American Hospital Association™
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Regulatory Advisory

July 30, 2021

CY 2022 Hospital OPPS/ASC Proposed Rule, Including Modifications to Price Transparency

At A Glance

The Centers for Medicare & Medicaid Services (CMS) July 19 released its calendar year (CY) 2022 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to standard updates, the rule would: reverse two policies related to the inpatient only (IPO) list and the ASC covered procedures list (CPL); significantly increase the civil monetary penalty for noncompliance with the hospital price transparency rule; solicit comments on establishing a new provider type called the Rural Emergency Hospital (REH); and modify the Radiation Oncology Model. Comments on the proposed rule are due by Sept. 17.

Our Take

In a statement shared with the media, AHA said that the proposed rule includes a number of proposals that will help hospitals and health systems better provide care in their communities. We were pleased that CMS recognized the unique role that hospital outpatient departments (HOPDs) serve in caring for patients by proposing to roll back two problematic policies it advanced last year. The first policy would have eliminated the list of medically complex services that Medicare will only pay for when performed in the inpatient setting, and the second would have allowed very complicated procedures to be provided in ASCs, both of which could have negatively impacted Medicare patients' safety and quality of care.

We also welcome the request for information on the REH model, which will help rural hospitals continue to serve as an access point to care in their communities. The pandemic has been especially challenging to rural facilities and this model will help to ensure that patients continue to have the access they need.

Key Takeaways

CMS proposes to:

- Update OPPS payments rates by 2.3% in 2022;
- Use CY 2019 claims data for CY 2022 OPPS and ASC ratesetting;
- Reverse the phased elimination of the IPO list;
- Reinstate several patient safety criteria for adding a procedure to the ASC CPL;
- Continue to pay for 340B drugs at Average Sales Price (ASP) minus 22.5%;
- Modify the hospital price transparency rule, including by significantly increasing the civil monetary penalty for noncompliance;
- Adopt three new measures for the Outpatient Quality Reporting Program, including one on COVID-19 Vaccination among Health Care Personnel;
- Require the Outpatient/ASC CAHPS Survey beginning CY 2023, and allowing survey administration via web
- Request feedback on several issues, including health equity and digital quality measurement;
- Solicit public comments on the establishment of the REH model; and,
- Make several modifications to the Radiation Oncology Model and officially launch the model on Jan. 1, 2022.

Further, although AHA is committed to helping patients access financial and other information patients need to make decisions about their care, we are deeply concerned about the proposed increase in penalties for non-compliance, particularly in light of substantial uncertainty in the interpretation of the rules.

Finally, we are disappointed that CMS proposes to continue to deeply cut OPPS payments to 340B hospitals, and we urge CMS to reverse this punitive policy in the final rule. These cuts directly harm 340B hospitals and their ability to care for their patients, contravening Congress' intent in establishing the 340B program. These cuts are enabled by a lower court's deference to the government's inaccurate interpretation of the law, which is the crux of the legal issue the Supreme Court will review in its upcoming term. For more than 25 years, the 340B program has helped hospitals stretch scarce federal resources to reach more patients and provide more comprehensive services. This proposal would undoubtedly result in the continued loss of resources for 340B hospitals and exacerbate the strain on these hospitals, especially as the COVID-19 pandemic continues.

What You Can Do

- ✓ **Participate in the AHA's members-only webinar** on Aug. 24 at 3 p.m. ET. Click here to register.
- ✓ **Share this advisory with your senior management team,** and ask your chief financial officer to examine the impact of the proposed payment changes on your Medicare revenue for CY 2022.
- ✓ **Share this advisory with your billing, medical records, quality improvement and compliance departments, as well as your clinical leadership team – including the quality improvement committee and infection control officer** – to apprise them of the proposals around the ambulatory payment classifications (APCs) and quality measurement requirements.
- ✓ **Submit comments to CMS with your specific concerns by Sept. 17 at www.regulations.gov.** The final rule will be published on or around Nov.1 and take effect Jan. 1, 2022.

Further Questions

If you have further questions regarding the proposed rule's provisions, contact Roslyne Schulman, director of outpatient payment policy, at rschulman@aha.org.

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Overview

The Centers for Medicare & Medicaid Services (CMS) July 19 issued its calendar year (CY) 2022 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to standard updates, the rule would: reverse two policies related to the IPO list and the ASC covered procedures list (CPL); significantly increase the civil monetary penalty for noncompliance with the hospital price transparency rule; solicit comments on establishing a new provider type called the Rural Emergency Hospital (REH); and modify the Radiation Oncology Model.

The agency also seeks comment on temporary policies and flexibilities implemented to address the COVID-19 public health emergency (PHE), particularly whether certain flexibilities have had a lasting shift in practice patterns and care delivery and should therefore be extended beyond the PHE.

Comments to CMS on the proposed rule are due by Sept. 17, and a final rule is expected around Nov. 1. The policies and payment rates will generally take effect Jan. 1, 2022.

Proposed Changes to the CY 2022 OPPS

OPPS Update and Linkage to Hospital Quality Data Reporting

The CY 2021 OPPS conversion factor is $82.797. To calculate the proposed conversion factor for CY 2022, the agency adjusted the 2021 conversion factor by the fee schedule increase factor and made further adjustments for various budget-neutrality factors. The fee schedule increase factor equals the proposed hospital inpatient market-basket increase factor of 2.5%, reduced by a productivity adjustment of 0.2 percentage points. **Thus, CMS applies the resulting fee schedule increase factor of 2.3% for the CY 2022 OPPS proposed rule.** Hospitals that do not meet outpatient quality reporting (OQR) program requirements are subject to a further reduction of 2.0 percentage points, resulting in a proposed fee schedule increase factor of 0.3%. Thus, the proposed CY 2022 OPPS conversion factor is $84.457 for hospitals meeting OQR requirements and $82.810 for hospitals that do not meet OQR requirements.

These payment adjustments, in addition to other proposed changes[1] in the rule, are estimated to result in a net increase in OPPS payment of approximately 1.8%, or $1.3 billion, in CY 2022, which includes beneficiary cost-sharing but not the estimated changes in enrollment, utilization and case-mix.

All Hospitals	1.8%
Urban Hospitals	1.8%
Large Urban	1.8%
Other Urban	2.4%

[1] This includes the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between Dec. 31, 2021 and Sept. 30, 2022, and adding estimated outlier payments.

Rural	1.8%
Sole Community	1.7%
Other Rural	2.0%

Taking into account estimated changes in enrollment, utilization, and case-mix, CMS estimates that OPPS expenditures for 2022, including beneficiary cost-sharing, will be approximately $82.7 billion; an increase of approximately $10.8 billion compared to 2021 OPPS payments.

Use of CY 2019 Claims Data for CY 2022 OPPS and ASC Ratesetting

Typically, CMS uses the most recently available claims data for rate-setting, which for CY 2022 rate-setting purposes would be CY 2020 claims data. Similarly, under ordinary circumstances, CMS would use cost report data from the most recent release, which for CY 2022 would be cost report data extracted from HCRIS in December 2020.

However, because the CY 2020 claims data and cost report data include services furnished during the COVID-19, which significantly affected outpatient service utilization, CMS determined that CY 2019 data would better approximate expected CY 2022 outpatient service utilization than CY 2020 data. **As a result, the agency proposes to set CY 2022 OPPS and ASC payment rates using the most recent complete data available prior to the COVID–19 PHE. This is the CY 2019 claims data and the same set of cost reports used for 2021 OPPS rate-setting.**

Proposed Site-neutral Payment Policies for Off-campus Provider-based Departments (PBDs)

CY 2021 Site-neutral Payment in Non-grandfathered (Non-excepted) Off-campus PBDs. Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that, with the exception of dedicated emergency department (ED) services, services furnished in off-campus PBDs that began billing under the OPPS on or after Nov. 2, 2015, or that cannot meet the 21st Century Cures "mid-build" exception, will no longer be paid under the OPPS, but under another applicable Part B payment system.

For 2022, the agency continues to identify the Physician Fee Schedule (PFS) as the applicable payment system for most of these non-grandfathered (non-excepted) services and will set payment for most non-grandfathered (non-excepted) services at 40% of the OPPS rate.

Continued Site-neutral Payment Cut for Hospital Outpatient Clinic Visits in Grandfathered (Excepted) Off-campus PBDs. **For CY 2022, CMS proposes to continue to pay for hospital outpatient clinic visit services furnished in grandfathered (excepted) off-campus PBDs at 40% of the OPPS payment amount.** The agency notes that it will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of outpatient department services.

AHA believes that the payment cut for hospital outpatient clinic visits threatens to impede access to care, especially in rural and other vulnerable communities. While we believe that CMS, by continuing the cut, has undermined clear congressional intent and exceeded its legal authority, unfortunately the Supreme Court on June 28 declined to

review the unfavorable ruling by the appeals court that deferred to the government's inaccurate interpretation of the law.

Proposed Payment Changes for Drugs, Biologicals and Radiopharmaceuticals

340B Drug Payment Policy, Including in Off-Campus PBDs. CMS proposes to continue its current payment policy for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program. Specifically, the agency proposes to continue to pay certain 340B hospitals for drugs purchased through the 340B program at Average Sales Price (ASP) minus 22.5%. As in previous OPPS rules, CMS proposes to extend this ASP minus 22.5% payment rate to 340B-acquired drugs furnished in non-grandfathered (non-excepted) off-campus provider-based departments and applies to biosimilar drugs and other drugs without an ASP purchased through the 340B program. For biosimilar products, CMS would pay at ASP minus 22.5% of the biosimilar's ASP. For drugs that that do not have an ASP, if a Wholesale Acquisition Cost (WAC) price is available, then payment would be set at WAC - 22.5%. If only a drug's Average Wholesale Price (AWP) is available, then CMS sets the payment at 69.46% of the drug's AWP. Affected 340B hospitals would continue to be required to report 340B claims using the "JG" modifier

CMS again proposes that this 340B payment policy does *not* apply to rural sole community hospitals, children's hospitals or PPS-exempt cancer hospitals consistent with the previous OPPS rules. Critical access hospitals (CAHs) and other hospitals exempt from either OPPS or from this 340B payment policy, in this proposed rule, would still be required to bill the informational modifier ("TB") on all drug claims. In addition, CMS reiterated its interest in revisiting its policy to exempt these hospitals from the 340B drug payment reduction in future rulemaking.

The agency notes that it continues to believe the current OPPS payment policy of ASP minus 22.5% for 340B drugs is appropriate given the July 31, 2020 U.S. Court of Appeals for the District of Columbia Circuit upholding of the Department of Health and Human Services' (HHS) interpretation of the OPPS statute. Further, CMS states it believes the HHS Secretary has discretion to propose a payment rate for 340B drugs based on the CMS' 2020 actual acquisition cost survey of 340B hospitals. In this rule, the agency explains it chose to maintain the current payment policy to maintain consistent and reliable payment for these drugs both for the remainder of the COVID-19 public health emergency (PHE) and after its conclusion to give hospitals some certainty as to payments for these drugs."[2]

The AHA, joined by member hospitals and health systems and other national organizations representing 340B hospitals in February appealed to the Supreme Court challenging HHS' nearly 30% cut to 2018 and 2019 Medicare OPPS drug payments for certain hospitals participating in the 340B program. A district court had sided with the AHA and found that the payment reductions were unlawful. However, in July 2020, two members of the three-judge panel of the U.S. Court of Appeals agreed to overturn that

[2] https://public-inspection.federalregister.gov/2021-15496.pdf

ruling, despite a spirited dissent questioning the majority's deference to the government's position.

