# Medicare Outpatient Prospective Payment System

Final Payment Rule Brief Provided by the Wisconsin Hospital Association
Program Year: CY 2021

## Overview

The display copy of the final calendar year (CY) 2021 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on December 7, 2020. 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:

- Add new service categories to the outpatient department prior authorization;
- Change the minimum level of supervision required for additional therapeutic services from direct to general supervision and include virtual presence of the physician in direct supervision for several other services;
- Exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analysis (MAAAs) from the OPPS packaging policy and revise the laboratory Date of Service (DOS) policy to include these tests;
- Eliminate of the Inpatient Only (IPO) list over the course of three calendar years;
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program;
- Change the Overall Star Rating methodology; 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/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-fc. Comments related to the interim Ambulatory Payment Classifications (APC) assignments and Healthcare Common Procedural Coding System (HCPCS) code status indicators are due to CMS by January 4, 2021 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "1736-FC". Comments related to the reporting requirements for hospitals and critical access hospitals (CAHs) to report acute respiratory illness during the public health emergency (PHE) for coronavirus (COVID-19) and the Radiation Oncology (RO) Model are due February 2, 2021 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "1736-IFC".

**Due to the resources dedicated to responding to the novel COVID-19 pandemic, CMS replaced the 60-day delay in the effective date of the OPPS final rule with a 30-day delay of the effective date of the final rule.**

An online version of the rule will be available on January 29, 2021 at https://www.federalregister.gov/d/2020-26819. Page numbers noted in this summary are from the display copy of the *Federal Register* (FR) of the final rule. A brief summary of the major hospital OPPS sections of the final rule is provided below. CMS estimates a $7.541B increase in payments for CY 2021 over CY 2020.

***Note:*** Text in italics is extracted from the August 12, 2020 of the *Federal Register* or the December 7, 2020 display copy of the *Federal Register.*

## OPPS Payment Rate

***DISPLAY pages 110 - 119***

The tables show the final CY 2021 conversion factor compared to CY 2020 and the components of the update factor:

| | Final CY 2020 | Final CY 2021 | Percent Change |
|---|---|---|---|
| OPPS Conversion Factor | $80.793 | $82.797 (proposed at $83.697) | +2.48% (proposed at +3.59%) |

| Final CY 2021 Update Factor Component | Value |
|---|---|
| Marketbasket (MB) Update | +2.4% (proposed at +3.0%) |
| Affordable Care Act (ACA)-Mandated Productivity MB Reduction | +0.0 percentage points (PPT) (proposed at -0.4 PPT) |

| | |
|---|---|
| Wage Index 5% Stop Loss BN | -0.08% (proposed at -0.10%) |
| Wage Index BN Adjustment | +0.20% (proposed at +0.27%) |
| 340B BN Adjustment | +0.00% (proposed at +0.85%) |
| Pass-through Spending / Outlier BN Adjustment | -0.04% (proposed at -0.05%) |
| Cancer Hospital BN Adjustment | +0.00% (as proposed) |
| ***Overall Final Rate Update*** | **+2.48%** (proposed at +3.59%) |

## Adjustments to the Outpatient Rate and Payments

- **Wage Indexes** ***(DISPLAY pages 119 – 135)*****:** As in past years, for CY 2021 OPPS payments, CMS will continue to use the federal fiscal year (FFY) 2021 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 had made a variety of changes that would affect the wage index and wage index-related policies in the FFY 2020 IPPS final rule. As it was adopted to be in effect for a minimum of four years in order to be properly reflected in the Medicare cost report for future years, for CY 2021 CMS will continue to increase the wage index for low wage index hospitals. Hospitals with a wage index value in the bottom quartile of the nation would have that wage index increased by a value equivalent to half of the difference between the hospital's pre-adjustment wage index and the 25th percentile wage index value across all hospitals. CMS will continue to offset these increases by applying a budget neutrality adjustment to the national standardized amount. In the FFY 2021 IPPS final rule correction notice, the value of the 25th percentile wage index is 0.8469 (proposed at 0.8420).

