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Regulatory Update: CMS Proposed Rule – Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

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Background & Summary

On Monday, July 29, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the calendar year (CY) 2020 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). The OPPS includes changes to payment policies, payment rates, and quality provisions for Medicare patients who receive care at hospital outpatient departments (HOPDs) or receive care at ambulatory surgical centers (ASCs).

This proposed rule also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. Among other proposed policies, CMS intends to continue the cuts to 340B hospitals as well as site-neutral payment policies between different Medicare sites of services. Additionally, the agency is proposing to increase transparency measures by requiring providers to publicly post privately negotiated rates for certain treatments and services. These policies and other elements of the OPPS rule are outlined in more detail below.

Comments are due September 27, 2019 and Vizient looks forward to working with members to help inform our letter to the agency.

OPPS Payment Update

CMS proposes to apply a fee schedule increase factor of 2.7 percent for CY 2020 (except for hospitals not meeting certain quality reporting requirements which would be subject to a 2 percent reduction, resulting in a fee schedule increase factor of .7 percent). The proposed increase factor of 2.7 percent is based on the proposed hospital inpatient market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of minus 0.5 percentage point. For CY 2020, CMS estimates that the total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) would be "approximately $79 billion, an increase of approximately $6 billion compared to estimated CY 2019 OPPS payments."

Overall, CMS estimates a similar impact for both urban hospitals (+2.0 percent) and rural hospitals (+1.9 percent). After accounting for inflation and other adjustments required by law, the proposed rule would increase outpatient operating payment rates by 2.0 percent in calendar year (CY) 2020. The table below details factors CMS included in their estimate.

Estimated Impact of the Proposed CY 2020 Changes for the Hospital OPPS

	Number of Hospitals	Proposed APC Recalibration (All Proposed Changes)	Proposed New Wage Index & Provider Adjustments	All Proposed Budget Neutral Changes (Columns 2 & 3) with Market Basket Update	Existing Off-Campus Provider-Based Department Visits Policy	All Proposed Changes
All Facilities*	3,734	0.0	0.1	2.8	-0.6	2.0
All Hospitals	3,627	0.0	0.1	2.9	-0.6	2.0

*(Excludes Hospitals Permanently Held Harmless and CMHCs)

Proposed Comprehensive APCs (C-APCs) for CY 2020

CMS uses complexity adjustments to administer an increased payment for particular comprehensive services. The agency packages payment for add-on codes into the comprehensive Ambulatory Payment Classification (C-APC) payment rate. CMS designates a service described by a Healthcare Common Procedure Coding System (HCPCS) code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator "J1". CMS lists the complexity adjustments proposed for "J1" and add-on code combinations for CY 2020 – along with other proposed complexity adjustments and cost statistics – in Addendum J of the proposed rule (available on the CMS website). For CY 2020, CMS is proposing to create two new C-APCs under the existing payment policy: 1) proposed C-APC 5182 (Level 2 Vascular Procedures); and 2) proposed C–APC 5461 (Level 1 Neurostimulator and Related Procedures). CMS reviews the services and the APC assignments under the OPPS annually, and this proposal would increase the total number of C-APCs to 67. Additionally, CMS is considering developing an episode-of-care for skin substitutes – and is seeking feedback on a potential C-APC for procedures using skin substitute products furnished in the hospital outpatient department setting.

Exclusion of Procedures Assigned to New Technology APCs from the C-APC Policy

Typically, new procedures that do not have enough claims history to establish an accurate payment are assigned to "New Technology APCs". For CY 2020, CMS is proposing to continue to exclude payment for any procedures assigned to a New Technology APC from being packaged when it is included on a claim with a "J1" service assigned to a C-APC. CMS notes that stakeholders have questioned if the policy in last year's final rulemaking would also apply "to comprehensive observation services assigned status indicator 'J2'" – and is therefore proposing that payment for services assigned to a New Technology APC will be packaged into the payment for comprehensive "J2" services. CMS reiterates existing policy[1] that observation services may not be used for post-operative recovery and, thus, observation services furnished with services assigned to status indicator "T" will always be packaged. However, the agency is seeking feedback on whether it would be "clinically appropriate to exclude payment for a for any New Technology APC procedures from being packaged into the payment for a comprehensive "J2" service" – beginning in CY 2020.

