



## AMERICAN COLLEGE OF SURGEONS

Inspiring Quality:  
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September 27, 2019

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1717-P

P.O. Box 8013

Baltimore, MD 21244-1850

RE: 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 (CMS-1717-P)

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1717-P) published in the *Federal Register* on August 9, 2019.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of surgical care is furnished in hospital outpatient departments (HOPDs) and ASCs, we have a vested interest in CMS' payment and related quality reporting requirements in these settings. With the ACS' 100-year history in developing recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer insight to the Agency's proposed revisions to hospital outpatient and ASC payment policies for CY 2020. Our comments below are presented in the order in which they appear in the rule.



## PROPOSED UPDATES AFFECTING OPPTS PAYMENTS

### *Proposed Recalibration of APC Relative Payment Weights*

### Proposed Changes to Packaged Items and Services

Under the OPPTS, CMS packages payments for multiple interrelated items and services into a single payment, which the Agency believes creates incentives for facilities to provide services efficiently and to manage their resources with flexibility. CMS notes that while there are a variety of items that could be used to furnish a service, some of which are more costly than others, packaging encourages facilities to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often occurs if separate payment is provided.

### **Packaging Policy for Non-Opioid Pain Management Treatments**

In the CY 2019 OPPTS/ASC rule, CMS reported findings from its analysis of utilization patterns for drugs that function as a surgical supply—specifically, Exparel®—in HOPDs and ASCs to determine whether the Agency's packaged payment policy affected the use of this drug. CMS asserted that, if this policy discouraged the use of or impeded access to Exparel, it would expect to see a significant decline in the utilization of the drug over time. The Agency stated that it had observed such a decrease in Exparel® use in the ASC setting after the drug's pass-through payment status expired in 2014 but did not observe a similar decrease in the HOPD setting. CMS therefore finalized a provision to unpackage and pay separately for the cost of Exparel® in ASCs for CY 2019. The Agency did not make any changes to its payments for non-opioid drugs in the HOPD setting.

For CY 2020, CMS proposes to continue its policy to pay separately for the cost of Exparel® when it functions as a surgical supply in the performance of surgical procedures when they are furnished in the ASC setting, and continue to package payment for Exparel® and other non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the HOPD setting. The Agency seeks comment on whether there are other non-opioid pain management alternatives for which its payment policy should be revised to allow separate payment in ASCs and HOPDs.

The use and abuse of prescription opioids has increased dramatically in recent years, and the ACS applauds CMS' efforts to identify and eliminate regulatory obstacles that inhibit utilization of non-opioid alternatives for pain management, including those obstacles related to coverage and reimbursement. **We support CMS' proposal to continue to unpackage and pay separately for the cost of**

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**non-opioid pain management drugs that function as surgical supplies when they are furnished in ASCs; however, we urge the Agency to expand this policy and allow for unpackaging of non-opioid pain management in all care settings in which surgery is performed. To further eliminate payment-related barriers to the use of non-opioid alternatives by physicians and facilities, the ACS urges CMS to provide separate reimbursement for opioid-sparing therapies administered by surgeons during the perioperative period;** these therapies are often cost-prohibitive for facilities under current Medicare policy because the fees associated with the provision of non-opioid medications—which may be significantly more expensive than opioid therapy—are bundled into the overall payment for “supplies” related to surgical procedures, such that a non-opioid medication is paid at the same fixed Medicare rate as an opioid for postoperative pain management, regardless of the difference in the cost of the two drugs.

In addition, for CY 2020, CMS is required by section 1833(t)(22)(A)(i) of the Social Security Act to review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For this review, CMS used Medicare claims data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products; the Agency stated that its review did not produce compelling evidence to suggest that revisions to OPPS payment policies for non-opioid alternatives are necessary.

**We believe that CMS’ current method to evaluate utilization of non-opioid alternatives (i.e., reviewing Medicare claims data for certain drugs before and after their pass-through status expired) is too narrow and excludes other factors that may be stronger indicators of the accessibility and use of opioid-sparing therapies by physicians and facilities, and we thereby encourage the Agency to investigate others barriers to access to non-opioid postsurgical pain management alternatives beyond pass-through payment status.** The ACS suggests that CMS create a new Current Procedural Terminology (CPT) code or modify existing codes to account for the work associated with opioid-sparing therapies furnished by surgeons, which we believe would provide the Agency with reliable claims-based data for a more extensive group of surgeon-administered non-opioid alternatives—including neural blockades and intravenous acetaminophen, among others—and enable CMS to better track utilization and identify access barriers via Medicare billing trends.