On July 2, 2021, the Supreme Court of the United States decided to take up AHA's petition asking to reverse a federal appeals court decision on this issue. In a statement, AHA General Counsel Melinda Hatton said, "We are hopeful that the Court will reject the appellate court decision deferring to the government's interpretation of the law that clearly imperils the important services that the 340B program helps allow eligible hospitals and health systems to provide to vulnerable communities, many of which would otherwise be unavailable."

Packaging Policy for "Threshold-packaged" and "Policy-packaged" Drugs, Biologicals, and Radiopharmaceuticals. The proposed payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status are based on fourth quarter of 2020 ASP data. Updates to the ASP-based rates will be published quarterly and posted on CMS' website through CY 2022.

CMS pays for drugs, biologicals and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment or separate payment (individual APCs). **For CY 2022, CMS proposes no change to the packaging threshold for "threshold-packaged" drugs, including nonimplantable biologicals and therapeutic radiopharmaceuticals. Therefore, the CY 2022 packaging threshold is proposed to be $130 per day, the same as in CY 2021.** Specifically, drugs, biologicals and radiopharmaceuticals costing $130 or less would have their cost packaged in the procedure with which they are billed, such as an outpatient clinic visit. Drugs, biologicals and radiopharmaceuticals costing more than $130 would be paid separately through their own APC.

There are exceptions to this threshold-based packaging policy for certain "policy-packaged" drugs, biologicals and radiopharmaceuticals. Consistent with current CMS packaging policy, the agency proposes to continue to package the costs of all anesthesia drugs; intraoperative items and services; drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure (e.g., skin substitutes), regardless of whether they meet the $130 per day threshold. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the proposed rule.

Proposed Payment for Drugs without Pass-through Status that are not Packaged. *Separately Payable Drugs and Biologicals.* For CY 2022 (with the exception of 340B-acquired drugs and biologicals), **CMS proposes to continue its current policy and pay for separately payable drugs and biologicals at the "statutory default rate" of ASP plus 6%.** CMS notes that this payment requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Payment for New Drugs Before ASP Data are Available. **CMS proposes to continue to pay for new nonpass-through Part B drugs and biologicals (that are not**

acquired under the 340B program) at a rate of WAC plus 3%. This rate only would apply during the period of time when ASP data for the new drug are unavailable.

Area Wage Index

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. For CY 2022, CMS proposes to continue its policy of applying a 60% labor-related share to determine hospital outpatient payments.

As it has done in previous years, CMS proposes to adopt the final fiscal year inpatient PPS post-reclassified wage index as the calendar year wage index for the OPPS. Thus, any policies or adjustments finalized in the FY 2022 IPPS final rule would be reflected in the final CY 2022 OPPS wage index. These may include policies to:

- Implement an imputed floor wage index adjustment for hospitals in all-urban states;
- Implement an occupational mix adjustment factor based on new calendar year 2019 survey;
- Continue its policy to cap any decrease in a hospital's final wage index at 5%;
- Continue its policy to increase the wage index value for low-wage hospitals; and
- Continue to exclude the wage data of urban hospitals that reclassify to rural areas when calculating the wage index for the rural floor.

For hospitals paid under the OPPS but not the IPPS, CMS proposes to continue its longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments.

For more information on proposed wage index policies for 2022, see the AHA FY 2022 inpatient PPS proposed rule Regulatory Advisory.

Proposed Recalibration and Scaling of APC Relative Weights

CMS proposes to recalibrate the relative APC weights using hospital claims for services furnished during CY 2019. As in previous years, the agency standardizes all of the relative payment weights to the APC 5012 (Level 2 Examinations and Related Services) because that is the APC to which HCPCS code G0463 (hospital outpatient clinic visit for assessment and management of a patient) is assigned. G0463 is the most frequently billed OPPS service. That is, CMS calculates an "unscaled" – i.e., not adjusted for budget neutrality – relative payment weight by comparing the geometric mean cost of each APC to the geometric mean cost of the APC 5012.

Although CMS has reduced payment for clinic visits furnished in excepted off-campus PBDs, it continues to use visits in these settings in determining the relative weight scalar. The agency notes that while the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. That is, the PFS-equivalent adjuster is applied to the clinic visit payment, not the relative weight, and that CMS' clinic visit payment policy is not budget neutral while changes to the weights are budget neutral.

To comply with budget-neutrality requirements, CMS compares the estimated unscaled relative payment weights in CY 2022 to the estimated total relative payment weights in CY 2021 using the service volume in the CY 2019 claims data. Based on this comparison, the CY 2022 unscaled APC payment weights are adjusted by a weight scalar of 1.4436. The effect of the adjustment is to increase the unscaled relative weights by about 44.36% in order to ensure that the CY 2022 relative payment weights are budget neutral.

Comprehensive APCs

There are currently 69 comprehensive APCs (C-APCs) that package together an expanded number of related items and services contained on the same claim into a single payment for a comprehensive primary service under the OPPS. **For CY 2022, CMS does not propose to create any new comprehensive APCs.** The complete list of CY 2022 C-APCs is in Table 1 of the proposed rule.

Proposed Changes to the Inpatient-only List

The inpatient-only (IPO) list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Prior to 2021, CMS annually reviewed the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using five criteria specified in regulation.

In the CY 2021 rule, CMS finalized a policy to eliminate the IPO list over the course of three calendar years beginning with the removal of 298 Healthcare Common Procedure Coding System (HCPCS) codes, including 266 musculoskeletal-related services. Because the agency would be eliminating the IPO list entirely over three years, the removed procedures were not assessed against the agency's longstanding criteria for removal. In its CY 2021 comments to CMS, the AHA opposed the elimination of the IPO list and recommended that the agency continue with its standard process for removing procedures from the IPO list. The IPO list was put into place to protect beneficiaries; many of its services are surgical and high risk. Given the depth and breadth of these procedures, we noted that it would be premature and myopic to adopt such a policy.

CMS now proposes to halt the elimination of the IPO list. It does so in order to allow for greater consideration of the impact removing services from the list has on beneficiary safety, and also to allow providers impacted by the COVID-19 PHE additional time to prepare to furnish appropriate services safely and efficiently when services are removed from the IPO list. In addition, after a clinical review and an evaluation of the services removed from the IPO list in CY 2021, the agency determined that none of the services removed in CY 2021 have sufficient supporting evidence indicating that they can be safely performed on the Medicare population in the outpatient setting, that most outpatient departments are equipped to provide the services to the Medicare population, or that the services are being performed safely on an outpatient basis. **Therefore, CMS proposes to add the 298 services removed**

from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. Table 35 in the proposed rule lists the proposed additions to the IPO list for CY 2022.

CMS also proposes to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list. CMS believes that assessing whether a procedure or service meets these criteria would allow for a more gradual removal of services from the IPO list, which also would allow stakeholders more time to evaluate the safety of the service in the HOPD and to prepare to safely furnish the services migrating off of the IPO list, if they so choose.

These criteria include:

- Most outpatient departments are equipped to provide the services to the Medicare population;
- The simplest procedure described by the code may be furnished in most outpatient departments;
- The procedure is related to codes that CMS has already removed from the IPO list;
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis; and
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

Furthermore, CMS is requesting comments on whether it should maintain the longer-term objective of eliminating the IPO list or if it should maintain the IPO list but continue to systematically scale the list back so that inpatient-only designations are consistent with current standards of practice.

Specifically, CMS is requesting comments on the following:

- What effect would the elimination or scaling back of the IPO list have on safety and quality of care for Medicare beneficiaries?
- What effect would the elimination or scaling back of the IPO list have on safety and quality of care for Medicare beneficiaries on provider behavior, incentives or innovation?
- What information or support would be helpful for providers and physicians in their considerations of site-of-service selections?
- Should CMS' clinical evaluation of the safety of a service in the outpatient setting consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the outpatient provision of a service may have fewer risk factors?
- Are there services that were removed from the IPO list in CY 2021 that meet the longstanding criteria for removal from the IPO list and should continue to be payable in the outpatient setting in CY 2022? If so, what evidence supports the conclusion that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the Medicare population in the outpatient setting?

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2022 and Subsequent Years

In the CY 2020 OPPS final rule, CMS established a policy to exempt procedures that are removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule for two calendar years following their removal from the IPO list.

However, in the CY 2021 OPPS final rule, noting that the phased elimination of the IPO list would mean that far more procedures would be subject to the 2-midnight rule, CMS finalized a policy that allowed procedures removed from the IPO list on or after Jan. 1, 2021, to be indefinitely exempted from these medical review activities. The agency stated that this exemption would last until it had Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting. Thus, for the exemption to end for a specific procedure, in a single calendar year CMS would need to have Medicare claims data indicating that the procedure was performed more than 50% of the time in the outpatient setting.

With the CY 2022 rule including a proposal to halt the phased elimination of the IPO list, CMS proposes to return to its previous two-year exemption policy. **That is, the agency proposes a two-year exemption from certain medical review activities for those procedures that were removed from the IPO list on or after Jan. 1, 2021.** Specifically, these procedures would be exempt from site-of-service claim denials under Medicare Part A, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to recovery audit contractors (RACs) for persistent noncompliance with the 2-midnight rule, and RAC reviews for "patient status" (that is, site-of-service). The agency believes that a two-year exemption would allow sufficient time for providers to become more familiar with how to comply with the 2-midnight rule and for hospitals and clinicians to become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures removed from the IPO list.

CMS is seeking comment on whether a 2-year time period is appropriate, or if a longer or shorter period may be warranted.

Hospital Outpatient Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. CMS again proposes to establish separate thresholds for community mental health centers (CMHCs) and hospitals. For CY 2022, CMS proposes to set the projected target for outlier payments at 1% of total OPPS payments. The agency proposes to allocate 0.01% of outlier payments to CMHCs for Partial Hospitalization Program (PHP) services.

CMS continues to include both a fixed-dollar and a percentage outlier threshold. But, in CY 2022, CMS proposes to increase the fixed-dollar threshold for outliers to $6,100, which is $800 more than in CY 2021, to ensure that outlier spending does not exceed the outlier target.

Thus, to be eligible for an outlier payment in CY 2022, the cost of a hospital outpatient service would have to exceed 1.75 times the APC payment amount (the percentage

threshold), *and be* at least $6,100 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare would make an outlier payment that is 50% of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate.

Transitional Pass-through Payments

Congress created temporary additional, or "transitional pass-through payments," for certain innovative medical devices, drugs, and biologicals to ensure that Medicare beneficiaries have access to new technologies in outpatient care. For CY 2022, CMS projects that pass-through payments will be 1.24% of total OPPS payments, or $1.02 billion. This includes $552.3 million in pass-through payments for devices and $472.4 million for drugs and biologicals. These payments are implemented in a budget-neutral manner.

Equitable Adjustment for Drugs, Biologicals and a Device Category with Expiring Pass-through Status

As required by law, OPPS transitional pass-through payments for drugs, biologicals or a category of devices can be eligible for transitional pass-through payments for at least two years, but not more than three years. CMS notes that if it finalizes its proposal to use the CY 2019 claims data, instead of CY 2020 claims data, in establishing the CY 2022 OPPS rates, it would effectively remove about one year of pass-through data collection time for rate-setting purposes for drugs, biologicals and devices with pass-through status.

Therefore, for CY 2022, CMS proposes to use its equitable adjustment authority to provide up to four quarters of separate pass-through payment for 21 drugs and biologicals whose pass-through payment status will expire on March 31, 2022, June 30, 2022, or Sept. 30, 2022, and six drugs and biologicals and one device category whose pass-through payment status will expire on Dec. 31, 2021. This would ensure that the agency has a full year of claims data from CY 2021 to use for CY 2023 rate-setting and would allow it to avoid using CY 2020 data to set rates for these pass-through drugs, biologicals, and the device category for CY 2022.