Proposed Wage Index Changes to the OPPS for CY 2020

CMS is proposing changes to the OPPS wage indexes that are in line with the Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) FY 2020 rulemaking. Under current law, CMS delineates hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). CMS is proposing that for the CY 2020 OPPS wage indexes, the agency would "continue to use the OMB delineations that were adopted under the OPPS, beginning with CY 2015 (based on the revised delineations issued in OMB Bulletin No. 13-01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15-01 and 17-01."

CMS is proposing to use the "FY 2020 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2020." Thus, any adjustments for the FY 2020 IPPS post-reclassified wage index – including, but not limited to – any proposed policies finalized under the IPPS to address wage index disparities between low and high wage index value hospitals would be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020. CMS believes that it is logical to use the IPPS wage index as the source of the adjustment factor for the OPPS since HOPDs are inseparable from the overall hospital itself.

Hospitals that are not paid under the IPPS but are paid under the OPPS do not have an assigned hospital wage index. In other words, non-IPPS hospitals that are paid under the OPPS have been assigned the wage index that they would have if they were paid under the IPPS based on geographic location and any applicable wage index adjustments. CMS is proposing to continue this policy for CY 2020. CMS is proposing to continue their existing policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county[2]. Additionally, CMS is proposing to apply the policies finalized under the IPPS FY 2020 rulemaking relating to wage index

[1] CY 2016 OPPS/ASC final rule with comment period
[2] Section 505 of the Medicare Modernization Act of 2003 (Pub. L. 108–173)

disparities to these hospitals. For CY 2020, the agency also proposes to include the rural floor adjustment to the wage index applying to non-IPPS hospitals.

CMS has posted on their website the hospital-specific estimated payments for CY 2020 – both the hospital-specific file layout and the hospital-specific file. CMS was able to provide hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 41 of the proposed rule (pg. 740); the agency does not provide data for hospitals whose claims they were unable to use. For hospitals paid under the OPPS, CMS estimates that the proposed update of the wage indexes would result in no payment change for urban hospitals overall, and an increase of 0.8 percent for rural hospitals.

Proposed OPPS Payment for Devices – Pass-Through Payment for Devices

CMS is evaluating seven applications for device pass-through payments for CY 2020, and is requesting stakeholder feedback on whether these applications meet the criteria for device pass-through payment status. Under current statute[3], the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years.

New Device Pass-Through Applications – Proposed Changes to Substantial Clinical Improvement Criterion

Current statute[4] provides for pass-through payments for devices, and requires CMS to use categories when determining the eligibility of these devices for pass-through payments. CMS continues to believe that, in order to facilitate beneficiary access, it is important that hospitals receive pass-through payments when devices may offer substantial clinical improvement. Additionally, CMS intends to target pass-through payments for devices where cost considerations are most likely to interfere with or hinder patient access[5] – and are proposing an alternative pathway that would grant fast-track device pass-through payment under the OPPS for devices approved under the Food and Drug Administration's (FDA) Breakthrough Device Program for applications received on or after January 1, 2020. Further details on the requirements are included in the application form itself, and CMS notes that they are open to meeting with applicants and/or potential applicants to discuss details in advance of any application and/or regarding the application criteria.

Request for Information and Potential Revisions to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion in the FY 2020 IPPS/LTCH PPS Proposed Rule

In the FY 2020 IPPS/LTCH PPS proposed rule[6], CMS requested information on the "substantial clinical improvement criterion" for OPPS transitional pass-through payments for devices – and noted they were considering potential revisions to the criterion. Additionally, CMS sought feedback on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that the agency may consider making in the FY 2020 IPPS/LTCH PPS final rule in order "to provide greater clarity and predictability." The agency notes that any revisions to the OPPS substantial clinical improvement criterion that is in response to the FY 2020 IPPS/LTCH PPS proposed rule will be included in the CY 2020 OPPS/ASC final rule. CMS is continuing to seek feedback from stakeholders in this proposal, and responses the agency receives, as well as any changes that may be adopted and finalized, will inform and be included in future rulemaking.

Proposed Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices

CMS is proposing an alternative outpatient pass-through pathway to facilitate access to "transformative medical devices" for Medicare beneficiaries beginning with applications received for pass-through payment on or after January 1, 2020. In line with policies discussed in the fiscal year (FY) 2020 IPPS/LTCH proposed rule[7], CMS is proposing to amend existing regulations to create an alternative pathway to demonstrating substantial clinical improvement that would enable devices approved under the FDA Breakthrough Devices Program to qualify for device pass-through payment under the OPPS.

