Medicare Outpatient Prospective Payment System

Payment Rule Brief — Calendar Year 2020 Final Rule Correction Notice

Overview

The final calendar year (CY) 2020 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on November 1, 2019. A correction to the rule was released on December 30, 2019. The final rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as regulations that implement new policies. The final rule includes policies that will:

- Attempt to reduce the growing disparity between high-and-low-wage index hospitals;
- Change the calculation of cost-to-charge ratios;
- Establish a process for prior authorization for certain covered outpatient department services;
- Establish requirements for all hospitals to make hospital standard charges available to the public;
- 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 final 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-FC.html. Comments related to the interim APC assignments and HCPCS code status indicators are due to CMS by December 2, 2019 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "1717-FC".

An online version of the rule is available at https://www.federalregister.gov/d/2019-24138. Page numbers noted in this summary are from the *Federal Register* (FR) of the final rule. A brief summary of the major hospital OPPS sections of the final rule is provided below.

On November 15, 2019 CMS released a supplement to the CY 2020 OPPS final rule that finalized policies related to price transparency which is available at https://www.hhs.gov/sites/default/files/cms-1717-f2.pdf.

Note: Text in italics is extracted from the November 12, 2019 copy of the *Federal Register* or the November 15, 2019 display copy of the Price Transparency final rule.

OPPS Payment Rate *FR pages 61182 - 61184*

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

	Final CY 2019	Final CY 2020	Percent Change
OPPS Conversion Factor	$79.490	$80.793	+1.64%

Final CY 2020 Update Factor Component	Value
Marketbasket (MB) Update	+3.0%
Affordable Care Act (ACA)-Mandated Productivity MB Reduction	-0.4 percentage points (PPT)
Wage Index 5% Stop Loss BN	-0.09%
Wage Index BN Adjustment	-0.09%
Pass-through Spending / Outlier BN Adjustment	-0.74%
Cancer Hospital BN Adjustment	-0.01%
Overall Final Rate Update	**+1.64%**

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes** *(FR pages 61184 – 61188)*: As in past years, for CY 2020 OPPS payments, CMS is adopting its proposal to use the federal fiscal year (FFY) 2020 inpatient PPS (IPPS) wage indexes, including all reclassifications, add-ons, rural floors, and budget neutrality adjustment.

  In order to address wage index disparities between high and low wage index hospitals, CMS adopted several changes that would affect the wage index and wage index-related policies in the FFY 2020 IPPS final rule. These include:

  - 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. CMS had proposed to decrease the wage index values for hospitals with a wage index value in the top quartile of the nation. However, due to comments received, CMS is adopting a budget neutrality adjustment to the conversion factor instead of to the wage index values of the top 25% of hospitals;
  - 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
  - Applying a budget neutrality adjustment of 0.9991 to the CY 2020 OPPS rate to account for this transition.

A detailed discussion of these adopted changes can be found on *Federal* Register pages 42325 – 42339 in the FFY 2020 IPPS final rule.

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 continuing to use a labor-related share of 60%.

- **Payment Increase for Rural SCHs and EACHs** ***(FR pages 61189 - 61190)*****:** CMS is continuing the 7.1% budget neutral payment increase for rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs). This payment add-on excludes separately payable drugs, biologicals, brachytherapy sources, 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 61190 - 61192):*** CMS is continuing 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 PCR of 0.90. After applying the 1.0 percentage point reduction mandated by the 21st Century Cures Act this results in the final target PCR being equal to 0.89 for each cancer hospital (as proposed), as opposed to the target PCR of 0.88 for CY 2019. Therefore, CMS has adopted a -0.01% adjustment to the CY 2020 conversion factor to account for this policy.
- **Outlier Payments** ***(FR pages 61192 - 61194)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is finalizing a CY 2020 outlier fixed-dollar threshold of $5,075. This is an increase compared to the current threshold of $4,825. Outlier payments will 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 61149 -61182, 61190 - 61272*

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

CMS is removing 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 2 views frontal&lateral; and
- HCPCS 93965: Extremity study

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

APC Category	Status Indicator	Final CY 2019	Final CY 2020
Pass-Through Drugs and Biologicals	G	60	78
Pass-Through Device Categories	H	1	6
OPD Services Paid through a Comprehensive APC	J1	63	66
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	330	329
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**	**766**

- **Calculation and Use of Cost-to-Charge Ratios (CCRs) *(FR pages 61150 - 61153)*:** CMS is adopting its proposal 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.

