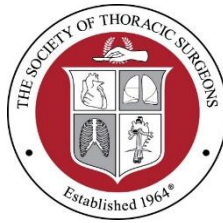


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September 15, 2025

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

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency [CMS-1834-P]

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Calendar Year (CY) 2026 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule. Founded in 1964, STS is a not-for-profit organization representing more than 7,800 surgeons, researchers, and allied healthcare 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.

Proposal to Eliminate the Inpatient Only (IPO) List

CMS proposes to eliminate the IPO list over a three-year transitional period that will begin in CY 2026, with the list being fully eliminated by January 1, 2029. To effectuate this policy, CMS proposes to eliminate the criteria for removing policies from the IPO list. However, if CMS were not to finalize the elimination of the IPO list, CMS seeks comment on whether it is more appropriate to update the list of criteria for removal. The first group of services to be eliminated will be Musculoskeletal Services in part due to Comprehensive Ambulatory Payment Classifications (C-APCs) for musculoskeletal services that will help to facilitate the transition.

STS strongly opposes CMS' proposal to eliminate the Inpatient-Only (IPO) list entirely. The IPO list provides essential patient safeguards by ensuring that highly complex, resource-intensive procedures are performed in the appropriate inpatient setting, where patients have access to the full scope of perioperative support, clinical expertise, and postoperative monitoring necessary to achieve safe and effective outcomes.

Thoracic and cardiac surgical procedures are among the most complex interventions, often involving high-risk patients with multiple comorbidities. These patients require specialized equipment, intensive monitoring, and immediate access to critical care resources, which may not be guaranteed in the outpatient environment. The IPO list has historically provided a clear, clinically grounded framework for protecting patient safety and maintaining high standards of care.

We are concerned that removing the IPO list would:

- Jeopardize patient safety by creating financial and operational incentives for payers and facilities to inappropriately shift complex surgeries to outpatient settings.
- Erode clinical decision-making by replacing established clinical safeguards with payer-driven site-of-service determinations that prioritize cost over quality.
- Introduce new compliance risks by exposing inherently inpatient procedures to the 2-midnight rule and subsequent audits.

The elimination of the IPO list could be used by payers to force procedures into the outpatient setting solely for cost reasons, without the appropriate safeguards in place to protect patients. Additionally, we are concerned that inherently high-risk procedures requiring use of the operating room and inpatient hospital resources may not always meet the 2-midnight rule, a Medicare standard used to determine whether a patient qualifies for inpatient admission and reimbursement. The 2 mid-night rule specifies that hospital stays expected to cross two midnights are considered inpatient; however, complex procedures often require extended recovery and monitoring that may not fit neatly into this timeframe. When such procedures do not meet the 2-midnight rule, hospitals may face audits or denials of payment, potentially discouraging appropriate inpatient care and threatening patient safety.

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. 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. Diminishing the IPO needlessly creates increased compliance and audit risk for procedures that clearly necessitate being inpatient procedures.

Most importantly, STS is concerned for the health and safety of patients and feels it is necessary that the IPO list be maintained to ensure that patients are receiving services in the appropriate setting of care.

While CMS suggests that C-APCs could help facilitate a transition, such a payment policy does not substitute for the rigorous clinical standards embedded in the IPO list. Surgical decision-making should be guided by patient need and clinical appropriateness, not by financial incentives or administrative convenience.

STS urges CMS to maintain the IPO list. If CMS does not finalize its proposal to eliminate the IPO list, STS would support an alternative approach to modernize and clarify the criteria for removal, provided that such criteria are rooted in patient safety, clinical evidence, and expert consensus.

Proposed Additions to Ambulatory Surgical Center (ASC) Covered Surgical Procedures and Covered Ancillary Services

For CY 2026, CMS proposes to revise the ASC Covered Procedures List (CPL) criteria, modifying the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, CMS is proposing to add 547 codes to the ASC CPL, consisting of 276 procedures based on revised criteria plus an additional 271 codes proposed for removal from the IPO list.