CMS is proposing to establish an alternative pathway for applications received on or after January 1, 2020, that would grant fast-track device pass-through payments for those devices already approved under the FDA

[3] Section 1833(t)(6)(B)(iii) of the Act
[4] Section 1833(t)(6) and Section 1833(t)(6)(B) of the Act
[5] 66 FR 55852; 67 FR 66782; and 70 FR 68629
[6] 84 FR 19368 through 19371
[7] 84 FR 19371 through 19373

Breakthrough Device program and have received FDA marketing authorization. In other words, if the device has received Premarket Approval (PMA), 510(k) clearance, or been granted a De Novo classification request, the device will not be evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining pass-through payment status. However, these devices must continue to meet the other requirements for pass-through payment status under current regulations[8]. Devices approved under the Breakthrough Devices Program, and approved for OPPS device transitional pass-through payment can be approved via the existing quarterly process – and would be announced through that process[9]. CMS plans to include proposals regarding these devices and whether pass-through payment status should continue to apply in the next applicable OPPS rulemaking cycle.

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Current statute provides for temporary additional payments – "transitional pass-through payments" – for certain drugs and biologicals. Under the OPPS, the average sales price (ASP) methodology uses several sources of data as a basis for payment – including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP).

Proposed Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2019

CMS is proposing that the pass-through payment status of six drugs and biologicals would expire on Dec. 31, 2019 (listed in Table 14 of the proposed rule, pg. 302). With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS's standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost, and compare it with the OPPS drug packaging threshold for that calendar year. For CY 2020, CMS is proposing a packaging threshold of $130. CMS is also proposing that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, the agency would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, CMS is proposing to provide separate payment at the applicable relative ASP-based payment amount – which for CY 2020, is proposed at ASP plus 6 percent. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2020

For CY 2020, CMS is proposing to continue pass-through payment status for 61 drugs and biologicals, listed in Table 15 of the proposed rule (pgs. 305-309). Additionally, there are four drugs and biologicals that have already had 3 years of pass-through payment status, but where legislation[10] requires CMS to extend pass-through payment status for an additional 2 years (effective October 1, 2018). The last 9 months of pass-through status for these drugs and biologicals will occur in CY 2020 – thus, they are also included in Table 15, bringing the total number to 65. CMS is proposing to continue to pay for pass-through drugs and biologicals at ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2020. CMS is also proposing to continue to pay for biosimilars with pass-through payment status based on their own ASP plus 6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC – rather than being calculated from the WAC price of the reference product.

CY 2020 OPPS Payment Methodology for 340B Purchased Drugs

In CY 2018 rulemaking[11], CMS finalized its proposal to pay for separately payable, non pass-through drugs and biologicals (other than vaccines) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent, effective January 1,

[8] § 419.66
[9] 81 FR 79655
[10] Section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141)
[11] CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370)

2018. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals have been excluded from this payment adjustment since CY 2018 – and Critical Access Hospitals (CAHs) are not reimbursed under OPPS, so this policy does not apply to them. These policy changes have not applied to drugs on pass-through payment status, which are required to be based on the ASP methodology – or vaccines, which are excluded from the 340B Program.

In the CY 2019 OPPS/ASC final rule with comment period[12] CMS finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus provider-based departments (PBDs) paid under the Physician Fee Schedule (PFS) – effective for CY 2019 and subsequent years. Additionally, in last year's rule[13] CMS finalized proposals to continue the 340B Program policies that were implemented in CY 2018 – with the exception of how the agency calculates payment for 340B-acquired biosimilars. CMS finalized their proposal to pay for non pass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP. For drugs or biologicals not purchased with a 340B discount, CMS continues to pay for drugs and biologicals at ASP plus 6 percent. Furthermore, for 340B-acquired drugs where ASP are not available for a drug or biological product, CMS also clarified and finalized their current policy to pay for separately payable drugs and biological products at 95 percent of the average wholesale price (AWP). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent, or 69.46 percent of AWP) continues to apply.