  In the FFY 2021 IPPS final rule, CMS adopted its proposal to update the Core-Based Statistical Areas (CBSA) for all providers based on the delineations published in the Office of Budget and Management (OMB) Bulletin No. 18-04 released on September 14, 2018. Since OPPS uses the IPPS wage indexes, these changes apply to OPPS as well. Included in the bulletin are new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs which are split apart or otherwise changed. CMS believes that these delineations better represent current rural and urban areas. As a result, provider wage indexes change depending on which CBSA they are assigned to. In order to alleviate significant losses in revenue, CMS is finalizing a transition period. Adopted delineations will be effective beginning January 1, 2020 and include a 5% cap on the reduction of a provider's wage index for CY 2021 compared to its wage index for CY 2020, with the full reduction of a provider's wage index beginning in CY 2022.

  The September 14, 2018 OMB Bulletin 18-04 can be found at https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.

  The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2021, CMS will continue to use a labor-related share of 60%.

- **Payment Increase for Rural SCHs and EACHs** ***(DISPLAY pages 137 - 139)*****:** CMS will continue 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** ***(DISPLAY pages 139 - 145):*** CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. CMS does 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, which is the same as the target PCR for CY 2020. Therefore, CMS has finalized a 0.00% adjustment to the CY 2021 conversion factor to account for this policy.

- **Outlier Payments** ***(DISPLAY pages 145 - 150)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is adopting a CY 2021 outlier fixed-dollar threshold of $5,300 (as proposed). This is an increase compared to the current

threshold of $5,075. 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

***DISPLAY pages 30 - 110, 161 – 552***

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 2021 are available in Addenda A and B of the final rule at https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-fc

The table below shows the shift in the number of APCs per category from CY 2020 to CY 2021 (Addendum A):

| APC Category | Status Indicator | Final CY 2020 | Final CY 2021 |
|---|---|---|---|
| Pass-Through Drugs and Biologicals | G | 78 | 94 |
| Pass-Through Device Categories | H | 6 | 10 |
| OPD Services Paid through a Comprehensive APC | J1 | 66 | 68 |
| Observation Services | J2 | 1 | 1 |
| Non-Pass-Through Drugs/Biologicals | K | 329 | 344 |
| Partial Hospitalization | P | 2 | 2 |
| Blood and Blood Products | R | 36 | 37 |
| Procedure or Service, No Multiple Reduction | S | 79 | 79 |
| Procedure or Service, Multiple Reduction Applies | T | 29 | 29 |
| Brachytherapy Sources | U | 17 | 17 |
| Clinic or Emergency Department Visit | V | 11 | 11 |
| New Technology | S/T | 112 | 112 |
| **Total** | | **766** | **804** |

- **Calculation and Use of Cost-to-Charge Ratios (CCRs)** ***(DISPLAY pages 31 - 36)*****:** In the CY 2020 final rule, CMS 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.

  In the CY 2020 final rule, to address concerns from commenters about the decrease in imaging payment in CY 2020 due to the transition period ending, CMS finalized an additional 2-year phased-in approach, with CY 2021 being the final year of the transition. Beginning with CY 2021, CMS set the imaging APC payment rates at 100 percent of the payment rate using the standard method. This includes those that use a "square feet" cost allocation method.

- **Blood and Blood Products** ***(DISPLAY pages 38 - 46)*****:** To encourage the use of new blood products that have been continually developed at a rapid rate recently, CMS had proposed to package the cost of unclassified blood products

reported by HCPCS code P9099 into their affiliated primary medical procedure and change the status indicator from "E2" to "N". However, CMS is not finalizing this proposal.

Instead CMS is finalizing its alternative proposal to make HCPCS P9099 separately payable with a payment rate equal to the payment rate for HCPCS P9043 (Infusion, plasma protein fraction (human), 5 percent, 50ml), the lowest cost blood product. The payment rate for this HCPCS code is $7.79 (proposed at $8.02). With this, CMS is changing the status indicator of HCPCS code P9099 from "E2" to "R". CMS chose the alternative proposal because it aligns with the general OPPS policy to pay "not otherwise classified" codes at the lowest available APC rate for a service category that also provides a payment for unclassified blood products when a service is reported on the claim.

