
Medicare Outpatient Prospective Payment System

Payment Rule Brief — Calendar Year 2020 Proposed Rule

Overview

The proposed calendar year (CY) 2020 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on July 29, 2019. The proposed rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as regulations that implement new policies. The proposed rule includes policies that would:

- Attempt to reduce the growing disparity between high-and-low-wage index hospitals;
- Change the calculation of cost-to-charge ratios;
- Establish requirements for all hospitals to make hospital standard charges available to the public;
- Establish a process for prior authorization for certain covered outpatient department services;
- Change the requirements for a medical device to qualify for device pass-through status;
- Revise conditions for coverage for organ procurement organizations;
- Change the inpatient only list;
- Change the two-midnight policy for inpatient stays for procedures removed from the inpatient only list;
- Change the minimum level of supervision required for hospital outpatient therapeutic services from direct supervision to general supervision;
- Continue the phase-in of payment changes for clinic services furnished in excepted off-campus provider-based departments; and
- Update payment rates and policies for Ambulatory Surgical Centers (ASCs).

A copy of the proposed rule and other resources related to the OPPS are available on the Centers for Medicare and Medicaid Services (CMS) website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-P.html>. Comments are due to CMS by September 27, 2019 and can be submitted electronically at <http://www.regulations.gov> by using the website's search feature to search for file code "1717-P".

An online version of the rule will be available at <https://www.federalregister.gov/d/2019-16107>. Page numbers noted in this summary are from the *Federal Register* (FR) version of the proposed rule. A brief summary of the major hospital OPPS sections of the proposed rule is provided below.

Note: Text in italics is extracted from the August 9, 2019 *Federal Register*.

OPPS Payment Rate

FR pages 39428 – 39429

The tables below show the proposed CY 2020 conversion factor compared to CY 2019 and the components of the update factor:

	Final CY 2019	Proposed CY 2020	Percent Change
OPPS Conversion Factor	\$79.490	\$81.398	+2.40%
Proposed CY 2020 Update Factor Component		Value	
Marketbasket (MB) Update		+3.2%	
Affordable Care Act (ACA)-Mandated Productivity MB Reduction		-0.5 percentage points (PPT)	
Wage Index Transition BN		-0.12%	
Wage Index BN Adjustment		+0.05%	
Pass-through Spending / Outlier BN Adjustment		-0.20%	
Cancer Hospital BN Adjustment		-0.02%	
Overall Proposed Rate Update		+2.40%	

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes (FR pages 39429 – 39432):** As in past years, for CY 2020 OPPS payments, CMS is proposing to use the federal fiscal year (FFY) 2020 inpatient PPS (IPPS) wage indexes, including all reclassifications, add-ons, rural floors, and budget neutrality adjustment.

CMS proposed several changes that would affect the wage index and wage index-related policies in the FFY 2020 IPPS proposed rule to address wage index disparities between high and low wage index hospitals, including:

- Increasing the wage index for hospitals with a wage index value in the bottom quartile of the nation by half of the difference between the hospital's pre-adjustment wage index, and the 25th percentile wage index value across all hospitals;
- Offset the estimated increase in payments to hospitals in the bottom quartile by decreasing the wage index values for hospitals with a wage index value in the top quartile of the nation;
- Remove wage index data from urban hospitals that reclassify as rural when calculating each state's rural floor and rural wage index;
- Applying a transitional 5-percent cap in which a hospital's FFY 2020 wage index cannot be less than 95% of its final FFY 2019 wage index; and
- Apply a budget neutrality adjustment of 0.9988 to the CY 2020 OPPS rate to account for this transition.

A detailed discussion of these proposed changes can be found on *Federal Register* pages 19,393 – 19,399 in the FFY 2020 IPPS proposed rule.

In the FFY 2020 IPPS final rule, CMS adopted its proposal to increase the wage index for hospitals with a wage index value in the bottom quartile of the nation by half of the distance between the hospital's pre-adjustment wage index, and the 25th percentile wage index value across all hospitals. However, in response to public comments, CMS is modifying the offset by applying a budget neutrality adjustment to the rate to account for the transition, rather than decrease the wage index for hospitals above the 75th percentile as proposed.

CMS also adopted its proposals of a transitional 5-percent cap in which a hospital's FFY 2020 wage index cannot be less than 95% of its final FFY 2019 wage index and the removal of wage index data from urban hospitals that reclassify as rural when calculating each state's rural floor and rural wage index.