For CY 2020, CMS is proposing to continue the 340B Program policies that were implemented in CY 2018, as well as the proposals finalized in CY 2019 to calculate payment for 340B-acquired biosimilars. CMS is also proposing to continue the policy finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

CMS's CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs are the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association et al. v. Azar et al.*, the United States District Court for the District of Columbia ("the district court") concluded "in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year[14]." Also in that decision, the district court acknowledged "the havoc that piecemeal review of OPPS payment could bring about'" in light of the budget neutrality requirement," and thus requested additional input from both parties on an acceptable resolution[15]. Following that ruling, in May of this year, after a discussion on the remedy (resolution), "the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded [the Secretary's] authority[16]."

In this proposed rule, CMS states: "Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is 'no easy task, given Medicare's complexity[17],' and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction." The district court further acknowledged that because HHS has already processed claims under the reduced rate, the agency would possibly have to recover payments made to providers – noting that this task would be both "expensive and time-consuming[18]." CMS disagreed with the district court's ruling, and on July 10, 2019, the agency was granted its request to enter final judgment in order to immediately appeal the decision. CMS states in this proposed rule that they do intend to pursue an appeal; however, the agency is moving forward with "steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal".

In order to begin developing a solution, CMS notes that it requires an opportunity for public input. Changes to the OPPS must be budget neutral – and reversal of the policy changes will cost an estimated $1.7 billion for 2018 alone. The OPPS is a budget-neutral payment system where the conversion factor (CF) is updated annually by the outpatient department (OPD) Fee Schedule (FS) increase factor (unless Congress stipulates

[12] 83 FR 59015 through 59022
[13] 83 FR 58981
[14] *American Hosp. Ass'n, et al. v. Azar, et al.*, No. 1:18-cv-2084 (D.D.C. Dec. 27, 2018)
[15] *Id.* at 35 (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted))
[16] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10-12
[17] *Id.* at 13
[18] *Id.* (citing Declaration of Elizabeth Richter)

otherwise). In other words, to ensure "budget neutrality", CMS will adjust the total OPPS rates by the amount necessary to account for the payment cuts (and repayment) – therefore applying budget neutrality across the payment system as a whole rather than solely across the impacted providers. CMS states that any solution "could have a significant economic impact on the approximately 3,900 facilities that are reimbursed for outpatient items and services covered under the OPPS." Furthermore, the agency also recognizes that any solution is likely to have a substantial impact on beneficiary cost-sharing.

CMS is soliciting initial public comment on how to formulate a solution that accounts for all of the complexities that the district court recognized. CMS is required to develop and propose a specific solution via the formal rulemaking process – and present the specific budget neutrality implications of said remedy. CMS states: "In essence, we would need to provide hospitals with sufficient notice of the impact of the remedy on their rates to enable them to comment meaningfully on the proposed rule." CMS notes that they plan to follow their own "best practices" for preparing notices of proposed rulemaking, which means that they would begin policy development in the year before issuing a proposed rule and begin the rule writing in the first quarter of the year. Thus, CMS expects to propose specific policies for a solution (for CYs 2018, 2019, as well the CY 2020 rates) in the next proposed OPPS/ASC rule, which would be for CY 2021. Policies put forth in next year's proposed rule will be informed by comments and input received from this proposed rule. However – CMS notes that in order for it to be potentially possible to propose and finalize any remedy in CY 2021 rulemaking, the agency would need to receive a final decision from the Court of Appeals "sufficiently early in CY 2020 (likely by March 1, 2020)."

The agency is using this proposed rule to solicit feedback on a myriad of potential solutions in advance of next year's rulemaking so that they are prepared to propose policies in the CY 2021 OPPS/ASC payment rule, if necessary (i.e., if CMS loses their appeal in the D.C. Circuit ruling). Specifically, CMS is seeking comments on the "best, most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy" – or whether there is an alternative policy "that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate." Additionally, the agency is seeking input on "whether, depending on the amount of those additional expenditures, [the agency] should consider spreading out the relevant budget neutrality adjustment across multiple years", and is requesting comment on both the advantages and disadvantages of these approaches.

Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2020, CMS is proposing to complete the second year of the two year phase-in of the payment reduction for the clinic visit services described by Healthcare Common Procedure Coding System (HCPCS) code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), furnished in excepted off-campus provider-based departments (PBDs). In the CY 2019 OPPS/ASC final rule with comment period[19], CMS finalized a payment methodology meant to reduce the volume of "unnecessary" outpatient department services by utilizing the Medicare Physician Fee Schedule (PFS) to reimburse for hospital outpatient clinic visits in excepted off-campus PBDs. The proposed PFS-equivalent rate for CY 2020 is 40 percent of the proposed OPPS payment (i.e., 60 percent less than the proposed OPPS rate) for CY 2020. Thus, excepted off-campus PBDs will be paid approximately 40 percent of the OPPS rate (i.e., 100 percent of the OPPS rate minus the 60-percent payment reduction applied in CY 2020) for the clinic visit service (HCPCS code G0463).