- **New Comprehensive APCs *(DISPLAY pages 50 - 70)*:** 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 <u>are included</u> in the C-APCs when they appear on the same claim as those services assigned to a C-APC. The C-APCs do <u>not</u> 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); certain preventive services; and procedures assigned to a New Technology APC either included on a claim with a "J1" or when packaged into payment for comprehensive observation services assigned to status indicator "J2" when included on a claim with a "J2" indicator.

  CMS is adopting two new C-APCs for CY 2021 for a total of 69 C-APCs:

  - Level 8 Urology and Related Services (C-APC 5378); and
  - Level 5 Neurostimulator and Related Procedures (C-APC 5465).

  A list of all CY 2021 C-APCs can be found on Display pages 68 - 70.

  In the Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency interim final rule with comment period (IFC), CMS implemented an exception to the OPPS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria. Specifically, CMS will always separately pay and not package into a C-APC any new COVID-19 treatment that meets the following criteria:

  - The treatment is an FDA approved (or indicated in the "Criteria for Issuance of Authorization") drug or biological product (which could include a blood product) authorized to treat COVID-19; and
  - The emergency use authorization for the drug or biological product must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

  This is in effect from the effective date of the IFC until the end of the pandemic.

- **Composite APCs *(DISPLAY pages 70 - 79):*** 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 ACs for:
  - Mental Health Services (APC 8010); and
  - Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008).

  For CY 2021, CMS is continuing 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 2021, CMS is continuing its current composite APC payment policies for multiple imaging services from the same family on the same date as well. Table 4, on Display pages 75 - 79, includes 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 (DISPLAY *pages 186 - 189*):** For CY 2021, 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 *(DISPLAY pages 79 – 106)*:** CMS will continue 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 2021, 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). Based on public comment, CMS believes that an additional drug, Omidria, qualifies as a non-opioid pain management drug that functions as a surgical supply and is excluding Omidria from packaging beginning October 1, 2020.

  Under current policy, certain clinical diagnostic laboratory tests (CDLTs) that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged to the primary service(s) provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. However, CMS does not pay for the test under OPPS and instead pays for it under CLFS when a CDLT is listed on the CLFS and meets at least one of four criteria.

  After reviewing stakeholder input, CMS believes that cancer-related protein-based Multianalyte Assays with Algorithmic Analysis (MAAAs) may be unconnected to the primary outpatient service during which the specimen was collected. MAAAs are similar to molecular pathology tests, which are excluded from the OPPS packaging policy, as they have a different pattern of clinical use and therefore are less tied to the primary service than more common and routine tests that are packaged. Therefore, CMS is adopting its proposal to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them under the CLFS. CMS will assign the following CPT codes status indicator "A": CPT 81490 (new to the list as of the final rule); CPT 81500; CPT 81503; CPT 81535; CPT 81536; CPT 81539. CMS states that new cancer-related protein-based MAAAs developed in the future will be excluded from packaging as well.

- **Payment for Medical Devices with Pass-Through Status *(DISPLAY pages 326 - 409)***: In the CY 2020 final rule, CMS finalized that a new medical device which is part of the FDA Breakthrough Devices Program and has received FDA marketing authorization within 2 to 3 years of the application no longer needs to demonstrate the substantial clinical improvement criterion to qualify for device pass-through status. 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 are currently seven device categories eligible for pass-through payment:
  - C1823 – Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads (expires 12/31/2021);
  - C1824 – Generator, Cardiac contractility modulation (implantable);
  - C1982 – Catheter, pressure-generating, one-way valve, intermittently occlusive;
  - C1839 – Iris prosthesis;
  - C1734 – Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable);
  - C2596 – Probe, image-guided, robotic, waterjet ablation; and
  - C1748 – Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable).

  As of the final rule, CMS has approved five new device pass-through payment applications for CY 2021: CUSTOFLEX® ARTIFICIALIRIS, EXALT™ Model D Single-Use Duodenoscope, Barostim NEO® System, Hemospray® Endoscropic Hemostat, and The SpineJack® Expansion Kit.

  In the proposed rule, CMS solicited comments on whether future payments for devices currently eligible to receive transitional pass-through payments should be adjusted if they were impacted by the COVID-19 public health emergency. If so, how should that adjustment be made and for how long. CMS is considering providing separate payment after pass-through status ends for these devices to account for the period of time that utilization of the devices was reduced. Comments can be found on Display pages 407 – 409.