  To address concerns from commenters about the decrease in imaging payment in CY 2020 due to the transition period ending, CMS is finalizing an additional 2-year phased-in approach. For CY 2020, CMS will calculate costs for the CT and MRI APCs listed above using both the standard method (all claims with valid CT and MRI cost center CCRs, including those that use a "square feet" cost allocation method) and the transition methodology (excluding providers that use a "square feet" cost allocation method) and will assign the imaging APCs payment rate representing 50 percent of each methodology. Beginning with CY 2021, CMS will set the imaging APC payment rates at 100 percent of the payment rate using the standard method.

- **New Comprehensive APCs *(FR pages 61158 - 61167)*:** Comprehensive Ambulatory Payment Classifications (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; charges for self-administered drugs (SADs); and certain preventive services.

In order to ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 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 will continue to exclude payment for these procedures. In this final rule, CMS is finalizing a policy to exclude payment for any procedures that are assigned to a New Technology APC from being packaged into payment for comprehensive observation services assigned to status indicator "J2" when included on a claim with "J2" procedures.

In the CY 2020 OPPS federal register, CMS adopted three new C-APCs:

- C-APC 5182: Level 2 Vascular Procedures;
- C-APC 5461: Level 1 Neurostimulator and Related Procedures; and
- C-APC 5495: Level 5 Intraocular Procedures.

A list of all CY 2020 C-APCs can be found on FR pages 61164 - 61166.

- **Composite APCs** ***(FR pages 61167 - 61173):*** 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 will 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 adopting its current composite APC payment policies for multiple imaging services from the same family on the same date as well. Table 6, on FR pages 61169 - 61173, displays the HCPCS codes that are 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 61211 - 61213***)**:** For CY 2020, CMS will 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 61173 - 61180)*****:** 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 adopting its proposal 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 (and not pay separately for these drugs when furnished in the OPPS setting). Under this policy, the only FDA-approved drug that meets this criteria is Exparel®.

  CMS sought comment on whether there are other non-opioid pain management alternatives that should also have separate payment. The summary of these comments and CMS' response can be found on FR pages 61177 - 61180.

- **Payment for Medical Devices with Pass-Through Status** ***(FR pages 61272 – 61279, 61335 – 61337)*****:** 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. In order to address barriers to health care innovation and ensure access to new critical and life-saving cures and technologies, CMS is finalizing that a new medical device which is part of the FDA Breakthrough Devices Program no longer needs to demonstrate the substantial clinical improvement criterion to qualify for device pass-through status. CMS had proposed that this policy would begin with applications received on or after January 1, 2020, but CMS is instead finalizing that the policy applies for devices that will receive pass-through payments effective on or after January 1, 2020 due to public comments. Even if a device waives the substantial clinical improvement criterion with this alternative pathway, the device still needs 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. In the proposed rule, CMS stated this was HCPCS C1822 – Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system. In the final rule, CMS states this is HCPCS C1823 — Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads. Clarification from CMS on which one is eligible for pass-through payment has not yet been received.

  As of the final rule, CMS has approved five new devices pass-through payment applications for CY 2020: Surefire® Spark™ Infusion System, Optimizer® System, AquaBeam® System, AUGMENT® Bone Graft, and CUSTOM*FLEX*® ARTIFICIAL*IRIS*.

- **Device-Intensive Procedures** ***(FR pages 61279 - 61299)*****:** 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% of the procedures mean cost, 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 adopting any changes to the device-intensive policy.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(FR pages 61299 - 61300)*****:** 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 adopting any changes to the no cost/full credit and partial credit device policies.

- **Payment Policy for Low-Volume Device-Intensive Procedures** ***(FR pages 61300 - 61301)*****:** For any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC, CMS will continue to calculate the payment rate for that procedure using the median cost for CY 2020. CMS is finalizing 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 assigning to APC 5495.

- **Payment for Drugs, Biologicals and Radiopharmaceuticals** ***(FR pages 61301- 61321)*****:** CMS pays for drugs and biologicals that <u>do not</u> 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 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 adopting 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 will continue to pay for therapeutic radiopharmaceuticals with pass-through payments status, based on ASP+6%. If ASP data are not available, payment instead will be made based on WAC + 3%; or 95% of average wholesale price (AWP) if WAC data are also not available.