CMS estimates that the total spending for these 27 drugs and biologicals and one device category for which it proposes to provide separate payment for the remainder of CY 2022 would be approximately $65 million for CY 2022. This includes $3.5 million for the device category and $61.5 million for the drug and biologicals. The drugs, biologicals, and device category to which this policy would apply are listed in Table 33 in the rule.

Partial Hospitalization Program (PHP) Proposed Payment Update

CMS proposes to follow its existing methodology to calculate the community mental health center (CMHC) and hospital-based PHP geometric mean per diem costs for CY 2022. Because the geometric mean per diem costs CMS calculated for CMHC and hospital-based PHP would both decline in CY 2022 compared to CY 2021, the agency proposes to instead use a cost floor for both types of PHP providers. That is, consistent with its established methodology, CMS proposes to maintain the geometric mean per diem costs finalized in the prior year, CY 2021, in order to protect access to PHP

services. This results in a proposed CY 2022 PHP per diem geometric mean cost for CMHCs of $136.14 and $253.76 for hospital-based PHPs.

The resulting PHP geometric mean per diem costs and payment rates for CY 2022 are in the table below.

Proposed CY 2022 PHP Geometric Mean Per Diem Costs and Payment

CY 2022 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs	Proposed Payment Rates
APC 5853	Partial Hospitalization (three or more services per day) for CMHCs	$136.14	$143.42
APC 5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$253.76	$267.31

Cancer Hospital Adjustment

For CY 2022, CMS proposes to continue to provide additional OPPS payments to each of the 11 "exempt" cancer hospitals so that each cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for other OPPS hospitals. However, as discussed above, given CMS' concerns with CY 2020 claims data as a result of the PHE, it believes that a target PCR based on CY 2020 claims and the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2021 rulemaking cycle.

Therefore, for CY 2022, CMS proposes to continue to use the CY 2021 target PCR of 0.89. This proposed PCR includes a 1.0 percentage point reduction required by a provision in the 21st Century Cures Act. That is, additional payments would be provided to ensure each cancer hospital had a PCR equal to 0.89. Table 4 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals. The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis.

Rural Adjustment for Sole Community Hospitals

CMS proposes to continue increasing payments to rural sole community hospitals, including essential access community hospitals, by 7.1% for all services paid under the OPPS, with the exception of drugs, biologicals, services paid under the pass-through policy, and items paid at charges reduced to costs. The adjustment is budget neutral to the OPPS and applied before calculating outliers and coinsurance.

Comment Solicitation on Temporary Policies for the PHE for COVID-19

In response to the COVID-19 pandemic, CMS undertook emergency rulemaking to implement a number of flexibilities to address the pandemic. While many of these flexibilities will expire at the conclusion of the PHE, CMS requests comment on whether

there are certain policies that should be made permanent. Specifically, the agency is seeking comment on the issues described below.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in their Homes. During the COVID-19 PHE, CMS provided temporary regulatory flexibility to allow hospital staff to furnish outpatient mental health services, education, and training services using telecommunication technology, where the clinical staff and patient are not required to be in the same location. These blanket waivers permit hospital clinical staff to furnish hospital outpatient mental health services, education and training services to a patient "in the hospital," which can include the patient's home, so long as it is provider-based to the hospital, the patient is registered as an outpatient of the hospital, and all services furnished by the hospital are ordered and supervised by a physician or qualified nonphysician practitioner. In these circumstances, hospitals may bill for these services as if they were furnished in the hospital.

Given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries, CMS is interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes. During the PHE, hospital staff have had the flexibility to provide these kinds of services to beneficiaries in their homes through communications technology; however, this flexibility is tied to waivers and other temporary policies that expire at the end of the PHE. CMS is concerned that once the PHE ends, these beneficiaries, who may have become accustomed to receiving these services in their homes, would need to physically travel to the hospital to continue receiving the services and that this could have a negative impact on access to care in certain areas.

Therefore, CMS is seeking comment on:

- The extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE, and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE.
- Whether hospitals have experienced increases during the PHE in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology.
- Whether there are changes that CMS should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes.

Direct Supervision by Interactive Communications Technology. As a result of the PHE, CMS has provided temporary regulatory flexibility that allows the required direct physician supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services to be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. Currently, this flexibility is intended to continue until the end of the PHE or Dec. 31, 2021, whichever is later.

Due to comments it has received on this temporary policy, CMS is requesting more information on the issues involved with direct supervision through virtual presence before implementing this policy permanently. The agency is therefore seeking additional comment on whether it should adopt this policy on a permanent basis. In particular, it wants feedback on:

- Whether and to what extent hospitals have relied upon this flexibility during the PHE and whether providers expect this flexibility would be beneficial outside of the PHE;
- Whether it should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond Dec. 31, 2021, to facilitate a gradual sunset of the policy;
- 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; and
- If this policy is made permanent, 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.

Payment for COVID-19 Specimen Collection in HOPDs. During the COVID-19 PHE, CMS used its authority to create a new evaluation and management code to support COVID-19 testing during the PHE; HCPCS code C9803 (*Hospital outpatient clinic visit specimen collection for SARS-CoV, COVID-19, any specimen source).* This code was created to meet the needs of the COVID-19 PHE, and CMS stated that it expected to retire this code at the end of the PHE.

HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures with a payment rate of $24.67 in CY 2021. It has a status indicator of “Q1,” which indicates that the OPPS will package services billed under HCPCS code C9803 when it is billed with a separately payable primary service, but pay separately when HCPCS code C9803 is billed without another separately payable primary service. The OPPS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test.

CMS is requesting comments on whether it should keep HCPCS code C9803 active and extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the PHE ends. If so, they seek input on why providers believe it would be necessary to continue to provide OPPS payment for this service, as well as how long payment should be extended for this code.

Beneficiary Coinsurance

Medicare law provides that the minimum coinsurance is 20% of the OPPS payment amount. The statute also limits a beneficiary’s actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,484 in 2021. CMS estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2022 will be 18.1%, slightly less than the percentage estimated for 2021.

Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Tests

In general, beneficiaries are not required to pay Medicare Part B coinsurance for colorectal cancer screening tests. However, colonoscopies and sigmoidoscopies that begin as a screening service, but have a polyp or other growth removed as part of the procedure, are no longer considered "screening" tests, and carry coinsurance requirements for beneficiaries. This has resulted in beneficiaries facing unexpected coinsurance charges because the procedure was classified as a diagnostic test instead of a preventive service screening test.

The Consolidated Appropriations Act of 2021 (CAA) addresses this issue by successively reducing, over a period of years, the percentage amount of coinsurance for all colorectal cancer screening tests (including a screening flexible sigmoidoscopy or screening colonoscopy test) so that for services furnished on or after Jan. 1, 2030, the coinsurance will be zero. In the CY 2021 Physician Fee Schedule, CMS proposes to modify its regulations to implement these changes.

In the CY 2022 OPPS proposed rule, CMS proposes a parallel change for the HOPD. That is, the agency proposes that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy could be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter. Providers must report HCPCS modifier "PT" to indicate a planned colorectal cancer screening service converted to a diagnostic service.

Low Volume Policy for Clinical, Brachytherapy, and New Technology APCs

Historically, CMS has used its equitable adjustment authority on a case-by-case basis to adjust how it has determined the costs for certain low-volume services, including establishing policies for low-volume device-intensive procedures and for low-volume procedures assigned to New Technology APCs. The agency also believes that additional items and services may benefit from a policy that applies to clinical APCs with significantly low claims volume available for rate-setting purposes. In particular, it notes that where there are fewer than 100 single claims from the most recent year available for rate-setting for an APC, there is often significant volatility in the payment rate for those APCs that could be addressed with a low-volume adjustment policy similar to its low-volume policies for device-intensive procedures and New Technology APCs.

Therefore, CMS proposes to designate clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims in the claims year used for rate-setting as low volume APCs. However, while its proposed criterion for a clinical or brachytherapy APC to qualify for the new low volume APC policy is that the APC have fewer than 100 single claims that can be used for ratesetting, for New Technology APCs with fewer than 100 single claims, CMS proposes to apply its methodology for determining a low volume APC's cost to the individual services assigned to New Technology APCs and then provide the final New Technology APC assignment for each procedure. Further, for items and services assigned to APCs proposed to be designated as low volume APCs, CMS would use up to four years of

claims data to establish a payment rate for each item or service. Finally, using multiple years of claims data, CMS proposes to choose the greatest of the median, arithmetic mean, or geometric mean cost to approximate the cost of items and services assigned to a low volume APC.

Using these proposed new criteria for CY 2022, CMS would designate two New Technology APCs, four clinical APCs and five brachytherapy APCs as low-volume APCs under the OPPS. Table 36 in the rule displays the APC geometric mean cost without the low volume APC designation, the median, arithmetic mean, and geometric mean cost using up to four years of claims data, as well as the statistical methodology used as the APC's cost for rate-setting purposes for CY 2022.

Hospital Outpatient Quality Reporting (OQR) Program

The Tax Relief and Health Care Act of 2006 required CMS to establish a program under which hospitals must report data on the quality of outpatient care to receive the full annual update to the OPPS payment rate. Hospitals failing to report the data incur a reduction in their annual payment update factor of 2.0 percentage points. In this rule, CMS proposes a number of updates to the OQR measure set and validation process, and requests feedback on several issues including potential new measures, data on health disparities and transitioning to digital quality measurement.

Adoption of COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure. For the CY 2024 reporting period, CMS proposes to adopt a measure that calculates the percentage of HCP eligible to work in the hospital for at least one day during the reporting period who received a complete vaccination course against COVID-19. The measure has been proposed for adoption in nearly all other quality reporting programs, including the ASC quality reporting program (ASCQR) and inpatient quality reporting program (IQR).

The measure would exclude persons with contraindications to the COVID-19 vaccine as described by the Centers for Disease Control and Prevention (CDC). For the purposes of this measure, "health care personnel" is defined — regardless of clinical responsibility or patient contact — as:

- Employees (all persons receiving a direct paycheck from the reporting facility);
- Licensed independent practitioners affiliated with, but not directly employed by, the reporting facility (including post-residency fellows); and
- Adult students/trainees and volunteers.

Facilities may include other contract personnel, but are not required to do so. Detailed specifications for this measure can be found on CDC's website.

To report this data, hospitals and ASCs would use the CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework; the OQR and ASCQR programs do not currently include any measures reported through NHSN, but general acute care hospitals use NHSN to report IQR measures such as influenza coverage among HCP. Hospitals would submit data through NHSN for at least one self-selected week each month, and the CDC would calculate a single quarterly rate by taking the average of the data submitted during the

quarter. If hospitals submit more than one week of data in a month, CDC would use the most recent week's data to calculate the rate.

If finalized, hospitals and ASCs would be required to submit data beginning Jan. 1, 2022. Acute care facilities would count HCP working in all inpatient or outpatient units with the same CMS certification number (CCN), including those physically attached to the inpatient acute care facility as well as those affiliated with but distant from the acute care facility (e.g., those sharing medical privileges or patients).

The measure is not endorsed by the National Quality Forum (NQF). In its preliminary recommendations, the NQF's Measure Applications Partnerships (MAP) Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation; the mitigating factors included well-documented evidence, finalized specifications, testing and NQF endorsement. However, the MAP Coordinating Committee lent conditional support to the measure, asking CMS to bring the measure back to the MAP once specifications were further refined. The Coordinating Committee also asked for the denominator population to align closely with the influenza vaccination coverage measure. CMS contends in the proposed rule that the measure has undergone some validity testing using NHSN data, and believes the measure is sufficiently specified for use in CMS quality reporting programs.