- **Device-Intensive Procedures** ***(DISPLAY pages 409 - 421)*****:** 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 CY 2021, CMS is not making any changes to the device-intensive policy.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(DISPLAY pages 423 - 426)*****:** 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 2021, CMS is not making any major changes to the no cost/full credit and partial credit device policies.

- **Payment Policy for Low-Volume Device-Intensive Procedures (*DISPLAY pages 426 - 429*):** 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 2021. For CY 2021 this would not apply to any procedure.

- **Payment for Drugs, Biologicals and Radiopharmaceuticals** ***(DISPLAY pages 429 - 474)*****:** 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 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 2021, CMS is adopting a packaging threshold of $130 (as proposed). 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 2021 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 2021, CMS will continue to pay for therapeutic radiopharmaceuticals with pass-through payments status as well as blood clotting factors, 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 that the pass-through status expire by December 31, 2020 for 29 drugs and biologicals, listed in Table 36 on DISPLAY pages 434 - 435 and by December 31, 2021 for 25 drugs and biologicals, listed in Table 37 on DISPLAY pages 437 - 439; and will continue/establish pass-through status in CY 2021 to 46 others, shown in Table 38 on DISPLAY pages 441 - 445.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes** ***(DISPLAY pages 516 - 545)*****:** 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 will continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high cost group in CY 2020 to the high cost group in CY 2021 as well. CMS will assign those with pass-through payment status to the high cost category.

  The list of adopted packaged skin substitutes, and their group assignments, may be found in Table 42 on DISPLAY pages 532 - 536.

In the CY 2020 rulemaking process, CMS solicited comment on two potential refinements to the existing payment methodology for packaged skin substitutes in order to stabilize payments for these products. CMS discusses the two in detail in this final rule while continuing to review the feasibility of each:

- Establish a lump-sum "episode-based" payment for a wound care episode (DISPLAY pages 520 - 523); 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 (DISPLAY pages 523 - 527).

CMS is also finalizing its proposal with modification to include both synthetic and biological skin graft sheet products in the description of skin substitutes, and therefore these products can be reported with graft skin substitute procedure codes.

- **Payment for Drugs Purchased under the 340B Drug Discount Program *(DISPLAY pages 474 - 516)*:** 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.

  Currently, a CMS pays a reduced rate of ASP – 22.5% of the products ASP, rather than ASP + 6% for nonpass-through for 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.

  Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. The 340B-acquired drug payment policies were 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 unless the Secretary obtained drug acquisition cost survey data from hospitals proving otherwise. CMS disagreed and appealed the decision, while also gathering survey data which confirmed that ASP – 22.5 percent is actually generous to 340B hospitals and supports an even lower payment rate.

  Using the survey data, CMS analyzed what the appropriate reduction to 340B drugs would be. Therefore, CMS had proposed to pay ASP – 28.7% (ASP – 34.7% plus an add-on of 6% of the product's ASP) beginning CY 2021. Based on comments to the proposed rule, CMS is instead finalizing its alternative proposal to continue the current policy to pay ASP – 22.5% as CMS believes that this would maintain consistent and reliable payment for these drugs both for the remainder of the COVID-19 PHE and after its conclusion. This also allows more time for CMS to further analyze hospital survey data for potential future use.

  The 340B adjustment also applies to those drugs for which pricing is determined based on WAC and average wholesale price (AWP). CMS is continuing that drugs acquired under WAC pricing would be paid at WAC – 22.5% (proposed at WAC – 34.7% plus 6% or WAC – 34.7% plus 3%), while those acquired under AWP pricing would be paid at 69.46% (proposed at 63.9%) of AWP.

  As in previous years, rural sole-community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals will be exempt from the 340B adjustment, and receive drug payments based on ASP + 6%. Critical Access Hospitals (CAHs) are exempt as well.

  CMS' established modifiers "JG" and "TB" will still apply. 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.

## Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services *(DISPLAY pages 561 - 597)*:** 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 2020 and final CY 2021 PHP payment rates:

| | Final Payment Rate 2020 | Final Payment Rate 2021 | % Change |
|---|---|---|---|
| APC 5853: Partial Hospitalization (3+ services) for CMHCs | $124.30 | $139.75 | +12.4% |
| APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs | $238.66 | $260.49 | +9.1% |

In the April 30, 2020 Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency interim final rule, hospital and CMHC staff were given the ability to furnish certain PHP services, incident to a physician's services, to beneficiaries in temporary expansion locations (including the beneficiary's home) as long as the location meets conditions of participation that are not waived. These provisions are as of March 1, 2020 and exist for the duration of the COVID-19 public health emergency. These services can be furnished using telecommunications technology if the beneficiary is registered as outpatient.

The data for both CMHCs and PHPs no longer supports the need for a cost floor and therefore CMS is not extending the established geometric mean per diem cost floor to CY 2021 and subsequent 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.

- **Removal of the Inpatient-Only List** ***(DISPLAY pages 597 - 641)*****:** Currently, the inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. Since the inpatient-only list was established, developments in medicine have made it safe and effective to provide more services in the outpatient setting. Therefore, CMS no longer believes there is a need for the inpatient-only list in order to identify services that require inpatient care and that is best left to clinical judgement as to whether or not the procedure can be performed appropriately in the hospital outpatient setting. CMS is adopting its proposal to remove the inpatient-only list.

  To allow for time to prepare for this change, CMS will transition services off of the list over a 3-year period, beginning CY 2021, with the list completely eliminated by CY 2024. CMS believes that removing the inpatient-only list will provide maximum availability of services in the outpatient setting to beneficiaries.

  For CY 2021, CMS is removing 266 musculoskeletal services from the inpatient-only list as many of these services have been removed in the last few years already, including TKA and THA, and because there is already a set of C-APCs for musculoskeletal services for payment in the outpatient setting. CMS is also removing an additional 32 HCPCS codes based on public comments. The list of the finalized services to be removed can be found on Display pages 625 – 641.

  CMS had solicited comment on the order of removal of additional services from the list during the 3-year transition period. These comments can be found on Display pages 620 – 625.

- **Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs (*DISPLAY pages 641 - 652)*:** In the CY 2020 rulemaking process CMS changed 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.

  However, this did not include all services. On March 31, 2020, CMS adopted an interim final rule to give providers flexibility to respond to the COVID-19 public health emergency. In this rule, CMS adopted a policy to reduce the minimum default level of supervision for non-surgical extended duration therapeutic services from direct to general supervision for the entire service for the duration of the COVID-19 public health emergency.

  CMS also clarified in the same interim final rule that the requirement for direct physician supervision for pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video real-time communications technology.

  Although these policies were adopted on an interim basis, CMS stated in the final rule that the policies should become permanent as both allow for additional flexibility in providing services. Therefore, CMS is adopting the policy to reduce the minimum level of supervision from direct to general for non-surgical extended duration therapeutic services beginning CY 2021. This does not preclude the hospital from providing direct supervision as appropriate.

However, CMS believes it is necessary to continue to evaluate whether direct supervision through virtual presence is appropriate before extending this policy permanently. CMS instead is extending the policy until the later of the end of the calendar year in which the COVID-19 PHE ends or December 31, 2021.

- **Two-Midnight Policy for Inpatient Stays** ***(DISPLAY pages 652 - 674)***: 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 reviews.

  In this final rule, CMS is adopting the removal of the inpatient-only list, which means the procedures currently on the IPO would be subject to the two-midnight rule reviews.

  In the CY 2020 final rule, CMS established a 2-year exemption from medical review activities including referrals to Recovery Audit Contractors (RACs), site-of-service claim denials, and RAC reviews for "patient status" for procedures removed from the inpatient only list for CY 2020 and forward. This will continue for procedures removed from the inpatient only list before January 1, 2021.

  Based on commenters concerns, CMS is finalizing an indefinite exemption period from medical review activities for those procedures removed from the inpatient only list on or after January 1, 2021. Once CMS has claims data to indicate a procedure is performed more than 50% of the time in the outpatient setting than the inpatient setting in a single calendar year, CMS will consider removing the exemption for that procedure.

