Kansas Hospital ASSOCIATION

Medicare Outpatient Prospective Payment System

Payment Rule Brief — Calendar Year 2021 Proposed Rule
August 31, 2020

Overview

The display copy of the proposed calendar year (CY) 2021 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on August 4, 2020. The proposed rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as regulations that implement new policies. The proposed rule includes policies that would:

- 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 DOS policy to include these tests;
- Change the rate for nonpass-through drugs purchased by hospitals through the 340B program;
- Elimination of the Inpatient Only (IPO) list over the course of three calendar years;
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program;
- Updates to the Overall Star Rating methodology; and
- Update payment rates and policies for Ambulatory Surgical Centers (ASCs).

A copy of the proposed rule and other resources related to the OPPS are available on the Centers for Medicare and Medicaid Services (CMS) website at https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-p. Comments are due to CMS by October 5, 2020 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "1736-P".

Due to the resources dedicated to responding to the novel coronavirus (COVID-19) pandemic, CMS is waiving the 60-day delay in the effective date of the OPPS final rule. There will instead be a 30-day delay of the effective date of the final rule.

An online version of the rule is available at https://www.federalregister.gov/d/2020-17086. Page numbers noted in this summary are from the *Federal Register* (FR) of the proposed rule. A brief summary of the major hospital OPPS sections of the proposed rule is provided below.

Note: Text in italics is extracted from the August 12, 2020 *Federal Register.*

OPPS Payment Rate

FR pages 48800 - 48802

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

	Final CY 2020	Proposed CY 2021	Percent Change
OPPS Conversion Factor	$80.793	$83.697	+3.59%

Proposed 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	-0.10%
Wage Index BN Adjustment	+0.27%
340B BN Adjustment	+0.85%
Pass-through Spending / Outlier BN Adjustment	-0.05%
Cancer Hospital BN Adjustment	+0.00%
Overall Proposed Rate Update	**+3.59%**

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes *(FR pages 48802 – 48804)*:** As in past years, for CY 2021 OPPS payments, CMS is proposing 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 in a budget neutral manner by applying a budget neutrality adjustment to the national standardized amount. In the FFY 2021 IPPS proposed rule, the value of the 25th percentile wage index is 0.8420.

  In the FFY 2021 IPPS proposed rule, CMS proposed 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 proposing a transition period. Adopted delineations would 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 2020, CMS is proposing to continue to use a labor-related share of 60%.

- **Payment Increase for Rural SCHs and EACHs *(FR pages 48804-48805)*:** CMS is proposing to 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 *(FR pages 48775, 48805 -48807):*** CMS is proposing to continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. Previously, CMS did this by providing a payment adjustment such that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals (and thus the adjustment was budget neutral).

  In order to determine a budget neutrality factor for the cancer hospital payment adjustment, CMS calculated a PCR of 0.90. After applying the 1.0 percentage point reduction mandated by the 21st Century Cures Act this results in the

proposed 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 proposed a 0.00% adjustment to the CY 2021 conversion factor to account for this policy.

- **Outlier Payments** ***(FR pages 48807 - 48808)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is proposing a CY 2021 outlier fixed-dollar threshold of $5,300. This is an increase compared to the current threshold of $5,075. Outlier payments are proposed to continue to be paid at 50% of the amount by which the hospital's cost exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

Updates to the APC Groups and Weights

FR pages 48778 - 48800, 48811 – 48900, 48940

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

The proposed payment weights and rates for CY 2021 are available in Addenda A and B of the proposed rule at https://www.cms.gov/apps/ama/license.asp?file=/files/zip/2021-nprm-opps-addenda.zip

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	Proposed CY 2021
Pass-Through Drugs and Biologicals	G	78	53
Pass-Through Device Categories	H	6	7
OPD Services Paid through a Comprehensive APC	J1	66	68
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	329	359
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	29	29
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		**766**	**774**

- **Calculation and Use of Cost-to-Charge Ratios (CCRs)** ***(FR pages 48779 - 48781)*****:** 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.

