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October 5, 2020

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1736-P

P.O. Box 8013

Baltimore, MD 21244-1850

RE: 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 (CMS-1736-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) 2021 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1736-P) published in the *Federal Register* on August 12, 2020.

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, the College has a vested interest in CMS' coverage, reimbursement, and quality reporting requirements applicable to these settings. With our 100-year history in developing policy 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 modifications to the hospital outpatient and ASC payment systems for CY 2021. Our comments below are presented in the order in which they appear in the rule.

PROPOSED UPDATES AFFECTING OPPS PAYMENTS

Proposed Changes to Packaged Items and Services

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Under the OPPS, 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

Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives

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. In the CY 2019 OPPS/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. In the CY 2020 OPPS/ASC rule, CMS reported findings from a second review of utilization patterns for drugs that function as a surgical supply in HOPDs and ASCs, and indicated that such review did not produce compelling evidence to suggest that revisions to OPPS payment policies for non-opioid alternatives are necessary.¹

CMS states in this rule that it does not believe that conducting a third review would yield different outcomes or new evidence that would prompt a change to payment policies under the OPPS or ASC payment system. Therefore, the Agency proposes to continue its policy to pay separately for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in ASCs and to continue to package

¹ 84 F.R. 61176-61180

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payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in HOPDs for CY 2021.

The use and abuse of prescription opioids has increased dramatically in recent years, and the ACS thanks CMS for its 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 non-opioid pain management drugs that function as surgical supplies when furnished in ASCs; however, we continue to urge the Agency to expand this policy and allow for unpackaging of non-opioid pain management in all care settings where surgery is performed.** 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.

To further eliminate payment-related barriers to the use of non-opioid alternatives by physicians and facilities, the ACS urges CMS to provide separate payment for opioid-sparing therapies administered by surgeons during the perioperative period. For example, when a catheter is inserted in an operative field and attached to an elastomeric pump that delivers local anesthetic at a controlled rate for a set duration, such work and related equipment is bundled into the cost of the procedure when furnished by the operating surgeon. However, if the same service is performed by an anesthesiologist, the work and related equipment is unpackaged and separately payable.

Additionally, we believe that the Agency's current method to evaluate utilization of non-opioid alternatives—under which CMS reviews 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. We thereby encourage the Agency to investigate other 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

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others—and enable CMS to better track utilization and identify access barriers via Medicare billing trends.

PROPOSED OPPTS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Proposal to Allow Synthetic Skin Graft Sheet Products to Be Reported with Graft Skin Substitute Procedure Codes

The CY 2014 OPPTS/ASC final rule describes skin substitute products as “... a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers...[T]hese products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue.”² The 2014 rule did not specifically mention whether synthetic products could be considered to be skin substitute products in the same manner as biological products, because there were no synthetic products at that time that were identified as skin substitute products.

In 2018, a manufacturer submitted a request to CMS that an entirely synthetic product that it claimed is used in the same manner as biological skin substitutes receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes. The Agency states that, while synthetic products were not initially described as a graft skin substitute product, it now believes that both biological and synthetic products should be considered to be skin substitutes for Medicare payment purposes. CMS therefore proposes to include synthetic products in addition to biological products in its description of skin substitutes for CY 2021. This new description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers.

The ACS supports CMS’ proposal to add synthetic products to its description of skin substitutes. We believe that the inclusion of both synthetic and biologic products in the Medicare definition of skin substitutes will better reflect advancements in technology since the definition was first developed in 2014 and may simplify reporting for synthetic products used to treat foot and leg ulcers.

SERVICES THAT WILL BE PAID ONLY AS INPATIENT SERVICES

² 78 F.R. 74825

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Proposed Changes to the Inpatient Only List

CMS proposes to eliminate the Inpatient Only (IPO) list over a three-year transitional period with the list completely phased out by CY 2024. This is a list of procedures that currently can only be paid for in a hospital inpatient setting. CMS would begin with the removal of nearly 300 musculoskeletal-related services in CY 2021, which would make these procedures eligible to be paid by Medicare in the hospital outpatient setting in addition to the inpatient setting.

The ACS strongly opposes the elimination of the IPO list. As stated in our previous comments to CMS, we agree with the removal of certain services from the IPO list for which there is evidence that they can safely be furnished in the outpatient setting. However, we are extremely concerned by CMS' proposed removal of various IPO procedures that do not have sufficient data to support the appropriateness of their performance on an outpatient basis. **We note that CMS does not provide any discernible rationale or description of efforts undertaken by the Agency before making this proposal to thoroughly examine each service on the IPO list and provide evidence that all such services can safely be performed in the outpatient setting.**

We believe that CMS' proposal is riddled with inaccurate clinical assumptions and fails to address a number of underlying implementation issues. **The ACS urges CMS to maintain its current annual IPO review process to identify procedures that should be removed or added, which offers stakeholders an opportunity to provide input and has been an effective mechanism to gather reliable and objective data regarding the safety and efficacy of procedures furnished in the outpatient setting.** We question if, in the absence of clinical evidence to substantiate elimination of the IPO list in this rule, CMS has considered the potential negative consequences of its proposal—several of which are outlined below—for Medicare beneficiaries, as well as for the physicians and hospitals participating in the Medicare program.

