

Calendar Year 2022 Hospital Outpatient Prospective Payment System Proposed Rule

On July 19th, 2021 the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2020 Hospital Outpatient Prospective Payment System (HOPPS) [proposed rule](#). This rule provides for a 60-day comment period ending on September 17th, 2021. The finalized changes are effective January 1, 2022.

Conversion Factor Update

CMS proposes to increase the conversion factor by 2.3 percent bringing it up to \$ 83.697 for CY 2022. This increase is based on the proposed hospital inpatient market basket percentage increase of 2.5 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.2 percentage point. CMS proposes further to adjust the conversion factor for to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. CMS proposes to calculate an overall budget neutrality factor of 1.0012 for wage index changes by comparing proposed total estimated payments from simulation model using the proposed FY 2022 IPPS wage indexes to those payments using the FY 2021 IPPS wage indexes, as adopted on a calendar year basis for the HOPPS. CMS proposes to maintain the current rural adjustment policy, and therefore proposes the budget neutrality factor for the rural adjustment to be 1.0000.

CMS proposes that hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Reporting (OQR) Program would be subject to a further reduction of 2.0 percentage points. Hospitals that fail meet the requirements would result in a conversion factor for CY 2021 of \$ 82.0650.

Due to COVID-19 PHE effects on outpatient service utilization in CY 2020, CMS proposes to utilize CY 2019 data to set CY 2022 OPSS and ASC payment rates.

Estimated Impact on Hospitals

CMS estimates that OPSS expenditures, including beneficiary cost-sharing will be approximately \$82.704 billion, which is approximately \$10.757 billion higher than estimated OPSS expenditures in 2021.

PROPOSED AMBULATORY PAYMENT CLASSIFICATION GROUP POLICIES

Imaging APCs

CMS does not propose any new changes to the APC structure for imaging codes. The seven payment categories remain. However, CMS has moved codes within these payment categories of which would cause changed pricing for 2022. CMS is making reassignments to the codes within the series to resolve and/or prevent any violations of the two times rule.

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Proposed CY 2022 Imaging APCs

APC	Group Title	SI	Relative Weight	CY 2021 Payment Rate	CY 2022 Proposed Payment Rate
5521	Level 1 Imaging without Contrast	S*	0.9829	\$80.90	\$83.01
5522	Level 2 Imaging without Contrast	S	1.3229	\$108.97	\$111.73
5523	Level 3 Imaging without Contrast	S	2.7960	\$230.13	\$236.14
5524	Level 4 Imaging without Contrast	S	5.8700	\$482.89	\$495.76
5571	Level 1 Imaging with Contrast	S	2.1703	\$178.55	\$183.30
5572	Level 2 Imaging with Contrast	S	4.4733	\$368.12	\$377.80
5573	Level 3 Imaging with Contrast	S	8.6880	\$715.18	\$733.76

*Procedure or Service, Not Discounted When Multiple; Paid under OPSS; separate APC payment.

Proposed APC Exceptions to the 2 Times Rule

CMS proposes exceptions to the 2-times rule based on the following criteria: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for up-coding and code fragments.

For 2022, CMS notes that in many cases, the proposed procedure code reassignments and associated APC configurations for 2022 are related to changes in costs of services that were observed in the 2019 claims data. Table 8, found below, lists the 23 APCs that CMS proposes to exempt from the 2 times rule for 2022 based on claims data from January 1, 2019, through December 31, 2019 and processed on or before June 30, 2020.

Table 8. Proposed APC Exceptions to the 2 Times Rule for 2022

2022 APC	APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast



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5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

Comprehensive APCs

For CY 2022, CMS does not propose the creation of any new comprehensive APCs (C-APCs). Thus, CMS proposes that the number of C-APCs for CY 2022 would be the same as the number for CY 2021, which is 69 C-APCs. Table 1. In the proposed rule details all 69 C-APCs.

Changes to New-Technology APCs

Proposed Changes to MRgFUS

There are currently four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which CMS proposes to continue to assign to standard APCs, and one that CMS proposes to continue to assign to a New Technology APC for CY 2022. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. Based on available 2019 claims data, CMS has identified 169 paid claims for CPT code 0398T (MRgFUS for treatment of essential tremors) with a geometric mean of \$12096.01. CMS proposes to place CPT code 0398T into APC 5463 with a payment rate of \$11,534.07.

