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March 16, 2018

Sent Via Email

The Honorable Alex Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21224

RE: Bundled Payment Care Improvement Advanced

Dear Secretary Azar and Administrator Verma,

On behalf of the members of The Society of Thoracic Surgeons (STS), I am writing to seek clarification and provide feedback on the Bundled Payment Care Improvement (BPCI) Advanced request for application (RFA) announced on January 9, 2018. While we recognize that the program was announced as an RFA without comment, we hope the following feedback on this important program will help support our mutual goal of making more Advanced Alternative Payment Models (APMs) available to specialty medicine.

Founded in 1964, STS is an international not-for-profit organization representing more than 7,400 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

General Comments

STS appreciates that the Center for Medicare and Medicaid Innovation (Innovation Center) continues to work to develop new and Advanced APMs as defined under regulations implementing the Medicare Access and CHIP Reauthorization Act. We also appreciate that the Innovation Center is focusing on developing payment models for specialty medicine where no Advanced APM options exist. STS is excited by the prospect of value-base payment that will help to improve care delivery for our patients. Through our quality measurement, public reporting, and other quality improvement initiatives using the STS National Database, we remain on the forefront of quality assessment and improvement. We continue to seek opportunities to work with the administration to share our expertise and ideas on how to build a payment model that truly recognizes health care quality.

That is why we were so disappointed to see the Innovation Center put forward a new APM, in the form of BPCI Advanced, that failed to build on any of the insight and feedback we have offered in response to previous payment models like our comments on the Coronary Artery Bypass Graft (CABG) Episode Payment Model (EPM). To be clear, STS opposed the implementation CABG EPM, not because we object to value-based payment, but because the CABG EPM would neither have lowered costs nor improved quality. For example, the CABG EPM used "all-cause mortality" as its primary quality metric. Thanks in large measure to STS-led quality interventions, the mortality rate for the CABG procedure is less than two percent. This means that the CABG EPM would not have been able to distinguish among the top 98 percent of the CABG procedures performed in the United States. CMS acknowledged this limitation in subsequent rulemaking. However, per the discussion below, we have found the quality metrics for the CABG episode in the first round of BPCI Advanced to be similarly limited.

The strength of the BPCI Advanced program is its ability to grow and adapt over time. While we wish we could have had more input on the initial episodes, we are encouraged that the BPCI Advanced program includes provisions that allow quality measures for each episode to evolve. We are actively working with CMS contractors on new measures for the CABG episode and were heartened by conversations with Innovation Center staff who indicated that they are open to working with us to improve the program. However, given how significantly the Innovation Center and the Department of Health and Human Services, as a whole, is invested in the success of the first round of BPCI Advanced applications, we would have hoped for a more thorough first round model.

While we appreciate the urgency to operationalize the BPCI Advanced program, the application and implementation process is aggressive. The accelerated timeline in conjunction with a lack of clarity on the logistical nuances of the program will certainly be a disincentive for physicians to participate in the model. The RFA, as written, is vague and does not provide adequate details on several components of the model, including firm details on benchmarking, the age of data, the quality measures attributed to each episode, and the MS-DRG exclusions. While we understand that submitting an application does not commit an organization to participate in the program, without clear guidance on the complex details of this program, we fear that potential participants, including cardiothoracic surgeons, will not seek to apply to the program without the necessary information. Therefore, **we encourage the Innovation Center to provide additional clarity on these important topics and reconsider the current timeline in order to ensure that model successfully encourages maximum participation. Without the release of a more detailed framework that addresses the complex details related to this model, we urge CMS to delay the application date and model timeline until these answers can be provided to potential participants.**

We regret that the Innovation Center did not consider our voluminous feedback on previous proposals before implementing this model and we are, nevertheless, cautiously optimistic about the future of BPCI Advanced. Although we have actively promoted the BPCI Advanced application to our membership, it would be a mistake to misinterpret a lack of enthusiasm for BPCI Advanced as a lack of enthusiasm for value-based payment. STS members are ready, willing, and (to the extent that their hospitals or practice groups are supportive) able to enter into APMs as soon as they become available to them. However, for the reasons discussed below, the cardiothoracic surgery-related episodes in BPCI Advanced may not be successful in this round of applications. Further, it would be a mistake to make these bundled payments mandatory at least until these issues are resolved.

Risk Adjustment Methodologies

Defining the benchmarks used to assess a physician's performance is essential to ensuring participant success in the new model. STS is concerned that the RFA does not provide specific details regarding the risk adjustment algorithms to be used, not only in the clinical episodes, but the target pricing and retrospective payment for each clinical episode.

STS appreciates the background information on clinical episode development as outlined in the "Target Price Specifications: Model Years 1 and 2" document published in February 2018. In it, the Innovation Center states that the clinical episodes in BPCI Advanced are created from CMS standard payments that reflect the cost of services following the removal of variations in spending due to geographical adjustments within the CMS payment systems. While we appreciate that the Innovation Center will risk adjust for the geographic considerations within the clinical episode payments, **we urge the Innovation Center to provide additional information and guidance on the risk adjustment methodology to be used for each clinical episode within the BPCI Advanced program.**

Additionally, we understand that the Target Pricing and subsequent retrospective payments for acute care hospitals (ACH) are established using a risk-adjusted prospective algorithm that includes patient composition, spending patterns compared to peer ACHs over time, and historical Medicare resource use expenditures. We also understand that the physician group practice (PGP) participants' target prices include the hospital benchmark price where the anchor stay or anchor procedure occurs, the PGP's historical risk-and peer-standardized efficiency, and the case mix. However, we maintain that it is also imperative that risk adjustment include clinical risk, socioeconomic status, and the cost of post-acute care when risk adjusting both the prospective target price and the retrospective prices following the model. These components will significantly impact the overall cost and quality components of the target price and retrospective payments for each clinical episode. Therefore, w**e urge CMS to provide greater detail on the risk adjustment methodology that will be used in calculating the target price and retrospective payments for both ACHs and PGPs.**

