
*Atrium Health (GA, NC)*

*Avera Health (IA, MN, NE, ND, SD)*

*Community Hospital Anderson (IN)*

*Erlanger Health System (TN)*

*Franciscan Missionaries of Our Lady Health System (LA)*

*Hartford Healthcare (CT)*

*Oregon Health & Science University (OR)*

*SSM Health (IL, MO, OK, WI)*

*University of Florida Health-Central Florida (FL)*

*University of Pittsburgh Medical Center (PA, NY)*

October 4, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Re: 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; RIN 0938-AU12]

Dear Ms. Verma,

The Provider Roundtable (PRT) submits the following comments on the Outpatient Prospective Payment System (OPPS), as published in the *Federal Register*.

The Provider Roundtable (PRT) includes 15 representatives from various health systems, serving patients in 19 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services by CMS, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual OPPS policymaking process. We appreciate the opportunity to provide our comments to CMS. A full list of the current PRT members is provided in **Attachment A.**

Please feel free to contact me at 765-298-2110 or via email at: *trinker@ecommunity.com*.

Sincerely,

Terri Rinker, MT (ASCP), MHA
PRT Chair and
Revenue Cycle Director
Community Hospital Anderson
Anderson, IN

## II. Proposed Updates Affecting OPPS Payments

Payment for Blood Not Otherwise Classified (NOC) Code

In an effort to encourage providers to utilize new blood products, CMS established a new HCPCS code (P9099) on January 1, 2020. This code is used to report and bill blood components and products that are not otherwise classified. This HCPCS code was assigned a status indicator of "E2" (SI-E2), meaning it is not payable by Medicare when submitted on an outpatient claim. Although this HCPCS code was meant to track utilization and cost, the SI-E2 means that all claim lines billed with P9099 are rejected, preventing CMS from tracking unclassified blood products through claims data.

In the Proposed 2021 OPPS Rule, CMS states that providers and stakeholders in the field have reported that there may be several additional new blood products entering the market by the end of CY 2021. This is a drastic change from the 1-2 new products that entered the market in the past 15-20 years. Until specific HCPCS codes are assigned, the unclassified code P9099 would be used to report and bill for these new products.

CMS considered utilizing the current methodology—assigning the same payment to P9099 as the APC with lowest blood product service payment—to address this situation. But, the agency rejected the method due to the potential for the cost of new unclassified blood components and products to be significantly higher than the lowest-paying APC in this category.

- **The PRT agrees that assigning the lowest-paying blood product APC payment to P9099 is inappropriate.**

Because of the issues with P9099 and the SI-E2, CMS proposes to package the cost of unclassified blood products into payment of the primary procedure by changing the status indicator of P9099 to SI-N (payment packaged into payment for other services, with no separate APC payment). CMS' reasoning for this proposal is that it will enable providers to report the cost of unclassified blood products and components and allow CMS to use these data for future rate-setting.

The PRT has several issues with this proposal:

1. This methodology differs from the payment methodology for current blood and blood products, which are always paid separately and not packaged into another procedure.
2. Under OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family, and are not packaged with another procedure.
3. The current primary procedure APCs do not have dollars included for any blood or blood products, therefore providers would receive essentially no payment for the new blood products/components.
4. We believe that hospitals and providers are less likely to report HCPCS code P9099 if there is not separate payment for it resulting from the assignment of SI-N.
5. Patient access to new blood product technologies is likely to be impacted if providers elect not to offer new blood products/components due to the lack of reimbursement.

It is not appropriate to assign SI-N to a category of **new** products for which costs are unknown, given that there is neither payment history for the individual item nor cost data available to package into a primary procedure. Without cost data, the packaging concept is null and void for

incorporating these new costs. If CMS implements the proposal, providers would be paid even less than the lowest-paying blood product APC payment. Essentially, providers would get no reimbursement for new blood products, which is unacceptable. In fact, this proposal will actually result in less reimbursement to a provider as the payment for the new blood product is included in the overall reimbursement for the procedure, but the cost is not.

CMS is seeking feedback on how providers can report these new blood products in a fair and equitable way. CMS states, "*because of the challenges of determining an appropriate payment rate for unclassified blood products, we are considering packaging the cost of unclassified blood product into their affiliate primary procedure*."

The PRT strongly urges CMS not assign SI-N and proposes two alternative solutions. We have spent considerable amounts of time considering our position since we presented at the HOP panel meeting in August 2020. We feel strongly that "no payment" under CMS' current proposal is not a viable option for providers, and could make new products less easy to access for beneficiaries. Instead, we offer two alternatives for CMS to consider.

> Option One: The PRT recommends that CMS implement a new status indicator, SI-R1, for P9099 in order to calculate charges to cost. The OCE edit logic could be coded for the specific status indicator to reduce the charges to cost.
>
> Option Two: If CMS is not able to create a new status indicator R1, then the agency should assign SI- R to P9099 and place it in a new blood product APC with payment that is based on the weighted average of all blood and blood product APCs.

Both options allow CMS to continue its longstanding OPPS payment policy for blood and blood products. Both provide separate reimbursement for new blood products and simultaneously collect data for use in future rate-setting. Both options allow the newly established HCPCS code to be routed to the correct APC for payment. Both options also facilitate patient access to new products and encourage providers to offer these new blood products/components without an unacceptable loss of payment.

A separate payment solution *must* be implemented until enough data are available to use in establishing a new HCPCS code. Providers must be paid "something" for these services, and there is currently no way to account for them, and no data available about them. Once a more specific HCPC code can be created for each new blood product, and CMS has collected the associated cost information, cost data can be used to assign the products to the most appropriate APC payment.

- **The PRT recommends that CMS assign a new status indicator "R1" to the not-otherwise-classified blood product HCPCS code P9099. The new SI-R1 would allow the calculation of charges to cost through programming of the OCE reimbursement logic.**

- **Alternatively, assign P9099 a SI of R and utilize the weighted average cost of all blood and blood products for assigning reimbursement to a new "Not otherwise classified blood and blood products" APC.**

## III. OPPS Ambulatory Payment Classification (APC) Group Policies

C. Proposed New Technology APCs

In CY 2002, CMS finalized changes to the time period during which a service can be eligible for payment under a New Technology APC. CMS will retain services within New Technology APC groups until sufficient claims data are available to determine an appropriate clinical APC. This policy allows CMS to move a service from a New Technology APC in less than two years if sufficient data are available. It also allows CMS to retain a service in a New Technology APC for more than two years if data are insufficient to base a decision for reassignment.

There were 52 New Technology APC levels for CY 2020, ranging from the lowest cost-band assigned to APC 1491 (New Technology—Level 1A [$0– $10]) to highest cost-band assigned to APC 1908 (New Technology—Level 52 [$145,001– $160,000]). The cost-bands identify the APCs into which new technology procedures and services are assigned, based on their estimated service costs. Payment for each APC is made at the mid-point of the assigned cost-band.

There is often a period of low utilization as emerging technologies develop and are adopted in clinical settings. We understand CMS' need for adequate claims data in order to assign proper APC placement; until those data are available, we support CMS' efforts to place new, low-volume services into New Technology APC bands.

The PRT appreciates the opportunity to comment on New Technology APCs and support CMS' efforts to provide payment for new technology services listed in the Proposed Rule.

*a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)*

CMS now has sufficient claims data for this procedure, and is proposing to assign HCPCS code 0398T ("Magnetic resonance image guided high intensity focused ultrasound, stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed") from a New Technology APC to the newly restructured clinical family of Neurostimulators.

- **The PRT supports this change.**

*b. Retinal Prosthesis Implant Procedure CPT code 0100T (Insertion of retinal prosthesis receiver pulse generator and retinal electrode array)*

The number of claims for the Argus II procedure (described with CPT code 0100T) continues to be very low, with substantial fluctuation in cost from year to year. As a result, CMS proposes to maintain the procedure's assignment in APC 1908: New Technology—Level 52 ($145,001-$160,000).

- **The PRT supports the maintenance of the current APC assignment.**

*c. Administration of Subretinal Therapies Requiring Vitrectomy - CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes)*

Voretigene neparvovec-rzyl is a gene therapy for a rare mutation-associated retinal dystrophy.

Historically, it is billed with the service described by HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach). CMS recognizes the necessity to accurately describe this unique procedure that is required to administer the therapy (described by CPT J3398). The agency proposes to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) for this procedure and assign is to APC 1561: New Technology—Level 24 ($3001–$3500).

- **The PRT supports the creation of this new HCPCS code and its proposed APC assignment.**

*d. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy*

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion[s] by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition[s] and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound [EBUS] guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention[s]).In CY 2020, this code was assigned to APC 0571 ($8250.50).

There is a low volume of claims for this service. CMS proposes to apply the policy by which it utilizes an equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs in order to generate an appropriate payment rate for the procedure. CMS proposes to assign this code to New Technology APC 1563, with a proposed payment rate of $4250.50.

- **The PRT opposes this change, due to the low volume of claims data. We request that CMS retain the code's current assignment within APC 1571.**

*e. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)*

For CY 2020, FFRCT was assigned to New Technology APC 1516 (New Technology—Level 16) with a payment rate of $1,450.50. In most recent claims data, CMS received 2,820 claims billed with CPT code 0503T. As these totals exceed the threshold of 100 claims for a procedure to be evaluated using the new Technology APC low-volume policy, CMS proposes to reassign the service described by CPT code 0503T to New Technology APC 1510 (New Technology—Level 10 ($801–$900)), with a proposed payment rate of $850.50 for CY 2021.

CMS' proposed payment rate ($850.50) is a reduction from CY 2020 and is significantly below the direct invoice / list cost of $1,400 that is required to provide FFRCT. CMS is relying on a small set of single procedure claims, which generates an inappropriately low geometric mean cost calculation for CY 2021. The PRT supports the use of value-based clinical protocols that are based upon the most accurate diagnostic tools available, including FFRCT. The continued and significant decreases in reimbursement for FFRCT, which is one such tool, will jeopardize PRT members' ability to provide this cutting-edge diagnostic service.

The PRT believes that CMS should assign 0503T to Level 3 Nuclear Medicine and Related Service APC (APC 5593), which has a payment rate of $1,336.28. This is the most accurate and appropriate assignment with respect to both calculated costs and clinical homogeneity because:

1) The other predominant tests that are used to diagnose suspected CAD are also in APC 5593, and include SPECT (CPT codes 78451-78453), and cardiac PET (CPT code 78459).
2) APC 5593 contains other tests that characterize blood flow in the body (e.g., CPT codes 78110, 78111).
3) APC 5593 contains other tests that characterize blood flow in organs, which is the same clinical characteristic as FFRCT (e.g., the liver (CPT Code 78202), the brain (CPT Code 78606) the kidney (CPT code 78708).

