Medicare Outpatient Prospective Payment System

Final Payment Rule Brief Provided by the Wisconsin Hospital Association
Program Year: CY 2022

Overview

The display copy of the final calendar year (CY) 2022 payment rule with comment period for the Medicare Outpatient Prospective Payment System (OPPS) was released on November 2, 2021. 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:

- Use CY 2019 claims data to set the payment rates due to the effect of the COVID–19 public health emergency (PHE);
- Halt the elimination of the Inpatient Only (IPO) list and add back in most services removed in CY 2021;
- Create a universal low volume APC policy;
- Amend price transparency requirements;
- Make changes to the Radiation Oncology model;
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program; and
- Update payment rates and policies for Ambulatory Surgical Centers (ASCs).

A copy of the final rule and other related resources are available on the Centers for Medicare and Medicaid Services (CMS) website at https://www.cms.gov/medicaremedicare–fee–service–paymenthospitaloutpatientpps/cms–1753–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 no later than 30 days after November 2, 2021 and can be submitted electronically at http://www.regulations.gov by using the website's search feature for "1753–FC".

An online version of the Display copy of the CY 2022 OPPS final rule is available at https://www.federalregister.gov/public–inspection/2021–24011/medicare–program–hospital–outpatient–prospective–payment–and–ambulatory–surgical–center–paymenthttps://www.federalregister.gov/d/2021–24011. Page numbers noted in this summary are from the *Federal Register*. A brief summary of the major hospital OPPS sections of the final rule is provided below. CMS estimates a $1.3B increase (as proposed) in payments for CY 2022 over CY 2021.

Note: Text in italics is extracted from the November 2, 2021 *Federal Register.*

OPPS Payment Rate

Display pages 31, 120 – 126, and 704 – 715

CMS typically uses the most up-to-date claims data and cost report data to set OPPS rates for the upcoming year. To avoid using claims data that is impacted by the COVID–19 Public Health Emergency (PHE), CMS is finalizing the use of CY 2019 data to approximate CY 2022 outpatient service utilization, instead of CY 2020 data.

The tables show the final CY 2022 conversion factor compared to CY 2021 and the components of the update factor:

	Final CY 2021	Final CY 2022	Percent Change
OPPS Conversion Factor	$82.797	$84.177 (proposed at $84.457)	+1.67% *(proposed at +2.00%)*

Final CY 2022 Update Factor Component	Value
Marketbasket (MB) Update	+2.7% *(proposed at +2.5%)*
Affordable Care Act (ACA)–Mandated Productivity	–0.7 percentage points (PPT) *(proposed at –0.2)*
Wage Index BN Adjustment	+0.01% *(proposed at +0.12%)*
Wage Index 5% Stop Loss BN	–0.01%
Pass–through Spending / Outlier BN Adjustment	–0.32% *(proposed at –0.38%)*
Cancer Hospital BN Adjustment	+0.00% *(as proposed)*
Overall Final Rate Update	**+1.67% *(proposed at +2.00%)***

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes** ***(Display pages 126 – 142)*****:** As in past years, for CY 2022 OPPS payments, CMS will continue to use the federal fiscal year (FFY) 2022 inpatient PPS (IPPS) wage indexes, including all reclassifications, add–ons, rural floors, and budget neutrality adjustment. CMS is adopting the revisions from the March 6, 2020 Office of Management and Budget (OMB) Bulletin 20–01 for the FFY 2022 Core Based Statistical Area (CBSA)–based labor market area delineations under the FFY 2022 Inpatient Prospective Payment System (IPPS) final rule. CMS stated that the delineation changes within OMB Bulletin 20–01 would not affect the CBSA–based labor market area delineations used under the IPPS. Therefore, specific wage index updates are unnecessary as a result of the adopted updates. This bulletin can be found at https://www.whitehouse.gov/wp–content/uploads/2020/03/Bulletin–20–01.pdf**.**

  In the FFY 2022 IPPS final rule, CMS reinstated the imputed floor wage index adjustment for hospitals in all–urban states effective for discharges on or after October 1, 2021. Specifically, the area wage index applicable under the IPPS to any hospital in an all–urban state may not be less than the minimum area wage index for the fiscal year for hospitals in that state. This impacts the following states for 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, D.C.