Adoption of Breast Screening Recall Rates Measure. CMS proposes to adopt this claims-based process measure beginning with the CY 2023 reporting period. The measure calculates the percentage of Medicare fee-for-service beneficiaries who received a traditional mammography or digital breast tomosynthesis (DBT) screening study and then received a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging of the breast in an outpatient or office setting within 45 calendar days of the first image.

CMS explains that, while performing breast imaging in the outpatient setting is important, superfluous screenings could result in increased prevalence of radiation-induced cancers in younger women; conversely, recalling too few women for follow-up imaging may lead to delayed diagnoses. Although there are no clinical guidelines suggesting the optimal proportion of imaging recalls, CMS cites "evidence from the clinical literature" suggesting the appropriate rates "should fall between 5 to 12 percent." In addition, CMS notes that the measure could potentially fill a gap in breast screening measures for the OQR. In its proposal, CMS states that it would develop a suite of education and outreach materials to aid measure implementation if the measure is finalized for adoption. The measure is not endorsed by NQF, and CMS currently has no plans to submit it for endorsement.

Removal of Fibrinolytic Therapy Received within 30 Minutes of ED Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3). CMS proposes to remove these two chart-abstracted process measures from the OQR beginning with the CY 2023 reporting period because a more broadly applicable measure on the topics covered by these measures is available. OP-2 assesses the number of acute myocardial infarction patients with ST-segment elevation on the electrocardiogram (i.e., STEMI patients) closest to arrival time who receive fibrinolytic therapy within 30 minutes of ED arrival. OP-3 assesses the median number of minutes

before outpatients with chest pain or possible heart attack who needed specialized care were transferred to another hospital capable of offering this care.

In short, these two measures assess whether patients receive timely care for STEMI in the ED. While this is a high-priority topic, chart abstraction is burdensome; in addition, the measures' populations are limited to patients receiving care in facilities that provide fibrinolytic therapy or who are transferred to a facility capable of percutaneous coronary intervention (PCI), but they do not capture patients who receive PCI at a PCI-capable facility. Therefore, CMS proposes to remove these measures and instead adopt a new, EHR-informed measure that includes and expands beyond the populations of OP-2 and OP-3 to assess the timeliness of STEMI care.

Adoption of ST-Segment Elevation Myocardial Infarction (STEMI) Electronic Clinical Quality Measure (eCQM). CMS proposes to adopt this measure in the place of OP-2 and OP-3 beginning with the CY 2023 reporting period. The measure calculates the percentage of ED patients with STEMI who received timely delivery of care, defined as:

- ED-based STEMI patients who received fibrinolytic therapy within 30 minutes of their arrival;
- Non-transfer ED-based STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival; or
- ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of their arrival at a non-PCI-capable hospital.

The measure is designed to be calculated by hospitals' certified EHR technology (CEHRT) using patient-level data and submitted to CMS. The agency believes that this eCQM would more efficiently and comprehensively measure timeliness of STEMI care as it would broaden the STEMI population for whom performance would be measured and incorporate contraindications to enhance the clinical applicability of the measure. In addition, the agency believes the measure would reduce the burden on facilities currently reporting similar data for the two chart-abstracted measures.

CMS proposes to adopt this measure for voluntary reporting in CY 2023, followed by mandatory reporting beginning in CY 2024; according to CMS, the incremental approach would allow hospitals time to implement workflow changes as necessary to submit data. For the CY 2024 reporting period, CMS would require hospitals to report one self-selected calendar quarter of data and then increase the number of calendar quarters required for reporting each year: two self-selected quarters in CY 2025, three in CY 2026, and all four in CY 2027 and beyond. CMS submitted the measure for NQF endorsement in January 2021; it is currently under review.

Required Reporting of Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31 and ASC-11). CMS proposes to restart reporting of this previously voluntary measure beginning with the CY 2023 reporting period. The measure assesses the percentage of adult patients who had cataract surgery and had improvement in visual function within 90 days following the surgery. Improvement is evaluated based on pre- and post-operative surveys, and hospitals and ASCs submit data on the measure via a CMS web-based tool.

In the CY 2015 OPPS/ASC final rule, CMS finalized the exclusion of the measure from the OQR and ASCQR because it was operationally difficult and providers were administering surveys inconsistently. Hospitals and ASCs were allowed to report the measure voluntarily. In this rule, CMS asserts that their "concerns have been ameliorated" after a review of voluntarily reported data, and hospitals and ASCs have had enough time to familiarize themselves with the measure and prepare to implement it. In addition, their research indicates that the inconsistent survey administration does not result in invalid data.

Required Reporting of Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e and ASC-15a-e). CMS proposes to require reporting of five measures based on the OAS CAHPS survey beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period. If finalized, all locations (on or off campus) of each eligible Medicare participating hospital that offers outpatient services or ASC would be required to participate in the OAS CAHPS survey unless they have fewer than 60 survey-eligible patients during the year preceding the data collection period.

These measures and the associated survey were delayed for mandatory implementation in the CY 2018 OPPS/ASC final rule due to a lack of sufficient operational and implementation data. In that rule, CMS cited the following concerns:

- Survey measures may not take patient response rates into account; response rates may differ widely by provider or by how the survey is administered.
- The national OAS CAHPS data may not be reliable.
- Administering the survey in the outpatient setting may result in high burden for providers.

CMS stated that it would review results from the National OAS CAHPS voluntary reporting program, which began in 2016, to ensure the survey measures appropriately and accurately capture patient responses without unnecessary burden. Citing their review, CMS now believes "that patients are able to respond to OAS CAHPS survey questions, and that those responses are reliable" and that any burdens associated with administration of the survey are outweighed by the benefits of the measures.

In addition to the three previously established survey administration modes —mail only, telephone only, and mail with telephone follow-up of non-respondents — CMS proposes to incorporate two additional administration methods: mixed mode web with mail follow-up of non-respondents and mixed mode web with telephone follow-up of non-respondents. This would be the first time CMS would allow the CAHPS survey to be administered online, which several stakeholders, including the AHA, have urged for years.

For all five proposed modes of administration, CMS proposes the following survey administration requirements for hospitals and ASCs via their CMS-approved vendors:

- Data collection must be initiated within 21 calendar days after the month in which a patient has a surgery/procedure.

- Data collection must be completed within 6 weeks (42 days) after initial contact of the eligible patient begins.
- Vendors must make multiple attempts to contact eligible patients, unless the patient refuses or the vendor learns that the patient is ineligible to participate in the survey.
- Vendors must collect survey data using the established quarterly deadlines, which generally would be posted on the OAS CAHPS Survey website.

All other data collection and submission requirements were previously finalized in the CY 2017 OPPS/ASC final rule; CMS is not proposing new vendor requirements in this rule. Details on vendors and data collection/submission are outlined in AHA's Regulatory Advisory for the CY 2017 final rule.

eCQM Reporting Requirements. In May 2020, the Office of the National Coordinator (ONC) 21st Century Cures Act final rule provided health IT developers up to 24 months from May 1, 2020 to update their EHR technology. ONC's November 2020 interim final rule extended the compliance deadline until Dec. 31, 2022, in order to reduce burden. In this rule, CMS proposes to require hospitals to use CEHRT updated consistent with the 2015 Edition Cures Update beginning CY 2023. CMS also made this proposal in the FY 2022 IPPS/LTCH PPS proposed rule.

In addition, CMS proposes that hospitals report data elements formatted according to the Quality Reporting Document Architecture (QRDA) standard, which also is required for eCQMs in the IQR. Specifically, CMS proposes that hospitals must submit eCQM data via the QRDA Category I file format. Hospitals would be allowed to use third parties to submit these files on their behalf, and may either use abstraction or pull the data from non-certified sources and then input the data into CEHRT to report via QRDA I. Files would have to reflect data for one patient per file and include the CCN, CMS program name, EHR patient ID, reporting period, and EHR submitter ID.

In this section of the rule, CMS also proposes exceptions for hospitals with few or no patients relevant to individual measures. First, if a hospital does not have patients that meet the denominator criteria (for example, if the hospital does not offer a service evaluated with a quality measure, like fibrinolytic therapy), it can enter a zero in the denominator for that eCQM and be considered compliant with reporting requirements. Second, for any quality measure for which hospitals have five or fewer applicable discharges per quarter (or 20 or fewer per year, Medicare and non-Medicare combined), the hospital could be exempt from reporting on that measure.

CMS proposes to require eCQM data submission by the end of two months following the close of the calendar year beginning CY 2023. This deadline is the same as that of the Medicare Promoting Interoperability Program and the IQR program. The review and corrections period for this data would run concurrently with the data submission period.

Validation Processes. To better align the OQR validation process with that of the IQR, CMS proposes several updates to previously finalized validation requirements. Validation is the process through which CMS assesses the accuracy of chart-abstracted data submitted to the agency. CMS performs both a random selection of hospitals and a selection of hospitals meeting certain criteria for validation. CAHs and other hospitals

not subject to OQR requirements are exempt from the validation process. Details on the process, as well as a list of hospitals selected for outpatient data validation in CY 2022, can be found here.

File Submission of Medical Records Requests. Currently, hospitals may submit paper copies of medical records or electronic versions of medical information for validation. However, CMS believes that electronic file submissions are more effective and efficient for hospitals selected for validation. Therefore, CMS proposes to require hospitals to submit only electronic files when submitting copies of medical records for validation. If finalized, hospitals would no longer be allowed to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation beginning with data submission for Q1 of CY 2022. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process. Reimbursement for submission would be the same, at $3.00 per chart. CMS also proposes to change the time period given to hospitals to submit medical records to the CMS Clinical Data Abstraction Center (CDAC) from 45 calendar days to 30 calendar days. These requirements align with those for the IQR.

Additional Targeting Criteria. As previously finalized, hospitals select a random sample of 450 hospitals for validation and an additional 50 hospitals based on specific criteria. Currently, a hospital will be preliminarily selected for validation if it fails the previous year's validation requirement or it has an outlier value (i.e., a measure value greater than five standard deviations from the mean measure values for other hospitals and indicating a poor score) for a measure based on the data it submits. Beginning with validations affecting the CY 2022 reporting period, CMS proposes to add the following criteria for targeting the additional 50 hospitals:

- Any hospital that has not been part of the random selection in any of the previous three years;
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75% (that is, hospitals in the statistical margin of error for their accuracy).

Expanding Extraordinary Circumstances Exemption (ECE) to eCQMs. CMS proposes to allow hospitals to request an exception from eCQM reporting requirements based on hardships preventing them from electronic reporting. These hardships could include infrastructure challenges or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification). CMS also proposes that newly participating hospitals can apply for an exemption for the program year due to the hardship of complying with newly applicable requirements. Hospitals would have to submit requests for an exception to CMS by April 1 following the end of the calendar year in which the extraordinary circumstances occurred.

Requests for Information. CMS requests feedback on several topics relevant to both the OQR and ASCQR.

Patient Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) Measure. Due to changes to the IPO procedure list and the ASC covered procedures list, CMS seeks input on quality measures to inform decision-

making regarding care and for quality improvement efforts as services become newly eligible for payment in the outpatient setting. One such measure for consideration would be a re-specified version of a patient-reported outcome-based performance measure for THA and TKA, which were removed from the IPO list in CY 2020 and CY 2018, respectively. The measure would report the hospital-level risk-standardized improvement rate in patient-reported outcomes following the procedures for Medicare FFS beneficiaries aged 65 and older. Improvement would be determined via pre- and post-operative assessments of hip or knee pain and functioning. The measure is endorsed by NQF for use in the inpatient setting, and CMS solicited comments on the potential future adoption of this measure in the IQR in the FY 2022 IPPS/LTCH PPS proposed rule.