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## PROPOSED OPPTS PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS WITHOUT PASS-THROUGH PAYMENT STATUS

### *Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes*

For CY 2020, CMS proposes to maintain its existing packaging policy for skin substitutes, under which such products are divided into either a high cost group or a low cost group to preserve resource homogeneity among Ambulatory Payment Classification (APC) assignments for the skin substitute application procedures. Skin substitutes in the high cost category are reported with appropriate skin substitute application CPT codes, while skin substitutes in the low cost category are reported with analogous skin substitute Healthcare Common Procedure Coding System (HCPCS) C-codes.

### Potential Revisions to the OPPTS Payment Policy for Skin Substitutes

Alternatively, the Agency solicits comment on a new payment methodology that would eliminate the high cost and low cost categories for skin substitutes and instead establish a single payment category and set of procedure codes for the application of all graft skin substitute products. Specifically, CMS suggests the following mechanisms to facilitate the transition from a high cost/low cost payment methodology to a single payment category methodology:

- Delaying implementation of a single category payment for one or two years after the payment methodology is adopted; and
- Gradually lowering the mean unit cost (MUC) and per day cost (PDC) thresholds over two or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

While the ACS recognizes that CMS seeks to stabilize payment for skin substitute products and related procedures to increase price transparency for facilities using such products, **we do not believe that the alternative single payment category methodology introduced by the Agency in this proposed rule contains enough detail for stakeholders to assess and provide informed feedback on the potential implications for patient care and out-of-pocket costs, the quality and accessibility of skin grafts, wide variances in the costs of skin substitute products, related coding and billing processes, and other factors. As such, CMS should not finalize any new alternative payment methodology at this time.** We encourage CMS to adhere to the notice-and-comment rulemaking process, and to officially propose any changes to OPPTS payment policies for skin substitutes with an adequate explanation of such proposals before finalizing such

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changes. **Until then, we support the Agency’s proposal to maintain its existing skin substitute payment methodology for CY 2020 and future years.**

## PROPOSED NONRECURRING POLICY CHANGES

### *Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals*

CMS proposes to change the default minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and critical access hospitals (CAHs). The Agency seeks comment on whether specific types of services should be excepted from this proposal.

**The ACS maintains that supervision requirements should be applied consistently across all sites of service to ensure patient safety and quality of care, and we support CMS’ proposal to eliminate its existing two-tiered system of supervision levels for hospital outpatient therapeutic services by setting a uniformly-enforceable supervision standard for such services rendered in hospitals and CAHs.** We ask that the Agency preserve an exception system that continues to allow physicians to use their clinical judgment to engage in the direct supervision for hospital outpatient therapeutic services when they believe that a greater level of supervision is warranted during the provision of such services. We also encourage CMS to make public a list of each service to which this policy, if finalized, would apply and offer medical specialty societies an opportunity to review this list and extract services for which they believe direct supervision requirements should be sustained.

### *Short Inpatient Hospital Stays*

### Proposed Change for Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A

CMS proposes to establish a one-year exemption from certain medical review activities for procedures removed from the inpatient only (IPO) list under the OPPI in CY 2020 and subsequent years. Specifically, during this one-year period, procedures that have been removed from the IPO list would not be eligible for referral to Recovery Audit Contractors (RACs) for site-of-service reviews within the first calendar year of their removal from the IPO list. In addition, these procedures would not be considered by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the two-midnight rule for

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purposes of referral to a RAC, nor would these procedures be reviewed by RACs for “patient status.”

**The ACS thanks CMS for its efforts to help facilitate compliance with its inpatient admission payment policies, but we believe that, even if a procedure is removed from the IPO list, there should be no barriers to payment for that procedure when performed in the inpatient setting, as the site-of-service determination is based on a physician’s clinical judgment regarding the site of care that is best suited to meet a given patient’s medical needs.** We question under what circumstances the Agency anticipates claims would be denied based on violation of the two-midnight rule due to site of service for a procedure that is furnished in the inpatient hospital setting but is not on the IPO list. As such, we seek clarification from CMS regarding the intent of this one-year grace period proposal.