Proposed CY 2022 Status Indicator (SI), APC Assignment, And Payment Rate for the MRgFUS Procedures

CPT/HCPCS Code	Long Descriptor	CY 2020 OPSS SI	CY 2020 OPSS APC	CY 2020 OPSS Payment Rate	Proposed CY 2021 OPSS SI	Proposed CY 2021 OPSS APC	Proposed CY 2021 OPSS Payment Rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1*	5414	\$ 2,623.21	J1	5414	\$2,6913.83

0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	\$ 2,623.21	J1	5414	\$2,6913.83
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S**	1575	\$11,236.21	J1	5463	\$11,534.07
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	\$12,314.76	J1	5115	\$12,630.52

*Hospital Part B Services Paid Through a Comprehensive APC; aid under OPSS; all covered Part B services on the claim are packaged with the primary "J1" service for the claim, except services with OPSS status indicator of "F","G", "H", "L" and "U"; ambulance services; diagnostic and screening mammography; rehabilitation therapy services; new technology services; self-administered drugs; all preventive services; and certain Part B inpatient services.

** Procedure or Service, Not Discounted When Multiple; Paid under OPSS; separate APC payment.

Fractional Flow Reserve Derived from Computed Tomography (FFRCT)

FFRC is a noninvasive diagnostic service that measures coronary artery disease by CT scans with CPT code 0503T. Although payment for analytics performed after the main diagnostic imaging procedures are packaged into the payment for the primary procedure, CMS determined in 2018 that CPT code 0503T should receive a separate payment because the procedure is performed by a separate entity. For 2021, CMS identified 3,188 claims with 465 single frequency claims. Using its standard methodology, CMS determined a geometric mean cost of \$804.35 and proposed to assign CPT code 0503T to New Technology



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APC 1510 (New Technology Level 10 (\$801- \$900) with a proposed payment rate of \$850.50. Based on comments from providers and other stakeholders indicating that the FFRCT service costs \$1,100 and the need for providers to learn how to bill for artificial intelligence services, CMS assigned CPT code 0503T to New Technology APC 1511 (New Technology – Level 11 (\$901-\$1000). For 2022, CMS proposes to continue to assign CPT code 0503T to New Technology APC 1511 (New Technology – Level 11 (\$901-\$1000), with a payment rate of \$950.50.

Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, CMS assigned three CPT codes (78431- 78433) describing services associated with cardiac PET/CT studies to New Technology APCs (APCs 1522, 1523, and 1523, respectively). For 2021, CMS did not receive any claims with these CPT codes and continued to maintain the 2020 assignment for 2021.

Brachtherapy

Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS proposes no changes to their brachytherapy policy for 2021.

CT and MR Cost Centers

In the 2020 OPPS final rule, CMS adopted a policy to apply 50 percent of the payment impact from ending the transition in 2020 and 100 percent of the payment impact from ending the transition in 2021. For 2020, CMS calculated the imaging payment rates based on 50 percent of the transition methodology (excluding square feet CCRs) and 50 percent of the standard methodology (including square feet CCRs). For 2021, CMS proposed to set the imaging APC payment rates at 100 percent of the payment rate using the standard payment methodology under the policy it adopted in the 2020 OPPS final rule. CMS is not proposing any further changes for 2022 and will continue to set imaging APC payment using the standard payment methodology.

CT Lung Cancer Screening

In the CY 2022 HOPPS Proposed Rule, CMS proposes to placing 71271 (Low Dose CT for Lung Cancer Screening) in the lowest Imaging without Contrast APC (5521), with payment rate of \$83.01. In addition, CMS proposes to place G0296 (visit to determine lung LDCT eligibility) in APC 5822, with a payment rate of \$76.73. The ACR has raised concerns about the inadequate payments for CT lung screening based on flawed hospital data in the past comment letters to CMS.

Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: packaged into the payment for the associated service or separate payment (individual APCs). Hospitals do not receive a separate payment for packaged items and may not bill beneficiaries separately for any packaged items; these costs are recognized and paid within the OPPS payment rate for the associated procedure or service.



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Threshold-packaged drugs under the OPSS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug’s average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2022, CMS proposes a packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status of \$130.

Payment Policy for Therapeutic Radiopharmaceuticals

CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS also proposes to determine 2022 payment rates based on 2019 geometric mean unit costs.

Other HOPPS Payment Policies

Proposed Payment Adjustments to Cancer Hospitals

The ACA requires an adjustment to cancer hospitals’ outpatient payments to bring each hospital’s payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals, the target PCR. The changes in additional payments from year to year are budget neutral. The 21st Century Cures Act reduced the target PCR by 1.0 percentage point and excludes the reduction from OPSS budget neutrality. The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis. For 2021, CMS updated its calculations using the latest available cost data at the time of publication of the 2021 OPSS final rule and determined a target PCR of 0.90. CMS reduced the target PCR from 0.90 to 0.89. Consistent with other policies to not use cost report data that span the COVID-19 PHE, CMS proposes to continue using the same cost data to determine the target PCR for 2022 that it used for 2021. Therefore, CMS proposes a target PCR of 0.90 reduced by 1.0 percentage point to 0.89.