Health Equity. CMS seeks comment on expanding the agency's efforts to address disparities in health outcomes across race and ethnicity. One method CMS is considering would stratify performance results in the hospital outpatient setting by dual eligibility. The agency identified six priority measures in the OQR as candidate measures based on evidence of existing disparities, procedure volume, and statistical reliability. CMS is interested in feedback on whether providing facilities with confidential reports that stratify their performance on these measures by dual eligibility for Medicare and Medicaid would be a helpful step in addressing disparities.

In addition, CMS is interested in using indirect estimation to identify the race and ethnicity of Medicare beneficiaries where this information is missing. This technique uses data from existing sources like the U.S. Census and Medicare administrative data (e.g., first and last names, or the racial and ethnic composition of the patient's neighborhood) to "impute," or infer, the demographic composition of hospitals' patient populations. CMS states it would not use indirect estimation to infer the race and ethnicity of individuals; rather, the approach would be used for making hospital and population-level estimates. While CMS believes that indirect estimation is statistically reliable, the agency recognizes it could unintentionally introduce measurement bias, especially if the source data used to infer population-level race and ethnicity are inaccurate.

Finally, CMS requests feedback on the possibility of facilities collecting a minimum set of demographic data elements using standardized and interoperable EHR standards. The agency notes that the 2015 Edition CEHRT standard supports a certified IT product's ability to collect social, psychological, and behavioral data; thus, CMS is interested in learning about potential future and current data collection practices (as well as challenges) to capture demographic data elements such as race, ethnicity, sex, sexual orientation and gender identify, primary language, and disability status.

Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR). The proposed rule includes a wide-ranging request for comment on CMS' plans to advance the use of digital quality measures (dQMs) and expand the agency's use of FHIR standards and application programming interfaces (APIs) for both current eCQMs and future quality measures. CMS states that its goal is "to move fully to digital quality measurement" by 2025. Along those lines, CMS solicits comments on several policy concepts.

CMS asks for input to refine its definition of a dQM, which the agency currently defines as "a software that processes digital data to produce a measure score or measure scores." Further, the RFI lists data sources for dQMs as including administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges or registries, and other sources.

CMS also asks for comment on a number of steps it is considering taking to enable a full transition to digital quality measures by 2025. This includes:

- Converting current CMS eCQMs to FHIR-based standards, thereby transitioning away from current quality data model (QDM) standards;
- Requiring the use of FHIR-based APIs for any measures that utilize EHR data, including eCQMs;
- Implementing dQMs that are "self-contained tools." That is, CMS is interested in promoting software solutions for dQMs that could, among other things:
    - Support the calculation of single or multiple quality measures;
    - Obtain data via automated queries from a broad range of digital sources (initially EHRs, but potentially also from claims data, patient-reported outcomes and patient-generated health data);
    - Generate measure score reports;
    - Be compatible with any data source;
    - Exist separately from data source systems;
    - Be tested and updated independently of data source systems;
    - Operate in accordance with health information protection laws and regulations;
    - Be deployable by hospitals, health IT vendors, health plans and/or CMS;
    - Be usable by non-technical end users; and
    - Have the ability to adopt to emerging advanced analytic approaches like natural language processing.
- Establishing and expanding policies for data aggregation by third-parties, including HIEs and clinical registries; and
- Developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector. The agency believes this would require a multi-stakeholder, joint federal, state and industry effort to align measure concepts, specifications and data elements.

Future Development of a Pain Management Measure for the ASCQR. Due to the high national prevalence of chronic pain as well as the increased attention to pain management in the midst of the opioid epidemic, pain management services are increasingly being offered as a form of early intervention and more of these procedures are being performed in ASCs. CMS analyzed claims data and found that pain management procedures were the third most commonly performed procedure category in ASCs in 2019 and 2020. Thus, the agency believes that a measure assessing pain management surgical procedures performed in ASCs would address a high priority topic not currently addressed in the ASCQR measure set, and seeks comment on the development of such a measure.

Safe Use of Opioids – Concurrent Prescribing eCQM in the IQR and Promoting Interoperability Programs. In the FY 2020 IPPS/LTCH PPS final rule, CMS finalized the required reporting of this eCQM in the IQR and Promoting Interoperability Programs beginning with the CY 2022 reporting period. In this rule, CMS seeks input for potential measure updates as the agency prepares for NQF re-endorsement of the measure, and to potentially inform any future rulemaking regarding the measure.

The measure assesses the proportion of inpatient hospitalizations for adult patients prescribed or continued on two or more opioids or an opioid and benzodiazepine concurrently at discharge. Stakeholders have voiced concern that required reporting of this measure could disincentivize clinicians from issuing concurrent prescriptions when appropriate, such as methadone and buprenorphine for treatment of opioid use disorder. While CMS states that providers are not expected to have a measure rate of zero, the agency plans to conduct additional testing of the measure that could inform possible future measure updates or exclusions. Thus, CMS seeks public input on potential updates as well as whether the measure should continue to be required for reporting (or whether the agency should allow hospitals to select the measure from the finalized set of eCQMs).

Proposed Changes to the CY 2022 ASC Payment System

The proposed rule includes the annual review and update to the ASC list of covered surgical procedures and covered ancillary procedures, as well as updated payment rates.

Updates and Changes to ASC Payment Policy

ASC Payment Update. For CYs 2019 through 2023, CMS set a policy to update the ASC payment system using the hospital market-basket update instead of the Consumer Price Index for all urban consumers. **As such, for CY 2022, CMS proposes to increase payment rates under the ASC payment system by 2.3% for ASCs that meet the ASC quality reporting requirements.** This proposed increase is based on a proposed hospital market-basket percentage increase of 2.5% minus a proposed productivity adjustment of 0.2 percentage point. CMS estimates that payments to ASCs would increase by $90 million in CY 2022 compared to CY 2021.

The resulting 2022 ASC conversion factor proposed by CMS is $50.043 for ASCs reporting quality data, and $49.064 for those that do not.[3]

Proposed Changes to ASC-covered Surgical Procedures

In the CY 2021 OPPS/ASC rulemaking, CMS substantially revised the regulatory criteria the agency uses to determine which procedures can be added to the ASC covered procedures list (ASC CPL) by eliminating certain general standards as well as all five of the general exclusion criteria. Instead, CMS added these criteria as non-enforceable "physician considerations." Based upon these revised criteria, the agency added 267

[3] By comparison, the proposed CY 2022 OPPS conversion factor is $84.457 for hospitals meeting OQR requirements and $82.810 for hospitals that do not meet OQR requirements.

procedures to the ASC CPL. Finally, CMS added a new provision which established that CMS will add a surgical procedure to the ASC CPL either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the revised criteria.

In AHA's CY 2021 proposed rule comments, we strongly opposed these proposals, which we felt substantially weakened the agency's ability to determine which surgical procedures may be added to the ASC CPL and resulted in far more and higher risk surgical procedures being covered. We expressed concern that this could negatively impact Medicare beneficiary safety and quality of care.

Proposed Changes to the ASC CPL for CY 2022. **For CY 2022, as urged by the AHA, CMS proposes to reinstate the requirements for ASC covered surgical procedures that had been in place prior to CY 2021.** CMS states that it concluded that many of the procedures added in CY 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary.

Specifically, CMS proposes to restore provisions stating that, subject to the exclusions listed below, ASC covered surgical procedures are those procedures:

1. Specified by the HHS Secretary as separately payable under the OPPS;
2. That would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC; and
3. For which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

CMS also proposes to restore the exclusion criteria for the ASC CPL that had been in place prior to CY 2021. Specifically, the agency proposes that covered surgical procedures do not include those that:

1. generally result in extensive blood loss;
2. require major or prolonged invasion of body cavities;
3. directly involve major blood vessels;
4. are generally emergent or life-threatening in nature;
5. commonly require systemic thrombolytic therapy;
6. are designated as requiring inpatient care under IPO list;
7. can only be reported using a CPT unlisted surgical procedure code; or
8. are otherwise excluded from coverage under Medicare.

CMS believes that adding appropriate procedures to the ASC CPL that meet the safety criteria that they are proposing to reinstate will have beneficial effects for Medicare beneficiaries and health care professionals, including increased access, better utilization of existing healthcare resources and expansion of the capacity of the health care system.

Comment Solicitation on Procedures that Were Added to the ASC CPL in CY 2021 and Would Not Meet the Proposed Revised CY 2022 Criteria. After evaluating the 267 surgery or surgery-like codes that were added to the ASC CPL last year, CMS clinicians determined that 258 of these surgical procedures may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC, and that nearly all would likely require active medical monitoring and care at midnight following the procedure. **Thus, CMS proposes to remove 258 of the 267 procedures that were added to the ASC CPL in the CY 2021 final rule.** Table 45 in the proposed rule lists the surgical procedures proposed for removal from the ASC CPL for 2022.

Based on its internal review of preliminary claims submitted to Medicare, the agency does not believe that ASCs have been furnishing the majority of the 267 procedures finalized in 2021. Because of this, CMS believes it is unlikely that ASCs have made practice changes based on the CY 2021 policy. Therefore, CMS does not anticipate that ASCs would be significantly affected by the removal of these 258 procedures from the ASC CPL.

For the final rule, CMS seeks input from commenters who believe any of the 258 procedures added to the ASC CPL in CY 2021 meet the proposed revised CY 2022 criteria and should remain on the ASC CPL for CY 2022. It requests any clinical evidence or literature to support commenters' views that any of these procedures meet the proposed revised 2022 criteria and should remain on the ASC CPL for 2022.

Nomination Process Proposal. **For CY 2022, CMS proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process.** The agency proposes that external parties, such as medical specialty societies or other members of the public, could nominate procedures to be added to the ASC CPL. CMS anticipates that stakeholders, such as physician specialty societies, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be performed in an ASC. If CMS identifies a surgical procedure nominated by an external party that meets the proposed general standards for covered surgical procedures and does not meet the proposed general exclusion criteria, it would propose to add the surgical procedure to the ASC CPL in the next available annual rulemaking.

Specifically, CMS would request stakeholder nominations by March 1 of the year prior to the calendar year for the next applicable rulemaking cycle in order to be included in that rulemaking cycle. For example, stakeholders would need to send in nominations by March 1, 2022, to be considered for the CY 2023 rulemaking cycle and potentially have their nomination effective by Jan. 1, 2023. CMS would include a summary of the justification for proposing to add or not add each nominated procedure, which would allow members of the public to assess and comment on nominated procedures during the public comment period. After CMS reviewed comments provided during the public comment period, it would in the final rule indicate whether or not the procedures would be added to the ASC CPL.

CMS is seeking comments on how it should prioritize its review of nominated procedures, in the event it receives an unexpectedly or extraordinarily large volume of

nominations for which CMS has insufficient resources to address in the annual rulemaking.
CMS believes that this nominations proposal would allow for the expansion of the ASC CPL in a more gradual fashion, which would better balance the goals of increasing patient choice and expanding site neutral options with patient safety considerations. CMS proposes to accept nominations for surgical procedures to be added to the ASC CPL beginning in CY 2023.

Packaging Policy for Non-opioid Pain Management Drugs under the OPPS and ASC Payment System

Generally, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. CMS has been examining this policy since 2019 in response to a recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis that CMS review and modify rate-setting policies that could discourage the use of non-opioid treatments for pain. Similarly, the 2018 enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act requires the HHS Secretary to review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives.