## PROPOSED UPDATES TO THE ASC PAYMENT SYSTEM

### *Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services*

#### Proposed Changes for CY 2020 to Covered Surgical Procedures Designated as Office-Based

For CY 2020, CMS proposes to assign the procedures described by CPT codes 93X00 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study*) and 93X01 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study*) to Ambulatory Payment Classification (APC) 5522 (Level 2 Imaging without Contrast). **The ACS disagrees with CMS’ proposal to assign code 93X00 to APC 5522 because this code represents a bilateral study, and as such, we urge the Agency to instead assign code 93X00 to APC 5523 (Level 3 Imaging without Contrast), which includes other codes that describe similar bilateral/complete duplex studies.**

### *Proposed Additions to the List of ASC Covered Surgical Procedures for CY 2020*

CMS solicits comments on methods to ensure beneficiaries receive surgical procedures in the ASC setting only as clinically appropriate, such as: (1) a new modifier that indicates the physician believes that the beneficiary would not be expected to require active medical monitoring and care at midnight following a particular procedure furnished in the ASC setting; (2) requirements for an ASC to have a defined plan of care for each beneficiary following a surgical procedure;

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(3) requirements for an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare.

We believe that the addition of a surgical procedure to the ASC covered procedures list (CPL)—which indicates that CMS has reviewed the clinical characteristics of the procedure and its similarity to other procedures that are currently included on the ASC CPL, and subsequently determined that the procedure can be safely performed in an ASC—is a reliable safeguard already in place to ensure the appropriateness of a procedure furnished in the ambulatory surgical setting. **We oppose the implementation of any unnecessary requirements that may create new administrative burden for ASCs and/or limit a physician’s ability to exercise their clinical judgment when making site-of-service determinations, and therefore ask that CMS refrain from implementing the modifier, plan of care, and procedure volume requirements described above.**

### **PROPOSED REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES**

CMS proposes to expand its hospital charge data public display requirements and seeks comment on ways to improve price transparency and present cost information in a consumer-friendly format to assist patients in making informed healthcare decisions. **The ACS welcomes CMS’ focus on price transparency and appreciates the Agency’s recognition of the complex nature of providing patients and providers with actionable data.** The information currently available to consumers on cost—particularly as it relates to out-of-pocket charges for in- and out-of-network care—is sparse and inconsistent. We encourage CMS to consider the following issues as the Agency sets policies related to the communication of hospital charges.

#### Proposed Definition of “Items and Services” Provided By Hospitals

Section 2718(e) of the Public Health Service Act requires that hospitals make public a list of the hospital’s standard charges for items and services provided by the hospital. CMS proposes that “items and services” provided by a hospital are all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. The Agency also includes in this proposed definition the services furnished by physicians and non-physician practitioners who are employed by the hospital. **We seek clarification from CMS regarding its definition of “employed,” given the numerous employment models (e.g.,**

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full employment by a hospital, independent contractor arrangements, etc.) utilized by physician practices and institutions across the country. The ACS believes that it is critical for CMS to clearly describe the parameters of hospital employment for the purposes of including the services furnished by hospital employees in its definition of “items and services” and for the broader charge data set published by hospitals.

#### Definitions for Types of “Standard Charges”

CMS proposes to define “standard charges” as the following:

- 1) *Gross charges*: The charge for an individual item or service that is reflected on a hospital’s chargemaster, absent any discounts; and
- 2) *Payor-specific negotiated charges*: The charge that the hospital has negotiated with a third party payor for an item or service.

**The ACS does not believe that these two types of charges are useful to consumers, as a patient cannot use standard charge information to derive how their individual health plan would actually pay for their hospital care.** We are concerned that patients will attempt to use information about hospitals’ standard charges to estimate their out-of-pocket costs and that such an estimate would not be an accurate reflection of the patient’s actual bill. Out-of-pocket cost is one of the most valuable types of price information for patients, but this information is challenging to provide to all beneficiaries across all payors. As we describe below, cost data for an entire episode of care by payor could prove to be the most useful readily available information for consumers.