  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. These changes were adopted to be in effect for a minimum of four years in order to be properly reflected in future Medicare cost reports. As such, CMS will continue to increase the wage index for low-wage index hospitals for CY 2022. 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 2022 IPPS final rule, the value of the 25th percentile wage index is 0.8437.

  In the FFY 2021 IPPS final rule, CMS implemented a 5% cap on the reduction of a provider's wage index for FFY 2021, compared to its wage index for FFY 2020, set to expire at the end of FFY 2021. In the FFY 2022 IPPS final rule, CMS extended the transition period through FFY 2022 for hospitals that received the 5% cap in 2021 (providers whose FFY 2021 wage index was less than 95% of their FFY 2020 wage index) in light of the COVID–19 PHE. This same adjustment will be applied in CY 2022 for OPPS.

  The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor–related. For CY 2022, CMS will continue to use a labor–related share of 60%.

- **Payment Increase for Rural SCHs and EACHs** ***(Display pages 143 – 145)*****:** 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 data supports a change to the adjustment.

- **Cancer Hospital Payment Adjustment and Budget Neutrality Effect** ***(Display pages 145 – 150):*** CMS will continue to provide payment increases to the 11 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).

  Due to the effects of the COVID–19 PHE, CMS is holding the target PCR equal to that of CY 2021. In order to determine a budget neutrality factor for the cancer hospital payment adjustment for CY 2021, CMS calculated a PCR of 0.90. The application of the 1.0 percentage point reduction mandated by the 21st Century Cures Act results in the final target PCR being equal to 0.89 for each cancer hospital. Since this is the same target PCR as that of CY 2021, CMS finalized a 0.00% adjustment to the CY 2022 conversion factor to account for this policy.

- **Outlier Payments** ***(Display pages 150 – 157)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is using CY 2019 claims to calculate a CY 2022 outlier fixed–dollar threshold of $6,175 (proposed at $6,100). This is a 16.5% increase compared to the current threshold of $5,300. 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 multiplier threshold and the fixed–dollar threshold are met.

Updates to the APC Groups and Weights

Display pages 38 – 116, 168 – 551, and 683 – 692

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 2022 are available in Addenda A and B of the final rule at https://www.cms.gov/medicaremedicare–fee–service–paymenthospitaloutpatientpps/cms–1753–fc.

The table below shows the update in the number of APCs per category from CY 2021 to CY 2022 (Addendum A):

APC Category	Status Indicator	Final CY 2021	Final CY 2022
Pass–Through Drugs and Biologicals	G	94	94
Pass–Through Device Categories	H	10	14
OPD Services Paid through a Comprehensive APC	J1	68	68
Observation Services	J2	1	1
Non–Pass–Through Drugs/Biologicals	K	344	355
Partial Hospitalization	P	2	2
Blood and Blood Products	R	37	39
Procedure or Service, No Multiple Reduction	S	79	81
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		**804**	**823**

- **Blood and Blood Products** ***(Display pages 38 – 40)*****:** For CY 2022, CMS is adopting its proposal to continue its policy to establish payment rates for blood and blood products using a blood–specific CCR methodology.

- **New Comprehensive APCs** ***(Display pages 44– 61)*****:** Comprehensive Ambulatory Payment Classifications (C–APCs) provide all–inclusive payments for certain procedures. A C–APC covers payment for all Part B services that are related to the primary procedure, including items currently paid under separate fee schedules. The C–APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un–coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C–APCs when they appear on the same claim as those services assigned to a C–APC. The C–APCs do not include payments for services that are not covered by Medicare Part B, nor those that are not payable under OPPS such as: certain mammography and ambulance services; brachytherapy sources; pass–through drugs and devices; charges for self–administered drugs (SADs); 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.

  A list of the final 69 C–APCs for CY 2022 C–APCs can be found on *Display* pages 59 – 60.

