California Hospital Association

Federal Regulatory Summary

from the California Hospital Association

SUMMARY OF FINAL RULE – DECEMBER 2021

CY 2022 Outpatient Prospective Payment System

Overview

In the November 16 *Federal Register*, the Centers for Medicare & Medicaid Services (CMS) published a final rule addressing rate updates and policy changes to the Medicare outpatient prospective payment system (OPPS) for calendar year (CY) 2022. The policy and payment provisions are generally effective for CY 2022 discharges, beginning January 1, 2022.

The following is a comprehensive summary of the final rule's acute care hospital provisions. In addition to annual payment and quality updates, the summary details policies related to the inpatient-only list, hospital price transparency regulation compliance, and modifications to the radiation oncology model.

The final rule also includes provisions for ambulatory surgical centers (ASCs). For a detailed summary of those provisions, please contact cmulvany@calhospital.org.

For Additional Information

Questions about this summary should be directed to Megan Howard, vice president of federal policy, at (202) 488-3742 or mhoward@calhospital.org, or Chad Mulvany, vice president of federal policy, at (202) 270-2143 or cmulvany@calhospital.org. Facility-specific CHA DataSuite analyses were sent under separate cover. Questions about CHA DataSuite should be directed to Alenie Reth, data analytics coordinator, at areth@calhospital.org.

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Summary of Key Provisions

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)
- Reverse the elimination of the inpatient-only (IPO) list and add back most services removed in CY 2021
- Create a universal low-volume Ambulatory Payment Classification (APC) policy
- Continue the reduction in payment to 340B hospitals for separately payable Part B drugs
- Amend price transparency requirements, increasing penalties for non-compliance
- Make changes to the radiation oncology model
- Update the requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The increase in OPPS spending due only to changes in the 2022 OPPS final rule is estimated to be approximately $1.27 billion. Considering estimated changes in enrollment, utilization, and case-mix for 2022, CMS estimates that OPPS expenditures, including beneficiary cost-sharing, will be approximately $82.1 billion, which is approximately $5.9 billion higher than estimated OPPS expenditures in 2021.

CY 2022 Proposed OPPS Payment Update

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 are impacted by the COVID–19 PHE, CMS is finalizing the use of CY 2019 data to approximate CY 2022 outpatient service utilization, instead of CY 2020 data.

The tables below 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
Market Basket (MB) Update	+2.7% (proposed at +2.5%)
Affordable Care Act (ACA)–Mandated Productivity MB Reduction	–0.7 percentage points (proposed at –0.2)
Wage Index BN Adjustment	+0.01% (proposed at +0.12%)

Pass–through Spending/Outlier BN Adjustment	–0.01%
Cancer Hospital BN Adjustment	–0.32% (proposed at –0.38%)
Overall Rate Update	**+1.67% (proposed at +2.00%)**

CMS estimates that the update to the conversion factor net of the multifactor productivity (MFP) adjustment will increase payments 2% in 2022 (market basket of 2.7% less 0.7 percentage points for MFP). Including changes to outlier payments, pass-through payment estimates, and the application of the frontier state wage adjustment, CMS estimates a 1.6% increase in payments between 2021 and 2022.

CMS notes the following estimated impacts in Table 71 of the proposed rule:

Facility Type	Estimated 2022 Impact (Final)
All Hospitals	1.6%
Urban – All	1.6%
Urban – Pacific Region	1.7%
Rural – All	1.6%
Rural – Pacific Region	1.2%

California estimated impacts provided by CHA DataSuite are noted in the table below; impacts will vary by hospital.

Impact Analysis	Dollar Impact	Percent Change
Estimated CY 2021 OPPS Payments	*$6,045,621,800*	
Marketbasket Update	$134,981,500	2.23%
ACA-Mandated Marketbasket Reduction	($34,995,400)	-0.58%
Other BN Adjustments	($16,661,700)	-0.28%
Wage Index (Wage Data and Reclassification)	$4,696,200	0.08%
Application of the Imputed Floor	$0	0.00%
Increasing Bottom Quartile Wage Index Values	$0	0.00%
5% Stop Loss Transition Wage Index	$0	0.00%
Change in Rural Adjustment	$0	0.00%
APC Factor/Updates	$14,095,900	0.23%
Estimated CY 2022 OPPS Payments	*$6,147,738,300*	
Total Estimated Change CY 2021 to CY 2022	***$102,116,500***	***1.69%***

The impact shown above does not include the impact of the sequestration reduction to all lines of Medicare payment authorized by Congress through FFY 2031. The Protecting Medicare and American Farmers from Sequester Cuts Act extended the 2.0% sequestration moratorium through March 31, 2022 and reduced the sequestration cuts to 1.0% for the following three months, resuming at 2.0% for the second half of the year. It is estimated that the impact of sequestration on CY 2022 OPPS PPS payments would be: -$76,846,300

Source: CHA DataSuite Analysis, December 2021

Updates Affecting OPPS Payments

Recalibration APC Relative Payment Weights

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 on the CMS website.

