extending hospital LOS up to 5.2 days longer than average still amounted to a lower cost than discharging the patient to a PAC facility.

To minimize the patient's stay and our resource utilization at a PAC facility, staff fostered relationships with facilities that meet quality and care criteria. This was achieved by implementing bi-directional electronic exchange of information, bi-weekly updates on high-risk patients, weekly calls with our interdisciplinary team, PAC report cards, and quarterly PAC committee meetings. By employing these strategies, we achieved an average LOS in our PAC facilities of 11 days compared to 20.75 days in other PAC facilities. Ultimately by

minimizing and standardizing patient's stay in inpatient discharge facilities and limiting their use, they have been able to meet our VBC goals

Multimodal pain management protocol

As the EOC increases to 90 days after discharge, surgeons are placing a greater emphasis on perioperative optimization, including pain management. Perioperative pain management and opioid burden affects LOS, is an independent risk factor for readmission when opioid abuse is present and is a major contributor to EOC costs. Traditional pain management protocols, including opioid patient-controlled analgesia (PCA), oral narcotics, and peripheral femoral nerve blocks (FNB), are effective at controlling pain but can prolong hospital LOS and delay return to function. Alternative protocols have been adopted with the hopes of preserving adequate pain control, minimizing narcotic use, reducing complications, and ultimately decreasing LOS.

In May 2014, an institution began an iterative modified pain management protocol that included the replacement of FNBs with intraoperative periarticular infiltration of liposomal bupivacaine (LB), the use of oral multimodal agents, the use of periarticular short acting injections and eventually the discouragement of PCAs. A retrospective analysis was then conducted two years later focusing on post-operative patient reported pain scores, narcotic use, and physical therapy (PT) milestones amongst the three cohorts (FNB, no LB, PCA; no FNB, LB, PCA; no FNB, LB, no PCA). Patients that received LB alone were more often discharged home ($p=0.010$), had a shorter LOS ($p<0.001$), incurred less hospital costs ($p=0.005$), consumed less narcotics, and had equivalent pain control ($p=0.214$).²⁴ To be successful in a VBC model, additional hospital costs need to be justified and changes in perioperative protocols need to be carefully employed. The evaluation of cost effectiveness for interventions in VBC needs to be evaluated over the entire episode, not just the hospital stay. Opioid sparse pain management protocols are now being trialed to improve these metrics even further.

- **What barriers in each of the following areas limit the full potential of innovation in Medicare and Medicaid?**

o **Payment and reimbursement**

One of the most significant challenges in payment and reimbursement reform is developing adequate risk adjustment methodologies within value-based models. Capturing medical complexity of the patient, or the medical complexity of a practice's patient population, and properly linking those characteristics to reimbursement is a key element of preserving access and defining what constitutes 'value'.

Without properly accounting for the clinical, cost, and quality variations among patients with different health and socioeconomic (SES) characteristics, it is impossible to accurately capture value for the system. Historically, AAHKS members have been assessed on readmission, re-operations, cost, and length-of-stay. Most importantly, whatever quality and cost assessments are used, they must be risk-adjusted or else the measures lose their

comparative value. Factors such as health status, stage of disease, genetic factors, local demographic and SES factors significantly impact the quality and outcomes of surgeries performed. These factors must be reflected in quality assessments to accommodate real variations in patient need and the costs of care.

Ultimately, bundled payment models can threaten patient access if they are not appropriately risk adjusted. The lack of risk adjustment/stratification in the CJR, for example, penalizes the hospitals and surgeons that treat the sickest patients. Furthermore, as CJR shifts towards regional benchmarking, TJA practices that care disproportionately for medically complex patients will be in direct competition with those that treat a healthier patient base. Without incorporating risk adjustment, the CJR will create a reimbursement environment that increasingly incentivizes cherry-picking and lemon-dropping. At minimum, it would seem consistent and appropriate to use the exclusion criteria and risk adjustments already being used in the CMS hospital-level, risk-standardized payment measure that is capturing 90-day total joint costs for all hospitals.