Patient Safety and Access

The various procedures on the IPO list have inherent risks, many of which pose a threat to even the healthiest of patients, but particularly to the older and sicker Medicare population. Finalizing the elimination of the IPO list would make major and complex procedures that typically require extensive inpatient treatment, such as trauma-related pelvic, acetabulum, hip and fragility fractures and amputations, payable in the outpatient setting. The ACS does not believe that, even with advancements in medical practice and technology, such complicated procedures can be provided safely in the outpatient setting. We remind CMS that even if a procedure may be performed safely in an outpatient site of service, the risk to the

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patient does not end when the patient is moved out of the operating room. Instead, the patient may face more risk in the post-operative period, and therefore require the resources and capabilities of an inpatient setting to prevent or manage complications following the procedure.

We are also concerned by the implications that the inevitable mass shift of procedures to the outpatient setting will have on the accessibility and affordability of care for Medicare beneficiaries. We wish to highlight that, per CMS rules, the copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible; however, a patient's total copayment for the cumulative cost of all outpatient services related to a single procedure may be equal to an amount greater than the inpatient hospital deductible.³ Therefore, patients treated in the outpatient setting may be subject to increased out-of-pocket costs that exceed the costs incurred had they been treated in the inpatient setting. **The ACS does not support any policies, such as the elimination of the IPO list, that may inappropriately shift cost onto patients and therefore discourage beneficiaries from seeking necessary care.**

Administrative Burden

The elimination of the IPO list would create increased documentation and audit burden for physicians and hospitals, and we question how CMS would begin implementing the IPO list phase-out in CY 2021 without first publishing specific program integrity and reporting guidelines to support provider education and compliance. The Agency does not specify how utilization reviews will occur for procedures performed on an inpatient basis once they are removed from the IPO list, and it remains unclear how physicians must indicate that the provision of a service in the inpatient setting is reasonable and necessary, if obtaining prior authorization is required, and when organization determinations will be made by CMS or its contractors. **We do not understand why CMS would eliminate a reliable and comprehensive list of services for which site-of-service reviews do not apply, leaving much room for confusion and delays in care as physicians, hospitals, and coding staff are stripped of clear guidelines for proving the medical necessity of inpatient care.** At a moment in time where the medical community is already dealing with tremendous financial and care delivery issues due to COVID-19, this type of dramatic shift in care and related administrative burdens could add to the mounting resource strains that facilities and physicians are already struggling to navigate.

³ Centers for Medicare & Medicaid Services. (2020). *Inpatient or outpatient status affects your costs*. What Medicare Covers. Retrieved from <https://www.medicare.gov/what-medicare-covers/what-part-a-covers/inpatient-or-outpatient-hospital-status>

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We are also concerned that other payors, including Medicare Advantage plans, will use the lack of the IPO list as a means to inappropriately force patients into the outpatient setting for cost-only reasons, regardless of the decisions made between the patients and their surgeons. In this proposed rule, CMS itself states that stakeholders have informed the Agency that removing a service from the IPO list creates expectations that the service must be furnished in the outpatient setting “regardless of the clinical judgment of the physician or needs of the patient.” We are disappointed that CMS disregarded this stakeholder feedback and proposes to eliminate the IPO list without instituting any safeguards against inappropriate behavior forcing procedures into the outpatient setting.

We reiterate that we do not believe that CMS applied a serious clinical review of the services on the IPO list proposed for deletion and seek clarification from the Agency about the general purpose for eliminating the IPO list. High-quality surgical care involves much more than providing services at the lowest possible cost, and CMS should not eliminate the IPO list as a mechanism to allow any procedure to be performed as an outpatient service without evidence of patient safety. As noted above, complications can occur with any surgical procedure, particularly during the post-operative period. For many services on the IPO list, such complications will be best identified early and treated promptly in the inpatient hospital setting. We believe that CMS would greatly benefit from coordinating with the surgical community to identify which specific procedures on the existing IPO list may be safely provided in an outpatient setting, instead of simply selecting a subset of codes for removal without first seeking input from the relevant specialty societies. **We urge the Agency to adhere to the notice-and-comment rulemaking process and officially propose any changes to OPPS payment rules with an adequate explanation of such proposals—including objective data analyses, clear coding and billing rules, adequate safeguards to ensure patient safety and care quality, and other details—before finalizing any policy as significant as the complete elimination of the IPO list.**