The table below shows the shift 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

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.

Brachytherapy Sources

If CMS does not have billing data to set the payment rates, it may use external data to set prices for brachytherapy sources. For 2018 through 2021, CMS used external data to set a payment rate for HCPCS code C2645 (brachytherapy planar source, palladium-103, per square millimeter) at $4.69 per mm^2. CMS proposed to continue this rate for 2022. It received no comments and is finalizing this rate for 2022.

Comprehensive APCs (C-APCs) for 2022

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 the OPPS. This includes certain mammography and ambulance services; brachytherapy sources; pass–through drugs and devices; charges for self–administered drugs; 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 in Table 2 beginning on page 63475.

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 two criteria:

- The treatment is a Food and Drug Administration (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.
- 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.

Calculation of Composite APC Criteria-Based Costs

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)
- Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008)

CMS did not propose or finalize any policy changes related to composite APCs for CY 2022.

Changes to Packaged Items and Services

CMS will continue its efforts to create more complete APC payment bundles over time to package more ancillary services when they occur on a claim with another service, and to only pay for them separately when performed alone.

For CY 2022, 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).

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.

Wage Index Changes

CMS is continuing to use a labor share of 60% and the fiscal year IPPS post-reclassified wage index for the OPPS in 2022. For non-IPPS hospitals paid under the OPPS for 2022, CMS is continuing its past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment.

For community mental health centers (CMHCs), CMS will continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. CMS notes that, consistent with its current policy, the wage index that applies to CMHCs includes the rural floor adjustment, but it does not include the out-migration adjustment, which only applies to hospitals.

CMS follows a parallel policy for the 2022 OPPS as it did for the FY 2022 IPPS. Hospitals that were subject to a 5% limit on the reduction in the 2021 wage index relative to the 2020 wage index will again be subject to 5% limit on the reduction in the 2022 wage index relative to the

2021 wage index. CMS will make this change budget neutral, necessitating a -0.01% budget neutrality adjustment to the conversion factor.

Sole Community Hospital (SCH) Adjustment

For 2022, CMS is continuing to apply a 7.1% payment adjustment under section 1833(t)(13)(B) of the Social Security Act (the Act) for rural SCHs — including essential access community hospitals — for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Cancer Hospital Adjustment

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. 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.

Outpatient Outlier Payments

To maintain total outlier payments at 1% 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.

New Technology APCs

Currently, there are 52 levels of New Technology APC groups with two parallel status indicators: one set with a status indicator of "S" (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of "T" (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A ($0 - $10)) through the highest cost band assigned to APC 1908 (New Technology – Level 52 ($145,001 - $160,000)). Payment for each APC is made at the mid-point of the APC's assigned cost band.

Establishing Payment Rate for Low-Volume New Technology Procedures

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 four 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 four 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.

Pass-Through Payments for Devices

There are currently 11 device categories eligible for pass-through payment:

Table 31: Expiration of Transitional Pass-Through Payments for Certain Devices

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823*	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable) nonrechargeable with carotid sinus baroreceptor simulation lead(S)	1/1/2021	12/1/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

**CMS proposes to continue to provide separate payment for C1823 through 2022.*

The pass-through payment status for HCPCS code C1823 is scheduled to expire on December 31, 2021. For 2022, CMS finalizes its proposal to use its equitable adjustment authority to provide separate payment for C1823 until December 31, 2022.

New Device Pass-Through Applications

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)
- AngelMed Guardian® System

Device-Intensive Procedures

Device-Intensive Procedure Policy for 2019 and Subsequent Years

Device-intensive APCs are procedures that require the implantation of a device and are assigned an individual HCPCS code–level device offset of more than 30% of the procedure's mean cost, regardless of APC assignment.

For 2022, CMS finalizes its proposal to assign device offset percentages using 2020 claims data to the 14 procedures listed in the table below. Eleven procedures were previously proposed, and three additional procedures were added based on the review of updated 2020 claims data.