  Lastly, CMS is finalizing the pass-through status to expire on December 31, 2019 for 6 drugs and biologicals, listed in Table 40 on FR page 61303; and continuing/establishing pass-through status

in CY 2020 to 79 others, shown in Table 41 on FR pages 61305 - 61310. In the CY 2020 OPPS final rule correction notice, CMS replaced HCPCS codes C9407 and C9408 with HCPCS code A9590.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes** ***(FR pages 61327 - 61335)*****:** 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 adopting its proposal 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 will also assign those with pass-through payment status to the high cost category.

  The list of finalized packaged skin substitutes, and their group assignments, may be found in Table 45 on FR pages 61333 - 61335.

  In the CY 2019 proposed rule, CMS had 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 solicited and received feedback on two of them in the CY 2020 rulemaking process:
  - Establish a lump-sum "episode-based" payment for a wound care episode (FR pages 61328 -61330); 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 61330 - 61331).

- **Payment for Drugs Purchased under the 340B Drug Discount Program** ***(FR pages 61318 - 61320, 61321 - 61327)*****:** 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 adopting its proposal 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-excepted 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%. Critical Access Hospitals (CAHs) are exempt as well.

  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 also collecting survey data on drug acquisition cost for CYs 2018 and 2019 to potentially be used in setting Medicare payments for drugs acquired by 340B hospitals in the future, and for developing a remedy for prior year reductions if necessary. CMS believes that the data will show that ASP – 22.5% is a conservative amount that overcompensates 340B hospitals.

In the event the survey data is not used to rectify the reductions, CMS received 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; the comments are found on FR pages 61323 - 61327.

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 public comments.

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services** ***(FR pages 61337 - 61352)*****:** 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-specific or hospital-specific data.

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

	Final Payment Rate 2019	Final Payment Rate 2020	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$120.58	$124.30	+3.1%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	$220.86	$238.66	+8.1%

  CMS had proposed for both CMHCs and hospital-based PHPs, 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. However, in the final rule CMS used the most recent updated data to calculate the CY 2020 geometric mean per diem costs and found that use of the cost floor was only needed for CMHCs. This was due to outliers in the data that heavily influenced the calculated geometric mean per diem and significantly lowered the value compared CY 2019. This is solely for CY 2020 and would not apply in future years.

  CMS will continue to make outlier payments to CMHCs 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 will 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 61352 – 61359)*****:** The inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2020, CMS is removing the following services from the inpatient-only list:
    - CPT code 27130— Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft;
    - 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;
    - CPT code 63268— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral;
    - CPT code 00670— Anesthesia for extensive spine and spinal cord procedures (for example, spinal instrumentation or vascular procedures);
    - CPT code 00802— Anesthesia for procedures on lower anterior abdominal wall; panniculectomy;
    - CPT code 00865— Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; radical prostatectomy (suprapubic, retropubic);
    - CPT code 00944— Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy; and
    - CPT code 01214— Anesthesia for open procedures involving hip joint; total hip arthroplasty.

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

- **Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals** ***(FR pages 61359 - 61363)***: 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 adopting its proposal 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 will be furnished under the physician's overall direction and control, but the physician's presence will not be required during performance of the procedure. CMS still will have the ability to change an individual hospital therapeutic service to a more intense supervision level through the rulemaking process. Also, a hospital can still require a higher level of supervision for certain services, if the hospital determines it is appropriate. CMS believes the supervision requirements continue to provide safeguards to Medicare beneficiaries that ensure they receive quality of care and that their health and safety is protected.

- **Two-Midnight Policy for Inpatient Stays** ***(FR pages 61363 - 61365)***: 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 modifying its proposal to establish a 2-year exemption (rather than 1-year) 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 the two calendar years of removal from the list. Information gathered when reviewing procedures that are newly removed from the inpatient only list during the 2-year exemption period could be used for educational purposes, but would not result in a claim denial.

- **Payment for Off-Campus Outpatient Departments** ***(FR pages 61365 - 61369)*****:** 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 OPPS), 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 and do not receive reduced payments.
- Drugs and biologicals that are separately payable under the OPPS (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 OPPS 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 OPPS rate for CY 2019 and fully reduced for CYs 2020+). These excepted PBDs continue to bill HCPCS code G0463 with modifier “PO”.