The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2020, CMS is proposing to continue to use a labor-related share of 60%.

- **Payment Increase for Rural SCHs and EACHs (FR page 39432):** CMS is proposing to continue the 7.1% payment increase for rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs). This payment add-on excludes separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. CMS will maintain this for future years until their data supports a change to the adjustment.
- **Cancer Hospital Payment Adjustment and Budget Neutrality Effect (FR pages 39429, 39432 – 39434):** CMS is proposing to continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. Previously, CMS did this by providing a payment adjustment such that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals (and thus the adjustment was budget neutral).

In order to determine a budget neutrality factor for the cancer hospital payment adjustment, CMS calculated a proposed PCR of 0.90 which, after applying the 1.0 percentage point reduction mandated by the 21st Century Cures Act, results in the proposed target PCR being equal to 0.89 for each cancer hospital, as opposed to the target PCR of 0.88 for CY 2019. Therefore, CMS has proposed a -0.02% adjustment to the CY 2020 conversion factor to account for this policy.

- **Outlier Payments (FR pages 39434 – 39435):** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is proposing a CY 2020 outlier fixed-dollar threshold of \$4,950. This is an increase compared to the current threshold of \$4,825. Outlier payments are proposed to continue to be paid at 50% of the amount by which the hospital's cost exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

Updates to the APC Groups and Weights

FR pages 39406 – 39428, 39438 - 39461

As required by law, CMS must review and revise the APC relative payment weights annually. CMS must also revise the APC groups each year to account for drugs and medical devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services, and new cost data.

The proposed payment weights and rates for CY 2020 are available in Addenda A and B of the proposed rule at <https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Addenda.zip>.

CMS is proposing to remove the following 5 HCPCS codes from the CY 2020 bypass list:

- HCPCS G0436: Tobacco-use counsel 3-10 min;
- HCPCS 71010: Chest x-ray 1 view frontal;
- HCPCS 71015: Chest x-ray stereo frontal;
- HCPCS 71020: Chest x-ray 2vw frontal&tat!; and
- HCPCS 93965: Extremity study

The table below shows the proposed shift in the number of APCs per category from CY 2019 to CY 2020 (Addendum A):

APC Category	Status Indicator	Final CY 2019	Proposed CY 2020
Pass-Through Drugs and Biologicals	G	60	72
Pass-Through Device Categories	H	1	1
OPD Services Paid through a Comprehensive APC	J1	63	66
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	330	322
Partial Hospitalization	P	2	2
Blood and Blood Products	R	36	36
Procedure or Service, No Multiple Reduction	S	79	79
Procedure or Service, Multiple Reduction Applies	T	31	29
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		743	748

Calculation and Use of Cost-to-Charge Ratios (CCRs) (FR pages 39407 – 39409): CMS is proposing to sunset the transition policy to remove claims from providers that use a “square footage” cost allocation method in order to calculate CCRs to estimate costs for the CT and MRI APCs identified below:

- APC 5521: Level 1 Imaging without Contrast;
- APC 5522: Level 2 Imaging without Contrast;
- APC 5523: Level 3 Imaging without Contrast;
- APC 5524: Level 4 Imaging without Contrast;
- APC 5571: Level 1 Imaging with Contrast;
- APC 5572: Level 2 Imaging with Contrast;
- APC 5573: Level 3 Imaging with Contrast;
- APC 8005: CT and CTA without Contrast Composite;
- APC 8006: CT and CTA with Contrast Composite;
- APC 8007: MRI and MRA without Contrast Composite; and
- APC 8008: MRI and MRA with Contrast Composite.

For CY 2020, CMS is proposing to use all claims with valid CT and MRI cost center CCRs, including those that use a “square feet” cost allocation method, to calculate costs for the CT and MRI APCs, listed above.

New Comprehensive APCs (FR pages 39409 - 39418): Comprehensive Ambulatory Payment Classifications APCs (C-APCs) provide all-inclusive payments for certain procedures. A C-APC covers payment for all Part B services that are related

to the primary procedure (including items currently paid under separate fee schedules). The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un-coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs when they appear on the same claim as those services assigned to a C-APC.

The C-APCs do not include payments for services that are not covered by Medicare Part B, nor those that are not payable under OPPS such as: certain mammography and ambulance services; brachytherapy sources; pass-through drugs and devices; and charges for self-administered drugs (SADs).