Final 2022 Device Offset Percentages Using 2020 Claims Data	
HCPCS Code	**Code Descriptor**
0266T	Implantation or replacement of carotid sinus baroflex activation device; total system
0414T	Removal and replacement of cardiac contractility modulation system pulse generator
0511T	Removal and reinsertion of sinus tarsi implant
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming and imaging guidance, posterior tibial nerve
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, imaging guidance, percutaneous
0614T	Removal and replacement of substernal implantable defibrillator pulse generator
66987	Extracapsular cataract replacement with insertion of intraocular lens prosthesis, complex
66988	Extracapsular cataract replacement with insertion of intraocular lens prosthesis, manual or mechanical technique
C9757	Laminectomy (hemilaminectomy), with decompression of nerve roots
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement, including angioplasty when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement, and atherectomy, including angioplasty when performed
0519T*	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)
0618T*	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens replacement or intraocular lens exchange

Final 2022 Device Offset Percentages Using 2020 Claims Data	
HCPCS Code	**Code Descriptor**
C9761*	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy and vacuum aspiration of the kidney, collecting system and urethra if applicable

*Procedures added based on updated claims data for the final rule.

The full list of device-intensive procedures is provided in Addendum P.

Device Edit Policy

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.

Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

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. For CY 2022, CMS is not making any major changes to the no cost/full credit and partial credit device policies.

Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

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 three full 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 at 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 beginning on page 63622; by December 31, 2022, for 26 drugs and biologicals listed in Table 38 beginning on page 63625; and will continue/establish pass-through status in CY 2022 to 46 others shown in Table 39 beginning on pages 63628.

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 rate setting, listed in Table 43 beginning on page 63662.

OPPS Payment Methodology for 340B-Purchased Drugs

For CY 2022, CMS will continue to pay ASP – 22.5% 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 its policy 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 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.

Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. The 340B-acquired drug payment policies are involved in a continuing lawsuit. In the case of *American Hospital Association et al. v. Azar et al.*, the district court concluded that CMS exceeded its authority with its large reduction to Medicare payments for CY 2018 and CY 2019 for drugs acquired through the 340B program, unless the Secretary obtained drug acquisition cost survey data from hospitals proving otherwise. CMS disagreed and appealed the decision, while also gathering survey data that confirmed that ASP – 22.5% 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, which was heard on November 30, 2021. While it is difficult at best to interpret how the Supreme Court will rule based on the justices' lines of questioning, it appears they were receptive to the arguments of 340B hospitals. The court's decision will be handed down by June 2022.

High/Low-Cost Threshold for Packaged Skin Substitutes

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 beginning on page 63653.

Hospital Outpatient Visits

For off-campus provider-based departments exempted from being paid a physician fee schedule equivalent rate, CMS is continuing to pay 40% of the full OPPS rates. This policy was upheld by a federal circuit court in 2020, and the Supreme Court denied certiorari. CMS did not propose any expansions of this policy for 2022.

IPO List

The IPO list specifies services/procedures that Medicare will pay only when provided in an inpatient setting.

In the CY 2021 final rule, CMS stated that it no longer sees the need for the IPO list in order to identify services that require inpatient care and, therefore, finalized the removal of the IPO list over a three-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 IPO 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 IPO 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
- 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 IPO list:

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

Table 48, beginning on page 63712, lists the procedures that will remain off the inpatient-only list and those that will be added back.

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

Nonrecurring Policy Changes

Medical Review of Certain Inpatient Hospital Admissions

In the CY 2020 final rule, CMS established a two–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 IPO list for CY 2020 and forward.

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

Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Beginning January 1, 2022, the Consolidated Appropriations Act (CAA) of 2021 allows for reduced co-insurance 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 procedures in the same clinical encounter.

For these screening tests, Medicare will pay 100% 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 nine years. This is illustrated in the table below.

Year	Medicare Payment %	Beneficiary Coinsurance %
2022	80	20
2023 through 2026	85	15
2027 through 2029	90	10
2030 and subsequent years	100	0

If these services are furnished as diagnostic tests rather than screening tests, patients are responsible for 20% of the associated co-insurance. 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 co-insurance required of Medicare beneficiaries.