Table 4 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPSS payments for 2022 ranging from 9.9 percent to 51.4 percent. No additional budget neutrality adjustment is required for the cancer hospital adjustment in 2022 compared to 2021.

Table 4. The Estimated Percentage Increase in OPSS Payments to Each Cancer Hospital for CY 2022, Due to The Cancer Hospital Payment Adjustment Policy

Provider Number	Hospital Name	Estimated Percentage Increase in OPSS Payments for CY 2020 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	31.3%
050660	USC Norris Cancer Hospital	9.9%
100079	Sylvester Comprehensive Cancer Center	16.5%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.8%
220162	Dana-Farber Cancer Institute	34.3%



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330154	Memorial Sloan-Kettering Cancer Center	38.1%
330354	Roswell Park Cancer Institute	14.0%
360242	James Cancer Hospital & Solove Research Institute	16.4%
390196	Fox Chase Cancer Center	11.2%
450076	M.D. Anderson Cancer Center	51.4%
500138	Seattle Cancer Care Alliance	46.5%

Proposed Measure Changes within the Hospital OQR Program

Proposed Removals Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination (p. 523)

CMS proposes to remove OP-2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention) and replace them with the proposed STEMI eCQM. O OP-2 and OP-3 measure the proportion of eligible STEMI patients who receive timely fibrinolytic therapy and timely transfer from an ED to another facility to receive appropriate care, respectively. They are manually reported using chart abstraction, which adds burden to the reporting entity. Removal of these measures is contingent on the finalization of the STEMI eCQM.

Proposals to Adopt New Measures for the Hospital OQR Program (p.525)

CMS proposes to adopt three new measures: COVID-19 Vaccination Coverage Among Health Care Personnel, Breast Screening Recall Rates, and STEMI eCQM.

COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) (p. 526)

Due to the public health emergency (PHE) COVID-19, CMS proposes to adopt a vaccination measure among HCP starting in the CY 2022 reporting period. Ongoing research has shown that fully vaccinated people without immunocompromising conditions have a very low risk of acquiring or transmitting COVID. Personal protective equipment (PPE) does reduce the likelihood of transmission, but COVID can still spread between HCP and patients during treatment, especially in long-term care (LTC) settings. Implementing this measure will help the CDC to track COVID-19 vaccination coverage among HCP in non-LTC facilities, including outpatient hospitals.

The measure was reviewed in early January by the National Quality Forum (NQF) Measures Application Partnership (MAP) Hospital Workgroup. While the workgroup did agree that this measure would bring value to the Hospital OQR program by providing transparency about the PHE and reducing infections, they did not support this measure for rulemaking, subject to the potential for mitigation. The workgroup wanted to see more evidence, finalized specifications, testing and NQF endorsement prior to supporting the measure. The measure was then reviewed by the NQF MAP Coordinating Committee in late January, which provided conditional support for rulemaking contingent on CMS resubmitting the measure to the MAP once the specifications were further refined. CMS provided preliminary testing information to the MAP in March and the MAP moved forward with their conditional support for rulemaking.



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Breast Screening Recall Rates (p. 537)

CMS proposes to adopt the Breast Screening Recall Rates measure beginning in the CY 2022 reporting period. This new measure would fill the gap that was left in the Hospital OQR Program measure portfolio with the removal of the Mammography Follow Up Rates measure (OP-9), which did not address digital breast tomography (DBT). The proposed Breast Screening Recall Rates measure would calculate the percentage of Medicare fee-for-service (FFS) beneficiaries from claims at the facility level for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting on the same day or within 45 days of the index image. There are no exclusions for this measure, and it is not risk-adjusted. The goal for this measure is a recall rate between 5-12 percent, as a high cumulative dose of low-energy radiation could signify high false-positives, and a significantly low recall rate could lead to delayed or undetected cases of cancer. The proposed recall rate range is not based on specific clinical guidelines but does use peer-reviewed consensus documents, including the ACR BI-RADS Manual 2013, that support the importance of appropriate recall rates.

The measure was reviewed in December 2020 and January 2021 by three NQF MAP workgroups: Rural Health, Hospital and Coordinating Committee. Some of the feedback included concerns on using a range (as opposed to a targeted value) which may be difficult for users to interpret, using consensus documents as the basis for the measure rather than clinical practice guidelines, not addressing social determinants of health, and not providing patient outcome information. All three groups voted to conditionally support the measure, pending NQF endorsement.

ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (p. 545)

CMS proposes to adopt the STEMI eCQM beginning with the CY 2024 reporting period. This eCQM measures the percentage of ED patients with a diagnosis of STEMI who received timely delivery of guideline-based reperfusion therapies appropriate for the care setting and delivered in the absence of contraindications. This measure would replace OP-2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention), which are manually chart-abstracted. The proposed STEMI eCQM would broaden the group of measured STEMI patients and better supports compliance with the full group of patients covered in the 2013 ACCF and AHA guidelines for the management of STEMI by measuring timeliness and appropriateness of care for STEMI patients in the ED. This measure would also assist the transition towards the use of EHR data in the HOQR program.

