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June 17, 2022

Chiquita Brooks-LaSure, MPP Administrator Centers for Medicare & Medicaid Services (CMS) Department of Health and Human Services 7500 Security Boulevard Baltimore, Maryland 21244-1850

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation [CMS-1771-P]

Dear Administrator Brooks-LaSure,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,600 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

Payment and Related Policies under the IPPS

Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

Changes to Specific MS-DRGs

CMS reviewed its decisions in the FY 2022 rule related to the MS-DRG assignment approach to surgical ablation. This included a review of the two general "scenarios" for patients undergoing surgical ablation

- Open concomitant (combination surgical ablation (i.e., open surgical ablation performed during another open-heart surgical procedure such as mitral valve repair or replacement, aortic valve replacement, or CABG).
- Minimally invasive, percutaneous endoscopic, standalone surgical ablation.

In last year's analysis, CMS noted that its surgical hierarchy policy results in most open concomitant surgical ablation procedures to result in an assignment to:

- MS-DRG 228 (Other Cardiothoracic Procedures with MCC)
- MS-DRG 229 (Other Cardiothoracic Procedures without MCC)

Rather than creating new MS-DRGs, CMS in FY 2022 finalized an approach to revise the surgical hierarchy, ensuring that the case is assigned to the MS-DRG representing the most complex component of the combination procedure by sequencing MS-DRGs 231-236 (Coronary Bypass) above MS-DRGs 228 and 229.

CMS received a request to review the open concomitant surgical ablation MS-DRG assignments again but believes it is too soon after the surgical hierarchy changes to make further revisions. Therefore, CMS believes "more time is needed before considering to again review the MS-DRG assignment of cases reporting procedure code combinations describing open concomitant surgical ablations."

Open concomitant surgical ablation is an efficient and effective procedure that allows treatment of atrial fibrillation and another clinical pathology in one procedure. This decreases the risk of future readmissions, the need for future repeat catheter ablation procedures, and patient mortality. Data from the STS National Database, the world's premier clinical outcomes registry for adult cardiac surgery, indicates that patients with atrial fibrillation typically present as older with more comorbidities, indicating that CMS should want to mitigate as much needless risk as possible and need for subsequent care. However, while more efficient and safer, treating atrial fibrillation concomitantly with an aortic valve, mitral valve, CABG or any combination of these procedures requires far greater resources due to the need for additional specialized equipment, longer operating room times, and a longer length of stay.

For FY 2022, CMS addressed concomitant treatment of open atrial fibrillation by revising the surgical hierarchy for the MS-DRGs in MDC 05 and for concomitant surgical ablation and CABG. CMS finalized the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS-DRGs 233 and 234 and changed the titles of these MS-DRGs to "Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively." However, this change did not address the disparity in payment with concomitant surgical ablation and valve procedures (aortic mitral, aortic and mitral valve). STS is concerned that the CMS proposal to wait, to determine if the changes made to the surgical hierarchy in MDC 05 and the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS-DRGs 233 and 234, does not address the concomitant procedure issues as outlined above because there is still no incremental corresponding payment for concomitant procedures involving surgical ablation. The current solution, additional payment to the hospital for concomitant procedures that fall into the same MS-DRG increases administrative burden by requiring the hospital to petition CMS for additional reimbursement for each case as an outlier. This additional administrative and cost burden to the hospital is a disincentive to change practice patterns and ultimately may limit patient access to the procedures.

If CMS is unwilling to create new MS-DRGs for concomitant valve and surgical ablation procedures, then STS urges CMS to revise the groupings for valve procedures with surgical ablation by reassigning these procedures from MS-DRGS 219 and 220 to MS-DRGS 216 and 217. This reassignment would create clinical coherence for the procedures and address the issue of additional resource utilization ensuring that hospitals are adequately paid for these procedures.

Additionally, standalone percutaneous endoscopic surgical ablation procedures are a rapidly growing therapy indicated for highly symptomatic patients who have already failed medical management and/or percutaneous catheter ablation procedures. The standalone percutaneous endoscopic surgical ablation procedures are often performed as hybrid procedures involving both a surgical component and a catheter-based procedure, where the surgeon performs an endoscopic epicardial ablation, and an echocardiologist

performs a percutaneous catheter endocardial ablation. These hybrid procedures may be performed in the operating room or in a hybrid operating room, or the surgical portion of the procedure may be performed in the operating room after which the patient is moved to the cath lab for the catheter-based portion of the procedure. These procedures are typically provided on the same day. For FY 2022, CMS finalized their proposal to maintain the current structure of MS-DRGs 219 and 220 as opposed to reassigning cases describing standalone percutaneous endoscopic surgical ablation procedures from MS-DRGs 228-229 to 219-220.