Comment Solicitation on Temporary COVID-19 Policies

In the CY 2022 proposed rule, CMS sought feedback on whether 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:

- *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in their Homes*: Public comments supported continuing OPPS payment for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital through the use of communication technology as a permanent policy post-PHE. CMS will continue to explore how hospital payment for virtual services could support access to care in underserved and/or rural areas.
- *Direct Supervision by Interactive Communications Technology*: 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 created by the PHE. Commenters supported allowing direct supervision of cardiac rehabilitation and pulmonary rehabilitation, and intensive cardiac rehabilitation services through two-way, audio/video communication technology on a permanent basis, or for a period of time following the conclusion of the PHE, such as until the end of 2022. Most commenters supported development of a service-level modifier to track and collect data, but a few commenters stated that it would be unnecessary and burdensome.
- *COVID-19 specimen collection (HCPCS C9803)*: CMS created HCPCS code C9803 for COVID-19 specimen collection to be used only during the COVID-19 PHE and only when no other service is provided by the hospital except a clinical diagnostic laboratory test. CMS plans to retire this code at the conclusion of the PHE. Commenters supported retaining this code permanently for hospitals.

CMS plans to consider the comments on all three topics for possible future rulemaking.

Use of 2019 Claims Data for 2022 Rate-Setting

In general, CMS finalizes its proposed policy, with modification, that the agency will use 2019 claims data for rate setting purposes unless there is a specific reason to selectively use 2020 data. For instance, CMS proposed to use 2020 data for 11 device-intensive procedures because it provides information not available in the 2019 claims data. With the 2020 data, CMS could set a more precise device offset rather than use a 31% default percentage or the one from a clinically similar procedure code. Similarly, CMS is establishing an additional limited exception in this final rule with comment period. If no significant 2019 claims data are available to make an APC assignment, CMS will use 2020 data for this purpose. CMS is finalizing its proposal as modified in response to public comments.

Extending Expiring 2021 Pass-Through Payment for 2022

As noted above CMS used 2019 claims data in establishing the 2022 OPPS rates. As these data will not reflect a full three years of pass-through payment for products with expiring pass-

through payments after 2021, CMS is extending pass-through payment for up to four quarters for these products. CMS proposed a one-time equitable adjustment to continue separate payment for the remainder of 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021, and September 30, 2022.

Extended pass-through applies to one device and 21 drugs — three of which would be packaged after pass-through expires. Extended pass-through payment will be made for between one and four quarters, depending on when the pass-through period expires. Table 52 lists drugs, biologicals, and the device that will receive extended pass-through payment.

Radiation Oncology (RO) Model

Background

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 five years to 4.5 years. However, on December 27, 2020, the CAA prohibited the RO model from beginning before January 1, 2022.

Final RO Model Regulations

CMS is adopting the further delay of the model to begin on January 1, 2022, with a five–year model performance period and a three–year baseline period from January 1, 2017, to 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.

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.

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.

- Brachytherapy from the list of included modalities – CMS believes inclusion could lead to reduced utilization of brachytherapy.

Separately, CMS is adopting its proposal to exclude all Maryland, Vermont, and U.S. 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.

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.

With regard to mergers, acquisitions, or other new business relationships that cause a CMS certification number (CCN) or taxpayer identification number (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 a change in CCN or TIN at least 90 days before the effective date of the change.

The RO Model as an Advanced Alternative Payment Model and Merit Based Incentive Payment System APM

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 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.

Reconciliation Process, Discount Factors, and Quality Reporting

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.

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

Beginning in performance year 1, CMS is finalizing that participants must begin submitting quality measure data. 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.

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. 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.

Extreme and Uncontrollable Circumstances Policy

Lastly, CMS is adopting an extreme and uncontrollable circumstance (EUC) policy that 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.

CMS lists adopted national base rates in Table 75 beginning on page 63925.

Partial Hospitalization Program Services

Partial hospitalization programs (PHPs) are intensive outpatient psychiatric programs that provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding 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 CY 2022 PHP payment rates:

	Final Payment Rate 2021	Proposed Payment Rate 2022	Percent 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%

Due to the COVID-19 PHE, CMS will use a cost floor equal to the per diem cost finalized in CY 2021 for both CHMC- and hospital–based PHPs. CMS is also finalizing its proposal to use CY 2019 claims and cost report data, rather than CY 2020, for rate setting.

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

Finally, CMS reminds providers that under its interim final rule (CMS–1744–IFC), hospital and CMHC staff may 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 for the duration of the COVID-19 PHE. These services can be furnished using telecommunications technology if the beneficiary is registered as outpatient.

Hospital OQR Program

CMS adopts several changes to the OQR Program, including the removal of two measures, the addition of three new measures, and the resumption of reporting for two previously delayed measures. CMS also finalizes updated data validation requirements and to expand applicability of the OQR Program's policy for extraordinary circumstances exceptions (ECE) to electronic clinical quality measures (eCQMs).