In January 2021, the STEMI eCQM was reviewed by the MAP's Rural Health Workgroup, Hospital Workgroup, and the Coordinating Committee. All three groups voted to conditionally support the measure, pending NQF endorsement.

Previously Finalized Measures in the Hospital OQR Program (p. 558)

The following table depicts the previously finalized measures in the HOQR program that are related to imaging:

Table 46: Hospital OQR Program Measure Set for the CY 2023 and Subsequent Years Payment Determination Related to Imaging

Number	Measure Name
OP-8	MRI Lumbar Spine for Low Back Pain
OP-10	Abdomen CT – Use of Contrast Material
OP-13	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
OP-18	Median Time from ED Arrival to ED Departure for Discharged ED Patients
OP-23	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
<i>None</i>	Breast Screening Recall Rates** <i>** if finalized, an OP/measure number will be assigned for this measure in the Final Rule.</i>

Hospital OQR Program Measures and Topics for Future Considerations (p. 561)

Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program (p. 565)

Consistent with the executive order on Advancing Racial Equity and Support for Underserved Communities through the Federal Government, in conjunction with the CMS Quality Strategy and Meaningful Measures Framework, CMS invites stakeholder comments regarding achieving health equity for all patients by implementing new health equity-focused policies.

The proposed rule states that "Significant and persistent inequities in health care outcomes exist in the United States." And that "belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area, or being near or below the poverty level" is associated with worse health outcomes. Unfortunately, the COVID-19 pandemic highlights many of these longstanding health inequities with higher infection rates, hospitalization, and mortality among Black, Latino, and Indigenous and Native American individuals relative to their white counterparts. Although different factors result in disparate health outcomes, CMS cites that limited access to high-quality care is a significant contributor. Therefore, CMS proposes improving data collection of the elements influencing inequities within their quality programs. CMS perceives that this would present opportunities for providers to receive the resources necessary to improve their care quality.

In the proposed rule, CMS mentions multiple ongoing efforts to close the health equity gap among its programs. Including transparency of health disparities, supporting providers and others with evidence-informed solutions to address social determinants of health for achieving health equity, and reporting to providers on gaps in the quality of the program in which they participate. In the proposed rule, CMS seeks feedback on incorporating the CMS Disparity Methods into the Hospital Outpatient Quality Reporting (Hospital OQR) program. These methods comprise two types of analyses, the Within-Hospital disparity method and the Across-Hospital method. Both stratify quality measure data by dual eligibility status (a demonstrated predictor of poor health outcomes) and illustrate variations in outcome rates among patient groups within a provider's patient population. However, each method's analysis renders different results informing how providers may improve their disparity gaps.

The Within-Hospital disparity method allows hospitals to make disparity size comparisons against other hospitals. In contrast, the Across-Hospital Method provides information on a hospital's performance when treating patients with certain social risk factors. Until CMS identifies specific factors for delivering the most valuable information to stakeholders, dual eligibility status is the proxy for social risk. CMS requests comments regarding exploring additional social risk factors, evaluating new sources of social risk factor data (and how to capture it), and examining the feasibility of social risk factors to influence outcome measures. They also request feedback on using dual eligibility designation as a proxy for social risk when publicly reporting on CMS' Care Compare website.

As part of their goal to achieve health equity across programs, CMS proposes bolstering the CMS Disparity Methods to consist of the following six Hospital OQR program quality measures.

- MRI Lumbar Spine for Low Back Pain (OP-8)
- Abdomen CT – Use of Contrast Material (OP-10)
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery (OP-13)
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32)
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35)
- Hospital Visits after Hospital Outpatient Surgery (OP-36).

CMS proposes expanding the CMS Disparity Methods to include two social risk factors (dual eligibility and race/ethnicity). CMS perceives that broadening the comprehensiveness of health equity information provided to facilities would improve the care delivered by providers. CMS requests comments on aggregating equity results of the six measures proposed to assess social risk factors to calculate a summary score. CMS identifies that this type of feedback could enhance the usefulness of the confidential equity results. Comments are sought regarding the confidential equity results tabulated from reporting the six measures (or other potential future measures), stratified by dual eligibility status.

CMS also seeks comment on the utilization of two indirect estimation algorithms for approximating, at the population level (e.g., hospital or health plan-level), the race and ethnicity of Medicare beneficiaries. The

proposed rule describes that indirect estimation relies on statistical analysis for inferring missing variables using a related set of readily available information. CMS notes that barriers to immediately collecting Medicare beneficiaries' demographic information in a low burden and standardized way, CMS proposes that indirect estimation serves as the temporary method for identifying race and ethnicity populations.