In order to ensure that there is sufficient claims data for services assigned to New Technology APCs, in the FFY 2019 final rule CMS excluded payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a "J1" indicator. CMS is proposing to continue to exclude payment for these procedures, but not to exclude New Technology APCs included on a claim with a "J2" status indicator from packaging into payment for comprehensive service.

For CY 2020, CMS is proposing to create two new C-APCs, bringing to total number to 67 C-APCs:

- APC 5182: Level 2 Vascular Procedures; and
- APC 5461: Level 1 Neurostimulator and Related Procedures.

A list of all proposed CY 2020 C-APCs can be found on *FR* pages 39415-39417.

- **Composite APCs (*FR* pages 39418 – 39423):** Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are six composite APCs for:
 - Mental Health Services (APC 8010); and
 - Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008).

For CY 2020, CMS is proposing to continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceed the maximum per diem payment rate for partial hospitalization services, those services will continue to instead be paid through composite APC 8010. In addition, the payment rate for composite APC 8010 will continue to be set to that established for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital.

For CY 2020, CMS is proposing to continue its composite APC payment policies for multiple imaging services. Table 5, on *FR* pages 39420 - 39423, displays the HCPCS codes that would be subject to the multiple imaging procedure composite APC policy and their respective families; as well as each family's geometric mean cost.

- **Payment Policy for Low-Volume New Technology APCs (*FR* pages 39453 – 39453):** For CY 2020, CMS is proposing to continue its policy established in CY 2019 that created a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims. This methodology may use up to 4 years of claims data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for assigning services to a New Technology APC.
- **Packaged Services (*FR* pages 39423 – 39427):** CMS is continuing its efforts to create more complete APC payment bundles over time to package more ancillary services when they occur on a claim with another service, and to only pay for them separately when performed alone.

For CY 2020, in order to address the decreased utilization of non-opioid pain management drugs, and to encourage their use rather than that of prescription opioids, CMS is proposing to continue to unpackage, and pay separately at ASP+6%, the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting.

CMS is seeking comment on whether there are other non-opioid pain management alternatives that should also have separate payment.

- **Payment for Medical Devices with Pass-Through Status (*FR* pages 39461 – 39483):** In order to address barriers to health care innovation and ensure access to new critical and life-saving cures and technologies, CMS is proposing that a new medical device which is part of the FDA Breakthrough Devices Program would no longer need to demonstrate the

substantial clinical improvement criterion to qualify for device pass-through status, beginning with applications received on or after January 1, 2020. The Breakthrough Devices Program was established by the 21st Century Cures Act to expedite the development and review of medical devices and device-led combination products that provide for more effective treatment/diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Even if a device waives the substantial clinical improvement criterion with this alternative pathway, the device would still need to meet the other requirements in order to qualify for pass-through payment status.

There is currently one device category eligible for pass-through payment: HCPCS C1822 – Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system.

CMS has not yet approved any new device pass-through payment applications for CY 2020.

- **Device-Intensive Procedures (FR pages 39483 – 39486):** CMS defines device-intensive APCs as those procedures which require the implantation of a device, and are assigned an individual HCPCS code-level device offset of more than 30%, regardless of APC assignment.

For new HCPCS codes describing device implantation procedures that do not yet have associated claims data, CMS applies a device offset of 31% until claims data are available to establish an offset for the procedure. In addition, CMS applies the CY 2016 device coding requirements to newly defined device-intensive procedures. Any device code would satisfy this edit when it is reported on a claim with a device-intensive procedure, regardless of if the device remains in the patient's body post-procedure.

For FFY 2020, CMS is not proposing any changes to the device-intensive policy.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices (FR page 39486):** For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital received a credit from the manufacturer. The offset can be 100% of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer; or 50% when a hospital receives partial credit of 50% or more.

CMS determines the procedures to which this policy applies using three criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (even if temporarily); and
- The procedure must be device-intensive (defined as devices exceeding 30% of the procedure's average cost).

For CY 2020, CMS is not proposing any changes to the no cost/full credit and partial credit device policies.

- **Payment Policy for Low-Volume Device-Intensive Procedures (FR pages 39486 – 39487):** For CY 2020, CMS is proposing to continue its policy where, for any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC, the payment rate for that procedure will be calculated using the median cost. CMS is proposing that for CY 2020 the only procedure to which this policy would apply continues to be CPT 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which CMS is proposing to assign to APC 5495.
- **Payment for Drugs, Biologicals and Radiopharmaceuticals (FR pages 39487 – 39505):** CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on the packaging threshold. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved since CY 2017 in order to grant a pass-through period as close to a full three years as possible, and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

For CY 2020, CMS is proposing a packaging threshold of \$130. Drugs, biologicals and radiopharmaceuticals that are above the \$130 threshold are paid separately using individual APCs and those below the threshold are packaged; the baseline payment rate for CY 2020 is the average sales price (ASP) + 6%.