#### Accurate and Relevant Cost Data

The ACS recognizes that CMS is statutorily required to facilitate the public posting of hospital charges; however, this process as currently proposed would dramatically increase administrative and financial burden for hospitals, and would not provide consumers with actionable information to make healthcare decisions. **We suggest that the Agency consider an alternative method of hospital charge data collection and communication using the Episode Grouper for Medicare (EGM); this alternative could be established through staged implementation of technology already available to CMS, and we encourage the Agency to develop a demonstration project over the coming year to assess its effectiveness.** We describe the EGM and how it could be used to satisfy statutory requirements to make hospital charge data public and produce useful information to patients in more detail below.

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The EGM was developed for CMS by a collaborative lead by Brandeis University to organize claims information into logical episodes of care. The EGM consists of both a software suite and a set of clinical episode definitions that have benefited from multiple rounds of physician review over several years. Originally created to provide Medicare cost information to CMS, the EGM could be configured to produce invaluable information for patients and providers trying to determine the cost of care in diverse situations, including those that include multiple services furnished by multiple providers. With an accessible, open source standard, all providers and payors could organize their reporting of price information in a consistent and comparable fashion to reflect a patient’s full experience for an acute event and its post-acute aftermath.

The EGM groups services logically and consistently into “service profiles” for a given episode of care, allowing for many types of consumer and provider-friendly price information to be derived from the use of this grouper logic. Service profiles by facility could use Medicare allowed payments to compare facilities and highlight differences in the pricing of standard services for that episode, as well as costs attributable to unanticipated complications that may arise after discharge (e.g., hospital readmission, skilled nursing care). Alternatively, holding constant a common set of services related to a particular type of episode, hospitals could report total cost of care first using Medicare allowed payments, and then by negotiated commercial insurer payment amounts.

Estimating the actual cost to consumers also typically requires information specific to a beneficiary’s insurance coverage, such as their benefits package, deductible, coinsurance responsibilities, and so forth. Thus, the service profile framework could be expanded more generally to inform data exchanges between payors, providers, and consumers. For example, CMS could leverage its partnership with the Da Vinci Project, an industry-led initiative to identify and implement care delivery use cases for the exchange of information between health plans and providers, to participate in the development of patient cost transparency and value-based care data exchange solutions, to advance the Agency’s mission to standardize hospital charge information.<sup>1</sup> Under such a model, a hospital or provider could query the insurance plan about a particular patient’s benefit design to receive an estimate of out-of-pocket costs for that patient for a given episode in order to inform decision-making and avoid surprise medical bills. Similarly, consumers could query their own payors about differential prices from local providers based on the standard taxonomy for service profiles as clinically meaningful units of pricing.

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<sup>1</sup> Health Level Seven International. (2019). Da Vinci Project members. Retrieved from <http://www.hl7.org/about/davinci/members.cfm>

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The ACS believes that the episode logic supporting these processes can be most readily accomplished and maintained by an impartial, nongovernmental, not-for-profit organization with the support and input of the medical community to verify clinical content. The ACS has been involved in the formulation of such an entity, called the Patient-Centered Episode System (PACES) Center, which was officially incorporated in 2019, to create a single industry standard for defining clinical episodes of care using the current medical record and payment systems, and based on consensus across multiple stakeholders including providers, payors, purchasers, and consumers. With the logic and specifications for episodes available in the public domain, there will be full transparency and a standard framework that interested parties can use to measure cost, set benchmarks, align quality metrics, and optimize value within and across systems and regions. While CMS proposes that hospitals publish any code (e.g., CPT, HCPCS, diagnosis-related groups [DRGs]) used by the hospital for purposes of accounting or billing for a given service, we believe that one open episode system is needed to:

- Define clinical episodes of care in a patient-centric manner;
- Better account for relevant services used to manage a patient episode;
- Promote alignment across payors' design and implementation of episode-based payment models as well as provider's assessment of all resources needed to co-manage a patient;
- Enable consistency between payment models, costs of producing care, and performance measurement; and
- Promote ability to identify true variations in costs and quality and establish comparisons within and across providers.<sup>2</sup>

We wish to highlight that PACES is the only episode grouper developed with inputs from across all specialties and is continuously governed and updated to remain current to the care models used today. In addition, the PACES grouper logic has nested episodes within a particular broader episode and, as such, assigns each dollar only once within the entire episode of care to ensure that no expense is counted twice. For example, if a patient has cancer, undergoes a surgical resection, chemotherapy, radiation, and concurrently encounters a bout of pneumonia, there will be many overlapping costs for services such as lab tests, imaging, electrocardiograms, and so forth; if the services furnished to treat the underlying cancer and the pneumonia each are assigned separate price models, many such services will be double-counted, thereby overstating the true price of the episode of care. To avoid distortions in price, the PACES logic assigns the

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<sup>2</sup> PACES Center. (2019). A common standard for the common good. Retrieved from <https://www.pacescenter.org/static/PACES%20-page%20Summary.pdf>

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cost of a specific service to a specific episode or splits the cost equally across all episodes so that the sum of all costs will true-up with the actual cost of care.