- **Payment for Off-Campus Outpatient Departments** ***(DISPLAY pages 552 - 561)*****:** 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 worked to ensure 2019 claims for clinic visits were consistent with the court's order and did not believe a change to the second year of the two-year phase-in of this policy was necessary. On July 17, 2020, the district court ruled in favor of CMS with regard to the CY 2020 reductions and therefore CMS does not need to change CY 2020 payments. For CY 2021, excepted off-campus PBDs will be paid at 40% of the OPPS rate for the clinic visit service, implemented in a non-budget neutral manner.

- **Prior Authorization Process for Certain OPDs** ***(DISPLAY 975 - 998)*****:** 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 adopted a prior authorization process when furnishing these services to ensure that Medicare is only paying for these services when medically necessary in the CY 2020 final rule.

  CMS is adopting its proposal to add two new service categories to this policy: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. The requirement for these two service categories will begin for dates of service on or after July 1, 2021.

  A list of the services that require prior authorization, included the two adopted categories, can be found in Table 74 on Display pages 996 – 998.

## Updates to the Hospital Outpatient Quality Reporting (OQR) Program

***DISPLAY pages 806 - 827***

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 codifying the policy that for public reporting purposes, the data collection and submission will be combined for hospitals sharing the same provider number across all of their campuses for all clinical measures. The Education Review Process for Chart-Abstracted Measures will also be codified in this final rule.

CMS will use the term "security official" defined as *"individual(s) who have responsibilities for security and account management requirements for a hospital's QualityNet account"* rather than "security administrator*"*. This would not add additional burden nor change the individual's responsibilities.

CMS is also adopting, beginning CY 2021, all submission deadlines that fall on a nonwork day are to be moved to the first day thereafter that is declared a work day. CMS is finalizing the same change to their reconsideration deadlines in order to align with the above change to the submission deadlines.

Beginning with CY 2023 payment determination, CMS is expanding the current review and corrections policy to measure data submitted through the CMS web-based tool. CMS will codify the review and correction policy for the data submitted through the web-based tool as well as for chart-abstracted measure data.

A table listing the 18 measures to be collected for CY 2023 payment determinations is available on Display pages 810 - 811.

## Overall Hospital Quality Star Rating

***DISPLAY pages 848 - 974***

The Overall Star Rating was first introduced in July 2016 and was made publically available on the Hospital Compare website. It provides a summary of existing hospital quality measure results reported to CMS through the existing quality programs. Hospitals are assigned one to five stars, five being the highest. The Overall Star Rating is published annually.

Beginning CY 2021, CMS is adopting its proposal to update the methodology for calculating the star ratings, with slight modification. CMS believes these updates will increase simplicity of the methodology, predictability of measure emphasis over time, and comparability among hospitals.

Specifically, CMS will retain several aspects of the current methodology while updating the following:

- Slight changes to the measure exclusion criteria due to the new calculation methodology;
- Elimination of measure score winsorization due to elimination of Latent Variable Model;
- Regrouping measures into five measure groups (Mortality, Safety of Care, Readmission, Patient Experience and Timely and Effective care), rather than seven, due to measure removals;
- Combined three existing process measure groups (Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging) into one new Timely and Effective Care group to ensure a sufficient number of measures within the process group;
- Using a simple average of measure scores to calculate group scores rather than the current statistical Latent Variable Model;
- Standardization of measure group scores by calculating z-scores for each measure group;
- Weight Timely and Effective Care at 12% of the hospital summary score and the other measure groups 22% (reweighting when necessary);
- Requiring at least 3 measures in 3 measure groups, one of which must be Mortality or Safety of Care;
- Placing hospitals into one of three peer groups by number of measure groups that meet inclusion criteria for k-means clustering; and
- Using data from a quarter within the prior year rather than using data from the same quarter as or the quarter prior to the publication of the Overall Star Ratings.

Due to comments received and analyses indicating the impact would not be as intended, CMS is not finalizing the following proposal:

- Stratifying the Readmission measure group according to proportion of dual-eligible patients using the same peer group quintiles from the Readmissions Reduction Program (hospitals that do not participate but have their proportion of dual-eligible patients available would be assigned peer groups and those without proportion of dual-eligible patients available would not have their group score adjusted).

