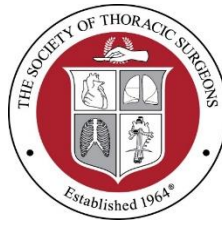


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September 19, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: [CMS-1717-P] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma,

On behalf of the members of The Society of Thoracic Surgeons (STS), I write to provide comments on the Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule published in the *Federal Register* on August 9, 2019. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,200 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.

Short Inpatient Hospital Stays ("2 Midnight Rule")

CMS reviewed its policies related to the 2 Midnight Rule for determining when an inpatient admission is considered "reasonable and necessary" for Part A payment. If a procedure is removed from the Inpatient Only (IPO) list it is then "subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs)" that may also then refer providers to Recovery Audit Contractors (RACs). CMS proposes a one-year exemption from RAC review for procedures that have been removed from the Inpatient Only list beginning in CY 2020. CMS notes that BFCC-QIOs might still review claims to provide education but claims cannot be denied for site-of-service or referred to a RAC. CMS specifically seeks input on the one-year time frame and whether a shorter or longer exemption period would be appropriate.

STS agrees with CMS that procedures that are removed from the IPO list should be exempt from RAC reviews for a designated period of time. It is difficult for physicians to determine how long any patient is going to be in the hospital and, initially, physicians may determine that there are still a number of patients that will need inpatient admission/care for procedures that are newly removed from the IPO

list. It is important for physicians and hospitals to begin adapting to the variances that may occur for these patients. It may also take time to identify and define the requirements and documentation related to these newly transitioned patients to determine when it is medically necessary for the patient to be in the hospital for > 2 midnights.

STS also believes that it will be important to get enough data for codes that are removed from the IPO list to analyze and determine whether or not the removal of the code from the IPO list was an appropriate decision. It will take more than one year of collecting data and analyzing it to obtain meaningful feedback to make these determinations and it is unreasonable to allow RAC reviews of these codes until such data is collected. **STS urges CMS to establish a two or three-year exemption from RAC review for codes that have been removed from the IPO list to allow for the flexibility of a gradual transition of these patients from the inpatient setting and time to collect data to ensure that the change is a good one.**

Covered Surgical Procedures Designated as Office-Based

CMS proposes to permanently designate the following codes as office-based for CY 2020.

TABLE 29.—ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2020

CY 2020 CPT Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	Proposed CY 2020 ASC Payment Indicator*
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed	G2	P3*
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	G2	R2*

STS is concerned with the proposal to designate the two bronchoscopy codes related to air leaks (31634, 31647) as permanent office-based procedures for CY 2020. These would be the only two bronchoscopy codes designated as office-based codes. Most ongoing air leaks occur in inpatients. They require a tube to continually evacuate the air in the pleural space until the source of the air leak is identified and stopped. This is supported by the typical patient defined in the RUC database for these codes. The typical patient for code 31634 is a patient with pneumonia and respiratory failure on a mechanical ventilator that develops a pneumothorax with a persistent air leak. The typical patient for code 31647 is a patient with a persistent air leak after a surgical resection that has not resolved with chest tube to suction for several days.

Per the RUC database, code 31634 represents a lower volume procedure with frequencies of 156 for 2017 and 153 for 2019. The RUC database claims data for 2018 also show that 79.7% of these procedures were performed in the inpatient hospital setting and 20.3% were outpatient hospital (on

campus) procedures. 2012 Medicaid data from the RUC database show that 91.50% of the procedures were inpatient procedures and 8.10% were outpatient hospital.

Code 31647 also represents a lower volume procedure per the RUC database with frequencies of 255 for 2017 and 317 for 2018. The RUC database claims data for 2018 show that 85.8% of procedures performed on Medicare patients were done in the inpatient hospital setting and 14.20% were performed in the outpatient hospital (on campus) setting. There is no data available for Medicaid.

STS disagrees with CMS' proposal to designate codes 31634 and 31647 as permanent office-based procedures and recommends that CMS keep the current ASC payment indicators of A2 for CPT code 31634 and G2 for CPT code 31647.

Requirement to Make Hospital Standard Charges Public

Hospitals are required to publish the cost of their standard charges. Under this proposal, hospitals will also be required to display the negotiated rates for all items and services, including the services provided by physicians and non-physicians employed at the hospital.