- **CMS should assign 0503T to Level 3 Nuclear Medicine and Related Service APC (APC 5593) with a payment rate of $1,336.28.**

The PRT also recommends that CMS implement a process to create generated single procedure (pseudo single) claims for 0503T, much as the agency has done for claims containing SI-J1 and SI-J2. This methodology appropriately presumes "no packaging" for 0503T and would enable CMS to use all of the claims in the GMC calculation. CMS can appropriately consider the total (vs. single) frequency to inform reimbursement for 0503T, since CPT 0503T is an independent diagnostic service, despite the fact that it is most commonly billed on the same claim as the CT Angiography (per CMS' Cost File data).

- **The PRT recommends that CMS implement a process to create generated single procedure (pseudo single) claims for 0503T, similar to the process that the agency uses for claims that contain SI-J1 and SI-J2.**

*f. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies*

Effective January 1, 2020, CMS assigned three CPT codes that describe the services associated with cardiac PET/CT studies (78431, 78432, and 78433) to New Technology APCs. CPT code 78431 was assigned to APC 1522: New Technology—Level 22 ($2001–$2500) with a payment rate of $2250.50; CPT codes 78432 and 78433 were assigned to APC 1523: New Technology—Level 23 ($2501–$3000) with a payment rate of $ 2750.50. CMS has not received any claims data representing these services and is proposing to maintain the current APC assignments.

- **The PRT supports this proposal.**

*g. Pathogen Test for Platelets/Rapid Bacterial Testing*

HCPCS code P9100 (Pathogen test[s] for platelets) was effective January 1, 2018. In CY 2020, based on claims data, CMS revised its APC assignment from New Technology APC 1493 to 1494: (New Technology—Level 1D ($31- $40). For CY 2021, CMS believes there are sufficient claims data to reassign the code from a New Technology APC 1494 to clinical APC 5732.

- **The PRT supports this proposal.**

*h. V-Wave Interatrial Shunt Procedure (HCPCS Code C9758; APC 1589)*

The V-Wave interatrial shunt is designed to regulate left atrial pressure in the heart of patients with severe symptomatic heart failure. A randomized, double-blinded control investigational device exemption (IDE) study is currently in progress for the shunt. All of the participants who

passed the study's initial screening receive a right heart catheterization and those in the experimental group additionally receive the V-Wave interatrial shunt.

In order to address concerns of the V-Wave's developer, regarding keeping the study blinded, CMS created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both experimental and control groups. (HCPCS code C9758: Blinded procedure for NYHA class III/ IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance.)

This service was assigned to New Technology APC 1589: New Technology—Level 38 ($10001– $15000). CMS has not received claims data representing this service, and no change in APC assignment is proposed.

- **The PRT supports maintaining the current APC assignment.**

*i. Supervised Visits for Esketamine Self- Administration (HCPCS Codes G2082 and G2083 APCs 1508 and 1511)*

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved Spravato™ (esketamine) nasal spray, which is used in conjunction with an oral antidepressant to manage treatment-resistant depression (depression in adults who have not benefited from other antidepressant medicines).

Due to risks of serious adverse outcomes from sedation and dissociation, as well as the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). Patients must be monitored by a health care provider for at least two hours after receiving a dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product can only be administered in a certified medical office where a healthcare provider can monitor the patient.

In order to ensure access, CMS created two new HCPCS codes, G2082 and G2083, effective January 1, 2020.

- G2082 (Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation).
- G2083 (Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes two hours post-administration observation).

G2082 was assigned to New Technology APC 1508: New Technology—Level 8 ($601–$700) with a payment rate of $650.50. G2083 was assigned to New Technology APC 1511: New Technology—Level 11 ($901– $1,000) with a payment rate of $950.50.

CMS has not received claims for either of these HCPCS codes, and proposes to maintain the current APC assignments.

- **The PRT supports maintaining the current APC assignments.**

D. Proposed OPPS APC-Specific Policies

Neurostimulators and Related Procedures (APCs 5461 through 5462)

CMS is proposing to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs. CMS states that this will allow the distribution of the costs between the different levels based on their resource costs and clinical characteristics. This revision will establish a five-level APC structure for the Neurostimulator and Related Procedures series.

- **The PRT agrees with the expansion of the neurostimulator C-APCs based on resources costs and clinical characteristics.**

Other CPT Codes

We ask CMS to review the following CPT codes within the C-APCs that we believe are disparate between cost and clinical characteristics.

*CPT 0425T and 0427T*

The PRT asks CMS to review the APC assignment for CPT codes 0425T (Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; sensing lead only), and 0427T (Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; pulse generator only). These two services are single claims with similar clinical characteristics and similar geometric mean costs.

| HCPCS | SI | APC | Payment Rate | Single Frequency | Total Frequency | Minimum Cost | Maximum Cost | Median Cost | Geometric Mean Cost |
|---|---|---|---|---|---|---|---|---|---|
| 0425T | J1 | 5463 | $12,780.91 | 1 | 1 | $18,928 | $18,928 | $18,928 | $18,928 |
| 0427T | J1 | 5465 | $29,967.81 | 1 | 1 | $16,731.24 | $16,731.24 | $16,731.24 | $16,731.24 |

- **The PRT recommends moving CPT 0425T from APC 5463 to 5465. This will align services with similar clinical characteristics and geometric mean in the same APC.**

| HCPCS | SI | APC Proposed CY 21 | APC Recommendation CY 21 |
|---|---|---|---|
| 0425T | J1 | 5463 | 5465 |

*CPT 0428T*

The PRT asks CMS to review the APC assignment of 5461 for CPT code 0428T (Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only).

| HCPCS | SI | APC | Payment Rate | Single Frequency | Total Frequency | Minimum Cost | Maximum Cost | Median Cost | Geometric Mean Cost |
|---|---|---|---|---|---|---|---|---|---|
| 0428T | J1 | 5461 | $3,498.13 | 1 | 1 | $22,111.24 | $22,111.24 | $22,111.24 | $22,111.24 |

The geometric mean of $22,111.24 is similar to that of APC 5465. Although in this category there is only a single claim, some of the clinical characteristics of this procedure are similar to other neurostimulators. Neurostimulators work by affecting the function of a nerve, either stimulating or blocking the nerve impulse, depending on the desired treatment. The neurostimulator for central sleep apnea consists of a generator and leads, with the generator implanted in the subcutaneous tissue of the chest, and the electrodes being attached to the phrenic nerve. The neurostimulator monitors the patient's respiratory signals during sleep and "fires" the electrode to stimulate the phrenic nerve to respond to any episodes of apnea. Based upon these clinical similarities to other neurostimulators, the PRT asks CMS to move CPT 0428T from APC 5461 to APC 5465.

- **The PRT asks CMS to reassign CPT 0428T to APC 5465.**

| HCPCS | SI | APC Proposed CY 21 | APC 5461 Geometric Mean Cost Range | APC Recommendation CY 21 | APC 5465 Geometric Mean Cost Range |
|---|---|---|---|---|---|
| 0428T | J1 | 5461 | ( $6,902.64 - $9,711.64) | 5465 | ($12,323.26 - $37,961.95) |

*CPT 64569*

The PRT asks CMS to review the APC assignment for CPT codes 64569 (Revision or Replacement of cranial nerve neurostimulator electrode array, including connection to existing pulse generator). CPT 64659 with APC 5463 has a geometric mean cost of $23,787.89 and is similar to the geometric mean and clinical service of CPT 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling) with APC 5464. We believe it is more appropriate for this CPT to be in the latter APC.

| HCPCS | SI | APC | Payment Rate | Single Frequency | Total Frequency | Minimum Cost | Maximum Cost | Median Cost | Geometric Mean Cost |
|---|---|---|---|---|---|---|---|---|---|
| 64569 | J1 | 5463 | $12,780.91 | 1 | 1 | $3,267.86 | $64,408.60 | $29,282.19 | $23,787.89 |
| 64590 | J1 | 5464 | $20,789.82 | 1 | 1 | $5,175.37 | $67,366.45 | $19,734.43 | $18,981.92 |

- **The PRT asks CMS to reassign CPT 64569 to APC 5464**.

| HCPCS | SI | APC Proposed CY 21 | APC Recommendation CY 21 |
|---|---|---|---|
| 64569 | J1 | 5463 | 5464 |

*CPT 63664 and 6366C*

The PRT requests CMS to reconsider the APC assignment for CPT 63664 (Revision including replacement, when performed, of spinal neurostimulator electrode plat/paddle[s] placed via laminotomy or laminectomy, including fluoroscopy when performed) and the new CPT code for 2021, 6366C (Revise spine eltrd) from APC 5463 to APC 5464. The geometric mean for these services is equivalent to the payment rate of $12,780.91.

| HCPCS | SI | APC | Payment Rate | Single Frequency | Total Frequency | Minimum Cost | Maximum Cost | Median Cost | Geometric Mean Cost |
|---|---|---|---|---|---|---|---|---|---|
| 63664 | J1 | 5463 | $12,780.91 | 1 | 1 | $2,257.78 | $57,348.86 | $12,966.97 | $12,577.75 |
| 6366C | J1 | 5463 | $12,780.91 | 1 | 1 | $1,571.91 | $61,502.73 | $11,581.07 | $12,633.81 |

- **The PRT requests CMS reassign CPT codes 63664 and 6366C to APC 5464.**

| HCPCS | SI | APC Proposed CY 21 | APC Recommendation CY 21 | APC 5463 Payment | APC 5464 Payment |
|---|---|---|---|---|---|
| 63664 | J1 | 5463 | 5464 | $12,780.91 | $20,789.82 |
| 6366C | J1 | 5463 | 5464 | $12,780.91 | $20,789.82 |

Urology and Related Services (APCs 5371 through 5378)

CMS proposes to create an additional APC in the Urology and Related Services series. The agency's rationale is to provide a distinguishing structure between the Urology APCs based on clinical and cost similarity for the procedures in the different levels.

CMS' claim data review identified the geometric mean cost for APC 5377 to be around 220 percent of the geometric mean cost of APC 5376. Claims data that are available for this CY 2021 OPPS Proposed Rule show an unusually large difference between the geometric mean costs of the Level 6 Urology APC and the Level 7 Urology APC—on both a dollar and percentage basis.

CMS proposes to create an additional APC 5378 (Level 8) and re-organize current APCs 5376 (level 6) and 5377 (Level 7). CMS believes this would address the lack of an appropriate level for procedures with geometric mean costs that fall between current APC 5376 and current APC 5377.