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

  For CY 2022, CMS will continue its policy that when the aggregate payment for specified mental health services provided by a hospital to a single beneficiary on a single date of service exceeds 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 2022, CMS will also continue its current composite APC payment policies for multiple imaging services from the same family and on the same date. Table 3 (*Display* pages 66 – 70) 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 190 – 195 and 683 – 692*):** For CY 2022, CMS will continue its policy (with modification outlined below) 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.

  However, CMS will utilize this policy through an adopted universal low-volume APC policy that is similar to the current New Technology APC low-volume policy but applies to clinical APCs and brachytherapy APCs in addition to New Technology APCs. It also uses the highest of the geometric mean, arithmetic mean, or median, based on up to 4 years of claims data to set the payment rate for the APC. Since the universal low-volume APC policy was finalized, CMS will end the separate New Technology APC low volume policy.

- **Packaged Services** ***(Display pages 70 – 116)*****:** CMS will continue its efforts to create more complete APC payment bundles over time in order 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 2022, 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 will 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 Hospital Outpatient Department (HOPD) setting).

  CMS requested comment on expanding this policy to HOPDs. Comments can be found on *Display* pages 79 – 82. Based on these comments, CMS does not believe it is appropriate to establish a similar payment methodology for drugs furnished in the HOPD setting but will continue to analyze utilization.

  Separately, in order to identify non–opioid pain management drugs and biologicals that function as supplies in surgical procedures for which revised payment under the ASC payment system would be appropriate, CMS is adopting two eligibility criteria for CY 2022 and subsequent years:

  - FDA approval and indication for pain management or analgesia; and
  - Per–day cost exceeds the drug packaging threshold.

  Currently, there are two products receiving separate payment in the ASC setting: Exparel and Omidria. CMS states that both would be eligible for separate payment in CY 2022 under the adopted criteria.

  CMS is finalizing that non–opioid drugs and biologicals currently receiving transitional drug pass–through status in the OPPS will not be candidates for this policy. Once the transitional drug pass–through status expires, the drug may qualify for separate payment under the ASC payment system if it meets the eligibility requirements.

CMS sought comments on whether there were any other non–opioid drugs or biological products that met the adopted criteria. Based on the comments, CMS is approving both Xaracoll and Zynrelef to receive separate payments under the ASC payment system as non–opioid pain management drugs that function as surgical supplies for CY 2022.

Additionally, CMS solicited comments on several policy modifications and additional criteria for revised payment for non–opioid pain management drugs and biologicals. Discussions on potential policy modifications and public comments can be found on *Display* pages 103 – 115.

- **Payment for Medical Devices with Pass–Through Status** ***(Display pages 302 – 436)***: There are currently eleven 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;
    - C1748 – Endoscope, single–use (that is disposable), Upper GI, imaging/illumination device (insertable);
    - C1052 – Hemostatic agent, gastrointestinal, topical;
    - C1062 – Intravertebral body fracture augmentation with implant (for example, metal, polymer);
    - C1825 – Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s); and
    - C1761 – Catheter, transluminal intravascular lithotripsy, coronary.

  As of the final rule, CMS has approved three of eight new device pass–through payment applications for CY 2022:
    - RECELL System;
    - Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) Catheter (had received preliminary approval effective July 1, 2021); and
    - AngelMed Guardian® System.

- **Device–Intensive Procedures** ***(Display pages 436 – 452)*****:** 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 procedures that were assigned device–intensive status, but were assigned a default device–intensive offset percentage of 31% or a device offset percentage based on claims from a clinically similar code in the absence of CY 2019 claims data (which is used for ratesetting), CMS is assigning a device offset percentage based on CY 2020 data for 14 procedures listed on *Display* pages 444 – 445 and 451 – 452, if available.