Proposed Prior Authorization Process and Requirements for Certain Hospital OPD Services

CMS routinely reviews specific hospital outpatient department (OPD) categories of services – and found "higher than expected volume increases for several services." Most of these services are under five general categories of services: 1) blepharoplasty; 2) botulinum toxin injections; 3) panniculectomy; 4) rhinoplasty; and 5) vein ablation. Therefore, CMS is proposing a prior authorization process as a "method for controlling unnecessary increases in the volume of the […] five categories of services." CMS is proposing that the prior authorization requirement would begin for dates of service on or after July 1, 2020 – in order for CMS to conduct outreach and education to providers, and for contractor operational updates to be in place.

[19] 83 FR 59004 through 59015

Proposed Changes to the Inpatient Only (IPO) List

For CY 2020, CMS is proposing to remove one procedure from the inpatient only (IPO) list – total hip arthroplasty (THA). This procedure is described by CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft). The agency is proposing to assign the THA procedure to C-APC 5115 with status indicator "J1".

CMS is also seeking feedback on the removal of six procedures from the IPO list. The table below contains the CPT codes under consideration to be removed from the IPO list:

CPT CODE	Long Descriptor
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression). Single interspace and segment; lumbar;
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression). Single interspace and segment; lumbar; each additional interspace and segment
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral

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

In the CY 2018 OPPS/ASC final rule with comment period[20], CMS reinstated the enforcement instruction which provides for the "nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services" in critical access hospitals (CAHs) and small rural hospitals having 100 or fewer beds, through December 31, 2019. CMS notes that these providers have continuously expressed to the agency that they have "insufficient staff available to furnish direct supervision", and cite difficulties in recruiting physicians and nonphysician practitioners in rural areas. CMS states that the approaching expiration of the most recent enforcement instruction has prompted the agency to consider changing the level of supervision for hospital outpatient therapeutic services for all hospitals and CAHs.

CMS believes that since 2010, the enforcement instructions and legislative actions have created a "two-tiered system of physician supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program." Direct supervision is required for the majority of outpatient therapeutic services in most hospital providers – while only general supervision is required in CAHs and small rural hospitals. Therefore, for CY 2020, CMS is proposing to "change the minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs." CMS asserts that this proposal will guarantee a standard, minimum level of supervision for each hospital outpatient service that is furnished incident to a physician's service. Further, CMS believes this policy sets an "appropriate and uniformly enforceable supervision standard for all hospital outpatient therapeutic services." The agency is seeking feedback on this proposal – and specifically is seeking input on

[20] 82 FR 59391

whether specific types of services (e.g., chemotherapy administration or radiation therapy) should be excluded.

Short Inpatient Hospital Stays – Proposed Change for Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2020 and Subsequent Years

Although procedures on the IPO list under the OPPS are not subject to the 2-midnight benchmark for purposes of inpatient hospital payment – the benchmark is applicable for procedures that have been removed from the list. Once procedures are removed from the IPO list, they are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs may also refer providers to the Recovery Audit Contractors (RACs) for further medical review. For CY 2020 and subsequent years, CMS is proposing to establish a "1-year exemption from BFCC-QIOs referrals to RACs and RAC reviews for "patient status" (that is, site-of-service) for procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on January 1, 2020." In other words, procedures that have been removed from the IPO list would not be eligible for referral to RACs for noncompliance with the 2-midnight rule for the first CY after they have been removed from the list. Furthermore, the BFCC-QIOs could not consider these procedures to determine if providers are exhibiting "persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor would these procedures be reviewed by RACs for 'patient status'."

Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy

CMS has twice extended the enforcement discretion period for implementation of the laboratory date of service (DOS) exception after learning from providers and suppliers affected by the policy that there are still many entities who will need additional time to implement the exception and come into compliance. The current enforcement discretion period is currently in effect until January 2, 2020. Additionally, CMS has continued to gauge the industry's preparedness to implement the laboratory DOS exception; [21] the list of specific laboratory tests currently subject to the exception is available for download on the CMS website.