PROPOSED NONRECURRING POLICY CHANGES

Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

Proposal to Allow Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services using Interactive Telecommunications Technology

CMS finalized on an interim basis during the COVID-19 public health emergency (PHE) to allow direct supervision of pulmonary rehabilitation, cardiac

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rehabilitation, and intensive cardiac rehabilitation services to be provided using interactive audio and video technology. This direct supervision requirement could be met by the supervising physician being immediately available to observe in real-time via audio/video communications technology throughout the performance of the procedure. The Agency proposes to adopt this policy permanently beginning in CY 2021.

The ACS supports direct supervision using audio/video technology as a provisional policy to remain in effect for the duration of the PHE to reduce exposure risks associated with the COVID-19 pandemic. Upon termination of the PHE, we *oppose* continued use of audio/video technology to provide direct supervision due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, endoscopic, or anesthesia procedures, a patient's health status can quickly change, and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation. It may not be possible for a supervising physician to recognize or meet these urgent clinical needs while being present for the service, and potentially other services at the same time, only through audio/video interactive communications technology.

We urge CMS to first consider additional guardrails to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use before proceeding with any virtual supervision policies outside of the PHE. For example, we urge the Agency to limit the number of clinicians a supervising physician may simultaneously engage with—as well as the number of incident-to relationships a supervising physician may be involved in at a given time—via audio/video technology. Irrespective of the supervision component associated with the provision of an incident-to service, we believe that, in general, the Medicare payment rendered for such service should match the allowed reimbursement amount under the OPPS for the provider type that furnished the majority of the service billed.

Proposed Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years

In the CY 2020 OPPS/ASC final rule, CMS established a two-year exemption from certain medical review activities for procedures removed from the IPO list under the OPPS in CY 2021 and subsequent years. Specifically, during this two-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 two calendar years of their removal from the IPO list. In addition, these procedures would not be considered by Beneficiary and Family-

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Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the two-midnight rule for purposes of referral to a RAC, nor would these procedures be reviewed by RACs for “patient status.”

CMS proposes in this rule to eliminate the IPO list with a transitional period of three years, beginning with the removal of all musculoskeletal procedures from the list in CY 2021. The elimination of the IPO list would thereby make all procedures currently on the IPO list subject to the two-midnight rule. The Agency indicates that it believes that, in order to facilitate compliance with its payment policy for inpatient admissions, the two-year exemption from certain medical review activities by the BFCC-QIOs for services removed from the IPO list under the OPSS in CY 2021 and subsequent years is necessary. Accordingly, CMS proposes to retain the existing two-year exemption even in the event that it finalizes the proposal to eliminate the IPO list.

The ACS has long expressed concerns about the two-midnight rule and its implications on beneficiary cost-sharing. Under the two-midnight rule, patients that spend less than two midnights in a hospital are treated as an outpatient, while patients that spend more than two midnights in a hospital are treated as an inpatient. The difference between having an “inpatient” and “outpatient” status on patients is profound, as Medicare generally covers most of the cost of inpatient services, while forcing beneficiaries to pay for a significant portion of outpatient services (beneficiaries generally face a 20 percent coinsurance for most outpatient services).

Additionally, as stated above, the ACS strongly opposes the proposed elimination of the IPO list and urges CMS to maintain its current process for reviewing services on the list for removal when there is evidence that such services can be safely performed in the outpatient setting. **We believe that, even if a procedure is removed from the IPO list (or if the IPO list is eliminated altogether), 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 care setting that is best suited to meet a given patient’s medical needs.**

UPDATES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM

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

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Proposed Changes for CY 2021 to Covered Surgical Procedures Designated as Office-Based

Each year, CMS reviews and updates the covered surgical procedures eligible for payment in ASCs. After analyzing the most recent volume and utilization data of covered surgical procedures currently assigned a payment indicator of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), the Agency identified seven covered surgical procedures that it believes meet the criteria for designation as permanently office-based. CMS states that these procedures are performed more than 50 percent of the time in physicians’ offices and are of a level of complexity consistent with other procedures performed routinely in physicians’ offices. The applicable CPT codes that CMS proposes permanently designate as office-based for CY 2021 are listed in the table below.

CPT Code	Descriptor	CY 2020 ASC Payment Indicator	CY 2021 ASC Payment Indicator*
11760	Repair of nail bed	G2	P3
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	J8	P3
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	G2	P2
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	G2	P2
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	G2	P2
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	G2	P2

*Payment indicators for CY 2021 are proposed rates subject to change in the CY 2021 OPPS/ASC final rule.

