AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

November 20, 2017

Seema Verma, MPH
Administrator,
Centers for Medicare and Medicaid Services
Baltimore, MD 21244
Submitted electronically via email

Subject: Centers for Medicare & Medicaid Services: Innovation Center New Direction

Dear Administrator Verma:

On behalf of the 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS) and that of the orthopaedic sub-specialty groups and state orthopaedic societies who agreed to sign-on to this letter, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) titled *Centers for Medicare & Medicaid Services: Innovation Center New Direction* published on September 20, 2017.

We commend CMS for incorporating stakeholder feedback in strategic planning for the Center for Medicare & Medicaid Innovation (CMMI or the Innovation Center). The AAOS is, also, encouraged by your op-ed in the Wall Street Journal published on September 19, 2017 further broadcasting this RFI as well as broadly outlining the new vision for the Innovation Center. Since the CMS leadership will review the existing programs and launch new payment and delivery models, the AAOS would like the Agency to consider the following amendments and issues. We have aligned each of our recommendations with the guiding principles listed in this RFI.

1. **Small Scale Testing: End All Mandatory Participation**

We continue to urge CMS to end all mandatory bundled payment models and revise the mandatory MSAs in the Comprehensive Care for Joint Replacement (CJR) model such that the whole model is voluntary. The model design and concept needs to be proven prior to disruptive innovation in the healthcare economy. In this regard, AAOS is encouraged by the cancellation of the Surgical Hip/Femur Fracture Treatment Model (SHFFT). On the other hand, a voluntary program (such as in the Bundled Payment for Care Initiative [BPCI] models) that allows surgeons, facilities, and non-surgical providers to tailor their episode-of-care models to their particular patient population would lead to far better patient care as well as more accurate and efficient payments. (Please note that we have additional comments on the Advanced BPCI model below.) A recent study from the Michigan School of Public Health found that Medicare's voluntary value-based experiments improved health outcomes. More specifically, the study

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found that participation in Medicare's value-based payment programs—such as the Meaningful Use of Electronic Health Records program, the Accountable Care Organization (ACO) programs, and the BPCI models—was associated with greater reductions in 30-day risk-standardized readmission rates under the Hospital Readmission Reduction Program.[1] All of these programs/models were gradually scaled up aiming at better care for Medicare beneficiaries without increasing the burden for Medicare providers. Once pilots are proven to have the results that they aim for, AAOS will surely be a strong proponent of adoption.

2. Incentivize Participation and Encourage Patient-centered Care: Introduce Physician Leadership

The importance of physician involvement and leadership should be kept in the forefront of the new direction for the Innovation Center. A recent op-ed[2] in a leading national daily noted that a generation ago, physicians led most hospitals, and mainly decided how care was delivered. Physicians had autonomy befitting their professional training and experience in the delivery of care. Today, most large health systems and insurance companies (apart from a few, such as the Mayo Clinic, the Cleveland Clinic, etc.) are led by nonclinical, business administrators to the detriment of health care delivery and patient outcomes.

Physician leadership becomes imperative as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) gets implemented via CMS' Quality Payment Program (QPP) and attribution algorithms become significant for accurate reimbursement. CMS should strongly consider physician-led payment models as the Agency adopts the recommendations of the MACRA Episode-Based Resource Use Measures Clinical Committee. In response to the CMS request for information on the MACRA Patient Relationship Categories (www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes.pdf), AAOS commented that the relationships and roles of physician (and non-physician) team members should be defined by the physician coordinating a bundle/episode of care. This is because physician-patient relationships are not linear, nor do they always exist within a defined timeline, but are oftentimes built on commonality of focus on reaching and maintaining health care goals and positive patient outcomes. The surgeon may only represent 15 percent of the cost of a surgical episode but controls 85 percent of healthcare expenditure. Thus, specialists may move between acute and continuing relationships with the same patient depending on the clinical nature of the particular episode of care. Having the hospital or another provider in charge of the bundle gives them inappropriate leverage over surgeons and other physicians and could allow the bundle leaders (such as the hospitals in the CJR model) to exclude physicians if those parties do not wish to

[1] Ryan, A. M., Krinsky, S., Adler-Milstein, J., Damberg, C. L., Maurer, K. A., & Hollingsworth, J. M. (2017). Association Between Hospitals' Engagement in Value-Based Reforms and Readmission Reduction in the Hospital Readmission Reduction Program. *JAMA Internal Medicine, 177*(6), 862-868.

[2] Jauhar, S. (2017, October 10). Shouldn't Doctors Control Hospital Care? The New York Times. Available: https://www.nytimes.com/2017/10/10/opinion/shouldnt-doctors-control-hospital-care.html

meet the leader's terms. If the primary goal of these innovative demonstrations is to manage resources while improving the quality of care, physicians should be incentivized to lead the episodes to improve efficiency and effectiveness.

3. Encourage Choice, Market Competition and Patient-centered Care: Physician-Owned Hospitals

We recommend that the Innovation Center launch a demonstration focusing on Medicare beneficiaries receiving care for chronic pain management and opioid use in physician-owned hospitals (POHs). The POHs have been consistently recognized for their quality of care and patient satisfaction in the Medicare program, due in large part to their physician leadership and the patient-centered care they are able to provide. The rapidly increasing rates of chronic pain and opioid misuse in the Medicare program demand innovative federal responses, and POHs are well-positioned to lead a new pain management and care coordination demonstration focusing on this critical patient population.

The demonstration would target at-risk Medicare beneficiaries and lift the current moratorium for selected POHs, allowing these hospitals to administer and oversee medication management and opioid utilization during beneficiaries' hospitalization and 90 days post-discharge. POHs would use innovative clinical and psychosocial interventions, such as 'patient navigators', which would bolster the tailored and holistic care furnished by these providers. In fact, POHs already use patient navigators leading to better patient outcomes and they also conduct pre-op opioid use analysis to identify at-risk patients, which should be incorporated into this model. Considering POHs' exceptional performance in Medicare quality programs and cost-efficiency, the demonstration would be expected to improve outcomes and reduce expenditures for both the Medicare program and beneficiaries – consistent with the goals of all Innovation Center demonstrations. In terms of quality of outcome, this patient-centered demonstration would measure and seek to improve numerous components of Medicare beneficiary health, including hospitalization rates, medication adherence, and general wellness. The measures used to evaluate the demonstration may assess improvement in opioid utilization and other pain management techniques (with the explicit goal of demonstrating a significant reduction in usage of morphine equivalent dosage of opioids used in post-operative management), readmissions, as well as selected population health measures such as tracking smoking cessation and obesity. The demonstration would therefore advance CMS' goal of using new measures that better tie payments to health outcomes. CMS has already recognized the need for opioid-related interventions targeting Medicare beneficiaries, finding that the "Medicare population has among the highest and fastest-growing rates of diagnosed opioid use disorder."[3] This demonstration presents CMS with a timely, patient-centered response to this issue, as POHs would provide targeted outreach focused on beneficiaries' post-surgical medical management of opioids.