- **The PRT agrees with the expansion of the Urology C-APCs based on resource costs and clinical characteristics.**

We ask CMS to review the following CPT codes within the Urology and Related Services C-APCs that we believe are disparate between cost and clinical characteristics.

*CPT 53410*

The PRT believes CPT 53410 (Urethroplasty, 1-stage reconstruction of male anterior urethra) and CPT 55875 (Transperineal placement of biodegraIdable material, periprostatic, single or multiple injection[s], including imaging guidance, when performed) should both be moved from APC 5375 to APC 5376.

| HCPCS | SI | APC | Payment Rate | Single Frequency | Total Frequency | Minimum Cost | Maximum Cost | Median Cost | Geometric Mean Cost | CV |
|---|---|---|---|---|---|---|---|---|---|---|
| 53410 | J1 | 5375 | $4,487.87 | 514 | 520 | $2,001.17 | $20,075.21 | $5,858.37 | $5,792.60 | 41.156 |
| 55875 | J1 | 5375 | $4,487.87 | 4059 | 4136 | $1,009.38 | $41,141.37 | $6,098.89 | $6,139.91 | 59.756 |

- **The PRT requests CMS to move CPT 53410 and CPT 55875 from APC 5375 to APC 5376.**

| HCPCS | SI | APC Proposed CY 21 | APC Recommendation CY 21 | APC 53750 Payment | APC 53760 Payment |
|---|---|---|---|---|---|
| 53410 | J1 | 5375 | 5376 | $4,487.87 | $8,395.62 |
| 55875 | J1 | 5375 | 5376 | $4,487.87 | $8,395.62 |

*CPT 55873, CPT 50081, and CPT 50562*

The PRT believes CPT 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring), CPT 50081 (Percutaneous nephrostolithotomy or pyelostolithotomy with or without dilation, endoscopy, lithotripsy, stenting or basket extraction; over 2cm) and CPT 50562 (Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation instillation, or uteropyelography, exclusive of radiologic services with resection of tumor) should be moved from APC 5376 to APC 5377.

| HCPCS | SI | APC | Payment Rate | Single Frequency | Total Frequency | Minimum Cost | Maximum Cost | Median Cost | Geometric Mean Cost | CV |
|---|---|---|---|---|---|---|---|---|---|---|
| 55873 | J1 | 5376 | $8,395.62 | 1191 | 1199 | $1,807.95 | $38,532.32 | $8,900.37 | $8,453.44 | 50.806 |
| 50081 | J1 | 5376 | $8,395.62 | 2438 | 2463 | $2,837.33 | $25,974.47 | $8,462.97 | $8,563.12 | 36.494 |
| 50562 | J1 | 5376 | $8,395.62 | 18 | 18 | $5,789.23 | $19,654.02 | $8,307.64 | $8,685.02 | 34.204 |

- **The PRT requests that CMS move CPT 55873, CPT 50081, and CPT 50562 from APC 5376 to APC 5377.**

| HCPCS | SI | APC Proposed CY 21 | APC Recommendation CY 21 | APC 53750 Payment | APC 53760 Payment |
|---|---|---|---|---|---|
| 55873 | J1 | 5376 | 5377 | $8,395.62 | $11,701.41 |
| 50081 | J1 | 5376 | 5377 | $8,395.62 | $11,701.41 |
| 50562 | J1 | 5376 | 5377 | $8,395.62 | $11,701.41 |

## IV. OPPS Payment for Devices

Proposed Pass-Through Payment for Devices

Transitional device pass-through payment policy is designed to facilitate beneficiaries' access to new and innovative devices. It enables adequate payment to be made for these new devices while the necessary cost data are collected for integration into the procedure APC. A device category is eligible for transitional pass-through payments for at least two, but no more than three, years.

In the 2017 OPPS/ASC Final Rule, CMS amended the pass-through payment policy so that the device category's eligibility period begins on the first date on which pass-through payment is made under the OPPS for any medical device described by the category. In the 2017 OPPS/ACS Final Rule, CMS also allowed for quarterly expiration of pass-through payment status for devices, enabling a payment period as close to three years as possible. CMS also established a policy to package the cost for devices that are no longer eligible for pass-through payment into the cost of the procedures with which the devices are reported in the claims data in order to set APC payment rates.

In the CY 2020 OPPS/ASC Final Rule, CMS established an alternative pathway for device pass-through payments. Under this pathway, a medical device that is part of the FDA's Breakthrough Devices Program, and which has received marketing authorization (e.g., PMA, 510(k) clearance, or a De Novo classification request), will not have to submit information supporting the substantial clinical improvement criteria to determine device pass-through payment status.

CMS received five applications for device pass-through consideration that are discussed in the 2021 OPPS/ASC Proposed Rule: three devices under the Alternative Pathway Device Pass-Through applications process, and two under the traditional Device Pass-Through application process.

The PRT supports all CMS efforts to facilitate payment for the innovative delivery of care. Pass-through payments ensure that Medicare beneficiaries have access to innovative services and reduce facilities' economic burdens. They provide adequate payment for services while necessary cost data are collected for use in the APC rate-setting process.

- **The PRT recommends that CMS retain pass-through payment status for a full three years regardless of the device's pathway to approval.**

We understand that pass-through payments are intended to be interim while CMS receives adequate claims data so that the agency can determine the proper APC assignment. In the Proposed Rule, CMS seeks comments about whether it should continue providing separate

payment in CY 2022 and future years for devices that are eligible for pass-through payment during the COVID–19 PHE, as these devices are typically involved in elective procedures. On March 18, 2020, CMS issued recommendations to postpone all elective surgeries due to the COVID–19 PHE. Significant healthcare resources have been triaged in order to assist the COVID–19 pandemic response, which created a reduced utilization of those resources used in elective services.

- **The PRT appreciates CMS' recognition of the interrupted pass-through payment cycle and making efforts to close that gap by extending the time-frame due to the unforeseen PHE.**

- **The PRT requests that CMS continue pass-through status for these devices for at least another year.**

- **With respect to the new device pass-through applications for CY 2021, the PRT fully supports CMS' approval of pass-through status for:**
  - **CUSTOMFLEX® ARTIFICIALIRIS (Alternative Pathway)**
  - **EXALT™ Model D Single-Use Duodenoscope (Alternative Pathway)**
  - **The SpineJack® Expansion Kit (Traditional Pathway)**
  - **BAROSTIM NEO™ System (Alternative Pathway)**
  - **Hemospray® Endoscopic Hemostat (Traditional Pathway)**

## V. B.6 - CY 2021 OPPS Payment Methodology for 340B Purchased Drugs

The PRT has previously provided comment to CMS and now reiterate our stance that reimbursement for 340B drugs should be *at least* ASP+6%. CMS continues to believe that, because hospitals pay less for 340B drugs, the agency should reimburse these facilities a lower amount for these drugs. CMS' view overlooks the fact that the 340B program, which was created with bipartisan support in 1992, exists because Congress intended the program to assist hospitals to care for low-income and other vulnerable patients. The 340B program was intended to provide additional resources to hospitals so they can provide services to the disproportionate number of low-income, vulnerable patients whom they treat.

CMS admits that it lacks the data needed to assess patient care and resource use under the 340B program. Many hospitals provide free housing for patients who need chemotherapy or radiation treatments, and/or provide transportation services to bring patients to chemotherapy and physician appointments, so they do not have to travel during treatment days. Many hospitals provide meals to family members while patients are in the hospital. Many facilities use 340B savings to support charity care and free care funds at their eligible hospitals, offer underinsured and uninsured patients discounted medications, and purchase equipment for some clinics to provide patient care. In these ways, the savings realized through the 340B program allow providers—consistent with Congressional intent in establishing the program—to expand the scope of charitable services offered to the community. The PRT fails to understand how CMS can make statements regarding hospitals' use of the savings, when the agency admits to a lack of understanding on where the savings are being realized.

Maintaining current 340B payment or making any further reductions poses an access to care issue, as these cuts may force entities to eliminate or scale back many important charitable health care programs. This reduction in access to health services will likely lead to more Emergency Department (ED) visits and contribute to worsening health outcomes. This impact is exacerbated for struggling rural hospitals. Although rural hospitals are not affected by the payment reductions, these reductions cause a domino effect as facilities' ED visits and acuity of patients presenting to the hospital will increase, further stretching resources.

- **The PRT continues to reiterate that *any* payment less than ASP+6% for 340B drugs is unacceptable.**

The PRT fundamentally and emphatically continues to disagree with CMS' policy of reimbursing for separately payable drugs obtained by Covered Entities via 340B purchasing at ASP *minus* 22.5 percent (ASP-22%) and definitely at ASP *minus* 28.7% (ASP-28.7%). The newest proposal is based on a survey that requested drug acquisition cost data for certain quarters during CY 2018 and 2019. CMS states that no 340B hospitals argued in prior rule-making comments that ASP-22% was incorrect; CMS expected the survey data to support that this rate is a *"conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program."*

The PRT strongly disagrees with this assertion; several of our member hospitals participate in the 340B program and have voiced their disagreement and supporting reasons ever since the proposal was first made.
The agency acknowledges that a 2005 GAO study found that the survey "created a considerable burden for hospitals as the data suppliers." Regarding the 340B survey, CMS notes that only 7% of surveyed hospitals responded with details; more than half (55%) responded via the quick survey option. More than one-third (38%) did not respond to either option. The agency should be concerned that only 7% of providers responded in detail, and similarly consider why 93% of providers *did not*.

While CMS had no control over the appearance of the novel coronavirus pandemic, the agency did institute its latest survey at a time when providers were struggling to handle the public health emergency (PHE): April 24 through May 15, 2020. Quite frankly, completing a survey was not at the top of the list of facility priorities.

CMS used the ceiling price as a proxy when the information was not provided as this <u>should</u> be the "maximum amount covered entities may permissibly be required to pay for a drug" under the 340B program, with the "expectation" that no hospital would pay for more than this price. The PRT believes it is indisputable that the low number of respondents with detailed information was related to the PHE. We also urge CMS not to move forward with the additional decrease. We maintain that this action is an over-reaching of the boundaries of CMS' statutory authority.

Hospitals have made significant efforts to reduce cost in order to make more services available to underserved; yet, for every effort that is made, there is a more significant decreases to reimbursement. This defeats the providers' efforts to serve these patient populations.

CMS confirms in the Proposed Rule that it recognizes *"the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients."* As

its rationale for this methodology, CMS states that *"reports"* indicate there has been no change to the charity care on hospital cost reports following the 340B program's implementation, and that hospitals availing themselves of discounted drug purchasing are not reinvesting these dollars into their communities. The PRT believes these statements are *completely false*.