Administrative Requirements (p. 578)

While there are no proposed changes to the rules regarding the security official who is responsible for the security and account management requirements for the hospital's QualityNet account, CMS does wish to clarify in this proposed rule that failure to maintain an active QualityNet security official will result in a finding that the hospital did not successfully participate in the Hospital OQR Program.

Claims-Based Measure Data Requirements for CY2024 Payment Determination and Subsequent Years (p. 582)

There are no proposed changes to the claims-based measure requirements. The following claims-based measures are required for CY2023 and subsequent years:

- OP-8: MRI Lumbar Spine for Low Back Pain (NQF #0514)
- OP-10: Abdomen CT – Use of Contrast Material
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669)
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539)
- OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
- OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687); and Breast Screening Recall Rates

Proposed eCQM Reporting and Submission Requirements (p. 591)

CMS has stated in previous rules that they intend to include electronic clinical quality measures (eCQMs) in the Hospital OQR Program. As previously stated, CMS proposed to adopt the STEMI eCQM measure beginning in CY2023. In this proposed rule, CMS suggested a progressive increase in the number of quarters for which hospitals will be required to report eCQM data.

For 2023, CMS proposes a voluntary submission period in which hospitals submitting STEMI eCQM data report any quarter(s) of data. For 2024, CMS proposes to require that hospitals report one self-selected calendar quarter of data. This pattern will continue with two quarters required in 2025, three in 2026, and finally all four quarters required in 2027. CMS requests comments related to this proposal.

Inpatient Only List

The IPO list was created based on the premise that Medicare should not pay for procedures furnished as outpatient services that are not reasonable and necessary to be performed in any other setting than inpatient.



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For CY 2022, CMS proposes to stop the elimination of the inpatient only (IPO) list after finalizing policy in CY 2021 to fully eliminate the list. After clinical review of the services removed from the IPO list in CY 2021, CMS proposes to add the 298 services removed from the IPO list.

In addition, CMS is soliciting comments on several policy modifications including whether CMS should maintain the longer-term objective of eliminating the IPO list or maintain the IPO list but continue to systemically scale the list back so that inpatient only designations are consistent with current standards of practice.

Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Medicare pays 100 percent of the payment amount for certain colorectal cancer screening tests that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. Thus, a beneficiary pays no cost-sharing for these screening tests.

When the colorectal cancer screening test benefit category was enacted into law, the statute specifically provided that if, during the course of a screening flexible sigmoidoscopy or screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but rather shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. The result was that beneficiaries faced unexpected coinsurance charges because the procedure was classified as a diagnostic test instead of a preventive service screening test.

Section 4104 of the ACA addressed this issue with respect to the deductible but not for any coinsurance that may apply. Section 122 of the CAA addresses this issue for the coinsurance by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible so that for services furnished on or after January 1, 2030, the coinsurance will be zero. The phased-in increases in the amount the Medicare program pays for these services on or after January 1, 2022 are as follows:

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

Comment Solicitation on Temporary COVID-19 Policies

In response to the COVID-19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement a number of temporary policies to address the pandemic, including policies to prevent spread of the infection and support diagnosis of COVID-19. CMS is seeking comment on whether any of the temporary policies described below should be made permanent.

Direct Supervision by Interactive Communications Technology

During the PHE, CMS waived the requirement for direct supervision to be provided through the physical presence of a physician or non-physician practitioner for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. CMS seeks comment on:

- Whether and to what extent hospitals have relied upon this flexibility during the PHE.
- Whether providers expect this flexibility would be beneficial outside of the PHE.
- Whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.
- Whether a service-level modifier should be required to identify when the requirements for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were met using audio/video real-time communications technology.

Request for Information on Rural Emergency Hospitals (REHs)

Section 125 of the CAA of 2021 establishes rural emergency hospitals (REHs) as a new Medicare provider type that will furnish emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week. In addition, an REH may elect to furnish other medical and health services on an outpatient basis as the Secretary may specify through rulemaking. REHs may not provide acute care inpatient services, except for skilled nursing facility services that are furnished in a distinct part unit. CMS seeks public comments through this RFI to inform its policy making.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs – Request for Information (p.504)

As released in the Hospital Inpatient Quality Reporting Program and Quality Payment Program proposed updates for calendar year (CY) 2022, CMS seeks stakeholder input through a formal Request for Information (RFI) on the transition of digital quality measurement (dQM) across Medicare quality performance programs by 2025. To maintain the alignment and harmonization outlined in the 2020 Department of Health and Human Services (HHS) Health Quality Roadmap, CMS is approaching HHS' priorities with other federal entities, like the Office of the National Coordinator on Health Information Technology (i.e., 21st Century Cures Act), to promote data interoperability and access.