- **Device Edit Policy** ***(Display pages 452 – 454)*****:** CMS requires claim processing edits when any of the device codes used in the previous device–to–procedure edits are present on the claim with a device–intensive procedure that includes the implantation of a device. CMS created a HCPCS code C1889 (implantable/insertable device, not otherwise classified) to recognize devices used during device–intensive procedures that are not described by specific Level II HCPCS Category C–Code. This HCPCS code satisfies the edit requirement.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices** ***(Display pages 454 – 456)*****:** 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 must be 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 (devices exceeding 30% of the procedure's average cost).

  For CY 2022, 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 457 – 459 and 683 – 692*):** Currently, for any device–intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC, CMS calculates the payment rate for that procedure using the median cost.

  CMS is adopting its proposal to establish a universal low-volume APC policy for clinic APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims. The payment rate would be established using the highest of the median cost, the arithmetic mean cost, or the geometric mean cost. Since the new policy was finalized, CMS is eliminating the current payment policy for low-volume device–intensive procedures.

  Currently CPT code 0308T is the only code subject to this policy.

- **Payment for Drugs, Biologicals and Radiopharmaceuticals *(Display pages 303 – 306, 459 – 506, 539 – 550, and 715 – 723)*:** 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 2022, CMS is finalizing 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 2022 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 2022, CMS will also 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 adopting its proposal that the pass–through status expire by December 31, 2021 for 25 drugs and biologicals, listed in Table 37 on *Display* pages 463 – 465; by December 31, 2022 for 26 drugs and biologicals listed in Table 38 on *Display* pages 467 – 468; and will continue/establish pass–through status in CY 2022 to 46 others shown in Table 39 on *Display* pages 471 – 476.

  CMS is adopting its proposal to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass–through payment status will expire between December 31, 2021 and September 30, 2022 due to the use of CY 2019 claims data rather than CY 2020 claims data in CY 2022 ratesetting, listed in Table 43 on *Display* pages 548 – 550.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes *(Display pages 521 – 539)*:** CMS divides skin substitutes into a high cost group and a low cost group in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a products per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group.

  CMS is adopting its proposal to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high cost group in CY 2021 to the high cost group in CY 2022 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 535 – 539.

- **Payment for Drugs Purchased under the 340B Drug Discount Program *(Display pages 506 – 521)*:** The 340B Drug Pricing Program, administered by the Health Resources & Services Administration (HRSA), allows participating hospitals and other healthcare 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, 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.

On January 10, 2021 the appellees filed a petition for a writ of certiorari in the Supreme Court. On July 2, 2021 the Supreme Court granted their petition.

For CY 2022, CMS will continue to pay ASP – 22.5 percent for drugs and biologicals acquired under the 340B program.

The 340B adjustment also applies to those drugs for which pricing is determined based on WAC and average wholesale price (AWP). CMS will continue that drugs acquired under WAC pricing be paid at WAC – 22.5%, while those acquired under AWP pricing be paid at 69.46% of AWP.

As in previous years, rural sole–community hospitals (SCHs), children's hospitals, and PPS–exempt cancer hospitals are exempt from the 340B adjustment and receive drug payments based on ASP + 6%. Critical Access Hospitals (CAHs) are exempt as well. CMS mentions revisiting these exemptions in future rulemaking.

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 551 – 575)*****:** 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 2021 and adopted CY 2022 PHP payment rates:

	Final Payment Rate 2021	Final Payment Rate 2022	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$139.75	$142.70	+2.1%
APC 5863: Partial Hospitalization (3+ services) for Hospital–based PHPs	$260.49	$265.97	+2.1%

  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 were 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.

  Due to the COVID–19 PHE, a cost floor equal to the per diem cost finalized in CY 2021 will be used for both CHMC and hospital–based PHP. As mentioned earlier, CMS is also adopting its proposal to use CY 2019 claims and cost report data rather than CY 2020.

  In addition, CMS is finalizing the use of the Medicare Cost Report as the source for cost report information used to calculate the geometric mean per diem cost for CMHCs beginning CY 2022.

  Lastly, 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. As done in prior years, CMS will apply an 8 percent outlier payment cap to the CMHC's total per diem payments.

- **Reinstating the Inpatient–Only List** ***(Display pages 575 – 661)*****:** The inpatient–only list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting.