Congress and CMS should also ensure that appropriate risk adjustment is implemented into MIPS quality measures so that the shortcomings of some APMs are not promulgated throughout the QPP. The lack of appropriate risk adjustment means that providers may be measured on factors outside their control which leads to a disequitable distribution of resources away from the costlier and more complicated patients which frustrates some providers from serving Medicare beneficiaries.

Effective risk adjustment or stratification can significantly improve physicians' willingness to participate in Advanced APMs or other models on what they see as fair ground. The prospect of being held accountable for factors not within their direct control is among the most demoralizing aspects of other value-based payment models.

- **Policy and regulation**

Providing choice and physician leadership are important policy principles that should guide the implementation of current and future innovation. As CMS considers innovative new policies, they should work closely with the physician community to ensure that the regulations implementing those policies do not interfere with the clinical decision-making of what is best for the patient.

Choice between APMs:

The CJR model was the first mandatory model to come out of CMMI. This was, by itself, controversial. CMMI authority is designed to initially test and evaluate demonstration programs; not mandate untested large-scale payment reform. CMS did ultimately reduce the number of mandatory MSA's, but they fell short of making CJR a voluntary program like the successful BPCI model.

When BPCI-A was announced as the successor to the BPCI demonstration, CMS reasserted CJR's mandatory nature in a new and harmful way. Participants in BPCI, who were located in

a CJR MSA, would not have the option of continuing under the BPCI-A model that they had volunteered to pioneer. Instead, CMS asserted CJRs supremacy over BPCI-A. AAHKS objected to this decision to eliminate choice between different viable APMs.

AAHKS not only objects to CMS prescribing one APM over another, but as new models become available, Congress should ensure they are available to physicians and entities operating under existing APM agreements with CMS, such as CJR, BPCI, ACOs, or other models. Some CMMI demonstrations have accepted applications only once. Certain providers may find themselves currently bound in any one of a number of APMs. Therefore, new demonstration models should be accepted over a several-year period to ensure current participants may smoothly transfer from one model to another. Alternatively, CMS could allow transfer of providers between APMs in the midst of a performance agreement.

Choice in APM Leadership:

Future and current innovative payment models should ensure that physicians have the opportunity to lead as initiators and conveners. Episode payment models without physician leadership increase the risk of significant decisions being made based on factors other than patient care. As discussed previously, CJR does not provide an opportunity for physician leadership and it has been the experience of AAHKS members that not all facilities participating in the CJR have coordinated with surgeons on care planning and management or on gain sharing.

In order to ensure real provider choice, Advanced APM models must be presented that have the option of physician conveners, facility conveners, or other non-physician conveners. APMs should specifically continue the BPCI practice of allowing non-physician organizations to serve as conveners. This is necessary to allow for Advanced APM participation for groups or physicians who wish to direct the clinical coordination but that otherwise lack the size and economies of scale to bear risk or provide the necessary infrastructure.

Clinical Choice:

Recently CMS took total knee arthroplasty (TKA) off of Medicare's inpatient only (IPO) list. This policy change opens up the opportunity to perform TKAs in the outpatient setting. While this is an innovative change, the policy was not reconciled with Medicare's "two-midnight rule". Consequently, while outpatient TKAs are only appropriate for a small cohort of Medicare beneficiaries, many are being inappropriately forced into the outpatient setting. This is a dangerous erosion of the doctor-patient relationship, and shows that innovation

Inpatient procedures that are not on Medicare's IPO list are subject to the "two midnight rule", which requires a patient stay spanning two-midnights to qualify the patient for inpatient care. Historically, many Medicare TKAs performed in the inpatient setting involved a stay that was shorter than two-midnights. This was not an issue for TKA's while on the IPO list, but when CMS removed TKAs from the list they did not provide any regulatory accommodations for those patients who required inpatient care, but would be discharged in fewer than two midnights.

Although AAHKS has engaged with CMS to resolve this issue, our members continue to have their patients forced into the outpatient setting against their clinical judgement. A recent poll resulted in 60% of our members reporting that their hospitals were now forcing all TKAs to be performed in the outpatient setting.