[3] CMS Opioid Misuse Strategy Memorandum, January 5, 2017. Available here.

Further, this demonstration would be developed in accordance with CMS' principles and objectives. For example, the demonstration would be launched in a voluntary, patient-centered and transparent manner, ensuring patients are fully engaged in the demonstration and maintain access to their preferred providers. We envision that POHs would elect to apply for this demonstration based on individual factors, such as their patient populations and resources, and the Innovation Center would then select POHs for participation based on their quality performance scores such as Medicare quality program performance, patient satisfaction rating, hospital readmission rates, and/or other appropriate metrics. This selective application process would help ensure all participants can provide exemplary care to beneficiaries impacted by the demonstration.

The demonstration is particularly aligned with CMS' very first guiding principle for the Innovation Center – promoting choice and competition in the marketplace based on quality, outcomes, and costs. These principles are especially critical in the hospital industry, as former CMS Administrator Dr. Mark McClellan and Brookings Institution Senior Fellow Dr. Alice Rivlin found that the "high prices resulting from market power and anticompetitive behavior … contribute to health care spending."[4] In the same study, they found that "concentration in the hospital market … can prevent competition" and limit payer and providers' ability to "promote reforms in care."[5] By lifting the moratorium for selected POHs, beneficiaries would have greater choice among high quality hospital providers and new access to innovative, patient-centered pain management programs.

Notably, this effort also advances the pain management-related goals of other Department of Health and Human Services' (HHS) agencies, specifically that of the National Institutes of Health (NIH). In an October 2017 congressional hearing, NIH Director Dr. Francis Collins asserted that it would be the NIH's "dream" to launch a small-scale demonstration targeted at pain relief and opioid management that involves hospitals and other entities in the care delivery system. We share Dr. Collins' vision and believe this POH-led demonstration could advance HHS' overall goal of improving medication utilization and addressing opioid misuse. The data generated from this demonstration would also help HHS and Medicare providers develop and identify "best practices" with respect to pain management and adherence among beneficiaries, which could help inform future value-based Medicare coverage and payment policies. The AAOS and our partners can provide further details on the design issues of this model to assist the Innovation Center.

4. **Benefit Design and Price Transparency: A) Publish Specific Details on Model Implementation and B) Remove Logistical Problems in Medicare's Administrative Rules**

[4] Mark McClellan and Alice Rivlin, *Improving Health While Reducing Cost Growth: What is Possible?* Brookings Institution, April 2014.

The AAOS appreciates CMS' commitment to reduce burden on clinicians. One way to reduce additional burden in a value-based reimbursement system is to provide real time data to clinicians on their own performance as well as that on the programmatic details. To illustrate further, as we discussed earlier, in 2017, CJR Track 1 i.e. the Certified Electronic Health Record Technology (CEHRT) track is the sole Advanced Alternative Payment Model (APM) available to orthopaedic surgeons. This information is available on the QPP website. However, more specific details are missing. For example, there are no details on the requirements for participating in CJR Track 1 in this rule. Without these important details, participants in the CJR model are left confused and without the ability to take advantage of the new regulations. More specifically, we urge CMS to finalize the CEHRT and nominal risk requirements for participants who are interested in CJR Track 1. This is urgent if these changes are to launch on January 1, 2018.

In addition, Medicare's eligibility and administrative rules create logistical difficulties and placement restrictions that are both costly and hinder coordinated care provision. For example, patients must be hospitalized for three days to qualify for care in a skilled nursing facility (the "three-day rule"), limiting discharge options and unnecessarily extending hospital stays. As the BPCI evaluation reports have revealed, the post-acute care sector is a great setting for further improvements in costs. However, surgeons and their respective patients should decide on discharge time and setting as every patient's context is unique.

5. **Expand Opportunities for Participation in Advanced Alternative Payment Models (APMs) and Create Physician Specialty Models: Update Advanced APM eligibility requirements**

We appreciate your support for innovative, value-based care delivery models. However, we have significant concern over the Qualifying Participant (QP) threshold (in the Advanced APM track) as currently defined in terms of Part B services and patients. These thresholds are impossible to reach for specialists such as orthopaedic surgeons. The current threshold definitions must be reviewed and altered in addition to the creation of new specialty focused APMs if CMMI intends to encourage higher participation levels in the Advanced APM track of QPP.

As you know, for 2017, CJR Track 1/i.e., the CEHRT track is the sole Advanced APM available to orthopaedic surgeons. Hence, we eagerly await the publication of the Advanced BPCI model's regulations. We hope that the Advanced BPCI model will allow voluntary participation and will provide a new pathway for our surgeons and their patients to join the Advanced APM track of the QPP. Further, the current BPCI program already fulfils the three criteria for an Advanced APM and should be designated as such. This will expedite the process for more providers to participate in an Advanced APM.

The BPCI models have shown that bundled payments offer a highly effective opportunity to improve patient/beneficiary care and reduce unnecessary and/or wasteful costs. Engagement in BPCI has allowed physicians, hospitals, and providers to develop and implement new patient care pathways, and coordinate care to solve complex patient care challenges. Hence, we are strongly supportive of the Advanced BPCI initiative that is likely to be announced soon. However, as you think through the new updates on the BPCI models, please consider our concerns regarding the current pricing methodology in these models as discussed below.

6. Benefit Design and Price Transparency: More Accurate Episode Target Pricing

Update BPCI Target Pricing: In an analysis conducted by one of the largest orthopaedic Awardee Conveners in the BPCI initiative, details were presented regarding the pricing methodology employed by the Innovation Center to account for various Medicare policy changes, geographic-specific wage changes (Wage Factor Adjustment), and national utilization trends (National Trend Factor or NTF) that occur over time. This pricing methodology is used to adjust historical target prices on a quarterly basis and is critical in determining whether participant physicians will share in the savings with Medicare or reimburse Medicare for costs that exceed the target. This methodology ultimately determines whether the program is successful and can be sustained. For three years, a consistently declining trend in price in the current BPCI models attributable to the NTF, has produced unanticipated and significant negative financial consequences for the physician group practices (PGP) convened under this convener. This pricing trend equates to about 7-8 percent price deflation in unmanaged orthopedic episodes of care, which, based on our information, appears in complete contradiction to Medicare's national cost trends.