  In the CY 2021 final rule, CMS stated that they no longer see the need for the inpatient–only list in order to identify services that require inpatient care and therefore finalized the removal of the inpatient–only list over a 3–year period, beginning CY 2021, with the list completely eliminated by CY 2024.

  In response to numerous public comments in opposition of the removal of the list, CMS is halting the elimination of the inpatient–only list. For CY 2022, CMS had proposed to add back in the 298 HCPCS codes that were removed in CY 2021. However, based on public comments, CMS is adding all but the following measures back on to the inpatient–only list:

  - CPT 22630: Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace lumbar;
  - CPT 23472: Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement [for example, total shoulder]);
  - CPT 27702: Arthroplasty, ankle; with implant (total ankle);
  - CPT 00630: Anesthesia for procedures in lumbar region; not otherwise specified;
  - CPT 00670: Anesthesia for extensive spine and spinal cord procedures (e.g., spinal instrumentation or vascular procedures);
  - CPT 01638: Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement; and
  - CPT 01486: Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement).

  CMS is also adding the following to the inpatient–only list:

  - CPT 0642T: Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach.

  The list of measures that will remain off the list and those that will be added back are on *Display* pages 637 – 661.

  CMS is amending the regulations to remove the elimination of the inpatient–only list over 3 years and codifying the five long–standing criteria to determine whether a procedure or service should be removed from the list.

- **Two–Midnight Policy for Inpatient Stays** ***(Display pages 661 – 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. 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 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.

  Due to the removal of the inpatient–only list, in the CY 2021 final rule, CMS adopted an indefinite exemption period from medical review activities for those procedures removed from the inpatient only list on or after January 1, 2021. Since CMS is adopting its proposal to halt the elimination of the inpatient–only list, it is rescinding the indefinite exemption period and is reinstating the 2–year exemption from medical review activities for procedures removed from the inpatient–only list beginning on or after January 1, 2021.

- **Payment for Off–Campus Outpatient Departments** ***(Display pages 550 – 551)*****:** 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 Medicare Physician Fee Schedule (MPFS) payment methodology to excepted off–campus PBDs for HCPCS code G0463. CMS will continue to pay 40% of the OPPS rate for excepted off–campus PBDs for basic clinic services in CY 2022. These excepted PBDs continue to bill HCPCS code G0463 with modifier "PO".

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

Display pages 860 – 1,023

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 adopting its proposal to remove the following measures from the CY 2023 reporting period/CY 2025 OQR program:

- OP–02: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival; and
- OP–03: Median Time to Transfer to Another Facility for Acute Coronary Intervention.

For the CY 2023 program, the OP–39: Breast Screening Recall Rates will be added. CMS is finalizing the OP–38: COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) for the CY 2024 program. Reporting for both measures is required, beginning CY 2022.

The following two measures with CY 2023 reporting period/CY 2025 payment determination voluntary followed by mandatory reporting have also been adopted:

- OP–40: ST–Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) for voluntary reporting (mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination); and
- OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS HCAHPS) Survey–based measures for voluntary reporting (mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination) with survey and vendor requirements outlined on *Display* pages 986 – 994.

CMS had proposed mandatory reporting beginning with the CY 2023 reporting period/CY 2025 program for the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure. However, CMS added a 2–year extension from the originally proposed timeframe to allow facilities sufficient time to prepare. Therefore, CMS has finalized that mandatory reporting of OP–31 will begin with the CY 2025 reporting period/CY 2027.

Beginning with the CY 2024 program, CMS is finalizing the following updates to the validation requirements:

- *"Use electronic file submissions for chart–abstracted measure medical record requests;*
- *change the chart validation requirements and methods; and*
- *update the targeting criteria."*

In order to allow more hospitals opportunity for validation in the OQR program, CMS is revising the criteria used to select 50 additional hospitals for validation by adding the following:

- *"Any hospital that has not been randomly selected for validation in any of the previous 3 years; and*
- *Any hospital that passed validation in the previous year, but had a two–tailed confidence interval that included 75 percent."*

Separately, CMS requested comments on several topics listed below with references to comment page numbers:

- *"Potential Adoption of Future Measures for the Hospital OQR Program*" (*Display* pages 944 – 945)*;*
- *"Potential Future Adoption and Inclusion of a Hospital–Level, Risk–Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty"* (*Display* pages 949 – 954)*;*
- *"Potential Future Efforts to Address Health Equity in the Hospital OQR Program"* (*Display* pages 968 – 978).