Age and Sharing of Data

The RFA states that three years of historical Medicare claims data will be released for Medicare fee for service beneficiaries during the determination of the target price. Older data will not provide an accurate representation of the applicant and therefore, will alter the appropriate target price and subsequent payment for a participant. **Therefore, we urge CMS to provide greater clarity as to the age of the data that will be released.**

Further, we appreciate that CMS has recognized the value of sharing cost information with entities participating in BPCI Advanced, as it has done with similar payment proposals in the past. We have long sought to combine Medicare claims information with the robust quality data contained in the STS National Database to facilitate the type of real value-based payment CMS is hoping to achieve. Unfortunately, Section 105(b) of MACRA, which requires CMS to provide "qualified clinical data registries" (QCDRs) with access to Medicare data for purposes of linking such data with clinical outcomes data and performing scientifically valid analysis or research to support quality improvement

or patient safety, has not been implemented according to Congressional intent. To date, The STS National Database, a QCDR, has not been able to access the data promised under statute.

Although BPCI Advanced will allow participants to access their own claims data, it is not clear to us that hospitals and providers have the resources or expertise to analyze these data to more effectively implement an APM. More importantly, hospitals already allocate considerable resources to supporting data managers to facilitate clinical data reporting to the STS National Database.

Because the hospitals have already invested these resources in a superior data tool to evaluate their own quality and performance, the hospitals themselves may prefer to have the claims data processed elsewhere. Further, the utility of the claims data is amplified exponentially by combining clinical and claims data sources.

Early results from similar BPCI policies have been reported, and we hope that CMS will learn from the experiences of the hospitals that have already engaged in similar data-sharing programs. The BPCI initiative actually recognized the need for a facilitator convener – an entity that serves an administrative and technical assistance function for one or more designated awardees/awardee conveners, and who would not have an agreement with CMS, bear financial risk, or receive any payment from CMS. In the recently-released BPCI report, one interviewee stated,

> I would say that probably one of the smartest things that CMS did was permit the facilitators to be part of this program because, at least my observation, it is just too heavy of a lift for individual hospitals to both undertake the care redesign that's necessary over the long run, as well as understand and interpret all of the data and the policies of the program.[1]

As CMS has already acknowledged the utility of data analysis, we hope future versions of this proposal will allow participants to benefit from the best information (and resources) available to them.

Quality Measures

Identifying appropriate quality measures is a vital component of the success of BPCI Advanced model. During the development of the CABG EPM, the Innovation Center used all-cause mortality as the primary quality measure. However, after a discussion requested by the STS, the Innovation Center recognized that this measure was not an appropriate or accurate measure to determine the quality of the episode. CMS and Yale University have worked with members of STS in the past to identify more appropriate measures and we are in active conversations with CMS and Yale on new 30 and 90-day CABG measures. However, BPCI Advanced includes a number of episodes that are relevant to cardiothoracic surgery, most (if not all) of which could benefit from our list of National Quality Forum-endorsed quality measures and robust clinical data. **We urge CMS to work with the relevant specialties to identify more appropriate quality measures across the BPCI Advanced program.**

MS-DRG Exclusions

[1] Group, Lewin. "CMS Bundled Payments for Care Improvements Initiative Models 2-4: Year 2 Evaluation and Monitoring Annual Report." August 2016: 89.

STS appreciates that the Innovation Center has provided a list of MS-DRG Exclusions from the Clinical Episodes List. However, we are concerned that this information was not published until one business day prior to the application deadline. The exclusion list is an important nuance within the program. Waiting to publish it so late within the RFA process provided significant hesitation to participants to move forward with the application process.

Currently, the BPCI Advanced website provides a definition list that outlines the 29 episodes and associated DRGs along with the MS-DRG Exclusion List. As the Innovation Center continues to publish the nuanced specifics within the program **we urge CMS to provide guidance as to what will happen to DRGs that are not captured in the definitions list or the exclusions list. Further, we urge the Innovation Center to provide additional clarity as to the methodologic pathway for an episode that 1) is triggered because of an admission for an MS-DRG (appropriately noted on the definitions list), and 2) a second admission occurs during the original 90- day episode window of the first encounter, but for a totally different MS-DRG (which may fit the definitions for a different and distinct episode)**

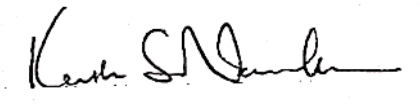
Employed Arrangements

Another complication that CMS may not have considered in announcing this proposal is the amount of agency individual cardiothoracic surgeons will have in their decisions to enter into an APM. While a good deal of effort has been spent by Innovation Center staff to educate our members on BPCI advanced, many of those members are not in a position to be able to opt in to BPCI Advanced at this time. This is not to say that we believe that BPCI Advanced in its current form should be implemented as a mandatory model. Rather, since many of our members are hospital-employed or part of other employment arrangements, additional education will be necessary to ensure that the whole health system is fully informed of these proposed changes in payment policy.

Conclusion

STS appreciates the Innovation Center's commitment to advancing APMs. We look forward to obtaining clarification on these important topics to better understand how cardiothoracic surgeons can successfully participate in the new BPCI Advanced. Please direct any questions to Courtney Yohe, Director of Government Relations, at cyohe@sts.org or 202-787-1230.

Sincerely,



Keith S. Naunheim, MD
President