For purposes of the CYs 2019, 2020 and 2021 OPPS/ASC rulemaking, CMS evaluated utilization patterns associated with specific non-opioid drugs that functioned as a supply to determine whether the packaging policy has reduced the use of these drugs. In each year, CMS stated that it did not observe significant declines in the utilization in HOPDs for a majority of the drugs included in its analysis, and, in fact, observed the opposite effect for several drugs that function as a supply. However, CMS' findings in the ASC setting were different from the HOPDs. For the non-opioid pain management drug Exparel in 2019 and 2020 and for Exparel and Omidria (another non-opioid pain management drug) in 2021, the agency found that ASCs had a decrease in claims and utilization of the drug after pass-through payments ended and the drug was packaged into the surgical procedures with which it was billed.

As a result, in the CYs 2019, 2020 and 2021 final rules, CMS unpackaged and paid separately at ASP plus 6% for these non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting. However, in these same years, the agency declined to pay separately for these drugs in HOPDs, despite recommendations from the AHA and others.

Proposed Policy for CY 2022. For CY 2022, CMS conducted another review of payments and utilization patterns for opioids and non-opioid alternatives in both the ASC setting and HOPD setting. The results were similar to the results in previous years. Generally, use of non-opioid pain management drugs continued to increase every year in the HOPD setting despite the fact that payment for these non-opioid alternatives being packaged into the payment for the procedure. In the ASC setting, where Exparel and Omidria are separately paid, CMS also saw utilization increases for these two drugs. However, the rate of increase in utilization in the ASC setting was much more substantial than in the HOPD setting. CMS notes that it has not found conclusive evidence to support the notion that the OPPS packaging policy, under which non-opioid

drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of non-opioid alternatives for pain management. **Therefore, for CY 2022, CMS proposes to continue to package payment for these non-opioid pain management drugs in the HOPD setting. However, it also is requesting comment on whether it should expand to the HOPD setting its current policy to pay separately, at ASP plus 6%, for non-opioid pain management drugs that function as surgical supplies.** It is doing this because it notes that even though packaging encourages efficiency and is a fundamental component of a prospective payment system, the overriding policy objective to reduce financial disincentives for use of non-opioid products leads it to reconsider its policy for HOPDs. In particular the agency request comments on:

- Whether similar disincentives for the use of non-opioid pain management drugs and biologicals identified in the ASC setting exist in the HOPD setting.
- If there is evidence supporting the expansion of this policy to the HOPD setting, including the clinical benefit that Medicare beneficiaries may receive from the availability of separate payment for these products in the HOPD setting;
- If it should treat products the same depending on the setting, ASC or HOPD. For example, whether products should have the same eligibility requirements to qualify for revised payment in the ASC and the HOPD settings; and
- How the additional comment solicitations described in the ASC setting, as described below, could also be applied to the HOPD setting.

Proposed Criteria for Eligibility for Separate Payment in ASCs for Non-Opioid Drugs that Function as Surgical Supplies. For CY 2022 and subsequent years, CMS proposes two criteria intended to identify non-opioid pain management drugs that function as supplies for which revised payment under the ASC payment system would be appropriate. Specifically, CMS proposes the following criteria:

Criterion 1: FDA Approval and Indication for Pain Management or Analgesia. The drug must be approved by the FDA under a new drug application, a generic drug application or, in the case of a biological product, licensed under provisions in the Public Health Service Act. Also, the drug or biological must have an FDA-approved indication for pain management or analgesia.

Criterion 2: Cost of the Product. A drug or biological would only be eligible for a payment revision under the ASC payment system if its per-day cost exceeds the drug packaging threshold under the OPPS; which for CY 2022 is proposed to be a per-day cost of $130. According to the agency, this is an appropriate requirement because it believes that a per-day cost of non-opioid drugs that is greater than the drug packaging threshold would have a greater impact on an ASC's overall procedure costs and so would more likely disincentivize the use of these drugs if they were packaged.

Using these proposed criteria, CMS determines that both Exparel and Omidria would continue to be eligible to receive separate payment in the ASC setting in CY 2022. CMS also requests comment on other potential policy modifications and additional criteria for revising payment for non-opioid pain management drugs. The agency also is interested in receiving information on any non-drug products that function as surgical supplies that comments believe should be eligible for separate payment under this policy. Similarly, it

also is seeking comment on if there are unique qualities of non-drug products that would make revised payment in the HOPD setting appropriate.

ASC Quality Reporting (ASCQR) Program

The Affordable Care Act required CMS to establish a program under which ASCs must report data on the quality of care delivered in order to receive the full annual update to the ASC payment rate. ASCs failing to report the data will incur a reduction in their annual payment update factor of 2.0 percentage points.

In addition to the OQR proposals that also affect ASCs detailed above (including the adoption of the COVID-19 Vaccination among HCP measure, requiring reporting of the previously voluntary Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, and required reporting of the OAS CAHPS survey and associated measures), CMS proposes to require reporting of four previously suspended ASC measures.

Restarting of Previously Suspended Measures. In the CY 2019 OPPS/ASC proposed rule, CMS proposed to remove four measures from the ASCQR: ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission. These measures were "topped out," meaning that ASC performance was high and unvarying across the country and there was little room for improvement; in addition, several stakeholders had raised concerns about the accuracy of the data informing these measures. In the final rule, however, CMS declined to remove these measures because they address topics the agency believes to be important to the public, and instead suspended their use while the agency revised their data collection processes.

In this rule, CMS proposes to resume data collection for ASC-1-4 beginning with the CY 2023 reporting period. Providers would submit data via the Hospital Quality Reporting (HQR) platform (the modernized version of the QualityNet Secure Portal). Facilities would be able to review and correct their data submissions up to the submission deadline.

Other Proposals

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

CMS proposes to amend several hospital price transparency rule policies in order to encourage greater compliance. Most notably, the agency is proposing to significantly increase the penalty for noncompliance. The new penalties would be scaled based on hospital size, as measured by bed count. CMS also proposes to prohibit certain actions that it has concluded are barriers to easily accessing hospitals' machine-readable files. Finally, CMS proposes to deem certain state forensic hospitals as exempt from these requirements.

In addition to these proposed changes, CMS offers clarity on the expected output of hospitals' online cost estimator tools and seeks comment on a number of measures

including best practices for cost estimator tools, the definition of “plain language,” opportunities for identifying and highlighting exemplar hospitals, and ways to improve standardization of the machine-readable files.

Civil Monetary Penalty Increase. CMS proposes to significantly increase the civil monetary penalty (CMP) for noncompliance of the hospital price transparency regulations. Currently, the maximum CMP for noncompliance is set at $300/day/hospital, even if the hospital is in violation of multiple requirements. Under the proposed change, the maximum CMP would be based on hospital size, as follows:

- Hospitals with 30 or fewer bed would maintain a $300/day maximum CMP; Hospitals with 31 to 550 beds would have a daily maximum CMP set at $10/bed; and
- Hospitals with greater than 550 beds would have a $5,500/day maximum CMP.

In the rule, CMS includes the following table to illustrate the daily and annual proposed penalties.

Proposed Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years. (Table 63)

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for Full Calendar Year of Noncompliance
30 or less	$330/hospital	$109,500/hospital
31 – 550	$310 – $5,500/hospital (equal to $10/bed)	$113,150 – $2,007,500/hospital
Over 550	$5,500/hospital	$2,007,500/hospital

For Medicare-enrolled hospitals, CMS proposes to use the most recently available, finalized cost report data to determine the number of beds. If the number of beds cannot be determined in HCRIS, such as for hospitals that are not Medicare-enrolled, CMS proposes to use documentation provided by the hospital to determine the bed count. If a hospital fails to provide the documentation as requested by CMS, the agency would impose the highest daily maximum CMP. If finalized, this increase would be effective Jan. 1, 2022. For all future years, the CMP will continue to be adjusted annually based on a multiplier determined by the Office of Management and Budget for annually adjusting CMP amounts.

CMS proposes using a scaling factor in order to increase the incentive for hospitals to comply without overly penalizing smaller hospitals. An alternative the agency considered would be increasing the maximum CMP for all hospitals to $1,000/day. The agency also considered using different scaling factors, including hospital revenue. For example, the agency could use hospital cost report data to determine a noncompliant hospital’s net patient revenue, and calculate the CMP at 0.1% of that amount. In addition, the agency considered whether and how to apply additional factors into scaling the CMPs, including other financial metrics; the nature, scope, severity and duration of the noncompliance; and the hospitals reasons for noncompliance.

CMS seeks comment on its proposed approach, as well on the alternative approaches they considered. Specifically, it asks which of the possible scales could be feasible, how the alternative factors (e.g., nature, scope, severity, duration, noncompliance reasons) should be assessed, and how different factors should be prioritized if multiple factors are considered in calculating the CMPs for noncompliance.

Prohibition of Additional Barriers to Accessing Machine-readable Files. In the hospital price transparency final rule, CMS provides hospitals discretion related to where and how the machine-readable files are posted, as long as the files are prominently displayed on a publicly-available webpage and the data is "easily accessible, without barriers, and the data can be digitally searched." CMS notes that in its experience, many hospitals are meeting these requirements. However, the agency us aware of some practices that are creating barriers to accessing and searching the data. Therefore, CMS proposes to explicitly prohibit activities that create barriers to "automated searches and direct file downloads through a link posted on a publicly available website."

CMS includes examples of such activities including common methods that hinder findability through searches and direct access to file content, such as through anti-automation tools or other technological devices, and the creation of file constructs and web forms that use an application programming interface to obscure access to the data in a single machine-readable file.

CMS seeks comment on other barriers that stakeholders have identified when trying to access hospital files. CMS also seeks comment on whether there are specific criteria the agency should consider when evaluating whether a hospital has "prominently" displayed the files on their websites or if there are methods of standardization (e.g., prescribed URL) that would ensure easy access.

State Forensic Hospitals. In the hospital price transparency final rule, CMS states that the regulations do not apply to federally-owned and operated hospitals, including hospitals operated by an Indian Health Program and hospitals operated by the US Departments of Veterans Affairs and Defense. That is because these types of hospitals do not treat the general public and their rates are not subject to negotiations. Since publication of the final rule, CMS has identified an additional type of hospital that fits that definition: state forensic hospitals. These facilities are public psychiatric hospitals that exclusively treat patients who are in the custody of penal authorities and who are not responsible for the cost of their care. Instead, these facilities are fully funded through state general funds. CMS proposes to update the regulation to include state forensic hospitals in the group of hospitals for which the regulations do not apply, as long as they provide treatment exclusively for individuals who are in the custody of the penal authorities. CMS estimates that there are 111 institutions that could meet this definition, slightly reducing the overall burden of the rule.

Price Estimator Tools. In the hospital price transparency final rule, CMS finalized a policy that hospitals with price estimator tools that meet certain specifications would be deemed to have met the shoppable service requirement. Such tools need to:

- Provide estimates for at least 300 services, included the 70 CMS-specific services as applicable;
- Allow consumers to access, in real-time, an estimate of the amount they should expect to pay for the service; and
- Be prominently displayed on the hospital's website without barriers to access (e.g., requiring a user account or password).

In this proposed rule, CMS clarifies that the estimates must be tailored to the individual patient and cannot be an average or price range for the service, based on a broad population of patients. CMS also states that hospitals that include disclaimers that the price is not what the hospital expects the patient to actually pay for the service, even absent unusual or unforeseen events, violates the necessary conditions meeting this requirement.

CMS seeks comment on other features that should be required for price estimator tools, best practices and common features for these types of tools, and solutions to common technical barriers. Specifically, CMS asks:

- What best practices should online price estimator tools be expected to incorporate?
- Are there common data elements that should be included in the online price estimator tool to improve functionality and consumer friendliness?
- What technical barriers exist to providing patients with accurate real-time out-of-pocket estimates using an online price estimator tool? How could such technical barriers be addressed?