The pricing data derived using PACES can be represented as a mean or median amount for a single hospital, and such data can be compared to that of other hospitals in the region. An example of these concepts for a colectomy episode is shown in Table 1, below.

**Table 1. Select Hospital Episode-Based Prices for Colectomy**

	Column A	Column B	Column C	Column D
Colectomy Services	Medicare Prices		Median Provider Prices	
	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile	Medicare	Commercial
<b>Preoperative</b>				
Pre-Surgical E/M	\$ 175	\$ 316	\$ 233	\$ 350
Pre-Surgical Imaging/Lab	\$ 218	\$ 202	\$ 201	\$ 543
Pre-Surgical Other	\$ 309	\$ 209	\$ 312	\$ 780
Subtotal	\$ 702	\$ 727	\$ 746	\$ 1,672
<b>Operative Stay</b>				
Facility	\$ 17,384	\$ 22,818	\$ 17,516	\$ 40,286
Operating Clinician	\$ 1,900	\$ 1,725	\$ 1,821	\$ 5,463
Anesthesia	\$ 549	\$ 339	\$ 478	\$ 1,912
Imaging/Lab Prof. Fee	\$ 125	\$ 139	\$ 167	\$ 668
Other Professional	\$ 58	\$ 58	\$ 45	\$ 79
Subtotal	\$ 20,016	\$ 20,069	\$ 20,027	\$ 48,408
<b>Post-Discharge</b>				
Readmissions	\$ 649	\$ 888	\$ 715	\$ 1,573
PAC-SNF/IRF/LTAC	\$ 556	\$ 669	\$ 602	\$ 1,144
Sequelae	\$ 1,402	\$ 1,511	\$ 1,454	\$ 3,490
PAC Other	\$ 2,361	\$ 2,578	\$ 2,494	\$ 4,988
Subtotal	\$ 4,968	\$ 5,646	\$ 5,265	\$ 11,194
<b>TOTAL</b>	<b>\$ 25,686</b>	<b>\$ 31,442</b>	<b>\$ 26,038</b>	<b>\$ 61,274</b>

Service Profiles

Price Differentials

Table 1 outlines price information for a colectomy episode for three representative hospitals. Columns A and B in Table 1 contrast service profiles for two hospitals in a particular geographic area in 2014, one with the 25th percentile and another with the 75th percentile total Medicare spending for colectomy. The substantial disparity in average Medicare spend for colectomy patients in these two hospitals reflects differences in the price of services during the preoperative, the index stay, and post-acute phases of care, as well as sequelae or other post-discharge complications. Such comparisons ideally would incorporate the most recently available data and adjustments for differences in comorbidities and relative complexity of the services rendered for a given episode of care.

Comparing Columns A and B illustrates the importance of episode price data; whereas some of the prices for specific services (e.g., pre-surgical services,



anesthesia) are higher in the 25th percentile hospital, the only way to see the full picture of the cost of care is to look at the total price of the colectomy episode, which shows that the overall lower price of the 25th percentile hospital is due in part to its lower post-discharge prices.

Columns C and D in Table 1 contrast the differential payment amounts between Medicare and commercial payors within a third hospital (i.e., the median provider in the same area in total Medicare spend for colectomy). For informed decision-making, it is important to assess price data for an episode in its entirety, not simply the respective prices for individual service items such as the surgeon's fee, a diagnostic test, or a day in the hospital.

While much work remains to achieve the PACES Center's mission, this work is moving forward and we believe it could complement and help bring to fruition the goals of CMS regarding price transparency. **To that end, we encourage the Agency to consider developing a demonstration project to test and measure the efficacy of PACES as a possible alternative to CMS' proposed hospital charge data display requirements.** The ACS would welcome the opportunity to facilitate a meeting with representatives of CMS and the PACES Center to discuss how our shared objectives can be accomplished.