The impact of the declining NTF has a compounding effect on an Episode Initiator's (EI) financial performance. Under the current pricing methodology and resulting NTF calculation, the more success physicians have in managing episodes and reducing cost, the faster the BPCI program moves toward unsustainability. So, despite achieving the Innovation Center's goals for the BPCI initiative on cost and quality, the PGPs convened under this Convener have been penalized financially because their care redesign efforts have been outpaced by the downward spiraling NTF.

The damage this has caused successful BPCI participants is quite discouraging – not only to the physicians in these groups that have worked very hard to reduce cost and improve outcomes under a new model of care and reimbursement, but to hundreds of other specialists who have become dubious of the government's ability to develop sustainable APMs. To illustrate further, the convener mentioned above has provided the analysis in the table in Appendix A for three physician group practices that are participating in BPCI under them. All three of these groups, despite driving costs down as much as 36 percent and achieving high quality outcomes, had to exit the initiative because they could not reduce their DRG spend enough to remain ahead of the

effect of the declining NTF. See Appendix A for the impact of the NTF on three PGPs in BPCI Model 2.

Under this scenario, it will not be financially viable for many other participants to remain in the BPCI program given the continuing investment each EI must maintain. As we can see from the above example, already some of the best performers in the BPCI program have decided to leave. Moreover, this BPCI Convener's projection is only one example of the number of defections that have occurred and will continue to occur in the initiative without intervention. This is likely to taint future bundled and alternative payment models developed by CMS. Hence, we propose that CMS and the Innovation Center consider the following options to address the current flaws in BPCI's pricing.

First, to address concerns with data transparency and accuracy in the current BPCI initiative, CMS should provide (to conveners that have been significantly impacted by the declining NTF and who request it) the actual data used to calculate the NTF for DRGs so impacted.

Second, to address pricing methodology concerns, the following actions should be undertaken:

1. elimination of the NTF or the placement of tighter limits on NTF changes,
2. complete exclusion of managed episodes from the NTF calculation,
3. elimination of the wage adjustment factor, and
4. reselection of episodes to enter Phase 2 for the remainder of BPCI.

Further, to help ensure the long-term stability and physician engagement in the next generation BPCI program, we strongly urge CMS to implement the following methodology changes in the pricing model:

- **Prospective Targets** – Prospective targets, distributed before the performance period begins, are essential for EIs to plan and predict their ability to succeed in the program.
- **Regional Pricing Targets** – Adopting regional pricing targets will allow high performers to be attracted to and retained within the program.
- **Elimination of the Wage Factor** – The Wage Factor is inherently unfair to some EIs and does not accurately reflect that actual price changes of the underlying costs.
- **Elimination of the National Trend Factor** – The NTF has been fraught with issues and is one of the main drivers of unsustainability of the program. Removing the NTF and replacing it with a more reasonable approach to measuring utilization changes is desperately needed.
- **Implementation of Episodic Risk Adjustments** – Some episodes are inherently riskier than others. Implementing a risk adjustment methodology would allow EIs to more effectively manage their patient population.

The AAOS and our partners believe that taking these steps will make the BPCI program sustainable and viable in the long-term as well as provide a pathway for specialist physicians to participate in Advanced APMs.

Separate Pricing for Total Ankle Arthroplasty (TAA): Another example is the target pricing for TAA paid via MS-DRGs 469/470 and thereby included in CJR. There is increasing evidence, which we would be happy to provide upon request, that the outcomes for TAA are at least equivalent to ankle arthrodesis and are preferable for some patients. Our concern is that grouping TAA with Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) with respect to MS-DRG payments and CJR, as well as grouping primary and revision TAA together, may make TAA financially non-viable for many hospitals. This may lead hospitals to limit physicians from performing TAA, particularly on patients with higher co-morbidities. This in turn would restrict patient access to what may be their best treatment option with respect to pain relief and functional activity.

Per the 2015 MedPar database, the standardized cost mean for primary TAA was $5,657 more than for all cases in MS-DRG 469 and $13,471 more in MS-DRG 470. The difference for revision TAA as compared to primary TKA and THA is likely higher. There are multiple potential reasons for this cost differential. Implant costs using more recently developed designs (as compared to hip and knee implants) are one reason.

Also, TAA is a fundamentally different operative procedure than TKA or THA in several important ways:

- The ankle region typically has poorer circulation and thinner soft tissue coverage than the hip and knee leading to a higher risk of wound complications and infection that may be more challenging and expensive to treat.
- Successful TAA often requires addressing concurrent ankle ligamentous instability, foot deformity, and muscle imbalance.
- When compared to THA and TKA patients, TAA patients are more likely to have post-operative cast immobilization and weight-bearing restrictions, often up to 6 weeks. This limitation in weight-bearing reduces independence in walking and can lead to longer inpatient stays, higher rates of placement in and length of stay at extended care facilities, and the need for offloading devices such as wheelchairs and rolling scooters. This is particularly relevant to the ongoing inclusion of TAA in the CJR initiative as the post-operative care differences will affect the costs under CJR.

Given these illustrations, we are requesting for separate target pricing for TAA episodes in CJR. In this context, we acknowledge and appreciate the most recent regulation to reassign the following TAA procedure codes from MS-DRG 470 to MS-DRG 469, even if there is no MCC (Major Complications and/or Comorbidity) reported: 0SRF0J9; 0SRF0JA; 0SRF0JZ; 0SRG0J9; 0SRG0JA; and 0SRG0JZ for FY 2018. We believe this will enable more hospitals to include

TAA in their musculoskeletal service line. This will enable Medicare beneficiaries to receive higher quality care and improve their overall access to TAAs.