Due to concerns regarding implementation and the readiness of stakeholders, CMS is considering making additional changes to the laboratory DOS policy. CMS states that hospitals specifically have informed the agency that they are "having difficulty with developing the systems changes necessary to provide the performing laboratory with the patient's hospital outpatient status, beneficiary demographic information, and insurance information, such as whether the beneficiary is enrolled in original fee-for-service Medicare or a specific Medicare Advantage plan." Performing laboratories require this information so they can bill Medicare directly for tests, rather than seeking payment from hospitals. Thus, CMS is considering three options for potential changes to the laboratory DOS exception. Specifically, CMS is seeking feedback on 1) changing the test results requirement[22]; 2) limiting the laboratory DOS exception[23] to advanced diagnostic laboratory tests (ADLTs); and/or 3) excluding blood banks and blood centers from the laboratory DOS exception[24].

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The Hospital Outpatient Quality Reporting (OQR) Program is aligned with that of hospital inpatient services, the Hospital Inpatient Quality Reporting Program (IQR Program). Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor.

For the CY 2022 payment determination for the Hospital OQR Program (i.e. beginning with October 2020 encounters), CMS is not proposing to add any measures, and is proposing to remove one measure: OP-33: External Beam Radiotherapy for Bone Metastases (NQF # 1822) Table 34 in the proposed rule (pgs. 511-512) summarizes the proposed Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years – including previously adopted measures and excluding the measure proposed for removal.

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[21] § 414.510(b)(5)
[22] 42 CFR 414.510(b)(5)(iv)
[23] 42 CFR 414.510(b)(5)
[24] 42 CFR 414.510(b)(5)

If CMS's proposal to remove OP-33 is finalized, the following previously finalized quality measures will require data to be submitted via CMS' QualityNet Website for the CY 2022 payment determination and subsequent years:

- OP-22: Left Without Being Seen (NQF #0499);
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

CMS is seeking feedback regarding the potential future adoption of four patient safety measures and outcome measures in general. The four specific patient safety measures CMS is considering for the Hospital OQR Program – that were previously adopted for the ASCQR Program – are: ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission.

OAS CAHPS Survey-Based Measures

In the CY 2018 OPPS/ASC final rule with comment period[25], CMS finalized a policy to delay implementation of the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period). At this time, CMS is not proposing any changes to the previously finalized requirements (and delay of implementation) related to survey administration and vendors for the OAS CAHPS Survey-based measures.

Proposed Ambulatory Surgical Center (ASC) Payment Update for CY 2020

Using the hospital market-basket methodology, for CY 2020, CMS is proposing to increase payment rates under the ASC payment system by 2.7 percent for ASCs that meet the ASC quality reporting requirements. This proposed increase is based on the hospital market-basket percentage increase of 3.2 percent minus a multifactor productivity (MFP) adjustment of 0.5 percentage point. Under the ASC Quality Reporting (ASCQR) Program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet quality reporting requirements. For CY 2020, CMS is proposing to apply a 0.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs not meeting these requirements. For CY 2020, the proposed updated ASC payment rates for covered surgical procedures and covered ancillary services are displayed in Addenda AA and BB, respectively. Table 36 in the proposed rule (pgs. 551-552) summarizes the proposed ASCQR Program measure set for the CY 2024 payment determination and subsequent years (including previously adopted measures).

Proposed Additions to the List of Ambulatory Surgical Center (ASC) Covered Surgical Procedures

In this proposed rule, CMS is continuing "to promote site-neutrality, where possible, between the hospital outpatient department and ASC settings." CMS is seeking feedback on ways to ensure that beneficiaries are receiving surgical procedures in the ASC setting "only as clinically appropriate." CMS notes that this could be done via the agency issuing a new modifier which would indicate that the physician believes the beneficiary is not expected to require "active medical monitoring and care at midnight following a particular procedure furnished in the ASC setting" – with the requirement that the modifier be included on the claims line. CMS could alternatively require that an ASC have defined plans of care for each beneficiary following a surgical procedure. Additionally, the agency could establish certain requirements for ASCs, for example, requiring a certain amount of experience in performing a procedure before being eligible for payment for the procedure under Medicare. CMS is seeking feedback on these options – as well as other options – in order to ensure that beneficiaries receiving surgical procedures are not at a significant safety risk when performed in an ASC.