CMS will revise the regulatory criteria by removing certain general standard and general exclusion criteria to a new section as nonbinding physician considerations for patient safety. CMS proposes to remove two of the general standards criteria which include:

- 1. Procedures that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC; and*
- 2. Procedures for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.*

CMS also proposes to remove the following general exclusions criteria:

- Generally result in extensive blood loss;*
- Require major or prolonged invasion of body cavities;*
- Directly involve major blood vessels;*
- Are generally emergent or life-threatening in nature;*
- Commonly require systemic thrombolytic therapy to a new section as nonbinding physician considerations for patient safety.*

As part of their proposal, CMS plans to maintain the general standard criteria that ASC covered surgical procedures are surgical procedures that are separately paid under the OPPI. The proposal also maintains the general exclusion criteria that covered surgical procedures do not include those surgical procedures that:

- Are designated as requiring inpatient care;*
- Can only be reported using a CPT unlisted surgical procedure code; or*
- Are otherwise excluded (eg, eye exams, hearing aids, some immunizations, cosmetic services, not reasonable and necessary services).*

CMS indicates that this proposal continues to build on their efforts to maximize patient and physician choice and access to care to further increase the availability of ASCs as an alternative and often lower cost site of care for Medicare beneficiaries.

While STS supports maximizing physician choice and affordable access to care for patients, we have significant concerns about the proposed changes to the criteria for procedures performed in ASCs. These revisions create substantial risks to patient safety and there are several procedures that are proposed for ASC coverage in Tables 80 and 81 of the proposed rule that are concerning.

Despite improvements in safety and quality, and the ability of ASCs to handle more complex procedures, it is crucial to recognize the differences in safety standards, equipment, and resources between ASCs and hospitals, especially in rural areas. By lowering the standards required for procedures performed in the ASC setting, CMS is unnecessarily exposing patients to significant safety risks.

High-risk procedures, such as electrophysiology (EP) ablation (93653, 93654), require immediate backup in case of complications. For example, a heart rupture during an EP ablation can be fatal without prompt cardiac surgery intervention. In hospitals, cardiac surgery standby is standard for these procedures, but ASCs lack a reimbursement mechanism to incentivize similar support. Additionally, ASC standards vary across states, and this proposal may unintentionally shift higher-risk procedures and patients into settings not equipped for them.

STS urges CMS to maintain the current standards for procedures performed in the ASC setting. With the proposed change in criteria, several procedures will be allowed in an ASC setting that pose a significant safety

risk to Medicare beneficiaries. For many of these procedures, standard medical practice dictates that the beneficiary would be expected to require active medical monitoring and care at midnight following the procedure. This is especially true for procedures that result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels and may be considered emergent or life-threatening in nature.

By removing these clearly defined important safeguards from the ASC criteria, we fear interference from financial incentives and administrative pressures that may influence clinical decision-making, potentially prioritizing cost savings over patient safety and quality of care. While we generally believe that physicians will make the best decisions for patients, it is unwise to assume that financial considerations will not play a role, which could introduce unnecessary risks for Medicare beneficiaries.

STS urges CMS to proceed cautiously and thoughtfully when implementing changes to the system, ensuring that all modifications are made with careful consideration of patient safety and quality of care. We strongly disagree with CMS' proposal to make procedures recently removed from the IPO list immediately available in ASCs. CMS should first collect performance and quality data on these procedures in the hospital outpatient setting before expanding ASC coverage. Changes should be systematic and measured, allowing time to assess the impact, such as elimination of the IPO and shifts to procedures performed in the outpatient setting before expanding to other settings like ASCs.

Thank you for considering these comments. For additional information or clarification, please contact Molly Peltzman, Associate Director of Health Policy, at mpeltzman@sts.org.

Sincerely,

A handwritten signature in black ink, reading "Joseph F. Sabik, MD". The signature is written in a cursive, flowing style.

Joseph F. Sabik III, MD
President