On September 17, 2019 the district court entered an order vacating the adoption of the CY 2019 policy to control unnecessary increase in OPPS service and volume. CMS asked the court to modify its order and allow the continuation of this volume control policy, or alternatively, to suspend the order to allow for more time to determine whether an appeal should be authorized. CMS was denied on October 21, 2019 and the court entered final judgment. Many commenters felt CMS should suspend the policy until ongoing litigation is resolved. Commenters also suggested methods for remediation, found on FR pages 61368 – 61369. CMS is working to ensure 2019 claims for clinic visits are consistent with the court’s order based on the volume control policy being vacated, and does not believe a change to the second year of the two-year phase-in of this policy is necessary. Therefore, for CY 2020 CMS is finalizing the full phase-in of the MPFS payment methodology to excepted off-campus PBDs (40% of the OPPS rate) for the clinic visit service, implemented in a non-budget neutral manner.

- **Prior Authorization Process for Certain OPDs** ***(FR pages 61446 - 61451)***: 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 adopting a prior authorization process when furnishing these services to 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, 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 65 on FR pages 61457 – 61458, with two additional codes added in the CY 2020 OPPS final rule correction notice:
  - J0586 – Injection, abobotulinumtoxina; and
  - J0588 – Injection, incobotulinumtoxina.

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

FR pages 61410 - 61420

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

CMS is finalizing the removal of one measure from the Hospital Outpatient Quality Reporting Program beginning with the CY 2022 payment determination (CY 2020 encounters), 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 pages 61413 61414 of the CY 2020 final rule.

Additionally, CMS sought 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. Comments about the future adoption of these measures can be found on FR page 61416.

Improving Price Transparency of Standard Charges

DISPLAY pages are from the November 15, 2019 CY 2020 OPPS Price Transparency final rule [CMS-1717-F2]

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, in a supplement to the CY 2020 OPPS final rule, CMS adopted additional requirements that support price transparency efforts and help healthcare consumers make more informed decisions, increase market competition, and drive down healthcare costs.

Effective January 1, 2021, CMS is adopting requirements for hospitals to publicly 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 will be laid out in Part 180—Hospital Price Transparency, added to Title 45 of the Code of Federal Regulations, and will include the following:

- Definition of a "hospital", in terms of the price transparency requirements, means an institution in any State either licensed by the State or approved as meeting hospital licensing standards by the locality responsible for licensing hospitals. This ensures that the requirements apply to all hospitals operating within the United States, including those not considered hospitals for purposes of Medicare participation, and would exclude ASCs and other non-hospital sites-of-care. This will also not apply to federally-owned or operated hospitals that do not serve the general public (except for emergency services) and whose payment rates are non-negotiable since their charges are already publicized to their patients. Critical access hospitals, hospitals located in rural areas, and hospitals that treat special populations will also be subject to the requirements as they treat the general public (*Display* pages 27 - 39);
- "Items and services" provided by hospitals include all 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. Those furnished by physicians and non-physician practitioners who are not employed by the hospital would not be included (*Display* pages 40 - 54);

- The definition of standard charges was finalized as the "*regular rate established by the hospital for an item or service provided to a specific group of paying patients"* (*Display* pages 54 – 67). CMS is also finalizing the two proposed types of standard charges to be made publicly available at least annually, separately by each hospital location, on the Internet in a single comprehensive machine-readable format:
    - Gross charges - charges individual items or services reflected on a hospital's chargemaster, without discounts (*Display* pages 68 – 74); and
    - Payer-specific negotiated charges - charges that the hospital has negotiated for an item or service with a third party payer (*Display* pages 74 - 112).

  In response to public comment, CMS is adopting three additional types of standard charges to be made public with the same standards and format:
    - Discounted cash price - the price the hospital would charge individuals who pay cash (or cash equivalent) for items and services. Hospitals that do not offer self-pay discounts can display the hospitals undiscounted gross charges (*Display* pages 115 - 121); and
    - De-identified minimum and maximum negotiated charges - the lowest and highest charges that a hospital has negotiated for an item or service with third party payers, respectively (*Display* pages 121 – 128).