In the Proposed Rule, CMS notes that it lacks the data needed to understand where patients are being served and how resource savings are being utilized. By its own admission, CMS does not understand where these monies are being utilized.
We believe that CMS may not be seeing what it expects in the cost report as a result of timing: the 340B program's implementation and increased costs resulting from Medicaid expansion efforts could mask CMS' expectations. Our own experience is that hospitals, including PRT member facilities, are *absolutely* providing and expanding services to our under-served and/or under-insured patients in our communities. We also are puzzled about where the funds go if CMS' calculations are off by millions, or perhaps billions, of dollars. Are these dollars lost to the OPPS system altogether? If CMS discovers an error in the calculations, would the agency implement an adjustment in OPPS' future years (as it has had to do so often under the IPPS and, most recently, to OPPS due to the inaccurate calculations related to lab packaging)? We are unclear how CMS can, in good conscience, move forward with a program for which the agency cannot make accurate financial estimates. For this reason alone, although there are many more, CMS cannot even consider implementing its proposal.

- **The PRT opposes CMS' proposal to reimburse for separately payable drugs obtained via 340B purchasing at ASP *minus* 22 percent or ASP *minus* 28.7 percent. The PRT strongly recommends CMS pay for all separately payable drugs, for all OPPS hospitals, at ASP plus six percent (ASP+6%).**

We also wish to raise operational considerations that CMS has not considered in its proposal. As CMS is aware, hospitals must meet many requirements before being approved by HRSA for participation in the 340B discount program. Once selected, however, hospitals continue to experience variability with respect to drug pricing under the 340B program. Many hospitals use a "virtual inventory system" for tracking 340B drugs. Hospitals must track, document, and achieve a certain number of "credits" in the system before they can access discount pricing vs. "regular" pricing. A facility can only receive 340B discount pricing *after* the credit requirement has been fulfilled. Discount availability is fluid and can change by individual drugs, by different manufacturers, and by time periods during the year. For this reason, a hospital's replenishment for stock of a specific drug at 340B pricing is dependent upon 340B pricing being available for that facility; if the pricing is not available, the hospital pays "regular" price for the replenishment.

Yet, CMS erroneously assumes that *all* hospitals that participate in the 340B program purchase *all* of their drugs under the discounted program. The drug supply system utilized for purchasing medications is completely separate from—and does not necessarily communicate with—the hospital's pharmacy drug dispensing system and the patient billing system. Because of the replenishment process noted above, it may be 3 to 10 days post-dispensing before the hospital knows whether a drug was replenished under 340B or at regular pricing. Even if a hospital *wanted* these systems to communicate more readily, the changes are cost-prohibitive due to expense and operational process changes and cannot be done immediately because this process is controlled by vendor Information Technology (IT) systems and changes are not made quickly.

The PRT notes that this is very probably the reason why some of the drug pricing for the detailed responses were above the HRSA ceiling, as CMS notes. If the hospital is participating in the program, it could be that the pricing submitted was exactly what the hospital paid for the drug in the reported time frame as it lacked enough credits and had not yet received the discount. It is egregious for CMS to consider this to be a "data entry" error. It is also quite possible that the specific drug was not available under the 340B program at that specific time; it does not mean that the hospital reported incorrect data.

A further concern with any OPPS payment reduction related to 340B is that the OPPS rate-setting process *already* accounts for 340B savings. Hospitals' cost reports already reflect the 340B acquisition based on expenses reported in the pharmacy cost center. These lower costs are already reflected in the drug cost-to-charge ratio (CCR), which will likely be lower since the cost to acquire these drugs is lower. The OPPS rate-setting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition, in the annual application of CCRs to pharmacy charges. Hence, the PRT believes it is inappropriate for CMS to seek additional reductions without considering the program's existing impact on OPPS rates.

The PRT appreciates CMS' desire to address the needs of under-served and low-income patients. The proposed redistribution of funds in the OPPS does not, however, accomplish that goal and is outside the purview of CMS with this payment system. Frankly, it is completely egregious for CMS to consider robbing funds that are intended for covered entities and to potentially redistribute those monies (including redistributing them to non-covered entities) through a budget neutrality mechanism. The proposed reductions in payments for drugs and redistribution of the savings across outpatient services within the OPPS conflicts with Congressional and HRSA's intent regarding 340B hospitals' use of cost savings to expand care for underserved patients.

Finally, CMS expresses concern about beneficiary coinsurance in the Proposed Rule. The PRT does not believe this is a valid concern; nor should it be used to justify this proposal, since the majority of beneficiaries have secondary insurance that covers patient responsibilities.

- **The PRT continues to vehemently object to the current methodology of reimbursement for 340B acquired drugs and strongly recommends that CMS return to ASP+6% reimbursement for all drugs reported under the OPPS.**

## VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

Off-Campus Outpatient Clinic Visits

The PRT reiterates our continued and strong opposition to the on-going payment reduction for Hospital Outpatient Visits represented by HCPCS Code G0463 reported with modifier -PO (G0463-PO). As stated in our previous comments, the PRT believes that CMS is circumventing Congressional intent by targeting services provided at "grandfathered" off-campus provider-based departments, and is doing so under the guise of "volume control." We urge CMS to reverse its course and to respect Congressional intentions.

We are very disappointed that the U.S. Court of Appeals, District of Columbia Circuit, reversed the U.S. District Court's ruling, which granted plaintiffs' motion to vacate the 2019 OPPS Final

Rule. We *fully support* the American Hospital Association's (AHA) efforts to seek a rehearing for this matter.

The PRT wishes to go on the record, once again, and urge CMS to halt this action, which will ultimately hamper or negate patients' access to care. As the AHA and the Association of American Colleges (AAMC) have noted, these payment cuts threaten hospitals' and health systems' ability to meet their patients' needs, particularly for patients who have the most complex needs and those living in vulnerable communities. We agree completely.

- **The PRT strongly urges CMS to eliminate on-going payment reductions for Hospital Outpatient Visit (HCPCS Code G0463 with modifier -PO).**

Telehealth

The PRT wishes, first and foremost, to acknowledge the diligent and timely work performed by CMS to respond carefully and safely to the global pandemic and public health emergency (PHE). The agency's response ensured that critical patient care services could be maintained during the PHE. Expanded access to telehealth services prevented patients from serious and potentially dangerous lack of access to care and ensured safe delivery of care for both patients and providers. On behalf of the entire provider community, we thank you for your hard work during the pandemic.

The international COVID-19 pandemic has sealed its place in healthcare history as the Great Disruptor of 2020. One of the most significant, but positive, disruptions has been the rapid acceptance of telehealth as an effective, safe, and efficient way to provide clinical services.

As a result of the waivers CMS implemented to ensure the continued stability of payment systems during the Public Health Emergency (PHE), patients have been able to access services via two-way telecommunications. Telehealth services have been enormously popular, and help foster both safety and efficiency of service provision. In fact, many patients and clinicians alike will likely resist returning to pre-COVID norms with respect to telehealth vs. in-person services.

Given that framework, the PRT finds it curious that the OPPS Proposed Rule is essentially silent with respect to telehealth services. The PRT understands that CMS is bound by existing regulation related to telehealth services. However, we submit that services provided by telecommunication (audio and video) has application in areas other than a professional service. In fact, we believe that certain services are great candidates for continued provision in telecommunication settings after the end of the PHE. This possibility has been clearly demonstrated during the pandemic, when multiple hospital outpatient services have been very safely, efficiently, and effectively provided via telecommunication means. Examples include medical genetics provided by genetic counselors; diabetic teaching services; and other teaching services provided by hospital outpatient areas. We note that physical therapy (PT), occupational therapy (OT), and speech pathology and language services (SLP) have also been provided in a safe, efficient, and effective manner during the PHE. Many of our providers report improved patient compliance with their PT, OT, and SLP plans for care; fewer missed appointments; and overall improved patient satisfaction from remote telecommunication services.

The PRT understands the existing regulation related to telehealth services; nonetheless, we encourage CMS to think creatively about how the agency can continue to advance service-

delivery in the telecommunication setting in the future.

The PRT urges CMS to consider opportunities to make suitable telecommunication services available to hospital outpatients.

Other Items

*Hospital Outpatient Visits (HCPCS code G0463)*

Once the Public Health Emergency (PHE) ends, the Hospital Without Walls Waiver will also end, leaving no provision for a hospital visit to be conducted in a patient's home. In the Medicare Physician Fee Schedule Proposed Rule, CMS discusses, at length, the fact that pharmacists and genetic counsellors will continue to be allowed to provide services at the top of their licensure.

The PRT requests that CMS consider the scenarios when the physician orders a hospital-employed pharmacist or counsellor to provide the same service to a patient, which, because of the patient's condition, should be provided at a remote site. There is no way for this service to be reported. One of the few positive outcomes during the PHE has been the provision of services at remote locations that are not directly related to a hospital or physician's office. Some patients will very much benefit from continuing this practice, including patients with diabetes, vascular issues, mobility issues, lack of convenient transportation, requirement to travel long distances for a face-to-face encounter, etc.

The PRT recommends that CMS decouple the patient's location and the professional's location and continue to recognize G0463 for the provision of services when the patient's situation warrants. The same service is being provided by the same professional, regardless of the patient's physical location. Beneficiaries will be more compliant with medical plans and treatment when these services can be provided conveniently for them. And, given that this has occurred during the PHE, it will be very difficult to explain to the beneficiary why this provision is no longer acceptable.

- **The PRT recommends that CMS create a permanent waiver to allow virtual, remote services provided by a hospital. This does not have to be limited to specific HCPCS codes and would fall under the Medical Staff to determine the situations under which this would be allowable and to establish guidelines for these services.**

## IX. Services That Will Be Paid Only as Inpatient Services

In the CY 2021 OPPS Proposed Rule, CMS proposes to eliminate the Inpatient only (IPO) List over time. The PRT is pleased by CMS' proposal, which reflects the long-standing request by both the PRT and other stakeholders that the agency eliminate the IPO List. Doing so will allow *physicians* to make the determination of the patient status of inpatient or outpatient, based on clinical decision-making. and will allow hospitals to be reimbursed when these procedures are safely and appropriately provided to Medicare beneficiaries as outpatients.

CMS also proposes to complete the process over three years, beginning with removing of approximately 300 musculoskeletal-related services from the IPO List, and assigning them to clinical APCs for CY 2021.