CMS is adopting its proposal to include Veterans Health Administration hospitals beginning with CY 2023. CAHs, which are already included in the star ratings, will continue to be included based on voluntary submission of quality data to CMS. However, CMS will maintain separate suppression policies for hospitals and CAHs when there are CMS data due to CAHs voluntarily submitting measure data and not being subject to CMS quality programs. This policy would allow CAHs to withhold their Overall Star Rating from public release on Hospital Compare.

CMS recognizes that the Overall Star Rating includes more than just hospital outpatient measures and plans to reference the finalized policies in the FFY 2022 IPPS rule as well.

## Revisions to the Laboratory Date of Service Policy

***DISPLAY pages 998 - 1109***

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.

CMS extended the enforcement discretion until January 2, 2020 because many providers needed additional time. The industry has informed CMS that many hospitals were 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 were not enrolled in Medicare and therefore did not have a system to bill Medicare directly.

Protein-based MAAAs that are not considered molecular pathology tests and are not designated as ADLTs are packaged under the OPPS at this time. As mentioned previously, CMS is excluding cancer-related protein-based MAAAs from the OPPS packaging policy. Therefore, CMS is adopting the exception to the laboratory DOS rule finalized in the CY 2018 final rule (described earlier in this section) to apply to these tests as well. This will mean that instead of paying for cancer-related protein-based MAAAs under OPPS, Medicare will pay for them under the CLFS and the laboratory that performed the tests will bill Medicare directly instead of seeking payment from the hospital if the test meets all the laboratory DOS requirements.

## Physician-owned Hospitals

***DISPLAY pages 1109 -1034***

A physician-owned hospital must satisfy all of the requirements of either the whole hospital exception or the rural provider exception to the physician self-referral law in order to receive payment for services referred by a physician owner or investor. This means that a physician-owned hospital may not increase the number of operating rooms, procedure rooms, and beds above what the hospital was licensed on March 23, 2010 unless CMS has granted an exception.

For high Medicaid facilities, CMS is revising its current regulations to allow a facility to request an exception to the prohibition on expansion of capacity at any time, rather than once every two years. With this, CMS will only allow a Medicaid facility to request one exception at a time in order to preserve CMS resources and maintain efficiency.

CMS is also adopting its proposal to remove the expansion cap on the number of operating rooms, procedure rooms, and beds that can be approved. In addition, CMS is removing the restriction that expanded facility capacity only occur in the hospital's main campus.

Separately, CMS is finalizing a revised definition of "baseline number of operating rooms, procedure rooms, and beds" as *"a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State."*

## Radiation Oncology (RO) Model

***DISPLAY pages 1037 - 1047***

On September 29, 2020 CMS published the Specialty Care Models to Improve Quality of Care and Reduce Expenditures that finalized the RO model. Since then, CMS has received requests to delay the model due to concerns implementing the model during the COVID-19 PHE. Therefore, CMS is using this rule to revise the model's performance period to begin on July 1, 2021, rather than January 1, 2021, and end on December 31, 2025 to ensure participation during the COVID-19 PHE does not further strain participant's capacity. CMS is soliciting comments on the updated performance period.

## Reporting Requirements during COVID-19 PHE

***DISPLAY pages 1047 - 1053***

CMS is establishing new Conditions of Participation (CoPs) requirements for hospitals and CAHs for tracking COVID-19 therapeutic inventory and usage as well as for tracking the incidence and impact of Acute Respiratory Illness during the COVID-19 PHE. CMS is requiring that the information and data be given to the Secretary of Health and Human Services as often and in the manner that the Secretary sets during the PHE. Specifically, CMS is revising the current COVID-19 PHE reporting requirements to now require reporting of:

- *"The hospital's (or the CAH's) current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the hospital (or CAH); and*
- *The hospital's (or the CAH's) current usage rate for any COVID-19 related therapeutics that have been distributed and delivered to the hospital (or CAH)."*

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

***DISPLAY pages 1034 - 1037***

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. Applications for hospitals that wish to apply for these slots must be received 90 days from the date of display in the *Federal Register.* 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) |
|---|---|---|---|---|---|---|
| 140240 | Westlake Community Hospital | Melrose Park, IL | 16984 | 8/14/2019 | 36.33 | 39.28 |
| 500012 | Astria Regional Medical Center | Yakima, WA | 49420 | 1/15/2020 | 12.03 | 13.02 |

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