7. Create Physician Specialty Models: Specialty-Focused Accountable Care Organizations (ACOs)

While AAOS agrees with and supports the substantial role of primary care providers in coordinating care, it is important for CMS to consider various models for specialist participation in ACOs. AAOS believes that specialists should be allowed to develop payment distribution contracts within an ACO that support improved patient-level outcomes and cost reductions achieved by specialists. AAOS also believes that the definition of an "ACO Participant" should be broadened/clarified so that midlevel providers (such as physician assistants, nurse practitioners, etc.) working with specialty group practices are not designated as providers of primary care services. This would ensure individual providers within those practices can participate in multiple ACOs. To further that end, it would also be helpful to have more explicit regulations allowing participation in multiple ACOs at the specialty group practice level. This not only furthers the goal of improving quality but provides increased access to care for more Medicare patients. It is also important to ensure that solo practitioners, small groups, and small hospitals have the option to participate.

Moreover, condition-specific ACOs are essential for the intended move to population-based health care delivery models. The evaluation reports of the Innovation Center's ACOs reveal that the Comprehensive End-Stage Renal Disease Care (CEC) Model saved $75 million which is more than the $68 million saved by Pioneer ACOs, and the $48 million saved by NextGen ACOs in the same period. Although this is the performance year 1 results for the CEC model, the quality and financial results point to the fact that disease specific ACOs are likely to improve care for Medicare beneficiaries and reduce costs. With disease-based spending targets, the responsibility for reigning in costs should be shared by the primary care providers and specialists who are co-managing patients and populations within a given disease. Hence, AAOS calls for CMMI to embrace the concept of surgical based ACOs and the Peri-surgical Home to address this issue.

Limiting ACOs to primary care negates adequate attention to half of the healthcare provided in this country. The basic design of the current ACOs being developed and led by the Innovation Center (including the Pioneer ACOs and the NextGen ACOs) are primary care focused. However, specialty care accounts for a large share of health care expenditure in this country and primary care physicians are not always the ideal gatekeepers of specialist care, leading to unnecessary services and patient frustration.[6] As we discussed earlier in this letter, the surgeon

[6] Peabody, J.W. & Huang, X. (2013). A Role for Specialists in Resuscitating Accountable Care Organizations. Harvard Business Review. Available: https://hbr.org/2013/11/specialists-can-help-resuscitate-accountable-care-organizations

may only represent 15 percent of the cost of a surgical episode but controls 85 percent of healthcare expenditure. Many specialists, including surgeons, are trained in health economics, business management and data analysis. Thus, they are ideal candidates to be held accountable for the entire care pathway and for managing the ACOs. Moreover, electronic health records (such as the CEHRT requirements), other health care technology innovations, primary care-specialist collaboration and appropriate quality measures are essential for ACO success. Advancing interoperability and implementing the requirements of the 21st Century Cures Act are critical in this regard.

Further, we would like to discuss the crossover issue of beneficiaries moving between care delivered through an ACO and a bundled payment provider entity. This movement raises the inevitable question of which provider receives "credit" and hence reimbursement for the quality of care delivered to the beneficiary in each respective care pathway. For example, a multi-comorbid knee replacement patient may require significant intervention to optimize their condition prior to surgery. This intervention may be provided through the specialist physician and as a result, patients receive a post-surgical outcome that is of higher quality than what would otherwise be expected of patients with a similar comorbid profile. That surgeon, as an Episode Initiator in a bundled payment model, should be reimbursed for achieving a higher quality outcome and perhaps a positive reconciliation payment for achieving a lower than target episode cost. However, it is very likely that this highly-optimized beneficiary is moved into an ACO where the primary care physician will in all likelihood, have a lower cost and will essentially accrue the benefits of a healthier beneficiary due to the work of the specialist physician in the bundled payment model. While this may seem like an extreme example, in fact, we believe it is occurring with regularity in markets in which these two models of care intersect. To illustrate, please see the two tables in Appendix B developed by a Physician Group Awardee/Convener in BPCI Model 2, comparing comorbidity incidence in their BPCI baseline (historic) data set, to patients during the 2016 performance period. These graphs show that the number and type of comorbidities per patient undergoing a lower extremity joint replacement are basically identical between the comparison periods. While these data serve to counter certain contentions that surgeons will cherry-pick healthier patients in bundled payments, it more importantly demonstrates that Medicare patients are as sick today as they had been in the historic 2009 to 2012-time frame, despite the proliferation of ACOs across the country. In other words, patient optimization in the primary care ACO model may be lacking. Yet we know many of these patients are now being cycled into ACOs in generally better health than when they entered the BPCI initiative.

The AAOS also suggests a method of combining risk-adjustments with payments based on quality metrics. The idea is that if a participant takes on more complex, comorbid patients (whether in a BPCI-type model, or Surgical ACO, etc.) she is eligible to receive an additional increase in the episode reconciliation payment. Physicians taking on higher comorbid patients receive additional payments relative to quality outcomes and utilization management, e.g., what other non-surgical processes were attempted before committed to surgery. This will help

recognize the work in pre-operative optimization process and the engagement of physicians in managing higher comorbid beneficiaries in the pre-, acute and post-acute care settings.

Hence, we urge CMS to develop ACOs focused on specialist physicians which will enhance the movement to population-based health care payment and delivery models.

8. **Expand Opportunities for Participation in Advanced APMs (appropriate data capture): Access to Medicare claims data by Qualified Clinical Data Registries (QCDR)**

The AAOS appreciates CMS' efforts to facilitate Medicare claims data access for QCDRs. However, in response to your specific question in this RFI on how to capture appropriate data to improve quality and control costs as well as design innovative payment models, we strongly request real-time access to Medicare claims data in a registry-user friendly format. Unless registries can validate their data with real-time Medicare and non-Medicare claims data, their findings exist in a virtual vacuum and are of little benefit. With validation, registries can provide CMS with information that saves lives, and improves physician and medical device performance, which can in turn provide significant cost savings to the Medicare program. Longitudinal device and patient tracking is nearly impossible without validation of patient encounters over time, location, and health services. Surveillance of the outcomes of patients and devices requires the ability to follow both the patient and device through time and changes in health care provider. In recent meetings with CMS, the AAOS was reassured that changes to the ResDAC application and data provision processes will prove satisfactory to meeting our QCDR data needs. However, as we have maintained throughout, the ResDAC program is designed to meet the needs of researchers using Medicare claims data and not for registries. Hence, we need immediate infrastructure (such as, claims database navigators) as well as an interface that will enable robust data validation needs of our QCDR. This will incentivize Medicare participant physicians to report their quality data as well as improve the care outcomes for Medicare beneficiaries.