  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 will set the imaging APC payment rates at 100 percent of the payment rate using the standard method. This includes those that use a "square footage" cost allocation method.

- **Blood and Blood Products** ***(FR pages 48781 - 48783)*****:** To encourage the use of new blood products that have been continually developed at a rapid rate recently, CMS is proposing to package the cost of unclassified blood products reported by HCPCS code P9099 into their affiliated primary medical procedure. Blood products are not typically packaged under the OPPS, but CMS does not believe it is possible to accurately determine an appropriate rate that would apply for all of the unclassified blood products that are currently reported using this HCPCS code. With this, CMS is also proposing to change the status indicator for HCPCS code P9099 from "E2" to "N".

  CMS is seeking comment on an alternative proposal that would 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 proposed payment rate for this HCPCS code is $8.02. If this option was finalized, CMS would change the status indicator of HCPCS code P9099 from "E2" to "R" instead.

- **New Comprehensive APCs** ***(FR pages 48784 - 48790)*****:** 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 proposing two new C-APCs for CY 2021:

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

  A list of all proposed CY 2021 C-APCs can be found on FR pages 48788 - 48790.

- **Composite APCs** ***(FR pages 48790 -48795):*** 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 proposing to continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceed the maximum per diem payment rate for partial hospitalization services, those services will continue to instead be paid through composite APC 8010. In addition, the payment rate for composite APC 8010 is proposed to 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 proposing to continue its current composite APC payment policies for multiple imaging services from the same family on the same date as well. Table 4, on FR pages 48792 - 48795, 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 48828 -48829*):** For CY 2021, CMS is proposing to continue its policy established in CY 2019 that created a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims. This methodology may use up to 4 years of claims data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for assigning services to a New Technology APC.

- **Packaged Services** ***(FR pages 48795 - 48799)*****:** CMS is proposing to 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 proposing to continue to unpackage, and pay separately at ASP+6%, the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting (and not pay separately for these drugs when furnished in the OPPS setting).

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 proposes to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them under the CLFS. CMS would assign the following CPT codes status indicator "A" if this proposal is finalized: CPT 81500; CPT 81503; CPT 81535; CPT 81536; CPT 81539.

- **Payment for Medical Devices with Pass-Through Status** ***(FR pages 48843 –48862, 48898 - 48900)*****:** In the CY 2020 final rule, CMS finalized 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. 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. CMS clarified in this proposed rule that the device must receive marketing authorization for the indication covered by the Breakthrough Device Program designation. CMS is also clarifying that the application for the device be received within 2 to 3 years of the initial FDA marketing authorization (or a verifiable market delay).

  There are currently seven device categories eligible for pass-through payment:
  - C1823 – Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads (expires 12/21/2021);
  - 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).

  CMS is proposing to approve two new device pass-through payment applications since the March 1, 2020 quarterly deadline:
  - CUSTOFLEX® ARTIFICIALIRIS; and
  - EXALT™ Model D Single-Use Duodenoscope.

  There are still three other devices that CMS is evaluating for pass-through payment status:
  - Barostim NEO® System;
  - Hemospray® Endoscropic Hemostat; and
  - The SpineJack® Expansion Kit.

  CMS is soliciting 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.

- **Device-Intensive Procedures** ***(FR pages 48863 - 48865)*****:** 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 proposing any changes to the device-intensive policy.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(FR pages 48865 - 48866)*****:** 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 proposing any major changes to the no cost/full credit and partial credit device policies.