CMS makes no changes to previously finalized OQR Program policies for measure selection, retention, and removal, data submission via the CMS web-based tool, population, and sampling requirements, the educational review and correction process for chart-abstracted measures, reconsideration and appeals procedures, public display of quality measures, and requirements for participation in and withdrawal from the OQR Program. A table in the appendix of this summary shows the previously and newly adopted OQR Program measures for payment determinations 2021 through 2026.

Measures for Removal

CMS finalizes its proposal to remove two chart-abstracted OQR measures beginning with the 2023 reporting period: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3). CMS removed these measures due to the addition of a new eCQM measure beginning with 2023 — described in more detail below — that it says is more broadly applicable and less burdensome than the existing measures.

Measure Additions

CMS adopts three new measures for the OQR Program: COVID-19 Vaccination Coverage Among Health Care Personnel, Breast Screening Recall Rates, and ST-Segment Elevation Myocardial Infarction (STEMI) eCQM.

COVID-19 Vaccination Coverage Among Health Care Personnel

CMS adds a new process measure to the hospital OQR Program beginning with the CY 2022 reporting period/CY 2024 payment determination to track the percentage of health care personnel (HCP) who receive a complete COVID-19 vaccination course, calculated as:

> Numerator: The cumulative number of HCP eligible to work in the health care facility for at least one day in the submission period and who received a complete vaccination course against SARS-CoV-2
> Denominator: The cumulative number of HCP eligible to work in the health care facility for at least one day during the submission period, excluding persons with contraindications to COVID-19 vaccination as described by the CDC

> Acute care facilities would count all HCP working in all inpatient or outpatient units that share a hospital's CCN, regardless of a unit's size or type.

CMS establishes an initial data reporting of January 1, 2022, through December 31, 2022, for the CY 2024 payment year. Data submission will be required quarterly, and data will be submitted through the CDC National Health Safety Network (NHSN) web-based surveillance system for at least one week each month; if a hospital reports more than one week per month, the most recent week of data will be used. Full measure specifications are available on the CDC website.

Notably, CMS has finalized the addition of this measure in the inpatient quality reporting program (QRP), skilled-nursing facility QRP, inpatient rehabilitation facility QRP, and inpatient psychiatric hospital QRP beginning with the FFY 2023 payment year.

In response to commenters concerned with reporting burden, CMS adopts two modifications to its proposal. First, the measure results will be publicly displayed in alignment with the requirement finalized for the inpatient QRP. Specifically, only the single most recent quarter's results will be publicly reported. CMS expects to being publicly reporting the measure with the October 2022 *Care Compare* refresh. Second, hospitals will report to CDC using their NHSN identifier (Org ID), and CDC will aggregate the data by CCN for transmission to CMS to be used for public display at the CCN level.

Breast Cancer Screening Recall Rates (OP-39)

CMS adds a new claims-based, facility-level process measure to the Hospital OQR Program beginning with the CY 2023 payment determination to track the percentage of patients who are recalled after traditional mammography or digital breast tomosynthesis (DBT) screening for additional outpatient imaging. The measure would be calculated as:

> Numerator: Beneficiaries who underwent screening mammography or DBT at a facility paid under the OPPS followed by diagnostic mammography, DBT, breast ultrasound, or breast MRI in an outpatient or office setting on the same day or within 45 days of the index image
> Denominator: Medicare FFS beneficiaries who underwent screening mammography or DBT at a facility paid under the OPPS (the index image)

This measure has no exclusions. CMS states that risk adjustment is not required for this process measure and that adjustment for social risk factors could mask potentially important inequities (e.g., variable rates for minority subpopulations). Full measure specifications are available on the CMS QualityNet website.

This claims-based measure does not require additional data submission by facilities. For the initial 2023 reporting period, CMS will use claims from July 1, 2020, to June 30, 2021, excluding data from Q1 and Q2 of 2020. For each subsequent year, the claims data collection period would be from July 1 through June 30, and the period would start on July 1 in the year that is three years prior to the applicable payment CY.

STEMI eCQM

CMS adds a new facility-level, electronic process measure beginning with the 2023 reporting period to track the percentage of emergency department (ED) patients with a diagnosis of STEMI who received timely delivery — absent contraindications — of guideline-based reperfusion therapies appropriate for the care setting. The measure will be calculated as:

> Numerator: All STEMI patients aged 18 years or over who meet any of the following criteria:
> 1) ED-based STEMI patients whose time from ED arrival to fibrinolytic therapy is 30 minutes or fewer; or 2) Non-transfer ED-based STEMI patients who received percutaneous coronary intervention (PCI) at a PCI-capable hospital within 90 minutes of arrival; or 3) ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital
> Denominator: All ED patients aged 18 or older diagnosed with STEMI who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies. Full measure specifications are available on the Electronic Clinical Quality Improvement Resource Center website.