CMS is required under current statute[26] to review and update the Covered Procedure List (CPL) at least every two years. The CPL list contains surgical procedures that are performed on an inpatient basis but can also be safely performed in an ASC. CMS is proposing to add nine procedures to the ASC list of covered

[25] 82 FR 59432 through 59433
[26] Section 1833(i)(1) of the Act

surgical procedures. These procedures, including the HCPCS code long descriptors and the proposed CY 2020 payment indicators, are displayed in the following table:

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

CY 2020 CPT Code	Long Descriptor	Proposed CY 2020 ASC Payment Indicator
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	J8
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)	J8
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	G2
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1

In addition to the three coronary intervention procedures CMS is proposing to add to the ASC-CPL, the agency is reviewing several other coronary intervention procedures for possible inclusion in future years. While CMS does not believe that these procedures (listed in Table 33 on pgs. 470-471) currently meet the criteria for inclusion, and is not proposing to add them to the ASC-CPL for CY 2020 – the agency is seeking feedback on whether stakeholders "believe they can be safely performed in an ASC setting and [if so] to provide any materials supporting their position."

Additionally, CMS is seeking feedback on potential modifications to the ASC-CPL. Specifically, the agency is requesting input on how they should "think about the role of the ASC-CPL compared to state regulations and market forces in providing payment for certain surgical procedures in an ASC." Any feedback received could help formulate new policies regarding how the agency determines which procedures are payable for Medicare fee-for-service (FFS) beneficiaries in the ASC setting while balancing safety and access. CMS is also seeking input on how the proposed additions to the list of ASC covered surgical procedures could impact rural hospitals – "to the extent rural hospitals rely on providing such procedures."

Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges

CMS believes that there is "a direct connection between transparency in hospital standard charge information and having more affordable health care and lower health care coverage costs." This proposed rule specifically states that: "In short, as articulated by the CMS Administrator [Verma] …transparency in health care pricing is 'critical to enabling patients to become active consumers so that they can lead the drive towards value'."

In accordance with the President's Executive Order[27] on "Improving Price and Quality Transparency in American Healthcare to Put Patients First" – CMS is proposing an expansion of hospital charge display requirements to include "charges and information based on negotiated rates and for (300) common "shoppable" items and services, in a manner that is consumer-friendly." CMS asserts that "health care consumers continue to lack the meaningful pricing information they need to choose the health care services they want and need despite prior requirements for hospitals to publicly post their chargemaster rates online."

The agency believes that these policies are critical towards advancing their goals to achieve price transparency in health care and notes that they are going to continue to explore other ways to enhance transparency efforts to allow patients to make informed health care decisions.

CMS is proposing to codify a specific set of requirements[28], and add a new "Part 180 – Hospital Price Transparency to title 45 of the Code of Federal Regulations (CFR)" – which would contain the regulations on price transparency.

Specifically, CMS is making proposals related to the following:

1) a definition of "hospital";
2) different reporting requirements that would apply to certain hospitals;
3) definitions for two types of "standard charges" (specifically, gross charges and payer-specific negotiated charges) that hospitals would be required to make public, and a request for public comment on other types of standard charges that hospitals should be required to make public;
4) a definition of hospital "items and services" that would include all items and services (including individual items and services and service packages) provided by the hospital to a patient in connection with an inpatient admission or an outpatient department visit;
5) requirements for making public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges for all items and services provided by the hospital;
6) requirements for making public payer-specific negotiated charges for select hospital-provided items and services that are "shoppable" and that are displayed in a consumer-friendly manner;
7) monitoring for hospital noncompliance with public disclosure requirements to make public standard charges;
8) actions that would address hospital noncompliance, which include issuing a written warning notice, requesting a corrective action plan, and imposing civil monetary penalties (CMPs) on noncompliant hospitals and publicizing these penalties on a CMS website; and
9) appeals of CMPs.

What's Next?

CMS publishes the final OPPS/ASC regulation around November 1, and the changes are effective at the beginning of the calendar year (January 1, 2020). The 60-day comment period closes on September 27, 2019. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. It is possible there will be substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for more information from our office when the final rule is released in November.

Additional Resources

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.

[27] Executive Order. Improving Price and Quality Transparency in American Healthcare to Put Patients First. June 24, 2019.
[28] Codifying further implementation of Section 2718(e) of the PHS Act