- **The PRT supports this change.**

In addition to the 300 musculoskeletal-related services, CMS is also seeking input on whether additional codes should be removed from the IPO List for CY 2021. The PRT recommends that CMS remove the following 16 HCPCS codes from the IPO List for CY 2021—we have made this request in prior rule-making years, as well. We suspect that CMS has evaluated these codes, to at least some extent, already. Thus, CMS should have some historical analyses and data to assist with rate-setting and appropriate APC assignment of the following codes:

| | |
|---|---|
| 35372 | Thromboendarectomy, including patch graft, if performed, deep (profunda) femoral |
| 35800 | Exploration for post op hemorrhage, thrombosis of infection, neck |
| 37182 | TIPS procedure |
| 37617 | Ligation, major artery, abdomen |
| 38562 | Limited lymphadenectomy for staging (separate procedure), pelvic and para-aortic |
| 43840 | Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury |
| 44300 | Open jejunostomy following a diagnostic laparoscopy |
| 44314 | Revision of ileostomy, complicated (reconstruction In-depth) separate procedure |
| 44345 | Revision of colostomy, complicated (reconstruction In-depth) separate procedure |
| 44346 | Revision of colostomy, with repair of paracolostomy hernia (separate procedure) |
| 44602 | Suture of small intestine accidental laceration |
| 49010 | Exploration, retroperitoneal area with or without biopsy(s) separate procedure |
| 49255 | Omentectomy, epiploectomy, resection of omentum |
| 51840 | Anterior vescourethropexy, or urethropexy (eg. MarshallMarchetti-Krantz Burch), simple |
| 56630 | Vulvectomy, radical partial |
| 61624 | Transcatheter permanent occlusion or embolization, percutaneous any method central nervous system |

The PRT believes this change will appropriately reimburse hospitals for services provided to Medicare beneficiaries in an outpatient setting when doing so is determined to be safe and appropriate by the physicians and clinicians involved with the beneficiary's care.

The PRT recommends that CMS review and use (to the extent applicable) Part B claims data in order to estimate costs for the appropriate C-APCs. CMS has assured us the claims data reported on claims that contained IPO procedures are available, even though the line items/claims were rejected or denied. We recommend that CMS use this data in the C-APC rate-setting for CY21

In the CY 2020 OPPS/ASC Final Rule, CMS finalized a two-year exemption from certain medical review activities related to the 2-midnight rule for procedures that are newly removed from the IPO List. CMS is proposing to continue the two-year exemption for procedures removed from the IPO List for subsequent years.

CMS requests comment regarding if the two-year time frame is adequate or should be longer. The PRT encourages CMS to make the period longer, especially in light of the volume of procedures that will be removed from the IPO List over the next three years. While two years is enough time for the smaller volume of procedures that have traditionally been removed from the List, it will take a longer period of adjustment over the three years for education and processes to be completed. We agree that medical necessity reviews will continue regarding the actual service

provided, the portion of the policy related to patient status and application of the 2-midnight rule should be extended for a total of six years. For procedures coming off the IPO List from January 1, 2021 through January 1, 2023 (no list anticipated beginning CY 2024), would carry this policy through the two-year window that is applicable for those procedures coming off the IPO List in January 2023 (the last year for removal of procedures from the IPO List based on the current proposal). This would allow time for the education for hospital staff and physician/non-physician practitioners and allow operational processes to be established and refined. Hospitals have spent significant time and resources to put the processes in place to accommodate the IPO List (which, we note, is not applicable to any other providers). It will, similarly, take time to "unwind" all of these processes.

The PRT asks CMS to consider not making the procedures removed from the IPO List subject to audit as related to the 2-midnight rule. Reiterating that patient status is based on the physician's clinical decision-making. The hospital will hold the financial burden of providing services to a patient in a hospital setting under the direction of a physician's clinical decision-making and orders. The PRT asks CMS to not penalize hospitals for physician's clinical decision-making based on the patient's inpatient or outpatient status.

Furthermore, the PRT asks that CMS confirm that the I/OCE logic will remain concerning the editing of an outpatient claim when the IPO procedure is designated as a "separate procedure." That is, if an outpatient procedure is billed on an outpatient claim along with an inpatient only procedure that is designated as a "separate procedure" by AMA, the claim will process and pay under the OPPS and only the line item with the IPO procedure defined as a "separate procedure" will reject. The PRT requests that CMS confirm this logic will remain until the IPO list is totally eliminated. As requested in prior year's comment letters, the PRT asks that CMS use a different status indicator such as "C1" to designate procedures that will not cause the entire claim to deny when performed in conjunction with another outpatient procedure.

In summary:

- **The PRT recommends CMS remove the additional 16 procedures noted above from the IPO List for CY 2021.**

- **The PRT recommends that CMS use Part B claims data to the extent possible to estimate costs and APC assignment and rate setting for procedures requested to be removed from the IPO List for CY 2021.**

- **The PRT recommends that CMS extend the audit for site of service moratorium for procedures being removed from the IPO List until January of 2026 due to the volume of procedures being removed, education requirements and refinement and changes to operational systems required.**

## X. Proposed Nonrecurring Policy Changes

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

The PRT agrees with CMS' proposal to make the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) general supervision for the entire service as a permanent policy. The PRT wishes to express it gratitude to CMS for recognizing that this has, and will continue, to provide flexibility to all hospital providers while also benefiting Medicare beneficiaries.

C. Comment Solicitation on OPPS Payment for Specimen Collection for COVID–19 Tests

In the interim Final Rule (CMS-5531-IFC), published on May 8, 2020 (85 FR 27604 through 27605), CMS created HCPCS code C9803: "Hospital outpatient clinic visit, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS COV-2) (coronavirus disease [COVID-19]), any specimen source." This code was established in response to the significant increase in specimen collection and testing for COVID–19 in Hospital Outpatient Departments (HOPDs) during the COVID–19 Public Health Emergency (PHE). HCPCS C9803 is assigned to APC 5731—Level 1 Minor Procedures, with payment rate of $22.98 and status indicator (SI) "Q1," effective March 1, 2020 and for the duration of the PHE.

CMS proposes to continue the APC and SI assignment in CY 2021, if the PHE continues. The agency also seeks comments about keeping C9803 active beyond the COVID–19 PHE, as well as whether CMS should extend or make permanent the OPPS payment associated with specimen collection for COVID–19 tests after the PHE ends, in order to support COVID–19 testing beyond the conclusion of the PHE.

The PRT agrees with CMS' APC and SI assignment for C9803, and requests that this be made permanent, until such time in the future that COVID-19 testing is not needed on a widespread basis.

We also request that the Final Rule include an explicit statement that HCPCS C9803 may truly be reported for "any specimen source" including—but not limited to—collection via nasopharyngeal swap, nasal swab, sputum collection, or blood collection, in order to support any and all current and future lab testing methodologies. Such a statement has been articulated in multiple CMS "Office Hours" calls, but has never been issued in written format via an FAQ or other instruction.

In addition, CMS has changed the status indicator for the following COVID-19 specimen collection codes to "B." While it is true that an OPPS payable claim should use HCPCS code C9803 for a COVID-19 specimen collection, when staff are obtaining specimens outside the hospital for non-patient specimens billed on a 014x claim, the payment is under the Clinical Laboratory Fee Schedule (CLFS) and not under the OPPS. Hospitals need the ability to properly report the specimen collection. The PRT believes the correct status indicator for these two codes is "Q4" so that it will process and pay under the CLFS when properly submitted on a 014x claim.

| | | | | |
|---|---|---|---|---|
| G2023 | Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source | 03/01/2020 | B | N/A |
| G2024 | Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source | 03/01/2020 | B | N/A |

- **The PRT agrees with CMS' APC and SI assignment for C9803, and requests that this be made permanent, until such time that COVID-19 testing is not needed on a widespread basis.**

- **The PRT recommends that CMS issue written guidance that HCPCS C9803 can be reported for any specimen source (i.e., nasopharyngeal swab, nasal swab, sputum collection, blood collection, etc.).**

## XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

Additions to the List of ASC Covered Surgical Procedures

We recognize that CMS is looking to decrease cost and promote site neutrality between hospital outpatient departments and ASCs (thereby allowing more procedures to be performed in ASCs), but note that there must be safety considerations for the beneficiary's well-being. Services provided in an ASC are elective procedures and emergent surgical services would not be expected in this setting. In fact, the patient's clinical condition and the level of post-operative care required by that patient is dependent on the clinical setting selected. An example is the provision of therapy services immediately post-op. Further, hospitals perform procedures in the operative suite that is best-equipped for that specific procedure, regardless of whether the patient is classified as inpatient or outpatient where the same resources are available to perform the procedure, regardless of the patient's status.

Despite this fact, some of the changes that CMS has made previously have generated concern on the part of the PRT, specifically about some "unanticipated" scenarios. We agree that the physician who is caring for a patient should determine the best site of service based on the individual beneficiary's clinical condition. We are concerned, however, that some of the procedures that *could* be added to the ASC list are of such a nature that an overnight stay is likely to be needed. CMS removed the requirement for ASCs to establish a transfer agreement with a hospital provider, however, which could lead to delayed transfer from an ASC to a hospital due to the hospital's volumes. The delay would not arise from the facility's refusal to accept the patient, but from hospital beds being full. One could argue that the patient could be sent to the Emergency Department (ED), but if the ED is overflowing, then there is another domino effect.

We understand that there are some requirements under conditions of participation (CoP) that will remain in place. Nonetheless, the PRT is concerned that a beneficiary may need a level of care that may be delayed since ASCs do not have all of the acute care capabilities that a hospital has—just by nature of the differences in the facilities. For example, no emergent scenarios or

trauma procedures would be performed at an ASC; however, the code for the procedure could conceivably end up on the ASC-covered procedure list due to being in a specific range of CPT codes. Without such guardrails, the PRT is concerned that some of these procedures would be provided in an ASC, where it is unsafe to do so. We urge CMS to proceed with caution regarding removing the clinical and patient safety guardrails to assigning codes to the ASC list.