Separately payable drugs and biological products that do not have pass-through status and are not acquired under the 340B program are paid wholesale acquisition cost (WAC)+3% instead of WAC+6%.

For CY 2020, CMS is proposing to continue to pay for therapeutic radiopharmaceuticals with pass-through payments status, based on ASP+6%. If ASP data are not available, CMS is proposing payment instead to be made based on WAC+3%; or 95% of average wholesale price (AWP) if WAC data are also not available.

Finally, CMS is proposing the pass-through status to expire on December 31, 2019 for 6 drugs and biologicals, listed in Table 14 on FR page 39488; and to continue/establish pass-through status in CY 2020 to 65 others, shown in Table 15 on FR pages 39490 - 39494.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes (FR pages 39505 - 39510):** CMS divides skin substitutes into a high cost group and a low cost group in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a products per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group.

CMS is proposing to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high cost group in CY 2019 to the high cost group in CY 2020 as well. CMS is also proposing to assign those with pass-through payment status to the high cost category.

The list of proposed packaged skin substitutes, and their group assignments, may be found in Table 19 on FR pages 39509 - 39510.

In the CY 2019 proposed rule, CMS requested public comment about refinements to the existing payment methodology for packaged skin substitutes in order to stabilize payments for these products. CMS considered four potential methodologies and discusses the comments received about two of them in this proposed rule:

- Establish a lump-sum “episode-based” payment for a wound care episode (FR page 39507); and
- Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products (FR pages 39507 - 39508);

CMS is reluctant to propose the episode-based payment methodology for CY 2020 due to the wide array of comments received. CMS is also not proposing the single payment category methodology at this time, but based on comments in the CY 2019 proposed rule believes there is potential of a single payment category to reduce the cost of wound care services for graft skin substitute procedures while providing a more equitable payment for products and lowering administrative burden. CMS is seeking feedback on a single payment category and may include this as part of a skin substitute payment policy in the CY 2020 OPPS final rule.

- **Payment for Drugs Purchased under the 340B Drug Discount Program (FR pages 39501 –39502, 39502 - 39505):** The 340B Drug Pricing Program, administered by the Health Resources & Services Administration (HRSA), allows participating hospitals and other health care providers to purchase certain “covered outpatient drugs” at discounted prices from drug manufacturers.

In CY 2018, due to a correlation between increases in drug spending and hospital participation in the 340B program, as well as CMS’ belief that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs, CMS changed the Medicare Part B drug payment methodology for 340B hospitals.

Specifically, for CY 2020, CMS is proposing to continue to pay a reduced rate of ASP - 22.5% of the biosimilar’s ASP, rather than the current rate of ASP + 6% for nonpass-through separately payable drugs and biosimilar biological products, if purchased under the 340B program. This includes those drugs (other than vaccines and drugs on pass-through payment status) provided at non-expected off-campus provider-based departments. CMS believes that 22.5 percent below the ASP (or WAC/AWP, where applicable) reflects the average minimum discount that 340B hospitals receive for drugs acquired under the 340B program.

Rural sole-community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals are exempt from the 340B adjustment, and receive drug payments based on ASP + 6%.

Effective January 1, 2018, in order to implement this payment adjustment, CMS established modifiers “JG” and “TB”. Modifier “JG” is used by non-exempt hospitals to report separately payable drugs that were acquired through the 340B program, and thus paid the reduced rate. Modifier “TB” is used by hospitals exempt from the 340B payment adjustment to report separately payable drugs that were acquired through the 340B program.