Since the inception of the Alternative Payment Model (APM) program within the Medicare Access and CHIP Reauthorization Act (MACRA), STS has tried to identify the appropriate benchmarks needed to determine appropriate financial risks required to develop a physician-focused APM. Without such data, we have been unsuccessful in bringing our value-based payment ideas to fruition. We believe that the release of hospital charge data and negotiated rates, when aggregated, may be beneficial in providing appropriate benchmarks for APM development. However, **we urge CMS to be careful in how this data is disseminated to prevent any additional distortions in the market.** By making hospital-based providers' salaries public, there is a risk of creating unfair negotiating practices between hospitals and providers. In addition, while cost transparency is important, value transparency should be the ultimate goal. Per the comments below, we hope CMS will prioritize policies that will help patients select the best value care—rather than the cheapest care.

Request for Information on Price Transparency

As CMS continues to improve policies related to price transparency, the agency has requested information on ways to improve the availability of existing quality of care information when developing price transparency tools. Specifically, CMS seeks information regarding the type of existing quality of care information that is most beneficial to patients and ways CMS can help providers and third parties create patient-friendly ways for this information to be disseminated.

STS appreciates the agency's efforts to create greater transparency on the cost of health care. While CMS continues its efforts of providing the patient with data they need to make the most appropriate medical decisions, it is of paramount importance that patients understand the value of healthcare, as a product of quality over cost. To better facilitate value transparency, the proposed rule attempts to address problems with the agency's ability to make publicly available information on the cost side of the value equation: namely, making negotiated hospital prices available for items and services. CMS has struggled with publicly communicating the quality side of the value equation in a way that can be useful to patients, even when reliable data exists. STS welcomes the opportunity to assist CMS in defining and

calculating value by marrying the Medicare claims data with outcomes measures collected in the STS National Database™. As a national leader in health care transparency and accountability, STS believes that the public has a right to know the quality of surgical outcomes¹. As a result, the Society established the STS Public Reporting initiative in 2010. This program allows participants in the STS National Database to voluntarily report their surgical outcomes on the STS website, the Consumer Reports website, or both. These star ratings were even published in Consumer Reports.

The STS National Database™ was established in 1989 as an initiative for quality assessment, quality improvement, and patient safety among cardiothoracic surgeons. The Database has four components—the STS Adult Cardiac Surgery Database, the STS General Thoracic Surgery Database, the STS Congenital Heart Surgery Database, and the STS Intermacs Database (mechanical circulatory support). The fundamental principle underlying the STS National Database initiative has been that surgeon engagement in the process of collecting information on every case, combined with robust risk adjustment based on pooled national data and feedback of the risk-adjusted data provided to the individual practice and the institution, will create the most powerful mechanism for change and improvement in the practice of cardiothoracic surgery for the benefit of patients. In fact, published studies indicate that quality of care has improved as a result of research and feedback from the STS National Database.^{2 3 4 5 6 7} The STS National Database has facilitated advancements in many aspects of health care policy, including NQF approval of 34 quality measures, public reporting of health care quality measures in collaboration with Consumer Reports, facilitation of medical technology approval and coverage decisions, and fostering cost savings that help cardiothoracic surgeons find the most efficient and effective way to treat patients.

The Society is in agreement with CMS that the most valuable tool for patients who are interested in making proactive choices about their health care is value transparency. If CMS were to adequately implement Section 105(b) of MACRA (Pub. L. 114-10), we would have access to Medicare claims data, or the cost denominator of the value equation. Unfortunately, the programs CMS has offered to implement that section of statute are not working.

Section 105(b) of MACRA 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 risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety. Unfortunately, neither of the pathways identified by CMS as methods to access Medicare claims data under section 105(b) fulfill the intended purpose of the statute. CMS asserts that QCDRs currently can

¹ The Society of Thoracic Surgeons. STS Public Reporting Online. <https://publicreporting.sts.org>. Accessed March 20, 2018.

² ElBardissi AW, Aranki SF, Sheng S, et al. Trends in Isolated Coronary Bypass Grafting: An Analysis of The Society of Thoracic Surgeons Adult Cardiac Surgery Database. *J Thorac Cardiovasc Surg* 2012;143:273-281.

³ Speir AM, Rich JB, Crosby IK, et al. Regional Collaboration as a Model for Fostering Accountability and Transforming Health Care. *Semin Thorac Cardiovasc Surg* 2009;21:12-19.

⁴ LaPar DJ, Speir AM, Crosby, IK, et al. Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs. *Ann Thorac Surg* 2014;98:527–533.

⁵ Osnabrugge RL, Speir AM, Head SJ, et al. Cost, Quality, and Value in Coronary Artery Bypass Grafting. *J Thorac Cardiovasc Surg* 2014;148:2729-2735.