Request for Comments on "Plain Language" Definition, Identifying and Highlighting Exemplar Hospitals, and Improving Standardization of Machine-readable File. CMS requests comment on a number of topics they are considering for future rulemaking.

Plain Language. First, CMS discusses the "plain language" requirement for shoppable services. CMS currently allows hospitals to define "plain language" on their own. However, the agency notes that in its review of hospital compliance, the agency has found that not all hospitals are utilizing what the agency would reasonably consider "plain language." Therefore, CMS requests comment on whether the requirement should be more specific to require a plain language standard, and, if yes, what that standard should be.

Exemplar Hospitals. CMS also recognizes that there are some hospitals that are going above and beyond the requirements by "embracing and exemplifying the spirit of consumer price transparency." The agency is looking for ways to highlight such hospitals, and are considering the following:

- Highlighting hospitals that are in compliance with various aspects of the hospital price transparency regulations in education and outreach materials or on existing CMS websites, for example, the hospital price transparency website or Care Compare.
- Publicizing the results of comprehensive compliance reviews on the agency's website.

- Collaborating with consumer organizations, health policy organizations, hospital accrediting organizations or others to develop a price transparency certification. Depending on how such a certification process would be structured, CMS might consider proposing future regulatory action to deem certified hospitals as being in compliance with our regulations.
- Integrating price transparency questions into patient experience of care assessments and surveys or other methods for integrating into hospital quality measurement and value-based purchasing initiatives.

CMS seeks comment on whether hospitals should be recognized for their price transparency efforts, and, if yes, feedback on the options they are considering for such recognition.

Machine-readable File Standardization. Finally, CMS is considering whether to be more prescriptive in their machine-readable file requirements, in order to allow for easier comparison across multiple hospital files. Specifically, CMS is seeking comment on the following issues:

- What is the best practice for formatting data such as hospital standard charge data? Is there a specific data format that should be required to be used across all hospitals? Are there any barriers to requiring a specific format to be used by all hospitals when displaying standard charge information?
- Are there additional data elements that should be required for inclusion in the future in order to ensure standard charge data is comparable across hospitals? What one(s)? Is such data readily found in hospital systems? In what ways would inclusion of such data impact hospital burden?
- Are there any specific examples of hospital disclosures that represent best practice for meeting the requirements and goals of the Hospital Price Transparency final rule?
- What other policies or incentives should CMS consider to improve standardization and comparability of these disclosures?
- What other policies should CMS consider to ensure the data posted by hospitals is accurate and complete, for example, ensuring that hospitals post all payer-specific negotiated charges for all payers and plans with which the hospital has a contract, as required by the regulations?

Radiation Oncology Model

At the direction of the Patient Access and Medicare Protection Act (PAMPA) of 2015, CMS developed the Radiation Oncology (RO) Model to test whether site-neutral, modality agnostic, bundled payments for radiotherapy (RT) could reduce Medicare costs while preserving or enhancing the quality of care. The model is mandatory for physician group practices (PGPs), HOPDs and freestanding radiation therapy centers that deliver RT services in randomly selected areas of the country. It was slated to launch on Jan. 1, 2021, but was delayed six months by CMS and an additional six months by Congress. **In this rule, CMS proposes to officially start the RO model on Jan. 1, 2022, declining to delay it further. This proposal comes despite urgings of AHA and many others to postpone the model's launch in light of the ongoing COVID-19 pandemic and the lack of available information on the model.** The model would have five 12-month performance periods, ending on Dec. 31, 2026. CMS also

proposes to update the baseline period for the model to run from Jan. 1, 2017 through Dec. 31, 2019.

CMS estimates that the Medicare program would achieve $160 million in net savings over the course of the model. The agency also estimates that based on the modifications proposed in this rule, Medicare FFS payments to PGPs in the model will increase by 5.5% and payments to HOPDs will *decrease* by 9.6% over the course of the model. However, these numbers may be deceiving in light of CMS' proposal in the CY 2022 Physician Fee Schedule rule to significantly reduce payment for radiation oncology services.

Changes to RO Model Participant Exclusions. CMS previously excluded from the model those RO practices in Maryland and Vermont, as well as any practice classified as an ambulatory surgical center, Critical Access Hospital (CAH) or Prospective Payment System (PPS)-exempt cancer hospital. CMS also excluded hospitals that are participating in the Pennsylvania Rural Health Model (PARHM) or that have been identified by CMS as eligible to participate in the PARHM.

In this rule, CMS proposes to exclude from the RO model only those HOPDs actually participating in the PARHM, rather than also excluding those that are not participating, but have been identified as eligible to participate. CMS explains that participants in the PARHM receive a global budget that covers RT services and would therefore receive overlapping payments if they participated in the RO model, but that those practices that are eligible for PARHM but not participating are not currently subject to this overlap. CMS also proposes to exclude participants in the Community Transformation track of the Community Health Access and Rural Transformation (CHART) Model because they too would receive double payment for RT services if they also participated in the RO model.

Low volume opt-out. CMS also proposes modifications to its low volume opt-out policy in light of the delayed start of the RO model. This policy allows PGPs, HOPDs, or freestanding RT centers that would otherwise be required to participate in the model to opt out for a given performance year (PY) if they have fewer than 20 episodes of RT services across all core based statistical areas (CBSAs) selected for participation in the most recent year with claims data available prior to the applicable PY. CMS clarifies in this rule that the base year for determining eligibility to opt-out will be the most recent year for which claims data is available, which is two years prior to the applicable PY. In addition, CMS proposes to codify that an otherwise required participant would not be eligible for the low volume opt-out if its legacy TIN or CMS Certification Number (CCN)[4] was used to bill Medicare for 20 or more episodes in the two years prior to the applicable PY across all CBSAs selected for participation in the RO Model.

Changes to Included Cancer Types and RT Modalities.

[4] CMS proposes to define "legacy CCN" as a CCN that an HOPD RO participant, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill for these services. Similarly, the proposed definition of "legacy TIN" is a TIN that a PGP or freestanding RT center RO participant, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill for these services.

*Removal of Liver Cancer from Included Cancer Type*s. **In this rule, CMS proposes to remove liver cancer from the list of 16 cancer types included in the model.** In doing so, the agency notes that treatment of liver cancer with RT services continues to develop, with limited guidance for first line use of radiotherapy. Therefore, liver cancer does not meet the inclusion criteria because it is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines. The remaining 15 cancer types are: Anal Cancer, Bladder Cancer, Bone Metastases, Brain Metastases, Breast Cancer, Cervical Cancer, Central Nervous System (CNS) Tumors, Colorectal Cancer, Head and Neck Cancer, Lung Cancer, Lymphoma, Pancreatic Cancer, Prostate Cancer, Upper Gastrointestinal (GI) Cancer, and Uterine Cancer.

Criteria for Determining Included Cancer Types. CMS also proposes to slightly modify the inclusion criteria for the model. As it currently stands, to be included in the RO model, a cancer type must be commonly treated with radiation and associated with current ICD-10 codes that have demonstrated pricing stability. To improve the clarity and consistency of its regulations, the agency proposes to modify this criterion 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; and the Secretary of Health and Human Services must not have determined that the cancer type is not suitable for inclusion in the RO Model.

Proposal to Remove Brachytherapy from Included RT Services. **CMS proposes to remove brachytherapy from the list of RT services included in the RO model.** This proposal reflects the feedback CMS has received since the publication of the 2020 RO model final rule, in which stakeholders expressed concern that the model undervalues the use of brachytherapy, especially in episodes of multimodality care. In this section of the rule, CMS also reaffirms its decision to omit Intraoperative Radiotherapy (IORT) from the model due to its limitation to certain disease sites.

Modifications to RO Model Pricing Methodology. CMS makes several proposals to modify the model pricing methodology. In addition, it provides examples of participant-specific professional and technical episode payments for a sample episode in Tables 60 and 61 in the rule. In Table 62, CMS summarizes the data sources and time periods used to determine the values of key pricing components for the updated baseline years of 2017-2019.

Assignment of Cancer Types to an Episode. In the 2020 RO model final rule, CMS provided guidance regarding episodes of care that involve treatment within the 90-day episode for a second cancer type, identified after a patient's initial cancer diagnosis. In those situations only, the following logic would apply:

1) If two or more claim lines fall within brain metastases or bone metastases or secondary malignancies, the episode is set to the cancer type with the highest claim count.
2) If there are fewer than two claim lines for brain metastases, bone metastases or secondary malignancies, the episode is assigned to the cancer type with the highest claim count among all other cancer types. The episode is excluded from

the model if the cancer type with the highest claim count is not included in the list of included cancers.

3) If there are no claim lines with cancer diagnosis meeting the previous criteria, then no cancer type is assigned to that episode and the episode is excluded from the model.

In light of stakeholder requests for feedback on this approach, CMS clarifies that that if there are not at least two claim lines for brain metastases or at least two claim lines for bone metastases or at least two claim lines for any other secondary malignancy, then it will assign the episode the cancer type with the highest line count among all other cancer types.

Sequestration. In the RO model final rule, CMS adopted the application of a 2% deduction from the model payment for sequestration. In this rule, in recognition that the rules for sequestration are often modified by legislation or regulation, CMS proposes to modify the model payment methodology to apply sequestration in accordance with applicable law.

Proposed National Base Rates. To simplify episode construction, attribution, and pricing, CMS proposes to exclude from the RO model's episode construction all Maryland, Vermont, and U.S. Territory claims, and all CAH, inpatient, ASC and PPS-exempt claims. Additionally, similarly to the participant exclusion proposals described above, the agency is proposing to exclude all claims of an HOPD participating in PARHM, as well as episodes that are attributed to an RT provider or RT supplier that is located in a ZIP Code not assigned to a CBSA for model participation.

With regard to the cancer-specific base rates, CMS proposes technical changes to maintain its weighting policy. Specifically, CMS proposes to weigh episodes that initiated in the first year of the baseline period at 20%, episodes that initiated in the second year of the baseline at 30%, and episodes that initiated in the third year of the baseline period at 50%. Proposed national base rates for the professional component (PC) and technical component (TC) for each cancer type included in the model is available in Table 58 of the rule.

Proposed Trend Factors. The trend factor is designed to update the base rate amounts to reflect current trends in FFS payment and volume of RT services. For each PY, CMS would calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the RO model. In this rule CMS proposes to slightly modify the trend factor calculation so that the numerator is the product of (a) the PC/TC FFS rate for the CY of the upcoming PY and (b) the average volume for each HCPCS code for included cancer types for the three years prior to the CY. The agency proposes to calculate the denominator as the product of (a) the average volume for each HCPCS code for included cancer types in the most recent year of the baseline period and (b) corresponding PC/TC FFS payment rate for the most recent year of the baseline period. Thus, the proposed trend factor calculation for PY 1 (2022) is as follows:

$$\text{2022 Trend Factor} = \frac{\text{(2019 volume * 2022 FFS rates paid under OPPS/PFS)}}{\text{---------- (2019 volume * 2021 FFS rates paid under OPPS/PFS)}}$$

(2019 volume * 2019 FFS rates paid under OPPS/PFS)

CMS will make the trended national base rates available on the RO model website prior to the start of the applicable PY, but after it issues the annual OPPS and PFS final rules.