The 340B-acquired drug payment policies are involved in a continuing lawsuit. In the case of *American Hospital Association et al. v. Azar et al.*, the district court concluded that CMS exceeded its authority with its large reduction to

Medicare payments for CY 2018 and CY 2019 for drugs acquired through the 340B program. CMS disagrees with the district court’s decision and is pursuing an appeal. However, if the court does not make a decision in CMS’ favor, CMS is crafting an appropriate remedy to reverse the policy change. CMS is soliciting comments on the appropriate OPPS payment rate for 340B-acquired drugs for CY 2020 and how to determine a budget neutral remedy for CYs 2018 and 2019. Some options include:

- Payment rate of ASP+3% for 340B drugs;
- Retrospective on a claim-by-claim basis;
- Prospective upward adjustment in the future to account for the underpayment in the past;
- Additional payments to those have been impacted by the underpayments, identified as those who submitted a claim for a drug with the “JG” modifier in CYs 2018 and/or 2019, outside the normal claims process and including a budget neutrality adjustment; or
- Other mechanism that could produce a result reasonable to hospitals not part of the 340B program, while maintaining budget neutrality.

If needed, CMS anticipates proposing a remedy for CYs 2018 and 2019, as well as changes to the CY 2020 rates, in the CY 2021 rule making cycle, based on comments in this proposed rule.

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services (FR pages 39512 – 39523):** The PHP is an intensive outpatient psychiatric program to provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding Community Mental Health Center (CMHC). PHP providers are paid on a per diem basis with payment rates calculated using CMHC- or hospital-specific data.

The table below compares the final CY 2019 and proposed CY 2020 PHP payment rates:

	Final Payment Rate 2019	Proposed Payment Rate 2020	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	\$120.58	\$124.59	+3.3%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	\$220.86	\$228.20	+3.3%

For both CMHCs and hospital-based PHPs, CMS is proposing to use the CY 2020 APC geometric mean per diem cost, calculated using the existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost, as the basis for developing CY 2020 APC per diem rates. This is due to an outlier in the data that heavily influenced the calculated geometric mean per diem and significantly lowered the value compared CY 2019. This is solely a CY 2020 proposal and would not apply in future years. In the final rule, CMS is proposing to use the most recent updated data to calculate the CY 2020 geometric mean per diem costs.

CMS is also proposing, for CMHCs, to continue to make outlier payments for 50% of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year. Additionally, CMS is proposing to continue to apply an 8 percent outlier payment cap to the CMHC’s total per diem payments.

- **Updates to the Inpatient-Only List (FR pages 39523 – 39525):** The inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2020, CMS is proposing to remove the following service from the inpatient-only list:
 - CPT code 27130— Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft.

CMS is not proposing to add any CPT codes to the inpatient only list for CY 2020.

In addition, the public is asked to comment on whether the following CPT codes should be removed:

- CPT code 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;
- CPT code 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;

- CPT code 63265— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical;
- CPT code 63266— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic;
- CPT code 63267— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar; and
- CPT code 63268— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral.

- **Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals (FR pages 39525 - 39526):** Currently, CMS requires direct supervision for hospital outpatient therapeutic services covered by Medicare that are furnished in hospitals as well as in provider-based departments of hospitals, including CAHs. Due to the difficulty of meeting this standard, CMS had created an interim nonenforcement (“enforcement instruction”) for CAHs and small rural hospitals with 100 or fewer beds that allowed Medicare administrative contractors to not evaluate or enforce the supervision requirements, set to expire after CY 2019.

CMS now believes that Medicare providers will provide a similar quality of services, regardless of whether the minimum level of supervision required is direct or general. Also, CMS believes the direct supervision requirement places an additional burden on providers and reduces flexibility to provide medical care, especially for CAHs and small rural hospitals.

Therefore, CMS is proposing to change the minimum level of supervision required for hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs beginning January 1, 2020. The procedure still would be furnished under the physician’s overall direction and control, but the physician’s presence would not be required during performance of the procedure.

- **Two-Midnight Policy for Inpatient Stays (FR pages 39526 -3928):** Hospital stays that are expected to be two midnights or longer are presumed appropriate for inpatient admission and are not subject to medical necessity reviews. Currently, procedures that are on the inpatient only list are not subject to the two-midnight policy for purposes of inpatient payment and therefore are not subject to medical necessity reviews. However, once the procedures are removed from the inpatient only list, the two-midnight rule is applicable and the procedures are subject to the reviews.

CMS is proposing to establish a 1-year exemption from medical review activities for procedures removed from the inpatient only list for CY 2020 and forward. Specifically, these procedures would not be eligible for referral to Recovery Audit Contractors (RAC) for noncompliance with the two-midnight rule and RAC “patient status” review within their first calendar year of removal from the list. Information gathered when reviewing procedures that are newly removed from the inpatient only list during the 1-year exemption period could be used for education purposes, but would not result in a claim denial.