### **ORGAN PROCUREMENT ORGANIZATIONS CONDITIONS FOR COVERAGE: PROPOSED REVISION OF THE DEFINITION OF "EXPECTED DONATION RATE"**

#### *Proposed Revision of the Definition of "Expected Donation Rate"*

CMS proposes to revise the definition of "expected donation rate" in the Conditions for Coverage (CFCs) that organ procurement organizations (OPOs) must meet in order for organ procurement costs to be paid under the Medicare program. The CFCs for OPOs require that an OPO must meet two of the three following outcome measures:

- 1) The OPOs donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle;
- 2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification;

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- 3) The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield.<sup>3</sup>

The expected donation rate used in the second outcome measure is calculated by the Scientific Registry of Transplant Recipients (SRTR). In 2009, the SRTR modified the definition of “expected donation rate” to specify that the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and donation service areas (DSAs) adjusted for patient characteristics (i.e., age, sex, race, and cause of death among eligible deaths).<sup>4</sup> CMS notes that, due to an oversight by the Agency, it did not make a corresponding change to its definition in the CfCs for OPOs to reflect the SRTR’s modifications, and therefore proposes to revise the definition of “expected donation rate” within its CfCs to harmonize the CMS definition with the SRTR definition. **We support the position of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) in aligning the SRTR and OPO CfC definitions of “expected donation rate” and believe that this revision would eliminate the potential for confusion in the OPO community due to different definitions of the same term.**

*Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations*

In this proposed rule, CMS seeks comment on a comprehensive update to the CfCs for OPOs and the Conditions of Participation for transplant centers regarding OPO outcome measure accuracy and reliability, along with the impacts of current outcome measures on OPO performance and availability of transplantable organs. **The ACS shares the concerns raised by the ASTS and the AST in regard to potential access barriers associated with the existing OPO outcome metrics.**

OPO performance is currently assessed by CMS based on “eligible donors” and “eligible deaths” as self-reported by OPOs. Such terms are used to define the denominator of the donor conversion ratio—one of the principal metrics by which OPOs are judged—which is generally defined as the number of donors per eligible deaths within an OPO’s territory. For the purposes of these regulations, a

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<sup>3</sup> 42 C.F.R. 486.318(a)-(b)

<sup>4</sup> Scientific Registry of Transplant Recipients. (2019). Technical methods for the OPO-specific reports. Retrieved from <https://www.srtr.org/about-the-data/technical-methods-for-the-opo-specific-reports/>

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“donor” is defined as a patient whose organs are recovered with the “intent to transplant,” while an “eligible death” is defined as a hospitalized, brain-dead patient  $\leq 75$  years of age without contraindications to donation.

**We believe that the existing “eligible deaths” and “donor” metrics are subjective, allow for misinterpretation of data, and may wrongly incentivize cherry-picking of deceased donors to improve OPOs’ performance statistics. More importantly, the definitions of these terms may mask missed opportunities for donation, and often produce ambiguous, noncomparable statistics on donor data.**<sup>5</sup> Formally declaring a patient as brain-dead requires extra documentation and testing that a hospital may not pursue if there is no interest or likelihood for donation. If an OPO fails to adequately pursue possible opportunities for donation, then many potential brain-dead donors will never be formally declared as brain-dead and thus will not be counted as “eligible.” Further, these metrics exclude from “eligible death” Donation after Cardiac Death, the second pathway to organ donation that is increasingly being utilized as a viable and appropriate method for reducing the gap that exists between the demand for and the available supply of organs for transplantation.<sup>6,7</sup> These problems represent missed organ donation opportunities and are not addressed by current OPO performance metrics. **The ACS believes that it is important to assess OPO performance using reliable, objective, verifiable, and practicable definitions reflective of the full scope of potential donors, and we urge CMS to review and consider revisions to its definitions of “donor” and “eligible death” to better capture the nuances of organ procurement for the purposes of outcome measurement and data integrity.**

CMS also solicits comment in this proposed rule on an OPO performance measure that would be based on available data on inpatient deaths derived from the Centers for Disease Control & Prevention (CDC) Detailed Mortality File and the National Center for Health Statistics’ National Vital Statistics Report. We agree that CDC inpatient mortality data should be reviewed for possible use in assessing OPO performance, and the feasibility of using these data has already