CMS establishes an initial voluntary reporting period beginning in 2023 for the 2025 payment determination. Mandatory submission will be required for the 2024 reporting period/2026 payment determination and subsequent years. During the voluntary reporting period, hospitals can submit data for any self-selected quarter. Once mandatory reporting begins, required data submission will increase annually by one quarter, starting with one self-selected quarter for 2024 and reaching four quarters of full calendar year data reporting for the 2027 reporting period/2029 payment determination and subsequent years.

Modifications to Previously Adopted Measures

CMS modifies reporting requirements for two previously adopted measures: Cataracts, Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536), and Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e).

Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31)

CMS initially adopted OP-31 in the OQR measure set since the 2016 payment determination; however, the measure was subsequently excluded — but not removed — and since 2017 voluntary submissions have been permitted. CMS notes that the measure has been consistently reported voluntarily by some facilities and the data publicly displayed. Therefore, CMS will return the measure to the OQR measure set. However, in a change from the proposed rule, mandatory reporting will begin with the CY 2025 reporting period/CY 2027 payment determination, rather than the CY 2023 reporting period/CY 2025 payment determination. Data will be submitted through a CMS web-based tool according to existing policies for the Hospital Quality Reporting (HQR) System (formerly known as the QualityNet Secure Portal).

Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e)

The OAS CAHPS survey set includes five measures designed to assess a patient's experience with care following a procedure or operation performed in a hospital outpatient department. The set was first adopted into the OQR Program in the 2017 OPPS final rule, for use beginning with the 2020 payment determination. However, CMS delayed implementation to allow time for further accrual of operational experience and implementation data from the National OAS CAHPS voluntary reporting program that began in 2016.

CMS states that results from voluntary reporting have confirmed that patients were able to reliably respond to the survey questions and, therefore, finalizes its proposal to implement the OP 37a-e measure beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination. Mandatory reporting will be required beginning with the CY 2024 reporting period/CY 2026 payment determination. CMS clarifies that hospitals that report voluntarily for 2023 will do so as part of the OQR Program rather than the current national voluntary program.

CMS also finalizes its proposal to add two data collection modes (web-based with either mail or telephone follow-up of non-respondents) beginning with the 2023 reporting period/2025 payment determination and subsequent years to the existing three modes (mail-only, telephone-only, and mixed — mail with telephone follow-up of non-respondents).

Hospitals are required to report through a CMS-approved survey vendor. Data collection must be initiated no later than 21 calendar days after the month in which the procedure or operation occurred and must be completed within 42 days after initial contact of an eligible patient begins. CMS requires that multiple contact attempts must be made unless the patient refuses or the survey vendor learns the patient is ineligible for survey participation. Hospitals that do not qualify for the low-volume exemption must collect survey data monthly and meet the established quarterly deadlines for data reporting to CMS. The low-volume exception applies to hospitals with fewer than 60 survey-eligible patients during the calendar year just prior to the data collection period — hospitals must be approved by CMS following submission of a completed participation exemption request form. Hospitals anticipating more than 300 completed surveys can choose to randomly sample their eligible patients as directed on the OAS CAHPS website.

Electronic Clinical Quality Measure (eCQM) Reporting under the OQR Program

CMS finalizes several requirements for reporting eCQMs under the OQR Program, beginning with the 2023 reporting period/2025 payment determination. OQR eCQM requirements will generally align with those of the hospital Inpatient Quality Reporting (IQR) Program and the Medicare Promoting Interoperability Program for hospitals. Hospitals will:

- Be required to register and submit data through the HQR system
- Be required to complete their eCQM data submission by May 15 in the CY following the close of the program's applicable reporting period (e.g., by May 15, 2024, for 2023), to align with ORR measure submission deadlines. This is a change from the proposed data submission deadline of February 29, which would have aligned with the IQR Program.
- Be required to use CEHRT updated to the 2015 Edition Cures update

- Be required to submit their eCQM data formatted according to the Quality Reporting Document Architecture Category I (QRDA I) content exchange standard
    - Hospitals may use chart abstraction of data or pull data from non-certified sources for entry into CEHRT and subsequent QRDA I file reporting.
    - Files would reflect data for one patient per file per quarter and contain all required identifiers, including hospital CCN.
    - Hospitals may engage third parties to submit data on their behalf.