CMS should also update and streamline the QCDR measure submission and use policies. During the 2017 QCDR measure review period, many QCDRs experienced a disorganized process with contradictions in the responses received from CMS staff and contractors. Moreover, CMS has rejected measures without providing any or sufficient rationale for QCDRs to respond or modify their submission. Both timely and detailed feedback is necessary for the program to operate well. As CMS considers whether QCDRs that develop and report on their own measures must fully develop and test (i.e. conduct reliability and validity testing) their measures by the time of submission, AAOS encourages CMS to consider the burdens extensive pre-submission testing may put on many smaller, sub-specialty, or nascent QCDRs.

In the QPP Year 2 Updates Proposed Rule (CMS-5522-P), CMS offers a route for one QCDR to seek permission from another QCDR to use an existing measure owned by the second registry. Yet the QCDR application currently does not ask about the ownership and licensing of non-

Merit-based Incentive Payment System (MIPS) measures. The AAOS echoes the concerns of the registry community in urging CMS to develop a process respectful of QCDRs' intellectual property interests. Relatedly, the proposed rule provides that a QCDR using another registry's measure must have permission by the time of self-nomination in order to include proof of permission for CMS review and approval. To provide more clarity, CMS should define what form this proof of permission would take to satisfy the requirements of the self-nomination application process.

9. Expand Opportunities for Participation in Advanced APMs (Appropriate Data Capture): Update the QPP Regulations

Apart from introducing new physician-led and specialty-focused Advanced APMs, AAOS urged significant updates to the MIPS track of the QPP. This is a necessary step given that CMS ultimately wants to increase participation in the QPP but currently many physicians will be outside this program either because of the exemption thresholds, other statutory exemptions and the complex requirements for Advanced APM Qualified Participants. In this regard, we have the following recommendations:

Two-year Lag: Quality improvement relies on timely and accurate feedback to the provider. The AAOS continues to believe that the two-year lag between the performance and payment years is problematic for physicians in terms of tracking their performance and managing that performance at required levels with delayed feedback. Mechanisms to allow more contemporary feedback are essential to any quality control endeavor. The intent of the MACRA statute is to create a change toward value in health care delivery and payment. With that time gap, there is no meaningful feedback: payment changes are either a nice "bonus" related to unclear processes or a "punishment" with little clarity as to how the practice could improve. Our suggestion is to require reporting under MIPS (especially for the active reporting requirement measures) for the first nine months of each performance year, allowing the last three months for reconciliation of the data such that the performance and payment feedback are available by January of the following year. CMS can use a full year of administrative claims data for the non-reporting measures for a better sample size. This would meet the goals of CMS by allowing rapid response to physicians without the two-year lag between performance and payment.

Provision of Data to Clinicians: In continuation of the discussion above, AAOS would like to re-emphasize our earlier comment for at least quarterly provision of clinician/practice data instead of the lagged feedback system across all the elements of the QPP. Access to timely data that reflect the performance scoring of clinicians is essential for the success of the QPP. Quality demands timely feedback. While historical data could be provided as a guide to clinicians, provision of real time data on a quarterly basis could better inform clinicians. The AAOS believes that small and even medium sized physician practices will not be able to participate effectively without quarterly feedback on their performance. Further, simplification of the QPP would benefit both the physician, practice, and CMS in providing effective timely feedback.

Virtual Groups: The AAOS appreciates the new proposals creating an option for solo and small practices to form virtual groups enabling their participation in the MIPS program and obtaining CEHRT qualification. However, we believe it will be challenging for the target practices to participate. Both the complexity of arranging the virtual groups and a continued need for expensive technology infrastructure may prove a barrier to solo and small practices. There are significant resources needed to set up and run the virtual groups including finding potential group members, drawing up of legal contracts, expensive third-party reporting as well as health information technology vendors and administrative staff to support the virtual group functioning to list just a few. Thus, a concern is that virtual groups will only be an alternative for those with greater resources. Since there will not be enough time to prepare for the 2018 performance year, additional flexibilities for virtual group reporting will be helpful in areas such as CEHRT, OSHA, and CDC requirements.

To help address these concerns, we urge CMS to provide extensive and individualized support and learning opportunities for clinicians and their practice management staff on how to create virtual groups or implement changes in these groups. CMS should also provide tools for solo and small practices to determine if forming virtual groups will be beneficial for their patients and their practices. It is essential for CMS to provide adequate information and simple and actionable guidelines to clinicians to make necessary decisions about forming virtual groups. Without simplifying the regulations associated with virtual groups, important resources may potentially be taken away from the care provided to Medicare beneficiaries.

The threshold for facility based reporting, that CMS introduced for 2018, would exclude most private practice providers delivering care in a hospital setting from this reporting option. Hence, we recommend that CMS consider lowering the threshold for participation, which would allow greater participation, particularly from solo/small groups. Expanding the facility based reporting concept would be beneficial for the following reasons:

1. Solo/small groups will have a less burdensome reporting/participation option as they collaborate with hospitals they work in;
2. Would promote coordination of care by aligning physician and hospital financial interest;
3. Foster physician leadership: since hospital performance would influence physician reimbursement, physicians would be incentivized to "participate in the process";
4. The program seems to be initially aimed at hospital employed physicians, since participation requires a high percentage of physician payments made in hospital setting (via location code); however, physician decisions have broad reaching impact on Medicare spending. Facility based reporting may bend down the cost curve by encouraging fiscal responsibility from physician stakeholders.

MIPS Quality Performance Category: The proposal to increase the data completeness threshold to 60 percent for the 2019 performance year may be too much, too soon, and too

optimistic. A gradual buildup of such thresholds will reduce additional burden on MIPS participating clinicians. A system that samples data is more economic and practicable. CMS proposes to identify topped out measures, and after three years will consider removal from the program through rulemaking in the fourth year. Although this applies only to CMS Web Interface measures and there will be enough consideration given before removing topped out measures, this is likely to be a problem for specialties, such as orthopaedics, that lack outcome measures. CMS can use "topped out" measures as controls for new and developing measures. Moreover, if a measure is going to be topped out, CMS should announce the status of the measure with sufficient time lag before it is removed from service to allow clinical processes time to adjust and redirect their resources. The practice of making an announcement at the end of a given year with implementation at the beginning of the next year (a 1-2-month lag) is not optimal. The announcements around the addition of new measures or removal of measures for a given year should be unified by CMS and announced at a consistent time each year. CMS needs to work with external measure validators and other stakeholders to streamline the process of development, validation, and adoption of new and meaningful measures.