⁶ LaPar DJ, Rich JB, Isbell JM, et al. Preoperative Renal Function Predicts Hospital Costs and Length of Stay in Coronary Artery Bypass Grafting. *Ann Thorac Surg* 2016;101:606-612.

⁷ LaPar, DJ, Speir AM, Crosby IK, et al. Postoperative Atrial Fibrillation Significantly Increases Mortality, Hospital Readmission, and Hospital Costs. *Ann Thorac Surg* 2014;98:527-533.

request Medicare claims data through the Research Data Assistance Center (ResDAC) data request process. This position ignored the fact that Section 105(b) is intended to provide QCDRs with access to Medicare data for quality improvement purposes, not just clinical research, and that the broad and continuous access needed for quality improvement purposes is fundamentally different than the access to Medicare data for research purposes provided by ResDAC.

In subsequent rulemaking, CMS decided to treat QCDRs as “quasi-qualified entities” for purposes of obtaining access to Medicare claims data for quality improvement, but maintained that QCDRs should use the ResDAC application process for research requests. The quasi-qualified entity program covers only the “quality improvement” portion of a QCDR’s access to claims data. If the same QCDR wanted to facilitate research combining cost and claims information, that QCDR would have to submit a separate application to ResDAC. In fact, if the QCDR already had the claims data in question through the quasi-qualified entity program, it would still need to apply and pay ResDAC for the same data. The ResDAC application is duplicative, time-consuming, and costly, with a significant lag between application approval and delivery of data.

At the same time, every new payment model released by CMS and the Center for Medicare and Medicaid Innovation includes a provision that hospitals and qualified participants should be able to access their own claims information and any additional information deemed necessary by the participant. Even this proposed rule attempts to make cost information more readily available to the public. Clearly, CMS understands the value of price transparency in health care, yet it is failing to implement statute that speaks to that purpose.

If CMS is truly interested in using its existing authority to provide information on the value of health care to the Medicare population, it will take another look at how it is implementing Section 105(b) of MACRA. Absent that ideal scenario, CMS should provide claims data to the providers with a straightforward breakdown of inpatient costs, provider costs, post-acute care costs, home health costs, readmission rates, and costs. Given these data and local or regional (not necessarily national) benchmarks, providers (and patients) will have an idea where care can improve and where there are opportunities to improve efficiency. If benchmark prices from big data are created, the methodology employed should be clear and include relevant stakeholders in the development.

Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs): Proposed Revision of the Definition of “Expected Donation Rate”

CMS proposes to update the definition of expected donation rate per 100 eligible deaths to “the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and donation service areas (DSAs). This rate is adjusted for the distribution of age, sex, race, and cause of death among eligible deaths” The proposed definition is consistent with the definition of the Scientific Registry of Transplant Recipients (SRTR).

We appreciate that the proposed definition is a step toward harmonizing standards with those of the SRTR. However, we encourage CMS to carefully look at the current OPO infrastructure and work to ensure that all OPOs are held to a high standard in order to ensure that our patients receive the life-changing organs they need. Because there is little to no competition between OPOs, should an OPO not be performing as expected, there are no alternatives for organ recovery. As a result, our patients may

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not receive the transplants they need. Sadly, this monopoly system does not hold OPOs accountable to uphold necessary standards to allow for better organ procurement.

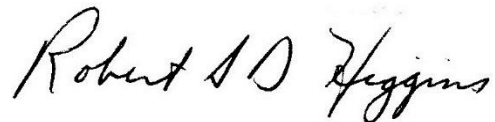
Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

CMS is proposing new prior authorization requirements for five outpatient department (OPD) services, including vein ablation.

While the OPD services proposed for prior authorization requirements fall outside the scope of cardiothoracic surgery, STS remains concerned about the overuse of prior authorization as a way to delay needed care. Prior authorization requirements are becoming increasingly burdensome for providers and are delaying needed treatment for our patients. **We urge CMS to be judicious in its use of prior authorization requirements.** Before any prior authorization requirements are implemented, it is imperative to consider how these requirements will increase the administrative burden for providers and patients, and most importantly, how prior authorization will delay the appropriate care needed for our patients and your beneficiaries.

Thank you for the opportunity to provide these comments. Please contact Courtney Yohe Savage, STS Director of Government Relations, at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink that reads "Robert S.D. Higgins". The signature is written in a cursive style with a large, prominent "R" and "H".

Robert S.D. Higgins, MD
President