CMS finalizes policies for two low-data-volume scenarios: 1) when a hospital has no data to report for a specific eCQM (zero denominator declaration); and 2) when a hospital does not meet the case threshold of discharges for a specific eCQM (case threshold exemption). When a hospital has zero patients meeting the denominator criteria of a given eCQM, the hospital can submit a zero denominator for the measure. A zero-denominator declaration counts as a successful submission for that eCQM. When a hospital has 1) reportable patients but not enough to satisfy a measure's denominator threshold criterion (case minimum) and 2) the hospital has five or fewer outpatient all-payer discharges to which the measure is applicable for the reporting quarter (or 20 or fewer for the year), the hospital may declare a case threshold exemption from reporting for that eCQM.

CMS also finalizes a new review and corrections period for eCQM data that will run concurrently with the data submission period. From the time the HQR system opens for QRDA I file submission until the submission deadline, hospitals will be able to run pre-submission test files as well as submit and review their actual data files and make corrections.

In addition, CMS expands the OQR Program's extraordinary circumstances exception (ECE) policy to cover eCQMs. Hospitals will be allowed to request hardship exceptions (e.g., due to insufficient internet access, health IT vendor loss of certification) under the ECE policy from required eCQM reporting for the 2024 reporting period and subsequent years. An exception must be requested by April 1 following the end of the reporting CY in which the hardship occurred (e.g., April 1, 2025, for 2024 hardships).

Hospital OQR Program Validation Requirements

CMS finalizes several changes to the OQR data validation process beginning with the 2022 reporting period/2024 payment to further align the OQR Program with the hospital IQR Program.

CMS discontinues the option for hospitals to transmit medical records for validation to the CMS Clinical Data Abstraction Center (CDAC) as paper copies or on CDs, DVDs, or flash drives. Only direct electronic submission of records stored as PDF files via a CMS-approved, CDAC-directed, secure file transmission process is permitted.

CMS also reduces the time for hospitals to submit records for validation to the CDAC contractor from 45 to 30 calendar days. Finally, CMS adds to the following additional targeting criteria used to select hospitals for validation: 1) not having been randomly selected for validation in any of the previous three years, and 2) having passed validation in the previous year with a two-tailed confidence interval that included 75%. The latter criterion identifies hospitals whose accuracy falls within the statistical margin of error and captures both passing and failing facilities.

Updates to Hospital Price Transparency Requirements

CMS finalizes several updates to its Hospital Price Transparency requirements. Specifically, CMS increases civil monetary penalties (CMPs) for noncompliance with price transparency requirements and prohibits certain conduct that the agency believes is a barrier to accessing the standard charge information. In addition, CMS will deem state forensic hospitals to have met the price transparency requirements.

Increasing CMPs

CMS provides an overview of the current process for enforcement of the hospital price transparency requirements, including issuance of a written warning notice to the hospital of the specific violation, submission of a corrective action plan from the hospital, and imposition of CMPs not to exceed $300 per day on the hospital if the hospital fails to provide or comply with its corrective action plan.

In response to what CMS deems as high rates of noncompliance with the requirements — which were effective January 1, 2021 — CMS finalizes its proposal to increase the maximum CMP using a scaling factor to establish the CMP amount for a non-compliant hospital. CMS will use the non-compliant hospital's number of beds as specified in hospital cost report data as the scaling factor to establish CMP amounts.

CMS establishes the following per-day CMPs for non-compliant hospitals:

- Non-compliant hospitals with 30 or fewer beds would have a maximum daily penalty of $300 *(maximum annual penalty of $109,500/hospital)*.
- Non-compliant hospitals with 31 to 550 beds would have a maximum daily penalty calculated as the number of beds times $10 *(maximum annual penalty of $113,150-$2,007,500/hospital)*.
- Non-compliant hospitals with more than 550 beds would have a maximum daily penalty of $5,500 *(maximum annual penalty of $2,007,500/hospital)*.

If the number of beds for the hospital cannot be determined using the Medicare cost report (for example, for hospitals that do not participate in Medicare), CMS will use documentation provided by the hospital. CMS will assess an additional CMP at the highest daily maximum amount for failure to provide documentation on the number beds. The above amounts will be adjusted annually beginning in 2023, using the multiplier determined by the Office of Management and Budget, for adjusting CMPs.