In addition, the jumping from a minimum 90-day performance period for Quality performance category in the 2017 performance year to a 12-month calendar year performance period in the 2018 performance year should instead be implemented gradually.

10. Incentivize Coordinated Care: Updates to the Stark Law

As AAOS and several of our partners have noted earlier in our comments to CMS and to the U.S. Congress, the structure of the Stark law has not been updated statutorily for more than two decades, and at this time, it limits the full potential of these innovative health care delivery models that incentivize care coordination. For example, the BPCI and CJR models reveal weaknesses in current Stark law. These kinds of payment models are value-based programs seeking to promote high-quality care and care coordination within individual health care entities and across multiple sites of service. However, the Stark law prohibits payment arrangements that consider the volume or value of referrals or other business generated by the participating parties. Further, the Stark law is a strict liability statute unlike other health care legislation, and therefore, unintentional and technical errors of physicians and their staff may lead to heavy penalties. Such strict liability statutes may discourage physicians from participating in coordinated care models. Indeed, the costs of compliance and disclosures required per the Stark law can be prohibitive for small and medium-sized physician practices participating in these models.

To address some of these issues, physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark Law requirements through fraud and abuse waivers. There must be similar exceptions/protections to physicians participating in APMs. CMS should have the regulatory authority to create exceptions under the Stark law for these types of payment arrangements and remove barriers to the development of such arrangements.

Specific recommendations are:

- Expansion of administrative authority to provide exceptions to physician ownership and compensation prohibitions to promote care coordination in MACRA programs. This empowers CMS to provide the same waiver authority to physician practices that was provided to accountable care organizations in the Affordable Care Act.
- Removal of the "value or volume" prohibition in the Stark law so that practices can incentivize physicians to abide by best practices and succeed in the new value-based alternative payment models. This protection would apply to practices that are developing or operating an alternative payment model. Items and services must be subject to fair market value except that they may not consider volume or value.
- Creation of a more workable standard that only triggers penalties for knowing and willful violations of the law, which is the current standard for civil penalty provisions of the Anti-Kickback Statute Violations of the Stark law with respect to physician ownership interests.

11. Incentivize Participation and Promote Competition: Risk-bearing

We believe that surgeons should have the ability to directly bear risks to actively participate in the value-based payment model and this ties in with our comment on establishing surgeons as head, or at least co-head, of the episodes. We agree with you that "providers need the freedom to design and offer new approaches to delivering care." [7] One of the ways to achieve this is to allow surgeons and other specialist physicians to take charge of their patients' health and health care. CMS should directly contract with surgeons rather than have hospitals as an intermediary. Otherwise, surgeons and other specialists have limited ability to control the process and outcomes of each episode leading to a sub-optimal outcome for the society.

12. Incentivize Participation: Gainsharing

Given your stated goal to "move toward a system that holds providers accountable for outcomes and allows them to innovate," [3] we suggest that there be no limits to gainsharing amounts among participants in value-based and coordinated care models. When surgeons actively participate in the value-based payment models, whether directly – as explained above – or otherwise, they should be able to fully share in the resulting cost reductions. Further, the MACRA statute highlights the importance of "medically necessary" services, and in this regard, AAOS regularly invests in member and patient education through clinical practice guidelines, appropriate use criteria, and patient safety considerations of orthopaedic procedures and overall musculoskeletal care. Given our strong commitment to the values of effective and efficient care, we believe that stinting of necessary care is not a threat for surgeons. Specifically, we believe that the current gainsharing limit of 50 percent of the total Medicare approved amounts during CJR episodes

[7] Verma, S. (2017, September 19). Medicare and Medicaid Need Innovation. *The Wall Street Journal.*

should be removed altogether. This will ensure healthy competition among all participants in the model and will ultimately provide better quality care and reduce the costs of health care.

13. Incentivize Participation and Price Transparency: Payment Changes for X-rays Taken Using Computed Radiography (CR) Technology

AAOS believes that the reduction in payments for services utilizing computed radiography technology is unreasonable. Providers who offer in-office services to improve access and convenience to patients should not be penalized for using traditional technology. In fact, CR is preferable to Digital Radiography (DR) in certain instances. For example, a full spine radiograph for scoliosis evaluation is ideally performed using CR. DR requires a patching together of separate views and results in a sub-par study. While some hospitals may be better positioned to make high fixed-cost investments, digital upgrade of a radiology suite costs is a financial barrier for others, including most individual and small practices. Decreasing payments furnished during CYs 2018 through 2022 by 7 percent and 10 percent thereafter, will force many orthopaedic providers to cease offering these services. To incentivize upgrades to DR, AAOS recommends offering bonus payments to providers analogous to the currently proposed 2015 CEHRT bonus under the Quality Payment Program (QPP) Year 2.

14. Incentivize Participation and Patient-centered Care: Introduce Socio-economic Risk Adjustment in Innovation Center Models

The AAOS urges CMS to include important patient characteristics such as age, socio-economic status (SES), marital status, clinical co-morbidities, functional status, etc. apart from the target price stratification that is used in many Innovation Center models. Per the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, HHS submitted a report to Congress on social risk factors in Medicare's value based payment models.[8] CMS should incorporate those recommendations in the payment design and resource use measures in the new payment models and demonstrations so as not to accentuate the health and health care disparities among the vulnerable Medicare and Medicaid beneficiaries. At the same time, this report from the Assistant Secretary for Planning and Evaluation (ASPE) found that safety-net providers were more likely to receive penalties and be disadvantaged.

These findings have been corroborated elsewhere. For example, a recent analysis of Medicare claims for patients in Michigan who underwent lower extremity joint replacement (LEJR) procedures in the period 2011–13 concluded that hospitals treating medically complex patients may be unintentionally penalized without proper risk adjustment. Reconciliation payments were found to be reduced by $827 per episode for each standard-deviation increase in a hospital's

[8] US Health and Human Services (2016, December). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Office of ASPE. Available: https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf

patient complexity. This study also estimated that risk adjustment could increase reconciliation payments to some hospitals up to $114,184 annually.[9] Thus, the CJR model needs financial, clinical, and socio-economic risk adjustment. Another important point raised by this study, referenced above, is that the CJR model is unique in that the target price is calculated as a blend of a hospital's historical episode spending and the average spending of other hospitals in the same region with the weight of the regional benchmark increasing over time, this is going to increase the financial disparity for hospitals treating more medically complex patients.