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<sup>5</sup> National Kidney Foundation. (2019). Position statement on reform of organ procurement organization (OPO) metrics. Retrieved from <https://www.kidney.org/news/position-statement-reform-organ-procurement-organization-opo-metrics>

<sup>6</sup> Organ Procurement & Transplantation Network. (2019). Donors recovered in the U.S. by donor type and donation after circulatory death. *National Data*. Retrieved from <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data>

<sup>7</sup> American Society of Anesthesiologists. (2017). Statement on controlled organ donation after circulatory death. Retrieved from <https://www.asahq.org/standards-and-guidelines/statement-on-controlled-organ-donation-after-circulatory-death>

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been validated by several OPOs.<sup>8</sup> However, the CDC database does have a number of significant shortcomings. As CMS itself notes, these inpatient mortality data may include potential donors in the denominator who would never clinically qualify as organ donors, and for this reason may understate OPO success in retrieving transplantable organs. In addition, we question the accuracy of hospital reporting of cause of death and variances in geographic or other factors that may impact OPO performance. **As such, the ACS recommends that CMS engage the CDC, along with the SRTR, OPTN, and Health Resources and Services Administration (HRSA) in efforts to examine publicly available data sources, including the CDC inpatient hospital mortality database, to identify and redress potential shortcomings of these data sources for use in conducting OPO assessments.**

## **PROPOSED PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN HOSPITAL OUTPATIENT DEPARTMENT SERVICES**

### *Proposal for a Prior Authorization Process for Certain Outpatient Department Services*

CMS proposes to use its authority under 42 U.S.C. § 1395l(t)(2)(F) to create a process through which providers would submit a prior authorization (PA) request for a provisional affirmation of coverage before a covered OPD service is furnished to the beneficiary and before the claim is submitted for processing.<sup>9</sup> The Agency asserts that PA for certain services would be an effective method for controlling increases in the volume of such services in the OPD setting. Using this process, CMS would establish the conditions of payment for OPD services that require PA; establish the submission requirements for PA requests; and provide for suspension of the PA process generally or for particular services.

### Prior Authorization as a Method for Controlling Unnecessary Increases in the Volume of Covered Outpatient Services

As a condition of Medicare payment under this proposal, a provider must submit a PA request for services on the list of OPD services requiring PA to CMS that includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Claims submitted for services that

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<sup>8</sup> Goldberg, D., Karp, S., Shah, M. et al. (2019). Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation. *American Journal of Transplantation*.

<sup>9</sup> 42 U.S.C. § 1395l(t)(2)(F)

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require PA but have not received a provisional affirmation of coverage from CMS or its contractors would be denied. Moreover, CMS proposes that even when a provisional affirmation has been received, a claim for services may be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information not available at the time the PA request is received.

Proposed List of Outpatient Department Services That Would Require Prior Authorization

CMS proposes to require PA for five categories of services: blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. The Agency asserts that these types of services show higher than expected, and therefore unnecessary, increases in the volume of utilization. The table below lists the specific procedures within the five categories of services CMS would include in its list of OPD services requiring PA.

**Proposed List of Outpatient Services that Would Require PA**

<b>CPT Code</b>	<b>Blepharoplasty, Eyelid Surgery, Brow Lift, and Related Services</b>
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis
67911	Correction of widely-opened upper eyelid
<b>CPT Code</b>	<b>Botulinum Toxin Injection</b>
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxinA, 1 unit
J0587	Injection, rimabotulinumtoxinB, 100 units
<b>CPT Code</b>	<b>Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and Related Services</b>
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted removal of fat from trunk

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CPT Code	Rhinoplasty, and Related Services
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
21235	Obtaining ear cartilage for grafting
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
CPT Code	Vein Ablation and Related Services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

**The ACS strongly objects to the introduction of any new PA requirements into the Medicare program, and urges CMS to withdraw its PA proposals for CY 2020.** We have numerous concerns with CMS’ proposed PA processes and the Agency’s interpretation of its statutory authority to make such proposals, which are described in detail below.