STS remains concerned with the continued decrease in the relative weights for MS-DRGs 228 and 229. The proposed reduction (228 from 5.3303 to 4.9526 and 229 from 3.4402 to 3.3056) in relative weights for 2023 will result in relative weight reductions of greater than 30% in reimbursement for MS-DRGS 228 and 229, which has occurred over the past six years, while patient comorbidity status has stayed constant. The resource utilization for the endoscopic ablation procedures is significant due to the specialized equipment and the need for hybrid operating room or the possibility the procedure may be performed in two different locations. Although the length of stay associated with stand-alone percutaneous endoscopic surgical ablation is less than all cases in MS-DRGs 228 and 229, the increased costs associated with the percutaneous endoscopic surgical ablation procedures supports regrouping the identified ICD-10 procedure codes for endoscopic surgical ablation currently assigned to MS-DRG 229 into the higher paying MS-DRG 228.

Hospital Readmissions Reduction Program: Proposed Updates and Changes

Flexibility for Changes That Affect Quality Measures During a Performance Period in the Hospital Readmissions Reduction Program (HRRP)

In the FY 2022 IPPS final rule, CMS adopted a policy for the duration of the COVID-19 public health emergency (PHE) that allows it to suppress the use of quality measures or patients with a diagnosis of COVID-19 in the HRRP, as well as other hospital programs like the Hospital Acquired Conditions Reduction (HAC) program and the Hospital Value-Based Purchasing Program (VBP) calculations if it determines that circumstances caused by the COVID-19 PHE significantly affected those measures.

STS supports the flexibilities CMS has provided regarding the suppression of quality measure calculation in the hospital quality programs, specifically as it relates to patients with a diagnosis of COVID-19. However, STS seeks clarification on how these measures will be calculated once the PHE has ended. STS urges CMS to consider maintaining these provisions post-PHE as COVID-19 will continue to affect quality measurement.

Changes to the Medicare Promoting Interoperability Program

Electronic Prescribing Objective: Proposed Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure and Technical Update to the E-Prescribing Measure

Proposal to Require the Query of PDMP Measure

Beginning with the EHR reporting period in calendar year (CY) 2023, CMS proposes to require the Query of PDMP measure, which was previously voluntary, necessitating a "yes/no" response for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

STS does not support requiring attestation to the Query of PDMP measure. The reporting of this measure is reliant on widespread availability of built out, functional PDMPs that seamlessly connect with provider EHR systems to avoid additional burdens. Additionally, CMS is continuing to work with industry and Federal partners to advance common standards for the exchange of information between relevant stakeholders. Until CMS has finalized providing the necessary services for a useful PDMP, STS feels that mandatory reporting for this program is not yet reasonable or appropriate.

<u>Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality</u> <u>Programs—Request for Information</u>

CMS seeks input on key considerations in the following five specific areas that could inform its approach to using the measurement and reporting of healthcare disparities to advance healthcare equity.

Principles for Social Risk Factor and Demographic Data Selection and Use

CMS describes several types of social risk factor and demographic data that could be used to stratify measures to more accurately evaluate healthcare disparities. CMS also discusses the advantages and disadvantages of different sources of data for disparity reporting, including patient-reported data (the gold standard) and administrative claims data such as ICD-10 Z-codes. CMS expects to continue evaluating patient-reported sources of social risk and demographic information, but is also considering three other sources of social risk and demographic data that would allow it to report stratified measure results:

- Billing and Administrative Data: CMS discusses limitations in these data's usability for stratification analysis.
- Area-based Indicators of Social Risk Information and Patient Demographics: these indicators pool area-level information to create approximations of patient risk or describe the neighborhood or context that a patient resides in.
- Imputed Sources of Social Risk Information and Patient Demographics: these data sources use statistical techniques to estimate patient-reported factors, including race and ethnicity.

STS is deeply committed to the elimination of bias and disparities in healthcare in general and specifically in cardiothoracic surgery. While we appreciate CMS' goal of reducing healthcare disparities to advance health equity, we have concerns over the use of social risk information and patient demographics to measure physician or hospital performance. At this time, there are no widely adopted national industry standards for the collection of race, ethnicity, and language (REL) data or social determinants of health (SDOH) data. For example, the Office of Management and Budget (OMB) classifies race as: White, Black/African American, American Indian/Alaska native, Asian, native Hawaiian/other Pacific Islander; and ethnicity as Hispanic/Latino or non-Hispanic/Latino. While our organization utilizes the standards set by the Office of Management and Budget (OMB) in our own data collection efforts, we feel it is limiting and in need of modernization. OMB leading advocates have pointed out that existing standards do not account for the variation that exists within groups. As a result, racial and ethnic group disaggregation has been recommended as an important part of surveillance by researchers and policymakers in this field to resist homogenization of disparate groups.¹

¹ Kader, Farah, and Clyde Lanford Smith. "Participatory Approaches to Addressing Missing COVID-19 Race and Ethnicity Data." *International Journal of Environmental Research and Public Health* 18, no. 12 (2021): 6559.