For a complete list of recommended risk variables, please see Appendix A of our comments on the CJR Proposed Rule available online at: http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/Issues/medicare/AAOS_CY2016_CMS_%20CCJR.pdf.

Priority List of Risk Variables

- Body Mass Index – The actual height and weight should be recorded. The BMI should not be captured from the administrative data. The height and weight are currently being recorded in many electronic health records (EHR).
- Race/Ethnicity – Race/ethnicity should be a patient-reported variable and may be recorded in the EHR.
- Smoking Status – Smoking status may be reported through administrative data, but additional information may be provided from the EHR.
- Age – Age is reported in administrative data.
- Sex – Sex is reported in administrative data.
- Back Pain – Back pain would be a patient-reported variable and recorded in the EHR. It has been noted to influence outcomes of joint replacement patients.
- Pain in Non-Operative Lower Extremity Joint – Pain in a non-operative lower extremity joint would be patient-reported variable and recorded in the EHR. It has been noted that pain in other extremities can influence the outcome of a total joint replacement.
- Health Risk Status – The actual comorbidities that should be included need further investigation. Both the Charlson morbidity index and the Elixhauser morbidity measure may identify appropriate comorbid conditions. To identify the patient's comorbid conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.
- Depression/Mental Health Status – The PROMIS Global or VR-12 will collect this variable, as well as the administrative data.
- Chronic Narcotic or Pre-Operative Narcotic Use – These variables affect patient outcomes

[9] Ellimoottil, C., Ryan, A. M., Hou, H., Dupree, J., Hallstrom, B., & Miller, D. C. (2016). Medicare's New Bundled Payment for Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients. *Health Affairs*,*35*(9), 1651-1657.

and requires additional consideration. The information should be available in the EHR.
- Socioeconomic Status – This variable affects patient outcomes and requires additional consideration. Further evaluation is required regarding how the data could be collected.

Future Desired List of Risk Variables

- Literacy
- Marital Status
- Live-in Home Support
- Family Support Structure
- Home Health Resources

Risk Variables to Not Include

- American Society of Anaesthesiologists Physical Status Classification (ASA) Score
- Range of Motion (ROM)
- Mode of Patient Reported Outcome Measure (PROM) Collection

In conclusion, the AAOS appreciates CMS and the Innovation Center for reaching out to stakeholders and taking this time for additional review of the Center's strategic direction. As noted above, we sincerely hope that the Agency will not further delay more detailed guidelines on the CJR CEHRT Track/Track 1, the Advanced BPCI model as well as announce new small-scale demonstrations and specialty focused ACOs that enable physician leadership, consumer choice and patient-centered care. We hope that CMS will consider our recommendations as new policy choices are considered and adopted. Please do not hesitate to get in touch with AAOS Medical Director, William O. Shaffer, MD, at shaffer@aaos.org if you have any further questions or comments. Thank you.

Sincerely,

William J. Maloney, MD
President, American Academy of Orthopaedic Surgeons (AAOS)

Cc: David A. Halsey, MD, AAOS First Vice-President
Kristy L. Weber, MD, AAOS Second Vice-President

Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
William O. Shaffer, MD, Medical Director, AAOS

This letter received sign-on from the following sub-specialty groups and state societies:

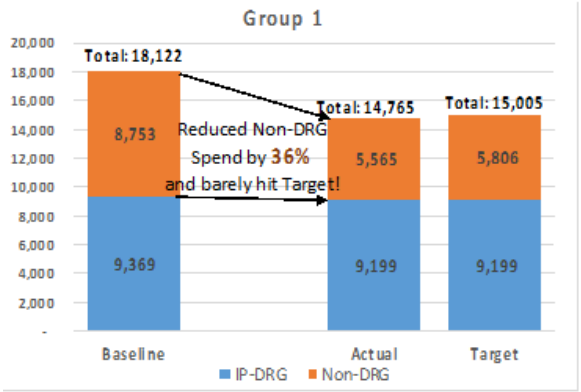
American Alliance of Orthopaedic Executives (AAOE)
American Association for Hand Surgery (AAHS)
American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Limb Lengthening and Reconstruction Society (LLRS)
Musculoskeletal Infection Society (MSIS)
Musculoskeletal Tumor Society (MSTS)
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
Pediatric Orthopaedic Society of North America (POSNA)
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
Society of Military Orthopaedic Surgeons (SOMOS)
The Knee Society (KNEE)

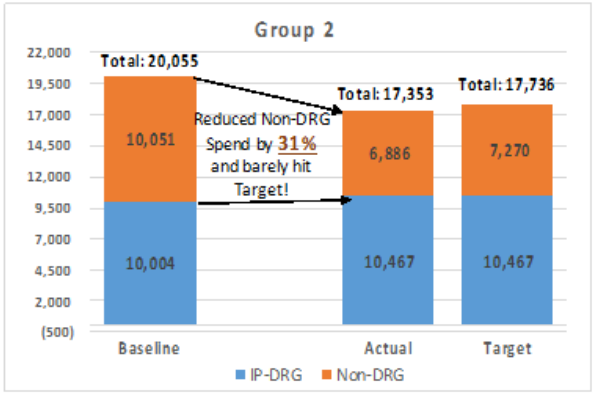
Alabama Orthopaedic Society
California Orthopaedic Association
Connecticut Orthopaedic Society
Eastern Orthopaedic Association
Florida Orthopaedic Society
Iowa Orthopaedic Societies
Kansas Orthopaedic Society
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Nevada Orthopaedic Society
New Jersey Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Dakota Orthopaedic Society

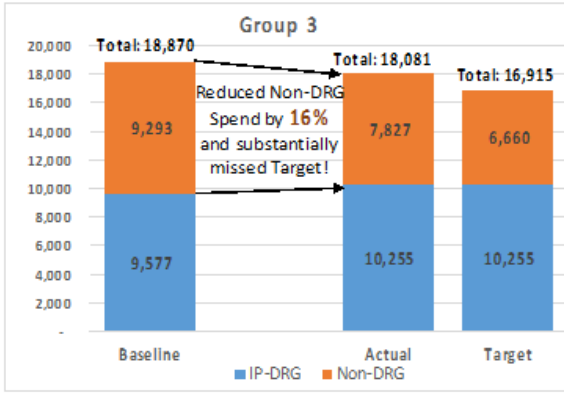
Pennsylvania Orthopaedic Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Southern Orthopaedic Association
Tennessee Orthopaedic Association
Texas Orthopaedic Association
Utah State Orthopaedic Society
Virginia Orthopaedic Society
Washington State Orthopaedic Association
West Virginia Orthopaedic Society
Western Orthopaedic Association