- **Administrative burden.** By CMS’s own admission in this rule, its proposed PA policies, if finalized, would significantly change how physicians bill for services and increase administrative paperwork and other costs to private sector providers by \$2.6 million in CY 2020, and \$19.8 million in CY 2025—in its discussion of this added financial burden on providers, the Agency states, “ we do not view decreased revenues from OPD services subject to unnecessary utilization by providers to be a condition that we must mitigate,”

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and does not propose any offsetting increases in payments for other services.<sup>10</sup> **As insurers continue to subject a growing number of services to PA, many physicians can no longer afford the increased practice costs related to compliance with PA requirements and are left with no option but to leave plan networks.** When a physician becomes out-of-network, beneficiaries must either seek care elsewhere or pay out-of-pocket, both of which inappropriately delay care and shift costs onto patients. **CMS' PA proposals could substantially obstruct patient access and lead to a decline in the number of physicians participating in the Medicare program.**

- **Barriers to payment.** Surgeons across the country are facing setbacks in furnishing services to patients—and being reimbursed for such services—even when they are in compliance with insurers' PA requirements. CMS indicates that, as a condition of payment, physicians would be required to submit a PA request to the Agency, and may proceed to furnish the services included in the PA request if the physician receives provisional affirmation (i.e., a preliminary finding that a future claim meets the Medicare coverage, coding, and payment rules) from CMS. However, the Agency states that it may deny a claim that received a provisional affirmation based on technical requirements or information not available at the time the PA request was submitted. **Payment for services for which PA was granted should not be later denied based on billing technicalities.** For example, reimbursement should not be withheld when the service performed is clinically comparable to an approved service but is more properly reported using a different CPT code or when a procedure's necessity was not anticipated, or the procedure is performed incident to, or during the course of, an approved operation.
- **Violation of statutory authority.** Medicare statute authorizes CMS to “develop a method for controlling unnecessary increases in the volume of covered OPD services.”<sup>11</sup> We wish to highlight that this provision does not actually authorize CMS to make any adjustments or changes to payment rates at all; instead, it merely authorizes the Agency to develop a method for controlling unnecessary increases in the volume of services, but does not govern how that method may be used in volume-control activities. If CMS determines that the volume of services has grown beyond amounts established through its methodology, it may make non-budget-neutral adjustments to address those unnecessary increases in volume—but only through across-the-

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<sup>10</sup> Centers for Medicare & Medicaid Services. (2019). *CY 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule*. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2019-08-09/pdf/2019-16107.pdf>

<sup>11</sup> 42 U.S.C. § 1395l(t)(2)(F)



board adjustments to all items or services paid under the OPPS. Specifically, if CMS determines that the volume of services has grown beyond amounts established through its methodology to control for unnecessary increases in the volume of covered services in the OPD setting, the Agency may appropriately adjust the update to the conversion factor (CF) otherwise applicable in a subsequent year.<sup>12</sup> The CF is a uniform amount that is used in the formula to calculate payment rates for all items and services paid under the OPPS, and a CF adjustment can increase or decrease the entire OPPS by a percentage-factor; however, the adjustment cannot reduce the relative payment rate for a particular set of items or services. If the Agency instead wants to make adjustments to payment rates for specific services, it must do so in a budget-neutral manner.<sup>13</sup>

While the Medicare statute allows for reductions to the total amount of Medicare payments in appropriate, limited circumstances through changes to the CF, there is no statutory mechanism allowing CMS to reduce the total amount of Medicare payments by targeting only selected services. By requiring budget neutrality for payment reductions targeting specific services, the statute is intended to limit any incentive for CMS to engage in unjust cost-control measures.

**Therefore, we believe that, contrary to CMS' assertion, 42 U.S.C. § 1395l(t)(2)(F) does not confer authority to apply PA to specific blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation procedures in response to unnecessary increases in the volume of OPD services.** Rather, as noted above, if the methodology developed by CMS shows that there are unnecessary increases in the volume of OPD services, the Agency's recourse is to modify the CF and effectuate an across-the-board reduction in payment rates under the OPPS. **The ACS does not support the application of PA to any services under the Medicare program, and we believe that there are existing mechanisms in place CMS can utilize (e.g., clarify Medicare coverage criteria within National Coverage Determinations for specific services, direct audit contractors to review claims submitted by providers whose ordering patterns stray significantly from clinical guidelines), to identify and control for potential overutilization of services that are not medically necessary.**

The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If

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<sup>12</sup> 42 U.S.C. § 1395l(t)(9)(C)

<sup>13</sup> 42 U.S.C. § 1395l(t)(9)(B)

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you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager, at [vollapally@facs.org](mailto:vollapally@facs.org).

Sincerely,

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