Specifically, CMS proposes to remove the general exclusion criteria set out in 42 CFR 416.166(c) (1) through (5), which are very important safeguards for beneficiaries:

> ASC covered surgical procedures do not include surgical procedures that:
> *"(1) Generally result in extensive blood loss;*
> *(2) Require major or prolonged invasion of body cavities;*
> *(3) Directly involve major blood vessels;*
> *(4) Are generally emergent or life threatening in nature;*
> *(5) Commonly require systemic thrombolytic therapy."*

The PRT strongly disagrees with this proposal; procedures that are currently excluded by these safeguards are major and potentially life-threatening procedures, and are appropriately excluded from performance in an ASC. By removing these safeguards, CMS is assuming that an ASC would be equipped to handle extensive blood loss, emergent and life-threatening procedures, and systemic thrombolytic therapy. ASCs are *not* equipped to handle these types of procedures, and beneficiaries' safety would be significantly jeopardized if they were performed in an ASC. If a beneficiary has one of these types of procedures in an ASC and experiences "extensive blood loss," the ASC would not be equipped to replace blood volume quickly (with blood products, blood expanders, large volumes of IV fluids, etc.), and the beneficiary will enter a very dangerous and life-threatening situation very quickly. The ASC does not have the same resources for managing this situation immediately, as hospitals do, and would have to call for emergency services to arrive and transport the patient to a hospital. This is very concerning, as valuable time is spent waiting for the emergency transport, during which time the beneficiary's life is potentially placed in jeopardy. Even if a physician believes that the individual beneficiary's clinical condition would allow these procedures to be done in an ASC, the risk of what might happen is VERY great.

The PRT recommends that CMS NOT remove these criteria completely. While there would be a cost savings from performing these types of procedures in an ASC, the cost savings must be weighed against the risk to the beneficiary. If CMS did not remove the criteria completely, procedures could be reviewed on an individual basis, based on the advances in medicine and technology, in order to determine if the individual procedure is appropriate for performance in an ASC. The PRT recommends that CMS reword 42 CFR 416.133(c) to state that "ASC covered surgical procedures do not typically include surgical procedures that" meet the 5 criteria in the CFR, "but a procedure will be reviewed specifically and thoroughly for inclusion on the ASC list."

Similar to the CMD policy to limit payment to ASCs to no more than physician office practice expense payment when the place of service for ASC-procedures is "office" for 50 percent or more of the volume of procedures, the PRT recommends that CMS not approve procedures for the ASC setting when 50 percent or more are not reported on hospital claims as elective. Stated another way, CMS should not approve procedures for the ASC setting when 50 percent or more of hospital claims report the procedures as a type of admission or visit of "1" for emergent or "2" for urgent, following NUBC requirements. This would correlate with procedures not being

appropriate for an ASC setting.

CMS proposes to choose one of two options for determining procedures that will be added to the *List of ASC Covered Surgical Procedures* as the agency dismantles the IPO List. Of these two proposals, the PRT supports the first alternative, which will vet the procedure with the professional societies, CMS' internal medical advisors, and other stakeholders to determine if the individual procedure is safe to be performed in an ASC. The first option reads as follows:

> *"Under the first alternative, we propose to establish a nomination process beginning in CY 2021 for procedures that would be added beginning in CY 2022 under which external stakeholders, such as professional specialty societies, would use suggested parameters to nominate procedures that can be safely performed in the ASC setting and meet all other regulatory standards."*

In summary:

- **The PRT recommends that CMS proceed carefully to ensure guardrails for patient safety (e.g., transfer agreements) are in place or reinstituted as procedures are nominated/considered for addition to the ASC procedure list and that procedures that are performed by hospitals and reported as emergency/urgent cases for more than 50 percent not be approved as ASC procedures.**

- **The PRT recommends that CMS explicitly state that "ASC covered surgical procedures do not typically include surgical procedures that" meet the 5 criteria in the CFR, "but that a procedure will be reviewed specifically and thoroughly for inclusion on the ASC list."**

## XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The PRT congratulates CMS on its efforts to promote the consistent delivery of high-quality and more efficient health care for Medicare beneficiaries under the Hospital Outpatient Quality Reporting (OQR) Program. We acknowledge and appreciate CMS' efforts to manage and alleviate the OQR's maintenance costs and administrative burdens under the Meaningful Measures Initiative. We also appreciate that the measures are limited to those that are truly "meaningful" and that improve care for the Medicare population. We are pleased that CMS has not introduced any new measures in the OPPS Proposed Rule for CY 2021.

The PRT appreciates the continued delay of OAS CAHPS Survey Measures. We remain concerned about the operational burden and repetitive nature of this extensive and complex outpatient survey, however. We continue to recommend the following, as we have recommended in previous comment letters:

- **The PRT requests that CMS carefully compare the proposed OAS CAHPS survey questions to the inpatient/HCAHPS version of the survey.**

- **The PRT recommends that CMS align the outpatient version of patient's experience of care survey with the current inpatient version from a content, timeline and administration method standpoint.**

- **The PRT encourages CMS to review these requirements to prevent duplication of effort on the part of providers and provide a uniform process for beneficiaries who will be completing the surveys.**

While the PRT supports CMS' proposal to modify the Star Rating System, we have concerns about the proposal to include Critical Access Hospitals (CAHs) and Veterans Health Administration (VA) hospitals in this system.

Under the proposal, we understand that CAHs would continue to report voluntarily. We are concerned by the proposal to allow CAHs to withhold reporting of their overall Star Rating until AFTER they have an opportunity to preview their data. This allowance does not align with CMS's goal of transparency and, in essence, allows CAHs to share positive Star Ratings, but avoid the publication of negative Star Ratings.

- **The PRT recommends that, if CAHs choose to participate in the Star Rating system by voluntarily reporting their data, reported data should be published.**

With respect to adding VA hospitals to the system, we agree that transparency and consumer choice both benefit from a complete comparison of facilities, regardless of whether they are run by the VA or not. CMS indicates that the addition of VA facilities has "*no direct influence on CMS-administered programs*" and that "*CMS intends to provide more information about the statistical impact of adding Veterans Administration hospitals to overall Star Ratings*." The agency provides neither time-frames nor details on when this information will be provided, nor what the impact of adding VA facilities to the system will be. The PRT asserts that this information will not be meaningful and can cause confusion to consumers and beneficiaries alike, when these unknowns remain in the equation.

- **The PRT urges CMS to delay adding VA hospitals to the Star Ratings system until more information has been provided about the statistical impact of the proposal.**

Star Ratings are intended to enable easy comparison of facilities. But, Star Ratings apply to facilities that provide acute inpatient and outpatient care, regardless of differences in the facility demographics and case mix. We agree with recommendations by other stakeholders, which were identified in the Proposed Rule, that Star Ratings should both factor in and account for differences in case mix and type of facility. Because the system does not compare "like" facilities, beneficiaries will not be able to make a fair or accurate assessment of these various facilities.

- **The PRT suggests that CMS explore methods to calculate Star Ratings in a manner that groups "like" facilities in the reporting structures. An "apples to apples" comparison is the only way to legitimately allow accurate consumer assessments between facilities.**

CMS proposes to stratify measure groups using the proportion of dual-eligible patients. While this proposal will be beneficial for specific measures, we do not believe this will provide an adequate representation of differences in the types of services a facility provides overall. Dual-eligible patients only partially contribute to an organization's case mix. Case mix is more typically a representation of the type and the complexity of services that are typically provided

by the organization.

We agree that the Latent Variable Modeling (LVM) methodology currently used to assign weights and determine the Star Ratings is complex, difficult to understand, and almost impossible to explain in layman's terms. Although we are well-versed in statistical modeling, many of the PRT members have struggled to decipher how the Star Ratings are calculated using LVM. The unpredictable results also make the variability difficult to interpret and less transparent. We believe that the use of a simple average of measure scores to calculate Star Ratings would be much more straightforward than the convoluted LVM method current used by CMS.

We are also concerned with the proposal to apply weights equally across all measures in each group. We believe it is unreasonable for the weights to be equally distributed within the Readmission measure group to both HOSPITAL-WIDE All-Cause Readmission measure (which includes most admissions) and the COPD Readmission measure (which includes only a very limited subset of patients). Facilities that serve a high proportion of the small subset of readmissions of difficult-to-manage COPD patients would be subject to unfair penalties.

- **The PRT requests that CMS work to identify a simpler and more transparent statistical method than LVM.**

- **The PRT urges CMS to continue to use a method that weighs measures within a single group, similar to the applicable and more equitable distribution currently used in the LVM model.**

The PRT is pleased that CMS acknowledges the impact of a patient's socio-demographic status (SDS) and social risk factors—such as lack of income, education, social support, and community resources—on providers' ability to successfully comply with OP Quality measures. The PRT supports CMS continuing to explore how best to account for social risk factors in the OQR program, given that these patients often require more intensive social services to achieve improved outcomes.

The PRT appreciates that CMS' continued attempts to stratify readmission measures group scores and proposes to factor in social risk factors. In prior comment letters the PRT has frequently noted that our patients' SDS and social risk factors have a direct impact on our ability to manage readmissions. And, the COVID-19 pandemic has intensified social and economic disparities, beneficiaries' ability to manage chronic conditions, comply with care needs, and control the recurrence and exacerbation of health conditions. Beneficiaries who have social risk factors may be at higher risk for noncompliance that can significantly and negatively impact their outcomes. This reality should be addressed in the agency's quality assessments.

- **The PRT recommends that CMS consider factoring the SDS into the calculation method for measures where patient behavior (i.e., compliance with medical advice) impacts his or her outcomes.**

The Proposed Rule suggests using "dual-eligibility" as the factor for risk adjustment. The PRT believes this is only a temporary solution and recommends that CMS consider the full range of differences in patient backgrounds that can (and do) impact outcomes. These include age, income (i.e., being at or near poverty level), educational attainment, belonging to a racial and/or

ethnic minority group, and living with a disability. All of these factors can impact a patient's ability to comply with medical advice and treatment.

- **The PRT urges CMS to avoid payment penalties that are based on incomplete data and instead ensure that all factors affecting health disparities are recognized.**

The PRT supports the position that social variances directly impact facilities' ability to prevent readmissions and supports the inclusion of these risk factors in the equation, which aligns with other CMS efforts. A Department of Health and Human Services (HHS) Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* included specific recommendations for risk adjustment for CMS's programs and quality efforts, including the Star Ratings.

- **The PRT urges CMS to consider the HHS recommendations to address social risk factors' impact on a facility's ability to manage readmissions.**

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

CMS began introducing prior authorization requirements for certain services in FY 2020. This year, CMS proposes to add two services to the list of those that will not be paid without proof of prior authorization, beginning for dates of service on or after July 1, 2021: Cervical fusion with disc removal, and implanted spinal neurostimulators.

Cervical Fusion Procedures

In the Proposed Rule, CMS states that there has been a huge increase in the number of outpatient cervical fusion procedures. These procedures are performed when a person's neck is unstable, in order to correct a pinched nerve or spinal compression. Cervical fusion is rarely the first option but is, rather, used when conservative measures have failed. It is usually indicated and performed for conditions that are the result of an injury or degenerative changes like osteoarthritis.