- **Data and reporting**

CMS must achieve a careful balance in the need for quality measurement and the administrative burden of collecting and reporting too much quality information. The administrative burden of reporting requirements under Medicare, including quality measures, often overburdens physicians who are trying to focus on direct patient care. Recent calls from MedPAC and others to repeal the MIPS track of the Medicare Quality Payment Program have cited the excessive burden of reporting requirements, and the limited incentives to improve care.

AAHKS is encouraged by the Meaningful Measures initiative CMS announced on October 30, 2017. We agree that “Clinicians . . . have to report an array of measures to different payers . . . Moreover, it’s not clear whether all of these measures are actually improving patient care.” We understand this initiative will consist of a comprehensive review of quality measures to determine which ones may be related to improving patient care and outcomes.

AAHKS has specific recommendations for improving the value of reporting in the response to the next question.

- **How can we develop better outcomes measures that accurately reflect quality, safety and value without burdening innovation?**

AAHKS fully supports the role of quality measures in the context of value-based care. When shared savings are available, quality measures are necessary to safeguard against rationing of care and to properly reward those providers who excel at providing value. However, Congress should recognize three fundamental problems:

- (1) the overall shortage of outcome measures available compared to process measures,
- (2) the specific shortage in outcome measures related to surgical procedures, and
- (3) patient-reported outcome measures alone do not reliably assess the performance of the surgeon or the outcome of the total joint arthroplasty (TJA) procedure.

Furthermore, when there are specific measures, sometimes they are not measuring the correct thing. For example, the timeframes currently applied under functional status outcome measures for TJA procedures (post-operative timeframe for evaluation of 60 to 180 days) are insufficient to assess the clinical outcome of the procedures. The most clinically appropriate time frame for a post-operative functional assessment should be at least from 180 days to one year following surgery, as TJA patients do not reach 90 percent functionality until at least 180 days after surgery. Full functionality is most likely to occur at one year following surgery.

AAHKS believes that the development of more accurate and simplified outcome measures, can be achieved. One solution is including the effective use of endorsed registries such as the American Joint Replacement Registry (AJRR). We encourage Congress and CMS to leverage the expertise and effort it took to develop these registries to enable value-based care reporting.

- **What are examples of successful cross-sector collaboration that has achieved positive health outcomes, patient personalization, and lower costs?**

Patient selection and comorbidity optimization

In the VBC setting, the shift in financial responsibility has placed a higher emphasis on preventing hospital readmissions, because all costs incurred in the first 90 days postoperatively are accrued to the bundle. Numerous studies have identified preoperative comorbidities that contribute to suboptimal postoperative patient outcomes and increased hospital costs. Reportedly, 18.45% and 5.65% of payments for an EOC would be sacrificed to cover readmission in patients with extremely severe comorbidities and major comorbidities, respectively. Modifiable risk factors (MRF) that have been shown to influence readmission include hospital length of stay (LOS), body mass index (BMI), diabetes, cardiovascular diseases, venous thromboembolic disease (VTED), infection risk factors (Staphylococcus aureus colonization, human immune deficiency virus infection, Hepatitis C infection) tobacco use, substance abuse, psychiatric conditions, frailty and fall risk.

Several risk stratification instruments exist, such as the American Society of Anesthesiologist (ASA) score, however they include both non-MRFs and MRFs. Furthermore, they simply categorize patients at risk for perioperative complications and fail to guide medical optimization protocols.

One institution implemented a Perioperative Orthopaedic Surgical Home (POSH) program, which includes a Readmission Risk Assessment Tool (RRAT), in 2013 to better stratify and optimize TJA candidates. The relationship between readmission after TJA and the RRAT score has been shown to be positively correlated with a RRAT score to be predictive of a high risk of readmission. Using the RRAT, surgeries for patients who are at a high risk for readmission are delayed until their MRFs are medically optimized. With the help of POSH, we have reduced 90-day readmission rates from 13% to 4% and current readmission rates continue to drop further. With the help of the POSH program and the RRAT, comorbidity optimization allows for the alignment of the hospital, surgeon, patient, and payer, while simultaneously emphasizing cost-effectiveness and quality in the provision of care. These perioperative optimization programs can be implemented in a cooperative manner with anesthesia, orthopaedic surgery, internal medicine, and other medical subspecialists.