CMS is also adopting several file format requirements, beginning with the CY 2023 reporting period, to align with the Inpatient Quality Reporting program:

- *"Must submit eCQM data via the QRDA Category I (QRDA I) file format;*
- *may use third parties to submit QRDA I files on their behalf; and*
- *may either use abstraction or pull the data from non–certified sources in order to then input these data into CEHRT for capture and reporting QRDA I."*

For the CY 2024 payment determination and subsequent years, CMS is adopting its proposal to discontinue the option to submit paper copies, CDs, DVDs, or flash drives containing medical records for validation. Hospitals will be required to submit only electronic files for chart–abstracted measures. CMS is also finalizing a 30 calendar day timeframe rather than 45 calendar days for submission of medical records.

Beginning with the CY 2023 reporting period/CY 2025 payment determination, CMS had proposed submission deadlines for eCQMs to be 2 months following the close of the calendar year, including the review and correction period. To allow more time for data submission and review, CMS is modifying its proposal and finalizing May 15 as the data submission deadline for CY 2023 reporting period/CY 2025 payment determination eCQMs. If May 15 is a weekend or federal holiday, the submission deadline may be moved to the next business day.

Lastly, CMS is adopting its proposal to expand the extraordinary circumstances exemption policies to eCQMs.

A table listing the 14 measures to be collected for CY 2023 payment determinations is on *Display* pages 938 – 939.

Price Transparency

Display pages 1,230 – 1,279

CMS is adopting its proposal to amend several price transparency requirements, beginning CY 2022, including:

- Use a scaling factor based on hospital bed count from the most recently available, finalized cost report data, to increase the penalty in a manner unique to the non–compliant hospital as such:
  - Noncompliant hospitals with 30 or less beds would have a maximum daily penalty of $300;
  - Noncompliant hospitals with 31 to 550 beds would have a maximum daily penalty calculated as the number of beds times $10; and
  - Noncompliant hospitals with greater than 550 beds would have a maximum daily penalty of $5,500.

  The maximum penalties are as such even if a hospital has multiple violations and are based on a full CY. If the number of beds is unavailable, CMS would use documentation provided by the hospital to determine the number of beds;
- Exclude state forensic hospitals from hospital price transparency requirements; and
- Requiring standard charge information on a machine–readable file to be accessible to automated searches and direct file downloads through a link posted on a publically available website.

CMS is also clarifying that the expected output of the hospital online price estimator tool must be a single dollar amount that is tailored to the individual seeking the estimate. The estimate also must reflect the amount the hospital anticipates being paid by the individual for the service.

Radiation Oncology (RO) Model

Display pages 1,132 – 1,230

On September 29, 2020, CMS published the Specialty Care Models to Improve Quality of Care and Reduce Expenditures that finalized the RO model. In the CY 2021 final rule, CMS delayed the start of the RO model to July 1, 2021 and changed the duration of the model from 5 years to 4.5 years. However, on December 27, 2020, the Consolidated Appropriations Act of 2021 (CAA) prohibited the RO model from beginning before January 1, 2022. With this, CMS is adopting the further delay of the model to begin on January 1, 2022 with a 5–year model performance period and a 3–year baseline period from January 1, 2017 – December 31, 2019.

CMS is finalizing to define or modify definitions of several model components due to the delay of implementation as well as other model modifications unrelated to the delay, some of which are outlined below.

HOPDs that are participating in the Pennsylvania Rural Health Model (PARHM) are finalized to be excluded from the RO model, rather than excluding both those participating and those identified as eligible for participation. Similarly, CMS is finalizing the exclusion of HOPDs participating in the Community Transformation Track of the Community Health Access and Rural Transformation Model (*Display* pages 1,146– 1,153).