The agency suggests that the increase in the occurrence of outpatient procedures is due to the change in the APC assignment for CPT 22551 and 22552, in which these two codes were moved to APC 0425, which increased the reimbursement rate. CMS notes that the use of these codes "almost tripled in 2012," which should be expected since CPT 22551 was removed from the Inpatient Only (IPO) List as of January 1, 2012. CPT 22552 remained on the IPO List until 2016 but, because it is an add-on-code, CMS' policy means that it would have been line-item denied, since the payable/primary procedure was not restricted to the inpatient setting. Beginning in CY 2016, CPT 22552 was removed from the inpatient only list and is part of a complexity adjustment for C-APCs.

These changes **easily** explain why CMS has seen an increase in the performance of these procedures on outpatient (OP) claims. The PRT members were not able to purchase the data for analysis as this is a very expensive process. Many of the PRT providers are members of the American Hospital Association (AHA) and understand from the AHA that they have analyzed the claims data between 2016 and 2018 for cervical fusions. Rather than reflecting an actual

increase in procedures, we understand that the claims data reflect that the actual number of procedures has stayed relatively stable over time; only the patient status has changed, which is *directly correlated* to the procedures being removed from the IPO List.

Has CMS performed an analysis based on the total number of claims that involve cervical fusions, or did CMS only look at the volume of outpatient claims? The outcome of this comparison is very important as the shift in site of service would be expected once the procedures came off the IPOI list. If CMS has not done this analysis, the PRT requests that CMS analyze these data from this perspective, as it would be inappropriate for CMS to look only at the outpatient volume. The PRT believes that this analysis will enable the agency to validate that this is not an actual increase in the number of procedures, but is merely a result of the codes being removed from the IPO List and physicians' determination that the procedure could be safely done as an outpatient for the specific beneficiary. The PRT requests that CMS disclose the results of this analysis and that this was the methodology utilized in determining that large increases in volume were determined to be occurring, and this was not just a change in the site of service. If CMS did not perform this analysis, this procedure should NOT be added to the prior authorization list based on the stated "increase in number of procedures," given that this increase is not supported by the claims data.

- **The PRT recommends that CMS not finalize the proposal for adding cervical fusions to the prior authorization list.**

<u>Implanted Spinal Neurostimulators</u>

Implanted Spinal Neurostimulators provide mild electrical signals that disrupt the signals nerves send to the brain and are used to reduce chronic pain.

CMS notes that, based on 2016-2018 claims data, these procedures have dramatically increased. This increase should not be unexpected in light of efforts taken to combat the opioid crisis and CMS' request for comment in a previous rule to assist in identifying alternative methods for pain management.

In the CY 2019 OPPS Final Rule, CMS stated:

- The opioid crisis was declared a national Public Health Emergency (PHE) in 2017. That year, the Department of Health and Human Services (HHS) presented an Opioid Strategy, which *"aims in part to support cutting-edge research and advance the practice of pain management."*

- CMS responded to the findings of the "*President's Commission on Combating Drug Addiction and the Opioid Crisis*" by changing the packaging of certain drugs (considered to function as a "supply") in the ASC setting. While these drugs remain packaged under the OPPS for hospitals, the agency's impetus was to address the opioid crisis through promoting non-opioid treatments. In reviewing claims, CMS noted that there was no decrease in the use of non-opioid drugs, specifically Exparel, in HOPDs — while there was a decrease in use in the ASCs, where Exparel was packaged.

  "*…we stated in the proposed rule that we were interested in comments regarding other non-opioid treatments besides Exparel that might be affected by our OPPS and ASC packaging policies, including alternative, non-opioid pain management treatments, such*

*as devices or therapy services that are not currently separable payable.*"

- CMS noted that the agency was seeking comments about items "*that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use and/or addiction*." CMS noted examples including a device and/or product that "*aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management*." CMS indicated in the Proposed Rule that it was also interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management.

  CMS stated ***"that this could include, for example, spinal cord stimulators used to treat chronic pain, such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable)****."* [Emphasis added.]

- CMS made the comment that, "*Several commenters, manufacturers of spinal cord stimulators (SCS), stated that separate payment was also warranted for these devices because they provide an alternative treatment option to opioids for patients with chronic, leg, or back pain. One of the manufacturers of a high-frequency SCS device provided supporting studies which claimed that patients treated with their device reported a statistically significant average decrease in opioid use compared to the control group. This commenter also submitted data that showed a decline in the mean daily dosage of opioid medication taken and that fewer patients were relying on opioids at all to manage their pain when they used the manufacturer's device.*"

  "*Response: We appreciate the detailed responses to our solicitation for comments on this topic.* ***We plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid and/or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessar*****y***."* [Emphasis added.]

  *"We note that some of the items and services mentioned by commenters are not covered by Medicare, and we do not intend to establish payment for noncovered items and Services. We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC payment system that will* ***encourage use of medically necessary items and services that have demonstrated efficacy in decreasing opioid prescriptions and/or opioid abuse or misuse during or after an outpatient visit or procedure****."* [Emphasis added.]

These factors **clearly** explain why CMS has seen an increase in the performance of these alternatives to opioids in outpatient (OP) claims.

- **The PRT opposes the CMS proposal for prior authorization for neurostimulators.**

The PRT understands CMS' need and desire to control costs. Unfortunately, introducing yet another process for providers and MACs to manage actually *increases* costs for both entities. In fact, costs and patient frustrations have only grown since CMS' prior authorization requirements began in July 2020.

We urge CMS to carefully consider the impact of its prior authorization requirements. CMS considers a 10-day decision turnaround to be acceptable, while other payers require only a few days. For a patient who is having severe pain and needs one of these procedures, waiting that long for a pain-relieving procedure will have negative effects. Patients are likely to seek more and more interim interventions while they wait for prior authorization, which will be expensive, result in poor outcomes, and not address the original need for the procedure.

Furthermore, providers face significant administrative burden as a result of the need to babysit prior authorization requests.

CMS should consider carefully how it will ensure that the MACs adhere to the 10-day timeline. The PRT has many questions about how CMS envisions this process being implemented. CMS must share the answers to the following questions with both providers and MACS, so that all information can be available for the prior authorization process:

- Has CMS considered whether the MACs can handle the incremental volume without exceeding the turnaround time?
- Has CMS defined what therapies must have been done and failed prior to their authorizing a cervical fusion?
- Given that there is an existing NCD for neurostimulators, if a patient meets the coverage requirement, why is a prior authorization required?
- Does CMS have other requirements that it has not yet published that MACs will require when a facility seeks a prior authorization? If so, will CMS require that the MACs additional requirements be consistent across all MACs, or will CMS allow differences based on the MACs determination?
- How does CMS envision facilities addressing the situation when they are governed by multiple MACs? As the chart on page 33 of this comment letter indicates, many PRT member hospital systems have multiple MACs. For any facility in this situation, the proposal would create not only a HUGE operational burden but also significant confusion and complication from having to determine which MAC's ruling on prior authorization applies to which individual beneficiary.
- How does CMS' prior authorization policy interacts with existing Advanced Beneficiary Notice (ABN) requirements? We are specifically curious about whether, if a patient's physician determines that the HOPD is the appropriate setting for that patient, and the clinical situation dictates that the procedure cannot wait 10 days for authorization, will the physician and patient be allowed to move ahead with the procedure if the patient signs an ABN, pays out-of-pocket, and then seeks a refund of their monies if the MAC approves the procedure at a later date?

The PRT also submits that CMS has not considered that beneficiaries may not be close to an ASC and/or that their physician may lack privileges at an ASC, leaving the hospital as the only option. The prior authorization requirements slow access to these procedures for any beneficiary

in this situation.

MACs are reporting a lot of confusion from the fact that ASCs and physician offices are asking for prior authorization when it is not required for them. Although it is logical that if a procedure requires prior authorization in one site of service, it should be required for all sites of service (as the procedure is the same) and because currently the coverage requirements are the same. If CMS insists on continuing to require prior authorization by hospitals for procedures, it must strive to ensure this is a smooth process before asking patients who need cervical fusions and neurostimulators to wait for prior authorization for a life-changing procedure. CMS should clarify the information and publish the results on how the process is working for the current five procedures that require prior authorization before considering any program expansion.

We also recommend that CMS publish the results of its current prior authorization policy with respect to financial savings and/or program effectiveness *before* expanding the policy to additional services.

In summary:

- **The PRT urges CMS to trust that physicians are trained to practice evidence-based medicine in the most efficient manner possible, and not to proceed with this proposal.**

- **The PRT strongly recommends that CMS not expand this policy specifically based on "increases in procedures" as there are very real and concrete reasons for the increased numbers. Moving a procedure off the IPO List and seeking non-opioid related pain control methods are both valid reasons for increased claims.**

- **If CMS insists on expanding this policy, the PRT urges CMS not to do so unless and until the process is smooth and confusion is mitigated, which impacts the MAC as much as it impacts the hospitals having to wait for the prior authorization.**

- **CMS should either require a shorter turnaround time for approvals or allow retroactive approval and reimbursement for patients who pay out-of-pocket in order to proceed with pain-relieving treatment.**

- **CMS should publish evaluation results of current prior authorization policies before expanding them to any additional services. CMS should also publish the results of the initial assessment of the process for the five procedures that began in July 2020.**

## Other Issues

National Coverage Determination (NCD) Elimination

While CMS did not solicit comment under the OPPS regarding retiring NCDs, the agency's proposal affects both professional and facility providers. For that reason, we are offering comments here on the impacts to the OPPS system.

The PRT understands that CMS proposes to sunset nine NCDs on the basis that they are not clinically pertinent and could impede innovation. We agree, in principle, that an NCD could be

retired if CMS determines that it is completely outdated with respect to evidence-based medicine, and when current medical practice points to different therapeutic or diagnostic services from that in the NCD.

Nonetheless, we are *very* concerned about access barriers that are very likely to occur nationwide, and across MACs, with the result that coverage and patient care could be significantly impeded. We outline our concerns below.

First, NCDs that address current therapeutic and/or diagnostic services act as a foundation (or floor) for consistent access to care by all Medicare beneficiaries. Retiring NCDs and relegating coverage determinations to the MACs would jeopardize this foundation and result in variations in care across MACs.

Second, medicine is very different than it was when Medicare began in the 1960s. It is much less appropriate for state or regional entities to make determinations about patient care than it was 60 years ago. The advent of evidence-based medicine means that a central entity should determine what best-practice therapeutic and/or diagnostic services should be available throughout the system, such as via an NDC, rather than leaving this up to a local entity.

Third, MACs lack the experience and resources to stay up-to-date on rapidly evolving evidence-based practices. For each MAC to assume this responsibility, so that it can make a determination about a service previously covered by an NCD, would be an enormous duplication of effort. MAC's medical directors simply cannot be experts in all aspects of medicine. Having an NCD issued from CMS as a whole fosters specialization and efficiencies and saves resources.