- **Payment Policy for Low-Volume Device-Intensive Procedures (*FR pages 48866 - 48867*):** For any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC, CMS is proposing to 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 *(FR pages 48867 - 48882)*:** CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on the packaging threshold. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved since CY 2017 in order to grant a pass-through period as close to 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 proposing a packaging threshold of $130. Drugs, biologicals and radiopharmaceuticals that are above the $130 threshold are paid separately using individual APCs and those below the threshold are packaged; the baseline payment rate for CY 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 is proposing to 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 proposing that the pass-through status expire by December 31, 2020 for 28 drugs and biologicals, listed in Table 21 on FR pages 48869 - 48870 and by December 31, 2021 for 26 drugs and biologicals, listed in Table 22 on FR pages 48871 - 48872; and is proposing to continue/establish pass-through status in CY 2021 to 46 others, shown in Table 23 on FR pages 48874 - 48875.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes *(FR pages 48891 - 48898)*:** CMS divides skin substitutes into a high cost group and a low cost group in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a products per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group.

  CMS is proposing to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high cost group in CY 2020 to the high cost group in CY 2021 as well. CMS is also proposing to assign those with pass-through payment status to the high cost category.

  The list of proposed packaged skin substitutes, and their group assignments, may be found in Table 27 on FR pages 48895 - 48897.

  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 proposed rule while continuing to review the feasibility of each:

  - Establish a lump-sum "episode-based" payment for a wound care episode (FR pages 48892 - 48893); 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 48893 - 48894).

  CMS is also proposing to include synthetic skin graft sheet products in the description of skin substitutes, and therefore can be reported with graft skin substitute procedure codes.

- **Payment for Drugs Purchased under the 340B Drug Discount Program *(FR pages 48882 - 48891)*:** 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 reduced rate of ASP – 22.5% of the biosimilar's 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, beginning CY 2021, CMS is proposing to pay ASP – 28.7% of the biosimilar's ASP (ASP – 34.7% plus an add-on of 6% of the product's ASP).

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

  As in previous years, rural sole-community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are proposed to 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" would 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.

  Alternatively, CMS is considering continuing the current policy to pay ASP – 22.5% as CMS continues to believe that this is an appropriate payment rate for drugs acquired through the 340B program.

  CMS will implement the $427 million drug payment reduction in a budget neutral manner by increasing the OPPS conversion factor across non-drug rates by 0.85%.

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services *(FR pages 48900 - 48908)*:** 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 proposed CY 2021 PHP payment rates:

	Final Payment Rate 2020	Proposed Payment Rate 2021	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$124.30	$126.22	+1.5%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	$238.66	$253.17	+6.1%

  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.

For CY 2021 and subsequent years, CMS is proposing to use a $121.62 CMHC APC geometric mean per diem cost floor as the basis for developing the upcoming year's CMHC APC per diem rate. CMS is also proposing the same for PHP, but with a $222.76 geometric mean per diem cost floor.

CMS is proposing to 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 is proposing to continue to apply an 8 percent outlier payment cap to the CMHC's total per diem payments.

- **Removal of the Inpatient-Only List** ***(FR pages 48908 – 48934)*****:** 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.

  To allow for time to prepare for this change, CMS is proposing to 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 proposing to remove 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. The list of the proposed services to be removed can be found on FR pages 48912 – 48934.

  CMS is soliciting comment on the order of removal of additional services from the list during the 3-year transition period.

- **Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs (*FR pages 48935 - 48936)*:** 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 believes that the policies should become permanent as both allow for additional flexibility in providing services. Therefore, CMS is proposing to adopt both these policies beginning CY 2021. If this proposal is finalized, it does not preclude the hospital from providing direct supervision as appropriate.

- **Two-Midnight Policy for Inpatient Stays** ***(FR pages 48936 - 48939)***: 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 proposed rule, CMS is proposing 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 exemption period would still apply to those procedures removed from the list. CMS is seeking comment on whether the 2-year period is the appropriate length for the exemption.

- **Payment for Off-Campus Outpatient Departments *(FR page 48900)*:** 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 *(FR pages 49027 - 49032)*:** 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 proposing 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 would begin for dates of service on or after July 1, 2021.