In addition, CMS is adopting its proposal to modify the cancer inclusion criteria such that a cancer type must be commonly treated with radiation, using nationally recognized, evidence–based clinical treatment guidelines in order to be included in the model. The treatment must also be associated with current ICD–10 codes with pricing stability determined by analyzing interquartile ranges of episode prices across cancer types. Lastly, the cancer type must be considered suitable for inclusion in the RO Model by the Secretary. If a cancer type does not meet all three requirements it will be removed from the RO Model (*Display* pages 1,161 – 1,163).

CMS is also finalizing several removals from the model:

- Liver cancer – CMS does not believe that liver cancer meets the inclusion criteria because it is not commonly treated with radiation per national standards (*Display* pages 1,163 – 1,164); and

- Brachytherapy from the list of included modalities – CMS believes inclusion could lead to reduced utilization of brachytherapy (*Display* pages 1,164 – 1,167).

Separately, CMS is adopting its proposal to exclude all Maryland, Vermont, and US Territory claims as well as all CAH, inpatient, ASC, PPS–exempt claims, and those participating in PARHM before episodes are constructed and attributed to a radiation therapy (RT) provider or supplier (*Display* pages 1,172 – 1,173).

Modification of the stop–loss limit policy is also being finalized. CMS states it would include all model participants that have fewer than 60 episodes during the adopted baseline period and furnished model RT services any time before the start of the performance period (*Display* pages 1,180 – 1,181).

With regard to mergers, acquisitions, or other new business relationships that cause a CCN or TIN change, CMS will calculate the RO participant's case mix adjustments based on all episodes and RO episodes attributed to the RO participant's legacy CCN or TIN. Historical experience adjustments would also use the legacy CCN or TIN. CMS is adopting its proposal to eliminate the requirement to provide notification of a new business relationship but adding a requirement to provide written notice of change in CCN or TIN at least 90 days before the effective date of the change (*Display* pages 1,181 – 1,183).

CMS is finalizing the definitions of status tracks for RO model participants under the Quality Payment Program with a modification to add a third track. To be included in Track One of the RO Model, RO participants must (1) use Certified Electronic Health Record Technology (CEHRT), (2), annually certify their use of CEHRT during the model performance period, (3) certify their use of CEHRT within 30 days of the start of each performance year, and (4) qualify as an Advanced Alternative Payment Model (APM) and a Merit-Based Incentive Program (MIPS) APM. RO participants that meet all of the above RO Model requirements in a performance year, except for use of CEHRT, will be in Track Two for the applicable year. RO participants that do not meet one or more of the RO Model requirements will be in Track Three.

If a beneficiary switches from traditional Medicare to Medicare Advantage during an episode before treatment is complete, CMS will consider this an incomplete episode. In this case, RT services would be paid the traditional Medicare rate instead of being paid under the RO Model. CMS is adopting a reconciliation policy to outline situations as such (*Display* pages 1,212 – 1,220).

As far as the discount factor, CMS is lowering the Professional Component (PC) from 3.75% to 3.5% and for the Technical Component (TC) from 4.75% to 4.5% due to the removal of liver cancer and brachytherapy (*Display* pages 1,183 – 1,187).

Beginning performance year 1, CMS is finalizing that participants must begin submitting quality measure data and that a 2% quality withhold for the PC would be applied to the applicable trended national base rates after the case mix and historical experience adjustments (*Display* pages 1,187 and 1,190 – 1,206).

Technical participants that are freestanding radiation therapy centers must notify CMS within 30 days if they begin providing the PC at any point during the model performance. These participants would also be required to report quality data by the next reporting period. Additionally, technical participants will also be provided an individual practitioner list (*Display* pages 1,206 – 1,209).

CMS is also adopting its proposal to allow RO participants the ability to review their individual practitioner list and add or drop necessary NPIs up until the last quality program determination snapshot date (*Display* pages 1,209 – 1,212).