Fourth, leaving discretion up the MACs will inevitably introduce confusion and inconsistency to coverage determinations. Historically, MACs have provided different coverage determinations for the same service. Providers experience this every day. It is highly likely that MACs will follow the same decision-making process that produces continued lack of uniformity. This lack of uniformity will be particularly problematic for facilities that serve patients and areas covered by more than one MAC. Many PRT hospital systems are governed by more than 1 MAC, based on feedback from 10 of our 15 members (see chart).

| **Provider** | **Number of Hospitals** | **Number of MACs** |
|---|---|---|
| A | 2 | 2 |
| B | 6 | 1 |
| C | 20 | 3 |
| D | 2 | 1 |
| E | 12 | 1 |
| F | 40 | 4 |
| G | 7 | 1 |
| H | 5 | 2 |
| I | 32 | 1 (2 jurisdictions) |
| J | 36 | 4 |

It will be challenging to track and complicated to explain why patient care is sometimes covered but sometimes not. Some of our providers serve patients who travel to a different state (i.e., where they have a second residence) and receive a service covered by Medicare. The MAC in this second state has deemed the service to be covered; the MAC in the first state has deemed it

to be non-covered. Beneficiaries who do not have multiple residences in multiple MAC jurisdictions do not have the luxury of residing where their needed services are covered; they are, thus, prevented from accessing services unless they have the monetary resources to pay for them outright.

Fifth, CMS' proposal to eliminate NCDs reduces guaranteed coverage for beneficiaries who participate in Medicare Advantage (MA) plans, since these plans are required to follow NCDs, but not LCDs. With enrollment in MA plans growing at a rapid rate, the PRT believes CMS' proposal will create new, and problematic, access to care issues for these beneficiaries.

- **The PRT opposes the proposal to eliminate specific NCDs and relegate coverage decisions to the MACs.**

Rather than implement this confusing and unnecessary policy, we recommend that CMS expand access to care and innovation by directing its MACs to examine the scientific evidence brought to them regarding aspects of care about which NCDs are silent; encourage MACs to grant meetings in a timely manner; and respond in a timely manner (i.e., within 60 days) to the request for coverage.

One suggestion is to designate the NCDs as the minimum floor or threshold for coverage of treatment, and explicitly clarify that MACs have discretion to cover therapeutic and diagnostic services above and beyond the NCD. The provider must prove that the circumstances meet the statutory definition of "medical necessity." If CMS implemented such a policy, we further recommend that any MAC coverage decision that exceeds an NCD be published in the Medicare coverage database, in a searchable manner that can be accessed by MACs and providers alike (PHI redacted, of course). This would demonstrate the specific circumstances when coverage was deemed medically necessary outside the minimum coverage and provide information to be used as a reference across all MACS. CMS would be able to rely upon this information to refresh/update the NCDs when and if the agency believes that to be necessary.

We think this approach balances the need for consistent and national beneficiary access with the need to keep access current with rapidly evolving evidence-based medicine.

<u>Remote Physiologic Monitoring</u>

While this was not specifically addressed by CMS in the OPPS Proposed Rule, the PRT offers comments regarding status indicator assignment for these services, since they are assigned Comment Indicator CH in Addendum B. Some of these codes are assigned status indicator V (visit) and others are assigned status indicator B (code not recognized under the OPPS; alternate code may be available). For many of these services, facility resources are involved in the service. Not receiving reimbursement after the Public Health Emergency (PHE) ends will place hospitals in a conundrum: how can the services be rendered to a patient, under a physician's direction, with a physician's order, but the specific code for the service is not reportable for reimbursement? The service is covered when provided by clinical staff in the physician's office; the only difference in the scenario is that the hospital staff communicates with the patient under the orders of a physician/non-physician practitioner. The PRT submits that CMS would prefer to have the granularity of a specific code that represents a service rather than an alternate code that is not as specific.

- **The PRT recommends that CMS change the status indicator for CPT codes 99457 and 99458 from B to V to support the services provided to beneficiaries under the order of a physician.**

Radiation Oncology 77295 Denial Issues

Several PRT members have recently experienced Radiation Oncology denial issues that we wish to bring to CMS' attention. This includes SRS (Stereotactic Radio Surgery) denials that have been addressed with the individual MACs. The response was that this was not announced but was as a result of the OIG's report "Review of Outpatient 3-Dimensional Conformal Radiation Therapy Planning Services" relative to IMRT services.

Stereotactic Radiosurgery (SRS) Denials

There are two recurring denials. First, providers are receiving incorrect denials for continuing physics (CPT 77336) due to the OIG report. Contrary to this, CMS states that it is acceptable to bill CPT code 77336 both as part of the course of IMRT or SRS, as long as the code is not provided as part of developing the treatment plan. This service includes patient safety, verification of dose calculations, treatment modifications, patient set-up, etc.

Second, providers are receiving incorrect denials based on bundling issues between CPT 77290 and CPT 77295. This has been standard practice and both services have historically been separately payable until recently. The facility started experiencing "take-backs" on previously paid SRS claims with CPT 77290 if CPT 77295 was billed on a later claim. We acknowledge that the CMS Claims Processing Manual includes the dialogue for this *edit related to IMRT* planning (CPT 77301).

When CMS was contacted, the explanation was that while an edit for SRS is not published, the IMRT edit includes SRS services. ASTRO has also identified the same issues and outlines them here: https://www.astro.org/Daily-Practice/Reimbursement/Practice-Management-Resources/OIG-Audit

While the IMRT services have had the cost for CPT 77295 packaged into CPT 77301 to encompass the full cost of the services, this is not true for the SRS codes. The OIG report noted:

> *We recommend that the Centers for Medicare & Medicaid Services (CMS) implement billing requirements (including, for example, a bundled payment similar to that for IMRT) and system edits to prevent additional payments for 3D-CRT planning services that are billed before (e.g., up to 14 days before) the procedure code for the 3D-CRT treatment plan is billed…*
>
> *CMS concurred with our recommendation and stated that it will consider whether implementing billing requirements in the future to prevent payments for additional planning services when reported with 3D-CRT would be appropriate.*

Providers have spoken with the MACs and been advised that the new reimbursement is based on an edit that is not published. None of the MACs can provide anything in writing to providers and said that they have known about it for several months. The MACs also acknowledged that this was the result of the OIG report. CMS has utilized a sub-regulatory process for cutting

reimbursement to hospital providers rather than going through the rulemaking process. While the impetus was an OIG report, without announcing this NEW edit and reimbursement impact, knowing that IMRT and SRS are two separate and distinct types of therapies, CMS not only applied an unpublished, unexplained edit, but applied it RETROACTIVELY.

All entities under HIPAA are required to submit claims consistent with HIPAA transaction sets, and CPT coding is part of the HIPAA transaction sets. CMS' payment policy for IMRT planning code 77301 was in response to AMA action which changed the definition of 77301 to incorporate planning codes performed prior to and on the day of the IMRT plan. When the AMA updated this specific CPT code, it created HIPAA transaction code set change, which precipitated the subsequent OPPS payment change for 77301 made in 2016. Please see the table below for a timeline.

| Timeframe | Action | Comments |
|---|---|---|
| 2013 | AMA revalued RVUs for IMRT Planning | AMA revalued RVUs for calendar day 2014 |
| 2013-2014 | NCCI Manual Updates following AMA revisions to expand existing same day edits to multi-day services, eff: 1/1/14 | Following AMA revisions, the National Correct Coding Initiative (NCCI) Policy Manual was updated to indicate that the same date of service procedure-to-procedure edits between CPT code 77301 and pre-IMRT plan simulation codes would be extended to include all simulation activities associated with the development of the IMRT plan whether these procedures are reported on the same or different dates of service, effective January 1, 2014. |
| June of 2015 | Astro Guidance published creating a lot of provider response | Astro Guidance was published as a result of the AMA revaluing of RVU for 77301. In that revision, the work process involved in creating an IMRT treatment plan was updated to include all simulation services performed in the development of the IMRT plan, and the practice expense relative value units (PE RVUs) associated with CPT code 77290 were included in the valuation of CPT code 77301. Concerns that guidance confused the initial clinical set-up with the actual simulation that happens downstream. The original intent was that the clinical set-up/SIM would be included and not separately billable but the actual simulation after imaging and treatment planning would be billable regardless of whether IMRT was selected or some other method. |
| 2015 | Discussion in November 2015 OPPS Final Rule | Final Rule cites Claims Processing Manual PUB 100-4, Chapter 4 section 200.3.2 that payment for services in CPTs 77300 (Dosimetry), 77280-77295 (SIM range, 77295: 3D RT Plan), 77305-77321 (teletherapy or Brachytherapy Isodose) planning), is included in IMRT planning when they are performed as part of developing an IMRT plan… under those circumstances, these codes should not be billed with 77301. CMS responded by providing the 2002 OPPS final rule stating payment for the code ranges are included in IMRT planning code 77301. |
| 2/26/16 | CMS published updates to PUB 100-04 with changes effective 4/4/16 with new language (red) | 200.3.1 - Billing Instructions for IMRT Planning<br>(Rev. 3741, Issued: 02-26-16, Effective: 04-01-16, Implementation: 04-04-16)<br>Payment amounts for the services identified by CPT codes 77014, 77280, 77285, 77290, 77295, 77305 through 77321, 77331, and 77370 are included in the APC payment for CPT code 77301 (IMRT planning). These codes should not be reported in addition to CPT code 77301 when provided prior to or as part of the development of the IMRT plan. |

The AMA did not make this change for CPT code 77295, however. The OIG's recommendations to apply edits in advance of CMS providing notice and comment for rate-setting is, we believe, tantamount to a violation of HIPAA transaction sets. Hospitals must follow correct coding per CPT principles, which CMS has stated in numerous guidelines and Internet-only manual instructions. If CMS decides to change the reimbursement methodology, then CMS should go through rulemaking regarding the change. Merely denying the valid CPT codes and charges is not making a payment policy determination, nor does it provide transparency to providers providing the service.

Furthermore, given the finalization of the Radiation Oncology Model, the PRT asks that CMS make adjustments in the calculation of appropriate payments to add back payment for the inappropriate denials.

Provider Roundtable: c/o Community Hospital Anderson, Anderson, IN
Attention: Terri Rinker, MT (ASCP), MHA, Revenue Cycle Director
1515 N. Madison Avenue, Anderson, IN 46011

Provider Roundtable

## Attachment A: Provider Roundtable Members

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