The ACS disagrees with CMS’ proposal to assign an ASC payment indicator of “P2” (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight) to CPT codes 23077 and 44408 for the following reasons:

- **CPT 23077 (Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm).** Code 23077 is a low volume code that has only exhibited an increase in office claims in 2019. CMS should not make apply a permanent office-based designation based on only one year of data for



a low volume code. Additionally, we believe the claims reported for this procedure suggest that CPT 23077 is being miscoded. Specifically, Medicare utilization data from 2017 indicate that 78 out of 277 claims (34 percent) for CPT code 23077 were reported by a single physician.⁴ Furthermore, that same physician reported these 78 claims for just 16 patients, which would indicate that such patients underwent multiple separate large sarcoma resections in an office setting. These utilization data are not plausible and indicate possible miscoding. **We request that CMS investigate such data and maintain the current ASC payment indicator of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) for CPT code 23077.**

- **CPT 44408 (Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed).** Code 44408 is a low volume code that has only exhibited an increase in office claims in recent years—such claims suggest that this procedure is being miscoded. Specifically, 2017 Medicare utilization data indicate that a single pulmonologist is reporting CPT code 44408 instead of the proper codes to reflect services that he/she is providing in the office, such as endoscopy through a tracheostomy stoma to clean out secretions.⁵ We do not believe that any pulmonologist would perform a colonoscopy, let alone perform a colonoscopy in the office setting. **We request that CMS investigate such data and maintain the current ASC payment indicator of “G2” for CPT code 44408.**

ADDITION OF NEW SERVICE CATEGORIES FOR HOSPITAL OUTPATIENT DEPARTMENT PRIOR AUTHORIZATION PROCESS

Controlling Unnecessary Increases in the Volume of Covered OPD Services

In the CY 2020 OPPS/ASC final rule, CMS established a prior authorization process for certain HOPD services using its authority under 42 U.S.C. § 1395l(t)(2)(F), which allows the Agency to develop a method for controlling unnecessary increases in the volume of covered HOPD services.⁶ As a condition

⁴ Centers for Medicare & Medicaid Services. (2019). *Physician and other supplier public use file: CY 2017*. Medicare Provider Utilization and Payment Data. Retrieved from <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/fs4p-t5eq/data>

⁵ Centers for Medicare & Medicaid Services. (2019). *Physician and other supplier public use file: CY 2017*. Medicare Provider Utilization and Payment Data. Retrieved from <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/fs4p-t5eq/data>

⁶ 84 F.R. 61142

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of payment under the Medicare program, prior authorization must be obtained for the following services when provided in the HOPD setting: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

Effective for dates of services on or after July 1, 2021, CMS proposes to require prior authorization for two additional service categories: (1) cervical fusion with disc removal, and (2) implanted spinal neurostimulators. The Agency asserts that these services show higher than expected, and therefore “unnecessary,” increases in the volume of utilization. The CPT codes for which CMS would require prior authorization are listed in the table below.

2021 Proposed List of Additional HOPD Services That Would Require Prior Authorization

CPT Code	Descriptor
Cervical Fusion with Disc Removal	
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Implanted Spinal Neurostimulators	
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

We are concerned that the Agency is misinterpreting an increase in the volume of utilization for certain procedures in the HOPD setting as “unnecessary,” when such increases may instead simply reflect an appropriate shift from inpatient to outpatient care over time. Specifically, CMS asserts that increases in HOPD utilization for CPT codes 22551 and 22552—which, according to the Agency, exhibited a 1,538.9 percent and 3,779.6 percent increase, respectively, in the HOPD setting between 2012 and 2018—is likely due to a change in Ambulatory Payment Classifications (APC) reimbursement rates for such codes, creating financial motivation to perform and bill for these cervical fusion with disc removal services more than may be considered medically necessary. We wish to highlight that, across all sites of service, the total volume of utilization for codes 22551 and 22552—which are still typically performed in an inpatient setting—changed minimally between 2012 and 2018. As such, we question whether the Agency is implementing prior authorization as a mechanism to control the total volume of utilization for various



services under the Medicare program, or, alternatively, to control site-of-service shifts from the inpatient to outpatient setting.

In addition, we note that the typical diagnosis for implantation of spinal neurostimulators—the second service category CMS proposes to subject to prior authorization—is failed medical management of pain with opiates and other adjuvant therapies. **Given the Agency's efforts to address the misuse and abuse of prescription opioids, along with its recognition that spinal neurostimulator devices are effective for controlling pain, we question why CMS would choose to further obstruct coverage for and access to non-opioid alternatives for the treatment of pain by requiring prior authorization for CPT codes 63650, 63685, and 63688.**

The ACS strongly objects to the introduction of any new prior authorization requirements into the Medicare program. We request that CMS investigate a possible misplaced assumption that all increases in the volume of certain HOPD services are “unnecessary,” and urge the Agency to rescind its proposal to require prior authorization for CPT codes 22551, 22552, 63650, 63685, and 63688 when furnished in the HOPD setting. We have numerous concerns with CMS’ prior authorization processes and the Agency’s interpretation of its statutory authority to make these proposals, which are described in detail below.