Application of Adjustments for HOPD or Freestanding Radiation Therapy Center with a Merger, Acquisition, or Other New Business Relationship, with a CCN or TIN Change. In this rule, CMS proposes to slightly modify the requirements for entities that are required to participate in the model, but that have a new TIN or CCN that results from a merger, acquisition or other new clinical or business relationship that occurs prior to Oct. 3, 2025. Specifically, CMS proposes to eliminate the requirement that RO participants provide a notification regarding all new clinical or business relationships that may or may not constitute a change in control. Rather the agency believes that requiring RO participants to submit written notice of a change in TIN or CCN at least 90 days before the effective date of any change would capture the potential risk associated with new clinical or business relationships. CMS also proposes minor changes to the calculation of the case mix and historical experience adjustments for participants with a TIN or CCN change.

Proposed Discount Factor. In the RO model final rule, CMS adopted discount factors of 3.75% for the PC and 4.75% for the TC. These discount factors represented a 0.25% decrease from the discount amounts CMS had originally proposed. **In light of proposals in this rule to remove brachytherapy and liver cancer from the model, the agency proposes to reduce the discount factors by an additional 0.25% each, which would result in a 3.5% discount factor for the PC and 4.5% for the TC.** CMS underscores that if the proposals to remove brachytherapy and liver cancer from the model are not finalized, the proposed reductions to the discount factors will also not be finalized.

Proposed Withholds. Due to the original six-month delay of the RO Model, CMS proposed to delay quality reporting requirements and the corresponding withhold to what would have been PY 2 (Jan. 1, 2022 through Dec. 31, 2022). **With the additional six-month delay and resulting proposed Jan. 1, 2022 start for the model, CMS now proposes to reinstate quality reporting requirements at the start of the model and the corresponding 2% withhold that would be applied to the applicable trended national base rates after the case mix and historical experience adjustments.**

COVID-19. CMS states in this rule that it is analyzing whether the COVID-19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historic levels. **CMS is considering removal of 2020 data from the calculation of any applicable baseline period or trend factor.** However, the agency is not considering the exclusion of 2020 from case mix adjustment at this time, because the case mix episodes are weighted equally (unlike the baseline period, where more recent episodes are given more weight than earlier episodes) and the case mix adjustment does not rely on the volume of RT services delivered. The agency is seeking comments on this approach to addressing utilization during the public health emergency.

Quality Reporting Requirements for Professional and Dual Participants. In the CY 2021 OPPS/ASC final rule, CMS delayed quality measure requirements until the second performance year. In this rule, CMS proposes that Professional and Dual participants submit quality measure data as well as certain clinical information not available in claims or quality measures starting Jan. 1, 2022 (PY1), regardless of when during the year the proposed model performance period begins. CMS explains that this timeline would allow participants to use their Merit-Based Incentive Payment System (MIPS) data submission to meet the RO model requirements.

For PY1, Professional and Dual participants would be 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; these participants would also be required to report data for one pay-for-reporting measure, Treatment Summary Communication—Radiation Oncology; data reported for this measure would be used to propose a benchmark to re-specify it as a pay-for-performance measure in PY3.

Finally, CMS would amend previously finalized policy to account for the delay of the Model so that CMS-approved contractors administering the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey for Radiation Therapy on behalf of the RO participants begin doing so as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

The RO model as an Advanced Alternative Payment Model (Advanced APM) and a MIPS APM. CMS reiterates its expectation that the RO Model will qualify as an Advanced APM and MIPS APM beginning in the first performance year of the model.

As part of its discussion on Advanced and MIPS APMs, CMS returns to its categories of model participants:

- A “Professional participant” is a Medicare-enrolled PGP, identified by a single TIN, that furnishes only the PC of RT services at either a freestanding radiation therapy center or an HOPD.
- A “Technical participant” is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CCN or TIN, which furnishes only the TC of RT services.
- A “Dual participant” is an RO participant that furnishes both the PC and TC of an episode for RT services through a freestanding radiation therapy center, identified by a single TIN.

In this rule, CMS proposes to create two tracks of participants. “Track One” would consist of Professional and Dual participants who meet the RO model requirements, including the use of Certified Electronic Health Record Technology (CEHRT), and who are eligible clinicians on a participation list. CMS would define “Track One” as an Advanced APM and MIPS APM track for Dual and Professional participants that use CEHRT. The agency would consider RO model participants in Track One as participating in the Advanced APM track of the RO model, and would make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO model participation list. If eligible clinicians who are Track One participants do not

meet the established QP thresholds, they would be considered MIPS APM participants and can report to MIPS using reporting options applicable to MIPS APM participants.

At the start of each PY, if Professional participants or Dual participants fail to meet any of the RO Model requirement, including the use of CEHRT, they would be moved into "Track Two" of the model for that PY. **CMS proposes to define "Track Two" to mean an APM for Dual and Professional participants who do not meet certain RO model monitoring requirements (as described in the next paragraph) and for all Technical participants.** RO participants that fall into Track Two will not be participating in an Advanced APM or MIPS APM for the RO model and therefore, CMS will not make QP determinations for the eligible clinicians on the RO model participation list for Track Two.

CMS explains that any failure to comply with the RO model requirements listed at 42 CFR § 512.220(a)(2) will result in Track Two status for RO participants. These include requirements to:

1) discuss goals of care with each Medicare beneficiary before initiating treatment and communicate to the beneficiary whether the treatment intent is curative or palliative;
2) adhere to nationally recognized, evidence-based treatment guidelines when appropriate in treating Medicare beneficiaries or document in the medical record the rationale for the departure from these guidelines;
3) assess Medicare beneficiaries' tumor, node, and metastasis cancer stage for the CMS-specified cancer diagnosis;
4) assess Medicare beneficiaries' performance status as a quantitative measure determined by the physician;
5) send a treatment summary to each Medicare beneficiary's referring physician within three months of the end of treatment to coordinate care;
6) discuss with each Medicare beneficiary prior to treatment delivery his or her inclusion in the model and related cost-sharing responsibilities; and
7) perform and document Peer Review for 50% of new patients in PY1, 55% of new patients in PY2, 60% of new patients in PY3, 65% of patients in PY4, and 70% of patients in PY5, preferably before starting treatment, but in all cases before 25% of the total prescribed dose has been delivered and within two weeks of starting treatment.

However, the agency also recognizes that it may not discover an RO participant's noncompliance with these requirements until after it has treated the participant as if it met Track One requirements, including potentially making QP determinations and APM incentive payments for that participant's eligible clinicians. In that situation, if CMS determines a Track One participant should actually be in Track Two, it would have made overpayments to the eligible clinicians. Yet CMS is concerned that a participant's minor noncompliance could result in overly harsh overpayment liability. **To that end, CMS is considering whether it should modify some of the requirements in § 512.220(a)(2) to lower the burden of compliance with those requirements. It also considers whether it should be able to make a portion of the payments based on the QP status of the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors.**

Individual Practitioner List. In the RO Model final rule, CMS codified that at the start of each PY, the agency will create and provide to each Dual and Professional participant an individual practitioner list which identifies by NPI each individual practitioner associated with the RO participant. CMS proposes to modify this policy to include that Technical participants that are freestanding radiation therapy centers will also be provided an individual practitioner list. CMS also proposes to modify model requirements so that RO participants have the ability to review their individual practitioner list and add or drop the necessary would from the list up until the last QP determination snapshot date (Aug. 31). This will allow more time for RO participants to review and certify their individual practitioner lists, as the requirement in the RO model final rule stated that participants were to notify CMS within 30 days if there were any additions or removals of eligible clinicians to the individual practitioner list.

Proposed Reconciliation Process. Reconciliation is the process by which CMS calculates reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. The true-up reconciliation is the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY.

Regarding incomplete episodes, CMS reiterates that incomplete episodes are those in which (1) an RT treatment is not furnished within 28 days following an RT treatment planning service; (2) traditional Medicare stops being the primary payer for an RO beneficiary; or (3) an RO beneficiary stops meeting the criteria for inclusion in the model. In the RO model final rule, CMS adopted a policy that the RO participant in any of these incomplete episodes would receive only the FFS payment it would have received for the RT services furnished to that RO beneficiary. Under this approach, CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. CMS also finalized a policy that for incomplete episodes in which traditional Medicare stops being the primary payer for an RO beneficiary, the RO participant would be paid only the first installment of the episode payment and not the end of episode payment.[5]

In this rule, CMS proposes to modify this policy such that for all incomplete episodes – including those for which traditional Medicare stops being the primary payer for an RO beneficiary - CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. This proposal is based upon CMS's determination that the data did not support paying RO participants only the first installment of an episode for this type of incomplete episode.

Proposed Extreme and Uncontrollable Circumstances Policy. In this rule, CMS proposes to adopt an extreme and uncontrollable circumstance (EUC) policy for the RO model which would allow the agency, in the event of an EUC, to revise the model performance period; grant certain exceptions to RO model requirements to ensure the

[5] In the RO model, CMS will make payments to RO participants in two equal installments, one at the start of an episode and one at its completion.

delivery of safe and efficient health care; and revise the RO model's payment methodology.

CMS proposes to define an EUC as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO model's requirements, and affects an entire region or locale. CMS also proposes using the following factors to help it identify RO participants that are experiencing an EUC:

- Whether the RO participants are furnishing services within a geographic area considered to be within an "emergency area" during an "emergency period" as defined in section 1135(g) of the Social Security Act.
- Whether a state of emergency has been declared in the relevant geographic area.

In the event that one or more of these conditions are met, CMS would announce that the EUC policy applies to one or more RO participants within an affected geographic area. **If an EUC were to be nation-wide and impact RO participants' ability to implement the requirements of the model at the start of the PY, the agency proposes that it could delay the start date of the model performance period by up to one CY.** If an EUC impacts participants' ability to comply with model's quality measure or clinical data element reporting requirements, CMS proposes that it could delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for participants to report data to CMS, as applicable.

Request for Information on Rural Emergency Hospitals

CMS includes in the proposed rule a request for information (RFI) asking for comments on a range of requirements and feedback related to Rural Emergency Hospitals (REHs), a new Medicare provider type established in the Consolidated Appropriations Act of 2021. Broadly, CMS is soliciting stakeholder input as it considers the health and safety standards that should apply to REHs in order for them to be certified to participate in the Medicare program. The agency also is seeking input on payment provisions, quality measures, and care coordination issues.

Specifically, CMS is soliciting comment on the following:

- Type and scope of services offered, including what outpatient medical and health services should be considered as eligible services.
- Health and safety standards, including licensure and conditions of participation. For example, CMS is seeking comments on what hospital emergency department requirements and what staff training and certification requirements should be mandated.
- Health equity issues, such as how REHs can help address social needs in rural areas and if there are additional factors to consider for specific populations.
- Quality measures, including quality reporting requirements, specification of measures, and public reporting of data. For example, what are the barriers and challenges to electronic submission of quality data, and what limitations

exist for case volume/mix or geographic distance that would be appropriate for CMS to consider.
- Payment provisions, including what payment reporting issues should be considered when estimating payments under prospective payment systems for service furnished.
- Enrollment process, such as the steps and timing for conversion to an REH.

Next Steps

The AHA will host a 90-minute, members-only webinar on Tuesday, Aug. 24 at 3 p.m. ET. Please register for this event at this link. Related materials and a recording of this webinar will be available on the AHA's OPPS webpage.

We encourage members to model the impact of the APC changes on expected CY 2022 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2021 will soon be available on the AHA's OPPS webpage. To access these, you must be logged on to the website.

Submitting Comments. The AHA urges hospitals and health systems to submit comments to CMS. Comments are due by Sept. 17, and may be submitted electronically at www.regulations.gov. Follow the instructions for "Comment or Submission" and enter the file code "CMS-1753-P." CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

Questions. If you have further questions regarding the proposed rule's provisions, please contact Roslyne Schulman, director of outpatient payment policy, at rschulman@aha.org.