Similar standardization challenges exist for the collection of SDOH data. In July 2021, the Office of the National Coordinator for Health Information Technology (ONC) included SDOH data elements in the United States Core Data for Interoperability version 2 (USCDIv2), however, the use of USCDIv2 is voluntary and adoption is not widespread. Additionally, area-based indicators, such as zip codes, are a more readily available, commonly used approach to account for SDOH. However, zip code areas are constructed to achieve efficient mail delivery, not to identify areas with similar sociodemographic status (SDS) and socioeconomic status (SES) features for biomedical research. Zip codes may include several dozen to more than a hundred thousand individuals, and they typically encompass far too broad an area to be considered a homogeneous SDS/SES grouping. Popular area-based indicators include those developed by the Area Deprivation Index (ADI). The ADI (available through the Neighborhood Atlas), was developed two decades ago and subsequently refined, adapted, and validated to the census block group/neighborhood level at the University of Wisconsin-Madison. This is widely regarded as one of the most comprehensive overall indicators of SDS/SES currently available, with 17 variables encompassing multiple SDOH domains.²

Given the challenges of inconsistent collection of health equity data, it cannot be accurately used to measure and compare performance. STS believes that there needs to be industry-accepted national standards in place prior to required collection and performance measurement of health equity data. Instead, voluntary reporting of health equity data could be beneficial in helping to establish industry-accepted standards. Moreover, STS would be interested in collaborating with CMS to help develop health equity data standards using the STS National Database which is continuing to develop and test new methodologies to capture health equity data. STS has recently acquired the ability to geocode a large majority of data records in the STS Adult Cardiac Surgical Database (ACSD), beginning with entries from 2008 and contingent only upon on the availability of a patient's street address. Through this mechanism, a census block group- level ADI score is now available for millions of STS ACSD records and will be used in future studies of race, ethnicity, and SDS/SES risk factors.

Continuing to Advance Toward Future Digital Quality Measurement

CMS seeks feedback on continued advancements to digital quality measurement and approaches to optimize data flows to support Fast Healthcare Interoperability Resources (FHIR)-based eCQM data retrieval and reporting across quality reporting programs, and specifically for the Hospital IQR Program. CMS recognizes that data sources for digital quality measures may include registries.

STS maintains the STS National Database, which was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. The Database has four components, each focusing on a different area of cardiothoracic surgery—Adult Cardiac Surgery, Congenital Heart Surgery, General Thoracic Surgery, and Mechanical Circulatory Support. Currently, the Adult Cardiac Surgery Database (ACSD) alone contains more than 7 million cardiac surgery procedure records and has more than 3,800 participating physicians, including surgeons and anesthesiologists, representing more than 90% of all adult cardiac surgery hospitals across the United States and Canada.

The measures contained in the STS National Database are National Quality Forum (NQF)-endorsed and were developed specifically for cardiothoracic surgeons by cardiothoracic surgeons to measure relevant

² Shahian DM, Badhwar V, O'Brien SM, et al. Social Risk Factors in Society of Thoracic Surgeons Risk Models. Part 1: Concepts, Indicator Variables, and Controversies. Ann Thorac Surg. 2022;113(5):1703-1717. doi:10.1016/j.athoracsur.2021.11.067

and necessary data for the purpose of quality improvement. However, the measures in the STS National Database are largely not included in CMS quality reporting programs due to the required adjustments that would be needed to fit the CMS models. For example, while CMS uses percentage rates to compare performance, the STS National Database uses a composite quality rating system to illustrate performance. The rating system adjusts for both performance rate and the corresponding confidence intervals to give a more accurate representation of performance.

STS supports CMS' effort to move towards digital quality measurement and appreciates CMS' recognition of the role that registries can play in this process. However, we encourage CMS to consider using more sophisticated statistical analyses, or alternative methods of representing performance measurement data that are more reflective of those employed by registries, to allow for better differentiation between providers and more relevant quality measurement. STS recognizes CMS' efforts to create alternative payment models that allow for variation in performance measurement and reporting such as BPCI-Advanced which is the largest episode-based bundled payment model, however, we continue to have issues adjusting our measures to meet the restrictions of the model.

Thank you for the opportunity to provide these comments. Please contact Courtney Yohe Savage, Vice President of Government Relations, at cyohe@sts.org or 202-787-1222 should you need additional information or clarification.

Sincerely,

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John H. Calhoon, MD President