- **Administrative burden.** By CMS’s own admission in the CY 2020 OPPS/ASC final rule, its prior authorization policies significantly change how physicians must bill for services and will result in a \$19.8 million increase in administrative costs to private sector providers by CY 2025. In its discussion of this added financial burden on physicians, the Agency stated, “we do not view decreased revenues from OPD services subject to unnecessary utilization by providers to be a condition that we must mitigate” and failed to offer any offsetting increases in payments for other services.⁷ **As CMS and other insurers continue to subject a growing number of services to prior authorization, many physicians can no longer afford the increased practice costs related to compliance with prior authorization 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’ prior authorization policies could**

⁷ 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>



substantially limit 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 comply with insurers’ prior authorization requirements. CMS indicates that, as a condition of payment, a physician must submit a prior authorization request to the Agency that includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Claims submitted for services that require prior authorization but have not received a provisional affirmation of coverage (i.e., a preliminary finding that a future claim meets the Medicare coverage, coding, and payment rules) from CMS or its contractors would be denied. Moreover, CMS states 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 prior authorization request is received. We wish to highlight the following example of a prior authorization denial experienced by ACS members: in the case of a patient requiring segmental phlebectomy for treatment of extremity pain and swelling following failed pain management using compression therapy stockings, prior authorization was obtained for CPT code 37766 (*Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions*), with the prediction that, based on a preoperative examination of the patient, the surgeon would need to remove more than 20 symptomatic veins. Once the procedure was performed, only 15 symptomatic veins were removed, which is more appropriately described by CPT code 37765 (*Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions*). When the surgeon reported code 37765, the correct code for the service ultimately furnished, the patient’s insurer denied the claim simply because the code reported was not the code for which prior authorization was granted (code 37766), despite the fact that code 37765 was the proper code to report for the procedure performed and also a less complex service with lower work relative value units (RVUs), meaning that such service was less expensive than the one the insurer had originally approved.

We believe that payment for services for which prior authorization was granted should not be later denied based on billing technicalities, and 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.

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- **Violation of statutory authority.** Medicare statute authorizes CMS to “develop a method for controlling unnecessary increases in the volume of covered OPD services.”⁸ 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-board adjustments to all items or services paid under the OPDS. 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 HOPD setting, the Agency may appropriately adjust the update to the conversion factor (CF) otherwise applicable in a subsequent year.⁹ The CF is a uniform amount that is used in the formula to calculate payment rates for all items and services paid under the OPDS, and a CF adjustment can increase or decrease the entire OPDS 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 adjust payment rates for specific services, it must do so in a budget-neutral manner.¹⁰

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 prior authorization to specific cervical fusion with disc removal and implanted spinal neurostimulator services—along with blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation services—in response to unnecessary increases in the volume of HOPD services. Rather, as noted above, if the methodology developed by CMS shows that there are unnecessary increases in the volume of HOPD services, the

⁸ 42 U.S.C. § 1395l(t)(2)(F)

⁹ 42 U.S.C. § 1395l(t)(9)(C)

¹⁰ 42 U.S.C. § 1395l(t)(9)(B)

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Agency's recourse is to modify the CF and effectuate an across-the-board reduction in payment rates under the OPPIs. **The ACS does not support the application of prior authorization 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.**

REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

In the proposed rule, CMS explains that it seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Therefore, the Agency has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program. The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR).

ACS Overview: *Quality is a Program, Not a Set of Measures*

While the ACS appreciates efforts to align quality reporting programs across settings, we want to highlight that the framework for building quality should be thought of as a clinical improvement program, and not a set of measures in a payment system. For many years, the ACS has raised concerns to CMS that the quality metrics currently used across federal incentive programs have failed to drive improvement in surgery due to their disconnected and sporadic nature and general lack of cohesive framework. CMS measures components of care discretely, such as the individual surgeon separately from the hospital, separately from the anesthesiologist, separately from the pathologist, etc., which creates an overly burdensome measurement system and a fragmented picture of "quality." This approach is disjointed, burdensome, of little value to patients and surgical teams, and has the unintended consequence of incentivizing gaming.