The five-part RFI seeks comments on the following:

- CMS acknowledges that reporting quality measurement data through electronic health records (EHR) imposes burden on those reporting. Data sources have evolved since the start of CMS quality programs. For instance, sources like administrative systems and electronically submitted clinical assessment data do not provide robust enough data required by emerging quality measures. CMS has shifted its measurement priorities from assessing clinical processes to clinical outcomes and patient-reported outcomes. Therefore, CMS proposes that quality measures should integrate with data sources capable of capturing this level of information.

- In this proposed rule, CMS defines dQMs as measures with “sources of health information that are captured and can be transmitted electronically and via interoperable systems.” For instance, in addition to administrative system and electronically submitted clinical assessment data, dQMs may also source information from case management systems, medical and wearable devices, as well as patient portal applications collecting patient-generated health data, health information exchanges (HIEs), or registries, to name a few. dQM elements must be standardized and interoperable among the different data sources to capture data from various digital sources. CMS is working with the free open source FHIR Framework (<http://hl7.org/fhir>) to capture electronic clinical quality measures (eCQMs). As described in the proposed rule, the FHIR Framework, which establishes a common language and process for all health information technology, would inform the dQM structure and data submission for CMS’ quality reporting programs. Given the potential adoption of FHIR and its standardized language, CMS is seeking comment on aligning quality measurement data with interoperability requirements. Comments are also sought on approaches that could support the inclusion of non-standardized data.
- To attain CMS’ modernized vision of quality measurement, this RFI seeks input on the potential redesign of CMS programs’ measures. Should the FHIR Framework be adopted into CMS quality programs, quality measures functionality may expand. For instance, CMS is considering defining and developing dQM software that could incorporate end-to-end measure calculation solutions utilizing data from FHIR-based resources (maintained by providers, payers, CMS, etc.) to calculate measure scores and generate reports.
- CMS is also considering a pathway to data aggregation as a method of supporting quality measurement. In other words, by implementing dQMs with their associated multiple data sources, data fragmentation would decline. Information stored in different locations would become accessible for meeting the criteria of a particular quality measure, thereby establishing a measurement-focused patient-centered care narrative. As stated in the proposed rule, ok
- In concordance with the HHS 2020 Quality Roadmap, CMS is attempting to align quality measure reporting programs across federal and state agencies and private payers by adopting a dQM portfolio that meets programmatic requirements across agencies. Such alignment would leverage existing HHS initiatives, like the CMS Meaningful Measures Framework 2.0.

Please see the entire solicitation of comments on advancing to dQM and the use of FHIR on page 518 of this proposed rule.

Radiation Oncology Model (page 677)

Background

Under the Radiation Oncology (RO) Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical radiation therapy (RT) services furnished during a 90-day episode to Medicare fee-for service (FFS) beneficiaries diagnosed with certain cancer types. The RO Model will be mandatory and encompass 30% of all eligible RO episodes, including 950 physician group practices (PGPs), hospital outpatient departments (HOPDs), and freestanding



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radiation therapy centers in 204 core-based statistical areas (CBSAs). In the Specialty Care Models final rule published in September 2020, CMS expected savings of \$230 million from the RO Model. However, in this proposed rule, CMS expects savings will be reduced to \$160 million due to proposed changes to the model including: the removal of brachytherapy, the removal of liver cancer, and revised performance period and baseline periods.

The Consolidated Appropriations Act (CAA), 2021, included a provision that prohibits implementation of the RO Model before January 1, 2022. In this rule, CMS proposes provisions related to the additional delayed implementation of the RO Model due to the CAA, 2021, as well as modifications to certain RO Model policies not related to the delay.

Performance Period

CMS proposes to modify the RO Model performance period to January 1, 2022 through December 31, 2026. CMS is also proposing that each performance period will be a 12-month period, unless the initial model performance period starts mid-year, in which case performance year (PY) 1 will begin on that date and end on December 31 of that year.

CMS proposes to add a definition for “baseline period” specifying which episodes are used in the pricing methodology. The baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in 2022. CMS proposes to modify the definition of “model performance period” to mean the five PYs during which RO episodes must initiate and terminate.

Participant Exclusions

CMS proposes to exclude from the RO Model only the HOPDs that are participating in the Pennsylvania Rural Health Model (PARHM), rather than excluding both HOPDs in the PARHM and those that are eligible to participate in the PARHM. CMS is also proposing that the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model is excluded from the RO Model.