Prohibiting Barriers to Accessing Machine-Readable Files

The hospital price transparency final rule requires hospitals to post to their website a machine-readable file that includes all standard charges (including gross charges, discounted cash prices, payer-specific negotiated rates defined as charges in the final rule, and de-identified minimum and maximum negotiated rates) for all hospital items and services. CMS also required that the standard charge information must be displayed prominently and clearly identify the hospital location with which it is associated. It must also be easily accessible and without barriers — including but not limited to being free of charge, without having to establish a user account or password, and without having to submit personal identifying information — and contained in a digital file, within which the standard charge information is digitally searchable.

CMS says that its review of hospital compliance has shown that hospitals have taken a number of actions that create barriers to accessing price transparency information. CMS provides the following examples of such barriers:

- Employing anti-automation tools such as form submission, or other technological devices that place a "locked door" in front of the content
- Requiring users to pass tests proving they are human users (for example, requiring the user to identify images that contain certain objects, such as vehicles, trees, or street signs)
- Requiring the user to agree to all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded
- Developing file constructs and web forms that obscure access to the data in a single machine-readable file through the use of Application Programming Interfaces

To address its concerns, CMS finalizes its proposal to specify that the hospital must ensure that the standard charge information is easily accessible, without barriers, including but not limited to the examples provided above. The additional requirement will prohibit practices CMS has encountered in compliance reviews, such as lack of a link for downloading a single machine-readable file, using "blocking codes," and requiring the user to agree to terms and conditions or submit other information prior to access. CMS notes that while the above are examples of prohibited practices, they are not intended to be an exhaustive list.

State Forensic Hospitals

Hospital price transparency requirements are not applicable to hospitals owned and operated by the Indian Health Service, Department of Veterans Affairs and Department of Defense. CMS finalizes its proposal to also exempt "state forensic hospitals" from the price transparency requirements, because these types of hospitals do not treat the general public, and their rates are not subject to negotiations. State forensic hospitals are public psychiatric hospitals that exclusively provide treatment for individuals who are in the custody of penal authorities. There are approximately 111 such institutions.

Price Estimator Tools

Hospitals can meet the requirement to make available price information for "shoppable services" by offering an internet-based price estimator tool. Citing language in the preamble of the hospital price transparency final rule, CMS clarifies that to satisfy the requirements using a price estimator tool, the tool must be "tailored to individuals' circumstances (whether an individual is paying out of pocket or using insurance) and provide real-time individualized out-of-pocket estimates that combine hospital standard charge information with the individual's benefit information directly from the insurer, or provide the self-pay amount, and cannot be an average or price range for the service, based on a broad population of patients.

In response to stakeholder feedback to the proposed rule, CMS adopted additional clarifications including allowing hospitals to include detailed disclaimers acknowledging the limitation of the estimation and advising the patient to consult with their health insurer to confirm individual payment responsibilities. CMS will also permit tools that allow individuals to manually input their insurance information, and further clarifies that price estimator tools can use prior reimbursement or claims data to develop patient cost estimates.

Finally, CMS notes that in the future there may be an opportunity to align requirements for a consumer-friendly display of standard charges with the similar requirements of the Transparency in Coverage regulations and implementation of the No Surprises Act.

Additional Requests for Comment

In the proposed rule, CMS sought comments on several topics to inform future policies, including improving price estimator tools, the definition of "plain language" to describe shoppable services, standardization of the machine-readable file, and how to highlight hospital best practices in complying with the requirements. CMS noted that it received approximately 396 comments but did not summarize or respond to these comments.

Appendix – Hospital Outpatient Quality Reporting Program Measures Table

SUMMARY TABLE OF HOSPITAL OQR PROGRAM MEASURES Payment Determination for 2021-2026							
NQF		**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	Removed	
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	Removed	
0289+	OP-5: Median Time to ECG	Removed					
0514+	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X	X
	OP-9: Mammography Follow-up Rates	Removed					
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	Removed					
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	Removed					
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Removed					
0491+	OP-17: Tracking Clinical Results between Visits	Removed					
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X	X
0499+	OP-22: ED- Left Without Being Seen	X	X	X	X	X	X
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X	X
0658	OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Removed					
1536+	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery					Delayed to 2027	Delayed to 2027
2539	OP-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X	X

	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	X	X	X	X	X	X
2687	OP-36: Hospital Visits After Hospital Outpatient Surgery	X	X	X	X	X	X
	OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures					Voluntary	X
	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)				X	X	X
	OP-39: Breast Cancer Screening Recall Rates			X	X	X	X
	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM					Voluntary	X

+ CMS notes that NQF endorsement for the measure has been removed.