For over half a century, the ACS has viewed quality as a program, with measurements serving as key components of such programs. Each of the ACS quality programs is built on a four-part model, known as the ACS Quality Model, that includes: 1) program-specific standards, 2) infrastructure needed for delivering high-quality care, 3) data collection and its use for care delivery and improvement, and 4) verification site visits to ensure implementation of the critical elements for optimal care. Amongst the most recognized of the ACS

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programs are the Trauma Center Verification Program, the Commission on Cancer (CoC) Accreditation, and the Metabolic and Bariatric Surgery Verification program. **The evidence supporting this model strongly suggests quality is not just a “measure,” as it is often defined. Rather, the evidence supports the concept that quality is a multi-component program that involves a coordinated team of clinicians and surgeons operating in a culture of excellence, with systems engineering for efficiency, appropriateness, proper resources applied within structure and processes, as well as measures for conformance and outcomes.** Integral to achieving high quality care, the “program” is informed through its data integration that leverages the knowledge gained through improvement cycles. In order to assure quality, the ACS’ experience shows that setting standards for care (both at the facility and individual clinician levels) and assuring, with rigor, that those standards are implemented is indispensable.

During this year we have had the opportunity to work with the Center for Medicare & Medicaid Innovation (the CMS Innovation Center) to develop a verification measure as part of the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model for the bariatric clinical episode. **This is the first time this type of representative set of measures will be implemented and specifically include a component (i.e., a verification measure) that addresses the fundamental infrastructures of a quality program focused overwhelmingly on the care of the patient.** The measures include the goals and outcomes important to the patient, while also valuing the infrastructure, resources, and processes needed to deliver optimal care and improvement.¹¹ To report the verification measure, the facility or physician group practice must be a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited bariatric center, which means it has met all the 2019 MBSAQIP (or similar program) standards. The goal of the measure is to incentivize bariatric-accredited centers to go beyond basic compliance of standards and to consider how to further enhance their compliance or work towards being exemplary. The verification measure includes six structural domains to score the bariatric surgery clinical episode which were chosen because they are strongly linked to safer and higher quality of care. **To appropriately build a quality program, we urge CMS to consider this order of priority:**

- 1. Define what is quality and improvement for a given condition or episode of care;**
- 2. Determine how quality and improvement should be measured,**

¹¹ Centers for Medicare & Medicaid Services. (2020). *The Bundled Payments for Care Improvement Advanced Model year 4: Quality measures fact sheet*. Retrieved from <https://innovation.cms.gov/media/document/bpci-advanced-my4-all-fact-sheets-sept2020>

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3. Determine the best reporting mechanics and data sources,
4. Determine how the measure data can be aggregated and reliably normalized for scoring,
5. Then align these elements to the physician and facility-level CMS incentive programs (i.e., Quality Payment Program (QPP) key measurements aligned with Hospital Value-based Purchasing Program (VBP), OQR, ASCQR, etc.)

ACS Goal for CMS Implementation of a Quality Framework

Below is a framework, based on the Donabedian Quality Model for Evaluating Care which illustrates ACS' long-term goals for implementing a quality program. Donabedian's structure, process, and outcomes quality model is a proven way to conceptualize quality of care.¹² The ACS' belief that surgical quality should be delivered (and measured) as a full program fundamentally operationalizes the entire Donabedian quality model. The figure below (Figure 1) conceptually demonstrates the layers for achieving surgical quality with the ACS Quality Verification Program at the base. This program sets the standards for structure and process components by defining the resources, infrastructure, and processes needed to achieve optimal quality improvement (QI). The ACS Clinical Programs set the standards for clinical care—these programs are where condition or specialty-specific standards are added (e.g., Bariatric, Trauma, Geriatrics). Layering on top of clinical accreditation are appropriate and adequate processes which further help to implement the care model. Moving up in the hierarchy of the key components are monitoring of clinical outcomes with accurate, clinical, risk-adjusted data (e.g., National Surgical Quality Improvement Program (NSQIP)) measured at the hospital level, followed by patient-reported outcomes (PROs), measured at the individual level. Each component of the quality model builds on and is interrelated to the others, pulling the information to assess the essential components for a patient, allowing for patients, clinicians, and payers to assess (more completely) the quality of care. The ideal for the systematically organized set of measures is to represent the spectrum of an effective quality program by focusing on each layer of this pyramid.

It is critical that CMS appreciate that this concept cannot be taken apart into individual components for implementation because it is the four-part model that has demonstrated improvements in care and fits the delivery system. **Through the ACS experience in creating quality programs, we know that the optimal and most advanced clinical patient care is given by providers who routinely perform both optimal clinical processes and optimal quality evaluation/**

¹² Donabedian, A. (2005). Evaluating the quality of medical care. *The Milbank Quarterly*, 83(4):691-729.