Lastly, CMS is adopting an extreme and uncontrollable circumstance (EUC) policy which would allow CMS to revise the model performance period, payment methodology, and grant exceptions, when needed. CMS is finalizing one modification to this policy from what was proposed; if CMS were to remove quality and clinical data submission requirements for impacted RO participants, CMS would choose to either (1) repay the quality withhold during the next reconciliation and award all possible points in the next calculation for impacted participants or (2) not apply the quality withhold during the EUC (*Display* pages 1,221 – 1,230).

Due to the COVID-19 PHE, CMS used a CMS RO participant email to reference a EUC currently in effect that states that the quality requirements for performance year 1 will be optional and the 2.0% withhold will not be applied to payments.

CMS lists adopted national base rates in Table 75 on *Display* page 1,175.

Temporary Policies during COVID–19 PHE

Display pages 693 – 704

In the CY 2022 proposed rule, CMS sought feedback on if any of the temporary emergency policies put into place during the COVID–19 PHE should be made permanent. The page references for comments on the topics are listed below:

- Services furnished by hospital staff to beneficiaries in their homes through use of communication technology for mental health services (*Display* pages 699 – 700);
- The need for direct supervision for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services when the supervising practitioner is available through two–way, audio/video communication technology (*Display* page 702); and
- COVID–19 specimen collection (HCPCS C9803) (*Display* pages 703 – 704).

Beneficiary Coinsurance for Colorectal Cancer Screening Test

Display pages 674 – 683

Beginning January 1, 2022 the Consolidated Appropriations Act (CAA) of 2021 allows for reduced coinsurance for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed when a beneficiary is diagnosed due to the results of a test, or if the colorectal cancer screening test calls for the removal of tissue or other matter or other procedure in the same clinical encounter.

For these screening tests, Medicare will pay 100 percent of the amount established under the applicable payment methodology and the beneficiary is not required to pay Part B coinsurance (except for barium enemas), phased in over 9 years (80% in CY 2022, 85% in CYs 2023 through 2026, 90% in CYs 2027 through 2029, and 100% in CY 2030). If these services are furnished as diagnostic tests rather than screening tests, patients are responsible for 20 percent of the associated coinsurance. Providers must continue to report HCPCS modifier "PT" to indicate a planned colorectal cancer screening service converted to a diagnostic service.

CMS is finalizing that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy could be viewed as part of this policy for the purposes of determining the coinsurance required of Medicare beneficiaries.

Request for Information – Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs

Display pages 836 – 859

CMS aims to move to fully digital quality measurement in quality reporting and value–based purchasing programs by 2025. CMS has heard from stakeholders about the technological challenges and burden of reporting eCQM data and is therefore currently working to convert the current eCQMs to FHIR. CMS is specifically looking for feedback on its potential use of FHIR, a free and open source standards framework, to define digital quality measures (dQMs) within hospital quality programs. Comments can be found on *Display* pages 853 – 859.

Request for Information – Hospital Inpatient Quality Reporting (IQR)

Display pages 1,279 – 1,286

CMS requested input on potential measure updates for the Safe Use of Opioids Concurrent Prescribing eCQM as CMS prepares for NQF re–endorsement in 2022. Currently, hospitals are required to report 3 self–select eCQMs and the Safe Use of Opioids eCQM. CMS also requested feedback on the requirement to report the Safe Use of Opioids eCQM or if it should be self–selected by hospitals. Comments can be found on *Display* pages 1,285 – 1,286.

Request for Information – Medicare Promoting Interoperability Program

Display pages 1,286 – 1,292

To maintain alignment with the hospital IQR program, CMS asked for input on potential measure updates for the Safe Use of Opioids Concurrent Prescribing eCQM for the Medicare Promoting Interoperability Program as well. Currently, eligible CAHs and hospitals are required to report 3 self–select eCQMs and the Safe Use of Opioids eCQM. CMS also requested feedback on the requirement to report the Safe Use of Opioids eCQM or if it should be self–selected by CAHs and hospitals. Comments can be found on *Display* page 1,292.

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