Another institution engaged the largest physical therapy group to be available for prehabilitation, where the expected post-acute rehab were demystified for patients. Those prehabilitation services acted as an added screen for patients with higher risk home environments and special rehabilitation considerations They also engaged some skilled nursing facilities and remodeled floors to act as a shorter stay units for post-op patients. Expectations on lengths of SNF stay were communicated to free-standing SNF's and more routinely honored.

- **How have population health, capitation, and direct provider contracting improved patients' health?**

Not very well. The cost savings in ACO's and preventative programs have not been impressive. Hospital managed bundles have also been disappointing in financial performance. Physicians need a financial incentive to participate in bundles and value-based care arrangements, and when they are the managers of the bundle, the best results are generally achieved. The sharing of savings with specialists within ACO and other population based insurance delivery systems has not been well delineated.

- **Are there examples of cross payer collaborations – such as employer-Medicare or employer-Medicaid – that have achieved promising results?**

The Indiana model of pay what you can Medicaid has been wildly successful and should be the paradigm for Medicaid reform in this country. When possible, all able-bodied individuals should have the opportunity to contribute what they can afford to their health care. This incentive system can then lead to a fully benefitted health insurance benefit when the beneficiary reaches full employment.

- **What employer sector innovations have had success bending the health care cost curve?**

Private bundles continue to enter the market. Direct contracting of industry and employers with health care delivery systems continue to improve cost effectiveness. The advent of the 90 day DRG for total joint replacement delivered in a VBC environment with quality and cost incentives appears to be a concept with enormous potential for all insured populations.

- **How can Congress help the Centers for Medicare and Medicaid Innovation Center achieve its purpose of developing and testing innovative payment and delivery models?**

AAHKS has been at the forefront of CMMI-created APMs, and submitted extended comments to CMMI's "new direction RFI" in November 2017. AAHKS supports the establishment of multiple A-APMs for physician participation under the Medicare Quality Payment Program, and subsequently encourages Congress to support CMMI authority to establish such models. However, we also believe that Congress should ensure that CMMI is thoroughly vetting its models with clinical stakeholders, and focusing on demonstration projects and not wide-scale mandatory programs.

- Congress should limit CMMI's ability to promulgate mandatory demonstration models.
- Congress should prohibit CMMI from limiting physician/provider choice between models, as they have with CJR taking precedence over BPCI.
- Models should be evaluated and demonstrated on a small scale before expanded nationally.

- CMMI should make draft demonstration models widely available for comment before finalization which will allow a wider range of provider and patient stakeholders to provide input into the model development and receive sufficient notice of key features.
- Physicians should be given the opportunity to assume risk in APMs; the physician should not be excluded from opportunity to act as a ‘convener’ or ‘episode initiator’.

VALUE-BASED ARRANGEMENTS

- **Please describe any value-based arrangements that you participate in by payer – Medicare, Medicaid, employer coverage?**

CJR (Medicare) and BPCI and BPCI-A (Medicare). Please see program and risk-sharing description in previous RFI section.

- **Which have been the most successful at reducing costs?**

Gainsharing helps in the achievement of VBC goals, as it aligns physicians with hospitals through shared risk and reward and the realization that all participants are able to improve efficiency and quality within their healthcare organizations. The better the alignment, the more chance for success.

Alignment of the physicians and the hospital as episode initiator, has allowed the physicians to share in the proceeds of providing BPCI care at EOC costs below the target price.

- **What changes were made in practice management or care delivery as a result of these value based arrangements?**

Examples of practice management change from BPCI program participants: instituted bi-weekly TJA physician resource utilization and quality performance reviews, including cost, Length of stay, discharge disposition, infection rate, VTE rate (blood clots), and readmission rate.

- **What effect did you observe on patient outcomes?**

Example results from BPCI program participant: a decrease in 90-day readmission rates by 6%, a decrease in length of stay by 1.6 days, decreased discharge to inpatient post-acute care facilities by 43% and a cost reduction of approximately 30% per episode of care.

What are some of the barriers to value-based arrangements for drugs, devices and therapies in Medicare and Medicaid?