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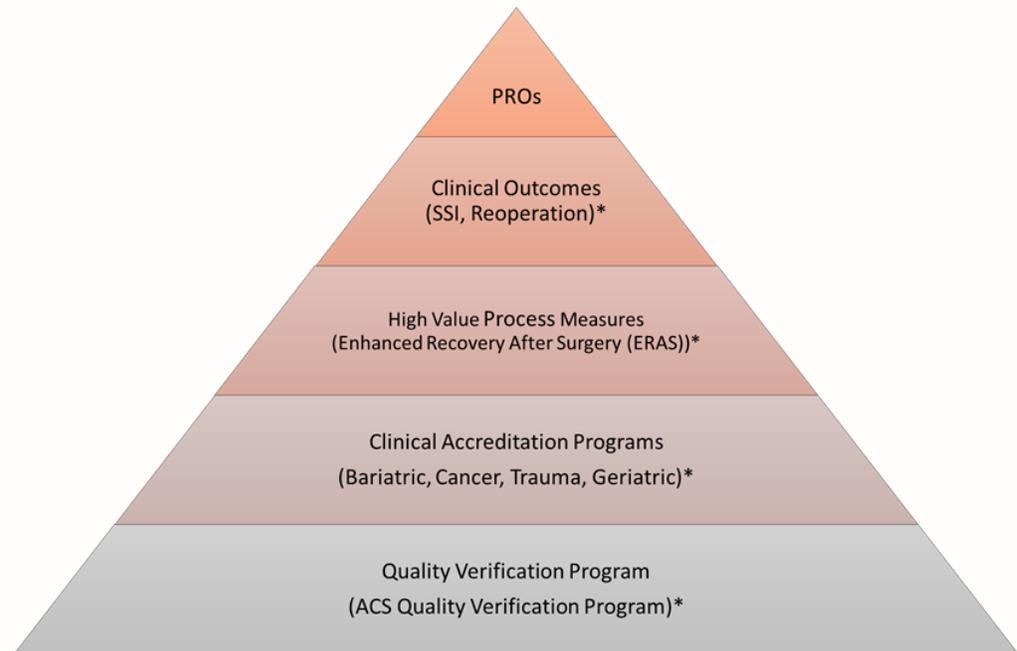
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improvement processes **ALL THE TIME**—not just in an incentive program. This type of program culture is what should be incentivized in federal quality programs.

Figure 1. Key Components to Building a Quality Program



Alignment of this model across inpatient, outpatient, and provider-based programs is not only achievable, but will ultimately reduce duplicative measurement for the care of the same patient and reduce overall measurement burden.

Below, Figure 2 illustrates surgical quality program alignment across the hospital and clinician incentive programs. The graphic depicts a team-based effort for a patient's condition or procedure. Similarly, we urge CMS to align the hospital measures in the hospital value-based purchasing program (VBP), OQR, ASCQR to come from the same pool, for example. Altogether, the impact would improve quality, greatly reduce burden by providing a consistent quality signal and fewer measures at lower costs.

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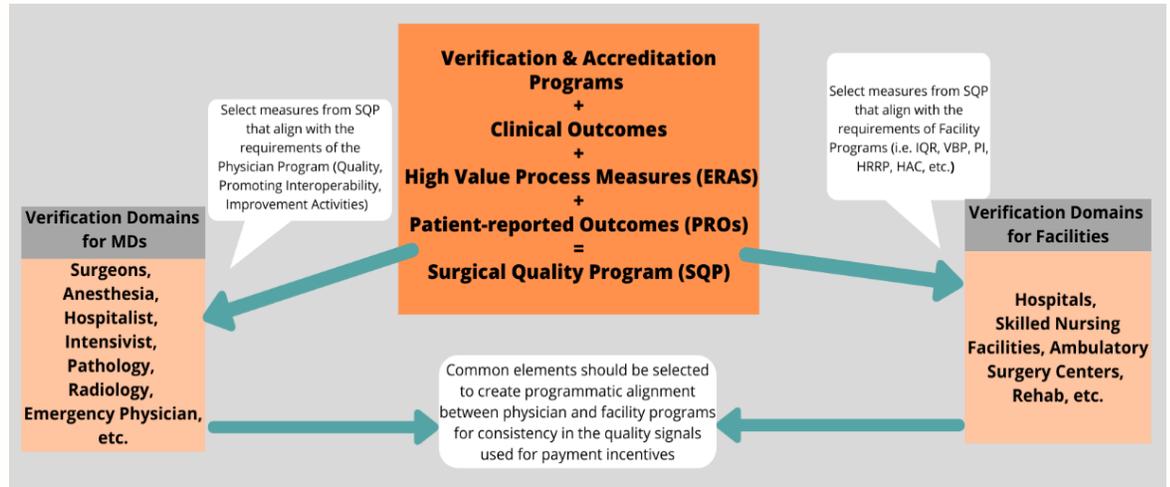
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Figure 2: Framework for Alignment Across Physician and Facility Programs