In prior rulemaking, CMS finalized that a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model, may choose to opt out if it has fewer than 20 episodes of RT services across all CBSAs selected. CMS clarified that the dates of data used to determine eligibility for low volume opt-out are the most recent year with claims data available, which is 2 years prior to the PY. At least 30 days prior to the PY start date, CMS will notify RO participants eligible for the low volume opt-out. CMS proposes that an entity would not be eligible for low volume opt-out if its legacy Taxpayer Identification Number (TIN) or legacy CMS Certification Number (CCN) was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation. CMS proposes that a legacy CCN means a CCN that an RO participant that is a HOPD, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses. CMS proposes that a legacy TIN means a TIN that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses. CMS proposes this change to remove any



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incentive for RO participants to change their TIN or CCN in an effort to become eligible for the low volume opt-out.

Changes to RO Model Episodes

CMS proposes to amend the criteria to include cancer types in the RO Model, so that: a cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; associated with current ICD-10 codes that have demonstrated pricing stability, which is determined by analyzing interquartile ranges of the episode prices across cancer types; and the Secretary must not have determined the cancer type is not suitable for inclusion in the RO Model. As a result of the proposed amended criteria, CMS proposes to remove liver cancer from the list of cancer types included. CMS proposes to remove brachytherapy as an included modality in the RO Model. The Agency expressed that it does not seek to incentivize or discourage the use of one modality over another, but to encourage providers to choose the RT services that are the most clinically appropriate. If finalized, CMS would continue to monitor the utilization of brachytherapy as a single modality and multimodality among RO participants compared to non-participants, and consider whether there is opportunity to adjust pricing for multimodality episodes and potentially add brachytherapy to the model in the future. If CMS removes brachytherapy, the Agency is requesting information on how payments for multi-modality care might be handled in the future.

Episode payment rates in the RO Model are modality-agnostic, and CMS does not have separate national base rates per included cancer type based on a specific modality. Because the evidence base for Intraoperative Radiotherapy (IORT) is limited to certain cancer types, and it is a modality that is not site neutral, it does not meet the qualifications for inclusion in the model. CMS is seeking comments on whether and how the Agency may include IORT in the model pricing methodology in future years.

Pricing Methodology

CMS had previously finalized that for sequestration, the Agency would deduct 2% from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rates. However, the requirements for sequestration may be modified by legislation or regulation, and as a result, CMS proposes to remove the percentage amount and indicating that sequestration will be applied in accordance with applicable law. CMS previously finalized that the Agency would exclude episodes in the baseline period that are not attributed to an RT provider or RT supplier. To simplify episode construction, attribution, and pricing, CMS proposes to exclude all Maryland, Vermont, and U.S. Territory claims and all critical access hospital (CAH), inpatient, PARHM HOPD, ASC, and PPS-exempt claims in the same manner: before episodes are constructed and attributed to an RT provider or RT supplier.

CMS has provided a summary level, de-identified file titled “RO Episode File (2017-2019)” on the RO Model website to further explain the RO Model’s pricing methodology.

CMS clarified that the number of national base rates will vary based on how many cancer types are included in the model. The Agency also clarified that Part B expenditures during the baseline period would be used to establish separate professional component (PC) and technical component (TC) national base



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rates for each of the included cancer types, the historical experience adjustments, and the case mix adjustments for PY1. The case mix adjustments for PY2-PY5 would be calculated using the case mix model from the baseline period with inputs from beneficiary characteristics from the most recent 3-year period.

As previously finalized, CMS will apply a trend factor (an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for services) to each of the national base rates. For each PY, CMS will calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not in the model. CMS clarified that the number of separate trend factors will vary depending on the number of cancer types included in the model. The trended national base rates will be made available on the RO Model website prior to the start of the applicable PY, after CMS issues the HOPPS and MPFS final rules.

CMS previously finalized a stop-loss limit of 20% for RO participants that had fewer than 60 episodes from 2016-2018. Under this policy, CMS would use no-pay claims to determine what these RO participants would have been paid under FFS compared to the model, and CMS would pay these participants retrospectively for losses in excess of 20% of what they would have been paid under FFS. Payments under the stop-loss policy will be determined under reconciliation, which occurs in August after the end of each PY, and a true-up of the reconciliation would take place one year later. CMS proposes to modify the definition of “stop-loss reconciliation amount” to mean the amount owed by CMS for the loss incurred under the Model to the RO participants that have fewer than 60 episodes during the baseline period and were furnishing RT services before the start of the model in the CBSAs selected. CMS proposes to lower the discount factor for PC from 3.75% to 3.5%, and for TC from 4.75% to 4.5%. CMS believes that their proposals to remove brachytherapy and liver cancer from the model will allow the Agency to lower these discounts.