- **Payment for Off-Campus Outpatient Departments (FR page 39528):** The Bipartisan Budget Act of 2015 restricted OPPS payments for services provided by certain off-campus outpatient departments (OPDs) of providers on or after January 1, 2017. Covered OPD services provided in these off-campus OPDs prior to November 2, 2015 would continue to be paid under OPPS, while those added after that date would be paid under the Medicare Physician Fee Schedule (MPFS):

- All excepted off-campus provider-based departments (PBDs) may bill for excepted services under the OPPS (using the claim line indicator “PO”). These include those furnished in a dedicated emergency department (ED), in an on-campus PBD, or within 250 yards from a remote location of a hospital facility.
- Excepted off-campus PBDs are allowed to relocate (temporarily or permanently), without loss of excepted status, in the rare event of extraordinary circumstances outside of the hospital’s control, such as natural disasters, seismic building code requirements, or significant public health and safety issues. Relocation requests will be evaluated by the CMS Regional Offices and either approved or denied. Excepted status is also be lost if ownership of the off-campus PBD changes, unless the new owner also acquires the main hospital and adopts the existing Medicare provider agreement.
- The MPFS is the “applicable payment system” for the majority of nonexcepted items and services furnished in an off-campus PBD. These services are paid under the MPFS at these established rates (or 40% of the

amount paid under OPSS), which continue to be billed on the institutional claim, and require the new claim line modifier “PN” which flags the service as nonexcepted, with some exceptions:

- Items and services assigned status indicator “A” are reported on an institutional claim and paid under the MPFS, Clinical Laboratory Fee Schedule (CLFS), or the Ambulance Fee Schedule, as appropriate, do not receive reduced payments.
- Drugs and biologicals that are separately payable under the OPSS (status indicators “G” and “K”) are paid at ASP +6%. Those that are always packaged (status indicator “N”) are bundled into the MPFS payment, and are not paid separately.

In CY 2019, in order to control what CMS deems an unnecessary increase in OPSS service volume for a basic clinic visit representing a large share of the services provided at off-campus PBDs, CMS expanded the MPFS payment methodology to excepted off-campus PBDs, for HCPCS code G0463, over a two year phase-in (70% of the OPSS rate for CY 2019 and fully reduced for CYs 2020+). These excepted PBDs continue to bill HCPCS code G0463 with modifier “PO”.

For CY 2020, CMS is proposing the full phase-in the MPFS payment methodology to excepted off-campus PBDs (40% of the OPSS rate) for the clinic visit service, implemented in a non-budget neutral manner.

- **Prior Authorization Process for Certain OPDs (FR pages 39603 - 39609):** In an effort to control for unnecessary increases in the volume of covered OPD services, specifically blepharoplasty, botulinum toxin injections, panniculectomy rhinoplasty, and vein ablation, CMS is proposing a prior authorization process when furnishing these services. This would ensure that Medicare is only paying for these services when medically necessary.

In order to allow time for providers to become acclimated with the process, CMS is proposing the requirement would begin for dates of service on or after July 1, 2020.

A full list of the services that would require prior authorization can be found in Table 38 on FR pages 39608 - 39609.

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

FR pages 39554 - 39561

The OQR program is mandated by law; hospitals that do not successfully participate are subject to a 2.0 percentage point reduction to the OPSS marketbasket update for the applicable year.

In the CY 2020 OPSS proposed rule, CMS is proposing to remove one measure from the Hospital Outpatient Quality Reporting Program beginning with the CY 2022 payment determination, OP-33: External Beam Radiotherapy (NQF #1822).

A table listing the 18 measures to be collected for CY 2022 payment determinations is available on FR page 39556 of the CY 2020 proposed rule.

Additionally, CMS is seeking comment on the future adoption of four patient safety measures, potentially specified for the hospital outpatient setting, in order to monitor these types of events, ensure that the occurrence remains rare, and for purposes of transparency:

- 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.

Improving Price Transparency of Standard Charges

FR pages 39571 - 39594

Effective January 1, 2019, CMS updated its guidelines to require hospitals to make a list of their current standard charges available via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate. This could take the form of the chargemaster itself, or another form of the hospital’s choice, as long as the information is in a machine readable format.

According to CMS, the current policy is not sufficient for consumers to make informed decisions based on prices of health care services, and the information needed is not currently available. Therefore, CMS is proposing additional requirements

that support price transparency efforts and help healthcare consumers make more informed decisions, increase market competition, and drive down healthcare costs.