Additional Considerations During the COVID-19 Pandemic

Everyone often quotes Winston Churchill when he was working to form the United Nations after WWII, “Never let a good crisis go to waste.” As terrible a pandemic that COVID-19 is, we should make note of several lessons learned in the pandemic when it comes to understanding quality. As a planet, we knew almost nothing about the virus, how it spreads, the impact it has on humans, acute treatment and the consequences, or long-term sequela. The first order of care was to understand the medical condition and begin to formulate a care model. Resources played a major role in supporting care team needs, patients’ needs, as well as clinical protection for caregivers. Data systems sprung up, and shared knowledge became the goal across the entire globe. The world turned into a massive observational data registry with every expert and every scientific filter applied. Revenue models and payment systems were secondary thoughts. The patient and their condition were the centerpiece. Surrounding these were the caregivers working as teams. And knowledge sharing could not have been more important.

Within all of these efforts, we find the ACS model for a quality program. It begins with the patient, their condition and their care team. The right structures and processes must be in place in order to effectively and efficiently deliver the intended outcomes. Knowledge sharing from all sources informs the care team and drives its improvement cycles. Then, a payment model is applied with incentives for optimally meeting the patient’s goals and outcomes, while minimizing avoidable harms. CMS used an abundance of caution in its payment models to assure an optimal care model for COVID-19 and that this model was



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adequately resourced to meet the challenges of the condition. HHS used its many assets held in its various agencies to enhance and filter the shared knowledge as it emerged across the scientific community. Both HHS and CMS demonstrated a laser-like focus on the patient and the outcomes. Payment and incentive programs were adjusted so as not to overly burden or distract from the care. This allowed for a patient-centered care model, a focus on resources and the knowledge assets used to inform the medical science during a crisis. As a government agency, the payment must be adequate, at the same time, without excess and without overtaxing and distracting from the ultimate goal for better healthcare.

Also, worth noting, COVID-19 was about success and rewarding success, not penalizing care. The impact of positive versus negative incentives on patient care and clinical focus deserves more testing. Both have an impact on individuals and with teams of clinicians. When faced with the challenges of COVID-19, the positive incentives and rewards along with the professionalism to overcome the disease for patients proved effective. We have witnessed increasing success with the management of those afflicted with COVID-19 through a reduced need for hospitalization, intensive care and mortality rates. These are the quality reporting and payment lessons learned from a pandemic. We should be careful to absorb them and not brush aside these lessons as a passing fad from the pandemic.

In 2021, the country will continue to struggle from the impacts of COVID-19. In order to control, address, and then begin to recover from the COVID-19 pandemic, extensive resources and efforts will be required from the entire healthcare industry. The pandemic has forced an extreme shift in how surgical care is delivered in areas with high incidence of COVID-19, including what services and programs can be prioritized during this time. During the pandemic, some health care services have diminished to meet the demand of the COVID-19 on a local level causing administrators to prioritize personal protective equipment (PPE) access and consider treatment modality—all while staying in business. Also, in areas of the country where the pandemic is more controlled, many patients continue to hold off on needed surgical services in fear of COVID-19 exposure. All these factors differ greatly at the local level, depending on which phase of the pandemic the health system is experiencing. These factors also make quality assessments in the CMS quality programs incredibly complex and further bring into question the meaningfulness of these programs.

As the country and our health system begins to recover in the coming years, we will need to consider various factors to ensure high-quality patient care. Do we as a nation simply hit the “reset” button and resume our former business models? Or do we hit “reset” with an appreciation for restoring surgical care by leveraging the lessons learned in the crisis? Quality infrastructures will have to go through a time of reconstruction to account for what was learned during the pandemic, and

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practices will need to determine what is necessary to restore revenue. Entire care teams were lost to COVID-19 and must be reestablished as we go forward in business recovery. Importantly, we strongly encourage CMS to take this time to pause and rethink lessons from the pandemic and ask questions about what we have learned, including the system-wide vulnerabilities and strengths the pandemic has uncovered—such as which aspects in our health system are broken and inadequate, which aspects of care delivery have changed, and what strategies have saved lives during the pandemic.

REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

See comments in the *Requirements for the Hospital Outpatient Quality Reporting (OQR) Program* section on page 16.

The ACS appreciates the opportunity to provide feedback on the OPSS and ASC payment system, and we look forward to continuing dialogue with CMS on these important issues. If you have questions about our comments, contact Vinita Mujumdar, Regulatory Affairs Manager, at vmujumdar@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,

David B. Hoyt, MD, FACS
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