CMS will apply a 2% quality withhold from each professional episode payment after applying the trend factor, geographic adjustment, case mix, and historical experience adjustments, and a discount factor to the national base rate. RO Model participants will have the chance of earning some or all of the withhold back based on their aggregate quality score (AQS). CMS proposes that RO participants submit quality measure data starting in PY1, and that starting in PY1, the 2% quality withhold for the PC will be applied. For PY1, Professional and Dual participants are required to submit data for three pay-for-performance measures: Plan of Care for Pain, Screening for Depression and Follow-up Plan, and Advance Care Plan. Professional and Dual participants will also be required to submit data for one pay-for-reporting measure: Treatment Summary Communication—Radiation Oncology; and data submitted for this measure will be used to propose a benchmark to re-specify it as pay-for-performance for PY3. All quality measure data will be reported using the RO Model secure data portal. CMS proposes to update the specification for the Treatment Summary Communication—Radiation Oncology measure, should new specifications from the measure’s steward meet the RO Model’s needs. CMS proposes that the CMS-approved contractor will begin administering the CAHPS Cancer Care Survey for Radiation Therapy on behalf of RO participants and CMS as soon as there are completed episodes (no earlier than the fourth month of PY1). Furthermore, CMS previously finalized that Professional participants and Dual participants must collect certain clinical



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information not available in claims or quality measures (clinical data elements (CDEs)). CMS proposes that Professional participants and Dual participants submit CDEs starting in PY1.

CMS proposes to modify the geography adjustment to align with the proposed model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. CMS is currently analyzing whether the COVID-19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historic levels, and will consider the removal of 2020 data from the calculation of any applicable baseline period or trend factor. CMS is not considering the exclusion of 2020 data from the case mix adjustment.

Advanced APM/MIPS APM

Criterion to be an Advanced APM includes: 1) use of certified EHR technology (CEHRT), 2) payment based on quality measures, and 3) financial risk. RO Model participants must annually certify their use of CEHRT, have their payment adjusted by a 2% quality withhold with the chance of earning some or all back based on their AQS, and have discount factors applied to RO Model payments. The RO Model also meets the criteria to be a MIPS APM, and any MIPS eligible clinician who is included on the individual practitioner list may report and be scored for MIPS as part of an APM Entity through the APM Performance Pathway. CMS proposes that the CEHRT requirement begin in PY1 of the proposed model performance period and that RO Model participants must certify their use of CEHRT at the start of PY1.

CMS proposes to define “Track One” of the RO Model to mean an Advanced APM or MIPS APM track for Dual participants and Professional participants that use CEHRT. Participants in Track One will be considered in the Advanced APM track of the RO Model, and CMS will make Qualifying APM Participant (QP) determinations for the eligible clinicians. If eligible clinicians who are Track One participants do not meet the thresholds to become QPs, they will be considered to be participating in a MIPS APM and can report to MIPS. CMS proposes to define “Track Two” of the RO Model to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements to participate as an advanced APM or MIPS APM; and Technical participants. Therefore, CMS will not make QP determinations for participants on Track Two. CMS proposes that if Technical participants in freestanding radiation therapy centers start providing PC at any point during the model performance period, they must notify CMS within 30 days.

In prior rulemaking, CMS established that an incomplete episode occurs when: 1) a Technical or Dual participant does not furnish TC to a beneficiary within 28 days following a treatment planning service or 2) when traditional Medicare stops being the primary payer, or 3) a beneficiary stops meeting all the beneficiary criteria. CMS proposes to modify this policy for incomplete episodes to allow the Agency to reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been. CMS is also proposing to modify the coinsurance associated with incomplete episodes so that it is set at 20% of the FFS amount applicable to the RT services provided.

Extreme and Uncontrollable Circumstances

CMS proposes to adopt an extreme and uncontrollable circumstances (EUC) policy for the RO Model which would allow CMS to revise the model performance period; grant certain exceptions for RO Model



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requirements to ensure the delivery of safe and efficient care; and revise the RO Model's payment methodology.

To help identify RO participants that are experiencing EUC, CMS would consider: 1) whether the RO participants are furnishing services within a geographic area considered to be within an "emergency area" during an "emergency period", 2) whether the geographic area within a county, parish, U.S. territory, or tribal government served as a condition precedent for 1135 waiver authority, or the National Emergencies Act, and 3) whether a state of emergency has been declared in the geographic area.

In instances where an EUC is nation-wide, CMS proposes that CMS may delay the start date of the model performance period by up to one CY. RO Model participants would be notified no later than 30 days before the model start date. If an EUC impacts RO Model participants' ability to comply with the quality measure or CDE requirements, CMS proposes that CMS may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS. If CMS removes quality and CDE requirements for affected participants due to EUC, CMS proposes that the Agency could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for those affected (which would potentially increase episode payments). CMS proposes that the Agency may modify the trend factor calculation for the PC and/or TC of an included cancer type when RO participants experience EUC.

The ACR's HOPPS Committee and staff will review these changes and will draft comments during the 60-day comment period. Those comments are due to CMS by September 17th, 2021.