Specifically, CMS is proposing to require hospitals to publically report charges and negotiated rates, and information for common shoppable items and services, in a consumer-friendly manner in order to facilitate decision making and allow consumers to compare prices across hospitals. This would be laid out in Part 180—Hospital Price Transparency, added to title 45 of the Code of Federal Regulations, and includes the following:

- Proposal to define a “hospital”, in terms of the price transparency requirements, by its licensure, either licensed by the State or approved as meeting hospital licensing standards, in order to ensure that the act applies to all hospitals operating within the United States, including those not considered hospitals for purposes of Medicare participation. Requirements would not apply to federally-owned or operated hospitals since these facilities do not serve the general public and their payment rates are non-negotiable. Critical access hospitals, hospitals located in rural areas, or hospitals that treat special populations would be subject to the requirements because they treat the general public, but CMS is soliciting comment on if exceptions should be made for these hospitals (*FR* pages 39575 - 39576);
- Proposal that “items and services” would include both individual and packaged items and services that can be provided in the inpatient or outpatient setting, including those furnished by physicians and non-physician practitioners who are employed by the hospital, for which a hospital has established a standard charge. Items and services furnished by physicians and non-physician practitioners who are not employed by the hospital would not be included (*FR* pages 39576 - 39577);
- Proposal that two types of standard charges, gross charges and payer-specific negotiated charges, be made publicly available at least annually, separately by each hospital location, on the Internet in a single comprehensive machine-readable format.
 - Gross charges would be those charges individual items or services reflected on a hospital’s chargemaster, without discounts.
 - Payer-specific negotiated charges would be those charges that the hospital has negotiated for an item or service with a third party payer.

CMS is also requesting comment on other types of standard charges that should be made public, such as volume driven negotiated charges; minimum, median and maximum negotiated charges; all allowed charges; discounted cash price; and median cash price (*FR* pages 39577 - 39585);

- Proposal that hospitals must publically display a list of “shoppable” services, created from the machine-readable file. CMS is proposing to define “shoppable service” as a service or package that can be scheduled in advance by a healthcare consumer, typically routine and non-urgent. The proposal includes that hospitals make payer-specific negotiated charges public for a total of 300 shoppable services, with 70 of those selected by CMS (listed in Table 37 on *FR* pages 39587 - 39589). If a hospital does not provide one or more of the 70 CMS selected services, the hospital must make public a list of as many as possible selected services and self-select the additional services to total the 300 required (*FR* page 39585 - 39589);
- File format requirements, requirements for the content, and a process to ensure the data is easily accessible to the public to guarantee uniformity of the data (*FR* pages 39581 – 39585, 39589 - 39591);
- Monitoring and assessment methods for hospital compliance, including CMS audit of hospital’s websites and monetary penalties for hospitals that fail to make their standard charges public in accordance with the requirements. A hospital would be provided a written warning from CMS before the penalty is applied, and have the opportunity to submit a corrective action plan (CAP) to CMS or comply with the CAP requirements. If the hospital fails to do so, the penalty is proposed at a maximum of \$300, with a cost-of-living adjustment. CMS plans to publicize penalties on the CMS website. The hospital would be required to pay the penalty in full within 60 calendar days after the date of notice of the penalty (*FR* pages 39591 - 39594);
- Lastly, CMS is proposing an appeals process for failure to meet the reporting requirements. The hospital must request a hearing within 30 days of notice of the lack of compliance (*FR* pages 39593 - 39594).

CMS Request for Information (RFI): Price Transparency

FR pages 39594 – 39595

CMS is seeking public comment on a number of additional price transparency topics, including:

- Improving availability and access to quality data to aid in the development of price transparency tools and communicating charges for third parties and health care entities. Specifically:
 - What type of quality data would be most beneficial?
 - How can health care providers and suppliers help patients use this data in conjunction with data on charges in decision making?
 - How can CMS help make patient-friendly interfaces for this information?
 - Would displaying volume and procedure complications with charge data be helpful to patients?
 - Should quality data be included with information about out-of-pocket costs to patients?
- Improving communication of health care providers and suppliers with regards to sharing charge information. Specifically:
 - Should CMS create Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) questions regarding communication about cost of care with patients?
 - Do any existing measures help patients assess accuracy of charges in advance of service?
 - What value-based purchasing initiatives could be improved by including assessments of how well providers engage in communication with patients about cost of care?