Appendix A

The following depicts the impact of National Trend Factor on three groups in BPCI Model 2 on their ability to manage to the Target Price (DRG 470 Non-Hip Fracture) for Q4 2016:





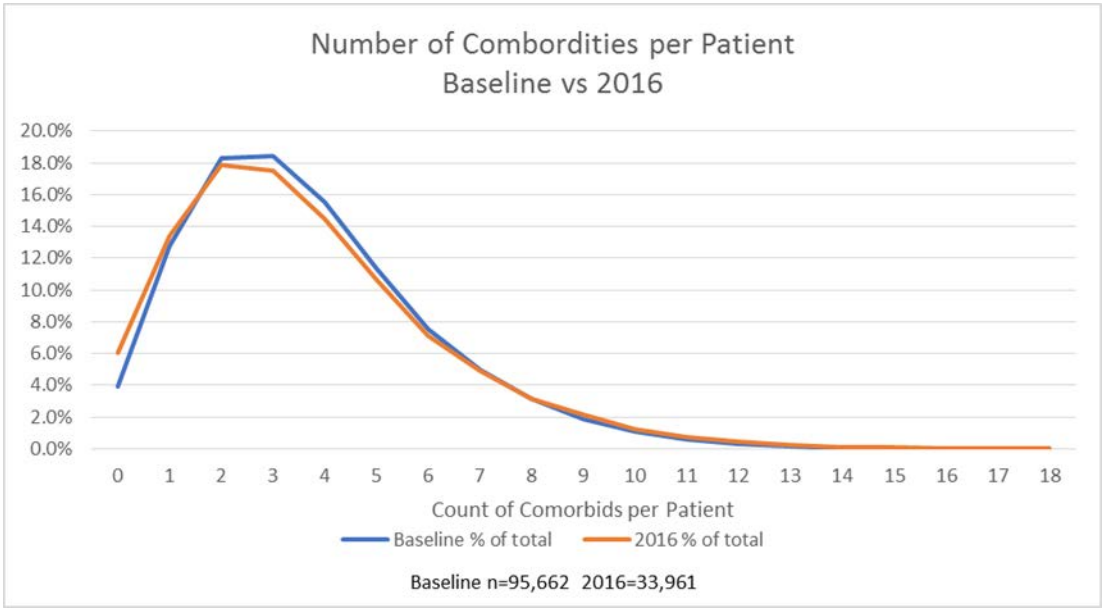


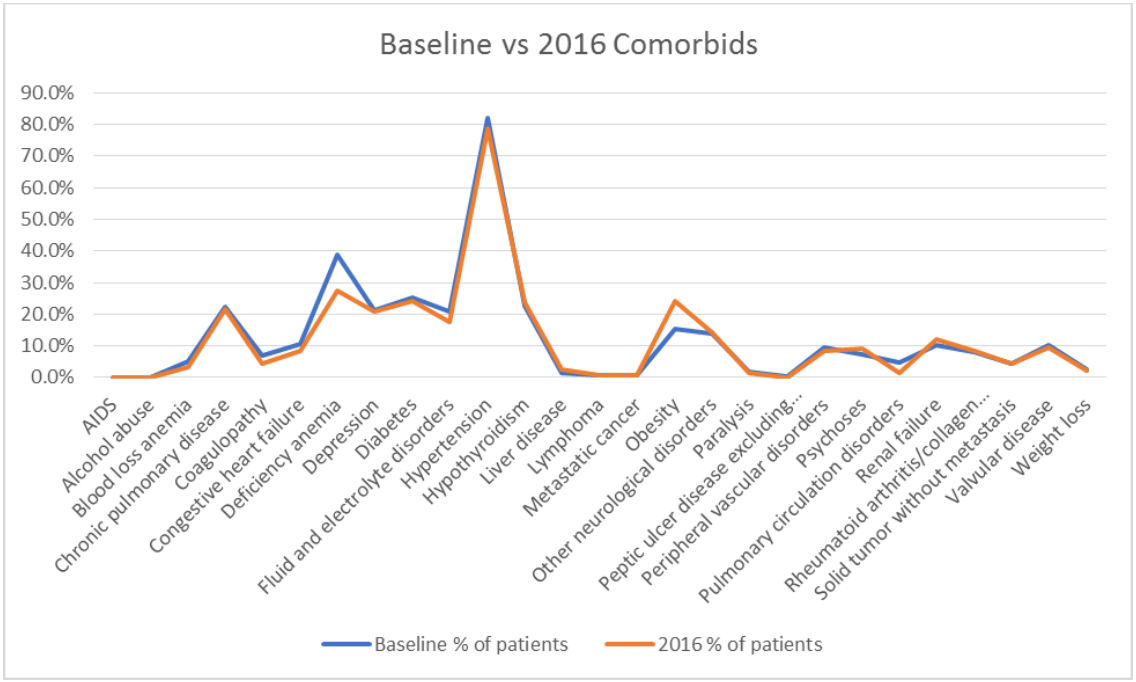
For Group 1 and Group 2, they **reduced their non-DRG spend by 36% and 31%, respectively, yet barely hit their Targets!**

For Group 3, their implied non-DRG spend has to be **less than $7,000** just to hit Target, a reduction of 28% compared to baseline.

These are some of the top performing groups in BPCI, **yet all have decided to exit the BPCI program**. Unfortunately, we have other top performing groups that are on the cusp of exiting the program because of the issues with the pricing methodology.

Appendix B
Source: Physician Group Awardee/Convener in BPCI Model 2




Baseline vs 2016 Comorbids
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
AIDS
Alcohol abuse
Blood loss anemia
Chronic pulmonary disease
Coagulopathy
Congestive heart failure
Deficiency anemia
Depression
Diabetes
Fluid and electrolyte disorders
Hypertension
Hypothyroidism
Liver disease
Lymphoma
Metastatic cancer
Obesity
Other neurological disorders
Paralysis
Peptic ulcer disease excluding...
Peripheral vascular disorders
Psychoses
Pulmonary circulation disorders
Renal failure
Rheumatoid arthritis/collagen...
Solid tumor without metastasis
Valvular disease
Weight loss
Baseline % of patients
2016 % of patients