



September 26, 2019

Department of Health and Human Services  
Attention: CMS-1717-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244  
*Submitted electronically via: [www.regulations.gov](http://www.regulations.gov)*

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

Dear Administrator Verma:

The Society of Interventional Radiology (SIR) is a professional medical association that represents approximately 8,800 members, including most US physicians who are practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally-invasive, image-guided therapies. SIR appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services CY2020 CMS Proposed HOPPS and ASC Rule.

**Prior Authorization**

CMS is proposing to implement a prior authorization requirement for Vein Ablation services in CY2020. CMS stated that they reviewed internal data and developed this list of services to address what they are referring to as unnecessary increases in outpatient department volume.

According to CMS, vein ablation had an average annual increase in the number of unique claims of approximately 11.1 percent from 2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 11.5 percent and an average annual increase in the number of unique patients of approximately 9.5 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense to the Medicare program, and the number of Medicare patients also far exceed the typical baseline rates or trends CMS identified (that is, the 9.5 percent average annual increase in the rate of Medicare beneficiaries receiving

vein ablation is significantly higher than the 1.1 percent average annual increase in the Medicare beneficiaries who received outpatient services over that eleven-year period ). Below are the vein codes are being proposed for future requirement of prior authorization:

- *36473 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated*
- *36474 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites*
- *36475 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated*
- *36476 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites*
- *36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated*
- *36479 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites*

SIR opposes CMS' proposal to expand the use of prior authorization as a mechanism to curb utilization. The use of prior authorization delays patient care and erodes the patient/provider relationship. The Agency should use existing mechanisms for utilization review if they suspect overutilization by one of its providers.

### **Device Pass-Through Payment Applications**

CMS is evaluating several applications for device pass-through payments and are seeking public comments in this CY 2020 proposed rule on whether these applications meet the criteria for device pass-through payment status.

#### **Surefire® Spark™ Infusion System**

CMS is inviting public comments on whether the Surefire® Spark™ Infusion System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

#### **Eluvia™ Drug-Eluting Vascular Stent System**

CMS is inviting public comments on whether the Eluvia™ Vascular Drug-Eluting Stent System meets the device pass-through payment criteria discussed in this section, including the cost criterion. They did note that the applicant for the Eluvia™ Drug Eluting Vascular Stent System also applied for the IPPS new technology add-on payment.

CMS' pass-through payment methodology allows for the diffusion of technology. SIR supports the Agency's review of device pass-through applications and encourages the establishment of clear criteria and approval guidelines.

### **Making Public Consumer-Friendly Standard Charges for a Set of 'Shoppable Services'**

CMS is proposing requirements for hospitals to make public standard charge data for a set of "shoppable services" the hospital provides in a form and manner that is more consumer-friendly. CMS proposes to define 'shoppable service' as a service that can be scheduled by a health care consumer in advance. Specifically, CMS is proposing that hospitals would do the following:

- Display payer-specific negotiated charges for at least 300 shoppable services, including 70 CMS-selected shoppable services and 230 hospital-selected shoppable services. If a hospital does not provide one or more of the 70 CMS selected shoppable services, the hospital must select additional shoppable services such that the total number of shoppable services is at least 300.
- Include charges for services that the hospital customarily provides in conjunction with the primary service that is identified by a common billing code (e.g. Current Procedural Terminology (CPT)/ Healthcare Common Procedure Coding System (HCPCS)/ Diagnosis-Related Group (DRG).
- Make sure that the charge information is displayed prominently on a publicly available webpage, clearly identifies the hospital (or hospital location), easily accessible and without barriers, and searchable.
- Update the information at least annually.

SIR appreciates the Agency's direction of providing transparent pricing to its Medicare beneficiaries. Such disclosures allow beneficiaries to have more control over their healthcare choices. SIR has concerns the proposal to publish 'shoppable services' will not achieve the intended goal. Providers and facilities have innumerable contracts, all with varying prices, many of which include non-disclosure clauses. We urge the Agency to work with stakeholders to operationalize the executive order in a meaningful way.

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

CMS' review of the CY 2018 volume and utilization data resulted in the identification of several other covered surgical procedures that they believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and they believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that they are proposing to permanently designate as office-based for CY 2020 are listed in Table 29. The following three vascular codes were identified in the CMS proposal:

- *36465 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)*

- *36466 Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg*
- *36482 Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated*

SIR agrees that the current Medicare utilization data suggests that these three vascular procedures are typically (greater than 50% of the time) performed in the office setting. CMS is proposing to assign a P2 payment indicator for CPT Codes 36465 and 36466 and a P3 payment indicator to CPT Code 36482. SIR questions the validity of CMS' ASC payment policy that assigns the lowest published payment rate crossing multiple payment systems because the services' "complexity [is] consistent with other procedures performed routinely in physicians' offices".

CMS believes it may be premature to assign office-based payment status to CPT code 36902 *Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty* at this time due to changes in this high utilization service (over 125,000 claims in 2018). Therefore, for CY 2020, they are not proposing to designate CPT code 36902 as an office-based procedure and continue to assign CPT code 36902 a payment indicator of "G2" – nonoffice-based surgical procedure paid based on OPFS relative weights.

SIR agrees with the CMS proposal to base ASC payment for CPT Code 36902 on OPFS relative weights. We believe the G2 payment indicator for CPT Code 36902 is appropriate.

#### Temporary Office-Based Status

CMS believes 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) are clinically similar to HCPCS code G0365 (Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)), which currently has an ASC payment modifier of P2 *Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPFS relative payment weight*. As such, CMS is proposing to add CPT codes 93X00 and 93X01 in Table 30 to the list of temporarily office-based covered surgical procedures and assigning an R2 payment indicator

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*Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight.* Because they have no utilization data for the procedures specifically described by these new CPT codes, they are proposing to make the office-based designation temporary rather than permanent, and they will reevaluate the procedures when data become available. SIR appreciates the temporary designation and will review the utilization data as it becomes available.

Thank you for reviewing our comments. If you have any questions, contact Sue Sedory, SIR Executive Director at [ssedory@sirweb.org](mailto:ssedory@sirweb.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Findeiss".

Laura Findeiss, MD, FSIR  
President

cc: Sue Sedory, Executive Director