Organ Procurement Organizations (OPOs) Conditions for Coverage

FR pages 39595 – 39597

OPOs are required to meet two of three outcome measures in order to receive payments from Medicare and Medicaid, one being that the observed donation rate must not be significantly lower than the expected donation rate for more than 18 out of 36 months of data.

CMS is proposing to revise the definition of “expected donation rate”, beginning with the 2022 recertification cycle, to match the Secretary’s Advisory Committee on Organ Transplantation definition. The proposed definition is *“the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and donation services areas”*, which differs from the current definition in that the expected rate is per 100 eligible deaths. CMS is also proposing to adjust this rate for age, sex, race, and cause of death, which also differs from the adjustments to current definition of Level I or Level II trauma center, Metropolitan Statistical Area (MSA) size, MSA case-mix index, total bed size, number of intensive care unit beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

In order to allow time for OPOs to comply with the proposed definition, CMS is proposing to adjust the time period of the expected donation rate for the 2022 recertification cycle to January 1, 2020 through December 31, 2020.

CMS RFI: Potential Changes to the OPO and Transplant Center Regulations

FR pages 39597 – 39598

CMS is considering updating the Conditions for Coverage (CfC) for OPOs and the Conditions of Participation (CoP) for transplant center requirements. CMS is seeking public comment on:

- The current OPO outcome measures indication of OPO performance;
- The implications of the current measures on OPO performance and availability of transplantable organs;
- Impacts of certification/decertification processes for OPOs on organ procurement and transplantation;
- Additional outcome measures or indicators of quality that could be used for OPOs; and
- Discrepancy between transplant center CoPs and OPO CfCs.

CMS is also soliciting feedback on if the following outcome measures would be valid for the OPOs:

- *“Actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation; and*
- *Actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation.”*

Potential Revisions to the Laboratory Date of Service Policy

FR pages 39598 – 39603

Date of service (DOS) is a required field on all Medicare claims for laboratory services. The requirements for DOS are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test or whether the laboratory performing the test bills Medicare directly.

If a test was ordered more than 14 days after a patient's discharge date, the DOS is the date the test was performed, and the laboratory would bill Medicare directly, for the test and the laboratory would be paid directly by Medicare. If the test is ordered less than 14 days after a patient's discharge date, the DOS is the date the specimen was collected from the patient and the hospital (not the laboratory) would bill Medicare for the test and then the hospital would pay the laboratory.

In the CY 2018 final rule, CMS adopted an exception to the current DOS regulations so that the DOS of molecular pathology tests and tests designated by CMS as Criterion (A) advanced diagnostic laboratory tests (ADLTs) is the date that the test was performed only if:

- The test was performed following the date of a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter;
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

Many hospitals and laboratories had administrative difficulties implementing the DOS exception and therefore CMS applied a 6-month enforcement discretion for the DOS exception in order to provide additional time for providers and suppliers to make necessary changes to their systems to bill for tests subject to the exception. CMS extended the enforcement discretion until January 2, 2020 because many providers needed additional time.

The industry has informed CMS that many hospitals are still struggling to make the necessary system changes to provide the performing laboratory with several data elements that are needed for the laboratory to bill Medicare directly for the test. Also, some laboratories are not enrolled in Medicare and therefore do not currently have a system to bill Medicare directly.

In response, CMS is considering making the following changes:

- Changing the test results requirement to specify that if the other four requirements are met, the ordering physician can decide if the results of the test guide treatment provided during a hospital outpatient encounter;
- Limiting the laboratory DOS exception to solely ADLTs and not molecular pathology tests; and/or
- Excluding blood banks and blood centers from the laboratory DOS.

Request for Feedback on Reporting

FR pages 39609

CMS is reviewing the relationship between hospital chargemaster and the Medicare cost report, specifically the use of the chargemaster in setting hospital payment and the costs associated with maintaining it. Medicare-certified hospitals are required to submit a cost report annually that includes charges by cost center for more than just Medicare. These charges are typically derived from the chargemaster and therefore CMS is assessing the value of the chargemaster. Specifically, CMS is soliciting feedback on the possibility of streamlining the Medicare cost reporting process and replacing or modifying the chargemaster in doing such.

Requirements for Grandfathered Children's Hospitals-within-Hospitals (HwHs)

FR pages 39609 - 39610

CMS is proposing to change the requirements for grandfathered children's HwHs to increase the number of beds within the hospital without resulting in the loss of their grandfathered status.

####