STS Headquarters
633 N Saint Clair St, Suite 2100
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org

Washington Office
20 F St NW, Suite 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacy@sts.org

September 22, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: [CMS-1736-P] Proposed Rule Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Dear Administrator Verma,

On behalf 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 12, 2020. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,500 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.

IX B. Proposed Changes to the Inpatient Only (IPO) List

Since 2000, the Centers for Medicare and Medicaid Services (CMS) has maintained an "Inpatient Only" list (IPO), identifying services that are non-payable under the Medicare Outpatient Prospective Payment System. In order to remove a service from the IPO, CMS historically reviews a list of criteria. For CY 2021, CMS proposes to commence a transition of all services off of the IPO, beginning in CY 2021 with all musculoskeletal procedures.

STS is concerned that the complete elimination of the IPO, even with the proposed transition period, could lead to unintended consequences and jeopardize patient safety. First, while we agree that our members select the site of service to perform a procedure based on the needs of the patient, we are concerned that the elimination of the IPO will be used by payers to force procedures into the outpatient setting solely for cost reasons. We also have concerns that procedures that are inherently high risk and require the use of the operating room and inpatient hospital resources may not always meet the 2 midnight rule. The IPO list ensures that inherently high risk procedures can be performed on an inpatient basis, regardless of the hospital length of stay, without the increased risk of medical review. While most inherently high risk cardiothoracic surgery procedures will meet the 2 midnight rule, we have significant concerns that once these procedures are subject to the 2 midnight rule and CMS begins reviews and audits for payment for these procedures in the inpatient setting that those types of

procedures will put physicians and the hospital at risk for increased scrutiny and possible penalties for appropriate patient care. Even with the two year moratorium on site of service reviews for procedures that come off the IPO, we do not believe that CMS has provided adequate safeguards for hospitals and physicians from being subjected to harsh payer tactics that could interfere with the patient-physician relationship and selecting site of service based on what is best for the patient. Elimination of the IPO list needlessly creates increased compliance and audit risk for procedures that clearly need to be done as inpatient procedures.

Second, CMS' proposal to create Ambulatory Payment Classifications (APCs) for all codes that come off of the IPO list is very concerning. CMS did not provide sufficient detail in the rule as to how they plan to create and price new APCs. Many procedures that are on the IPO list will not fit into existing APC criteria without disrupting the clinical and cost coherence of the APC. For specialties like cardiothoracic surgery where the majority of procedures are included on the IPO list due to their inherent high complexity, CMS has not provided any information on how they will transition and manage these codes ensuring patient safety without putting the physician and hospital at risk. CMS also indicates that the influx of procedures could cause changes in the geometric mean as those procedures start to populate the pricing data for those APCs and have offered little information as to how they will manage this change. The process that CMS currently has in place, to consider removal of procedures from the IPO, works. It allows for adequate review of criteria that take patient safety and new clinical practice into account. It is not clear to us what policy goal has been achieved if CMS will start to pay in the outpatient setting for a procedure that cannot meet the criteria of "*most outpatient departments are equipped to provide the services to the Medicare population.*"

STS believes the current criteria for removal from the IPO list are reasonable and do not prevent a barrier to providing services in the outpatient setting for procedures when that becomes clinically appropriate. Because the IPO serves as a safeguard against unnecessary site of service audits and bad payer behaviors, STS recommends that CMS does not finalize its proposal to begin elimination of the IPO and instead continues to review procedures, as appropriate, for removal from the IPO based on the current criteria. In the event that CMS *does* finalize its proposal to begin the elimination of the IPO, because of the clinical and resource intensity of the procedures our members provide for patients, STS recommends that CMS extend the transition period allowing them time to review data on transitioned codes to ensure that it is not inadvertently impacting patient safety or payer behavior or increase the compliance risk for physicians and hospitals. If the policy is finalized, STS also recommends that CMS delay the removal of cardiothoracic procedures from the IPO until the final year of transition.

In addition, CMS has previously exempted from RAC reviews those procedures that have been removed from the IPO. 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. It will also be important that CMS has a clear understanding of which procedures may still require hospital inpatient resources, but do not meet the 2 mid-night rule so that they are not subject to RAC review.

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 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 three or four-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.

X. B. Proposed Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A

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. CMS established a policy with "a *benchmark* providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation;" in addition, admissions for services on the inpatient only list would be considered appropriate.

CMS also previously finalized the 2 midnight *presumption* and contrasts the 2 midnight presumption against the 2 midnight benchmark noted above.

- The 2 midnight *benchmark* represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment. The starting point is when the beneficiary begins receiving hospital care either as a registered outpatient or after inpatient admission.
- The 2 midnight *presumption* relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2 midnight presumption. For the 2 midnight presumption, the "clock" starts at the point of admission as an inpatient.

CMS discusses its approach for determining whether the 2 midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Part A payment. For stays spanning less than 2 midnights after admission, the admission would not be subject to the presumption, but may still be appropriate under the 2 midnight benchmark, which CMS continues to believe "gives appropriate consideration to the medical judgment of physicians and also furthers the goal of clearly identifying when an inpatient admission is appropriate." STS urges CMS to clearly delineate and create benchmarks for services where hospital resources are necessary for inherently high risk procedures but may not meet the 2 midnight rule. This ensures that these services are recognized and not unduly subject to review.

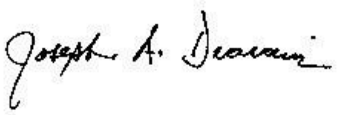
XVII. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

During CY 2020 rulemaking, finalized a new OPPS prior authorization process. In that rulemaking cycle, CMS discussed concerns about the higher than expected volume increases for five general categories of services, all of which it supposed were attributable to performance as a cosmetic procedure: blepharoplasty, botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. Here, CMS is expanding the list of categories subject to prior authorization to (a) Cervical Fusion with Disc Removal; and (b) Implanted Spinal Neurostimulators. As CMS had proposed last year, they would give providers until July 1st to prepare for the addition to the prior authorization list.

STS reiterates its concerns about the implementation of prior authorization policies that put undue administrative burden on providers and patients. While the outpatient department (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. Furthermore, using increase in procedural volume as a criterion for adding a procedure to the OPD prior authorization list is arbitrary and ignorant to clinical need. 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, Director of Government Relations, at cyohe@sts.org or 202-787-1222 should you need additional information or clarification.

Sincerely,



Joseph A. Dearani, MD
President