Stark and Anti-kickback (“AKS”) statutes need to be modernized to eliminate barriers to value-based arrangements. The necessity for every APM to receive a waiver from these laws is evidence that they are incompatible with a value-based delivery system. Furthermore, even in a fee-for-service environment the limitations of the statute and ambiguity of its terms have created a legal morass that burdens the most sophisticated physician groups; sometimes resulting in massive penalties for technical violations of the law. The laws are so complicated, and the penalties so disproportionate, that there is a major disincentive to pursue a value-based arrangement for fear of an inadvertent technical violation. Modernizing the laws, without discarding the program integrity elements, would substantially lower barriers for value-based arrangements.

AAHKS recommends that Congress makes Stark and AKS reform a priority in the 116th Congress. There are three areas of Stark/AKS modernization that AAHKS believes Congress and the Administration should address:

- 1) Establish Stark and AKS exceptions for value-based arrangements;
- 2) Eliminate disproportionate fines for technical violations of law; and,
- 3) Clarify key terms in statute and expand CMS authority to issue advisory opinions.

Congress and the Administration should work with stakeholders to create general safe-harbor criteria for value-based arrangements. These criteria would provide an exception to Stark/AKS laws for financial arrangements that involve sharing risk, or include other incentives that are designed to realize value in the system. The Secretary should also be given authority to identify additional arrangements that would qualify for an exception from Stark/AKS.

The Stark law, because it does not require ‘intent’, can generate massive penalties for mere technical violations of the law. These penalties do not serve the public interest and are a major compliance burden. An example of this would be something as simple as a missing signature on a document. We propose that these technical violations be excepted from Stark/AKS penalties, or at least be limited to a civil monetary penalty.

Finally, one of the most significant challenges to Stark/AKS compliance is ambiguity and inflexibility in the law, and the inability of CMS to provide clarification. AAHKS recommends that Stakeholders, Congress and CMS provide clarification to terms such as “Fair Market Value” and “Commercial Reasonableness”. We also recommend that CMS be permitted and encouraged to use the Advisory Opinion process to clarify the regulations when there are stakeholder questions and concerns about compliance. This flexibility could help clarify traditional considerations, like volume and value of referrals, and also confirm compliance with the newly established value-based exception to Stark/AKS.

- **What role should Medicare play in creating value-based arrangements and encouraging manufacturers, payers and providers to take on risk?**

Medicare can be an important innovator of value-based models. By providing multiple APMs with elements like gainsharing, maintaining flexibility, physician leadership and choice between programs, CMS can drive delivery system reform.

However, under the current Stark/AKS regime, CMS is starving the Medicare population of innovation in the marketplace. By modernizing Stark/AKS, lowering the barriers for value-based arrangements that span across multiple payors, CMS can help harmonize delivery system reform across the entire patient population – including the Medicare population.

TECHNOLOGY AND HEALTH IT

- **What impact does health IT and Data interoperability have on successfully running value-based payment models and contracting? What are some ways to improve interoperability and the sharing of data?**

In order to continue to adapt and improve within the value-based/bundle payment environment, it is imperative for APM participants to measure and track their performance. The use of real time data to track quality metrics, such as complication and readmission rates, financial performance and discharge to PAC facilities and other quality metrics realized, allows for the successful evaluation of individual provider performance and the distribution of reimbursement from VBC proceeds. Data gathered on these performance and quality metric reviews allows for the group as a whole and individual surgeons to understand what challenges they are faced with in reaching certain VBC goals.

Monitoring EOC cost composition, average spend amounts, readmission rates, discharge disposition rates, and physician scorecards provides actionable data to work towards VBC goals. It has enabled physicians to score themselves relative to their peers and acceptable standards of the institution and then if acceptable performance is not realized, examination, counseling, observation, and advice are generated to change behavior.

- **What technology is needed to integrate physician networks to be able to effectively manage a population's health?**
- **What new technology exists to lower costs, improve efficiency, or improve the quality of care that isn't already widely-deployed?**

Generally, care management goals can be achieved through the addition of FTE's or technology. Technology platforms can allow institutions with limited resources or lower volumes to implement standardized care management and clinical pathways without high financial costs.