  A list of the services included in the two proposed categories can be found in Table 53 on FR page 49030. The current list of services that require prior authorization can be found in Table 54 on FR pages 49031 – 49032.

Comment Solicitation on OPPS Payment for COVID-19 Test Specimen Collection

FR pages 48939 – 48940

CMS created HCPCS code C9803 – *Hospital outpatient clinical visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source* in response to the increase in testing for COVID-19 in HOPDs. In addition, CMS had assigned HCPCS code C9803 to APC 5731 – Level 1 Minor Procedures for the duration of the public health emergency with a status indicator "Q1".

CMS is proposing to continue to assign HCPCS code C9803 to APC 5731 with a status indicator "Q1" if the COVID-19 public health emergency continues into CY 2021.

CMS is looking for comments on whether or not HCPCS code C9803 should remain active beyond the COVID-19 emergency and if OPPS payment should be made permanent for COVID-19 specimen collection tests after the emergency period ends. The comments should include the reasoning for continued payment and the timeframe. If the HCPCS code is kept active, CMS is also soliciting comment on if it should continue to be assigned to APC 5731.

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

FR pages 48984 - 48991

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.

In addition, CMS is proposing to codify 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 is also proposed to be codified in this proposed rule.

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

Beginning with CY 2023, CMS is proposing to expand the current review and corrections policy to measure data submitted through the CMS web-based tool. CMS is proposing to 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 *FR* page 48986.

Overall Hospital Quality Star Rating

FR pages 48987, 48996 - 49027

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 proposing to update the methodology for calculating the star ratings. CMS believes these updates will increase simplicity of the methodology, predictability of measure emphasis over time, and comparability among hospitals.

Specifically, CMS is proposing to 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;
- Adding a new measure group: Timely and Effective Care (made up of the previous Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging) to ensure a sufficient number of measures within the process group;
- Using a simple average of measure scores to calculate group scores rather than Latent Variable Model;
- Standardization of measure group scores by calculating z-scores for each measure group;
- 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);
- Weight Timely and Effective Care at 12% of the hospital summary score and the other measure groups 22%;
- Requiring at least 3 measures in 3 measure groups, one of which must be Mortality or Safety of Care; and
- Placing hospitals into one of three peer groups by number of measure groups that meet inclusion criteria for k-means clustering, contingent on the continued inclusion of CAHs in the star ratings; 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.

CMS is also proposing to include Veterans Health Administration hospitals beginning with CY 2023. CAHs, which are already include in the star ratings, are proposed to continue to be included based on voluntary submission of quality data to CMS. However, CMS proposes to separate suppression policies when there are CMS data errors for CAHs 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 policies that are finalized in the FFY 2022 IPPS rule as well.

Revisions to the Laboratory Date of Service Policy

FR pages 49032 - 49036

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 currently have a system to bill Medicare directly. In response to industry concern, CMS finalized excluding molecular pathology tests performed by a laboratory that is a blood bank or center from the laboratory DOS exception.

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 proposing to exclude cancer-related protein-based MAAAs from the OPPS packaging policy. Therefore, CMS is proposing for the exception to the laboratory DOS rule adopted in the CY 2018 final rule (described earlier in this section) to apply to these tests as well. This would mean that instead of paying for cancer-related protein-based MAAAs under OPPS, Medicare would pay for them under the CLFS and the laboratory that performed the tests would bill Medicare directly instead of seeking payment from the hospital if the test meets all the laboratory DOS requirements.

Physician-owned Hospitals

FR pages 49036 – 49039

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 proposing to revise its current regulations to allow a facility to request an exception to the probation on expansion of capacity at any time, rather than once every 2 years. With this, CMS is proposing to only allow a Medicaid facility to request one exception at a time in order to preserve CMS resources and maintain efficiency.

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

Separately, CMS is proposing to revise the definition of "baseline number of operating rooms, procedure rooms, and beds" to *"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."*