- Hospitals must publically display of a list of payer-specific negotiated charges, de-identified minimum and maximum negotiated charges, and discounted cash prices for a total of 300 consumer friendly "shoppable services", created from the machine-readable file; 70 of which are selected by CMS (listed in Table 3 on *Display* pages 190 – 192). CMS is finalizing the definition of "shoppable service" as a service that can be scheduled in advance by a healthcare consumer, typically routine and non-urgent. When a shoppable service is accompanied by an ancillary service, it must be presented as a group of related services. If a hospital does not provide one or more of the 70 CMS selected services or does not offer 300 shoppable services, the hospital must make public a list of as many as possible CMS selected services and self-select the additional services to total the 300 required (or as many as possible). Hospitals must ensure commonly provided services within the hospital are chosen, and are instructed to take into consideration utilization or billing rate of the service when selecting services (*Display* page 161 - 192);

- File format requirements, requirements for the content, and a process to ensure the data is easily accessible to the public are included to guarantee uniformity of the data. The data must be publicly available, prominent, and without any barriers to access. Additionally, CMS adopted a policy for hospitals to meet the public display requirements for "shoppable services" (listed on *Display* pages 145 – 146) by developing an Internet-based price estimator tool that displays the same information (*Display* pages 128 – 161, 192 - 228);

- CMS outlined monitoring and assessment methods for hospital compliance, including CMS audit of hospitals websites and monetary penalties for those hospitals that fail to make their standard charges public in accordance with the requirements. A hospital will 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 finalized penalty is a maximum of $300 per day, with a cost-of-living adjustment. CMS plans to publicize the notice of monetary 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 (*Display* pages 228 - 265);

- Lastly, CMS is adopting 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 (*Display* pages 265 - 269).

Organ Procurement Organizations (OPOs) Conditions for Coverage

FR pages 61434 – 61435

OPOs are required to meet requirements for 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 revising the definition of "expected donation rate", beginning with the 2022 recertification cycle, to match the Scientific Registry for Transplant Recipient's definition. The finalized 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 adopting its proposal to adjust this rate for age, sex, race, and cause of death, which also differs from the adjustments to the 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 definition, CMS proposed to adjust the time period of the expected donation rate for the 2022 recertification cycle to 12 months from January 1, 2020 through December 31, 2021. CMS is not finalizing the proposal as it may have unintended consequences.

In response to comments and to ensure fairness for OPOs, CMS is modifying its proposal to require OPOs to meet the standards of one of the two other outcome measures (the donation rate of eligible donors measure or the aggregate donor yield measure) for the 2022 recertification cycle only.

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

FR pages 61435

CMS received comment on updating the Conditions for Coverage (CfC) for OPOs and the Conditions of Participation (CoP) for transplant center requirements as well as two outcome measures for OPOs which can be found on FR page 61435.

Potential Revisions to the Laboratory Date of Service Policy

FR pages 61436 - 61446

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 patients 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.

CMS is keeping the expiration of the enforcement discretion as January 2, 2020. However in response to industry concern, beginning CY 2020 CMS finalized excluding molecular pathology tests performed by a laboratory that is a blood bank or center from the laboratory DOS exception. CMS did not finalize the following changes discussed in the proposed rule:

- 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; and
- Limiting the laboratory DOS exception to solely ADLTs and not molecular pathology tests.

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

FR pages 61465 - 61466

CMS is adopting its proposal to allow grandfathered children's HwHs to increase the number of beds within the hospital without resulting in the loss of their grandfathered status.

Notice of Teaching Hospital Closures and Opportunity to Apply for Available Slots

FR pages 61446 - 61467

The ACA authorizes the redistribution of residency slots after a hospital that trained residents in an approved medical residency program closes. This final rule is being used to notify hospitals of two such closures, and the opportunity to obtain additional residency slots. Hospitals that wish to apply for these slots must submit their applications by January 30, 2020. The closed teaching hospitals are:

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422 Adjustments)	Direct GME FTE Resident Cap (including +/- MMA Sec. 422 Adjustments)
390290	Hahnemann University Hospital	Philadelphia, PA	37964	9/6/2019	556.81	574.82
510039	Ohio Valley Medical Center	Wheeling, WV	48540	9/20/2019	22.93	22.93