AAOS
American Association of Orthopaedic Surgeons

CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule Summary

On July 19, 2021 the Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) proposed rule (CMS-). Below is an in-depth summary of key changes:

Link to rule text: https://www.aaos.org/globalassets/advocacy/issues/cy-2022-opps-proposed-rule.pdf
Link to tables: https://www.aaos.org/globalassets/advocacy/issues/cy-2022-opps-proposed-rule-tables.pdf

Proposed Updates Affecting OPPS Payments

CMS is proposing to use the CY 2019 claims data to rate set for CY 2022 to account for the impact of the public health emergency on the CY 2020 data.

CMS is soliciting feedback on a proposal to expand the current policy, in ASC settings of separate payment at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies during the performance of surgical procedures in the ASC, to the HOPD setting.

"ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may affect these providers more acutely than hospital outpatient departments; and ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Additionally, we are seeking comment on what evidence supports the expansion of this policy to the HOPD setting, including the clinical benefit that Medicare beneficiaries may receive from the availability of separate or modified payment for these products in the HOPD setting." (pg. 71)

"For CY 2022 and subsequent years, we are proposing two criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C). The proposed criteria are intended to identify non-opioid pain management drugs and biologicals that function as supplies in surgical procedures for which revised payment under the ASC payment system would be appropriate."

- Criteria 1: FDA approval and indication for pain management or analgesia
- Criteria 2: Cost of the drug

"We propose that non-opioid drugs and biologicals currently receiving transitional drug pass-through status in the OPPS would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment system." (pg. 75)

Potential additional criteria: product utilization, FDA-approved drugs that do not have an indication for pain management but are supported by other groups, and peer-reviewed literature

Specifically, CMS is "seeking comment as to whether we should consider specialty society or national organization (such as a national surgery organization) recommendations of non-opioid pain management products that function as surgical supplies and reduce opioid use in the ASC setting, as evidence that a product

meets criterion one, where a drug or biological does not have an FDA indication for pain management or analgesia." (pg. 79)

For non-opioid drugs and biologicals, CMS is "proposing to pay separately at ASP plus 6 percent for non-opioid pain management drugs and biologicals that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and meet our other proposed criteria." (pg. 82)

Proposed Conversion Factor Update
"In summary, for 2022, we propose to use a reduced conversion factor of $82.810 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of – 1.647 in the conversion factor relative to hospitals that met the requirements). For 2022, we propose to use a conversion factor of $84.457 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.3 percent for CY 2022, the required proposed wage index budget neutrality adjustment of approximately 1.0012, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.32 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2022 of $84.457." (pg. 91)

Proposed Hospital Outpatient Outlier Payments
"For this CY 2022 OPPS/ASC proposed rule, using CY 2019 claims data and CY 2021 payment rates, we estimated that the aggregate outlier payments for CY 2021 would be approximately 1.06 percent of the total CY 2021 OPPS payments. We provided estimated CY 2021 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts - Provider-Specific Data file on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/index.html." (pg. 109)

Proposed Beneficiary Copayments
"For CY 2022, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004."

"In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent."

"The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2022 are included in Addenda A and B to the proposed rule (which are available via the Internet on the CMS website)." (pg. 119)

Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
Proposed OPPS Treatment of New and Revised HCPCS Codes
CMS recognizes the release of new CPT and Level II HCPCS codes and makes the codes effective outside of the formal rulemaking process via OPPS quarterly update Change Requests (CRs), and based on review, CMS

assigns the new codes to interim status indicators (SIs) and Ambulatory Payment Classifications (APCs). In the OPPS, the APC assignment determines the payment rate for an item, procedure, or service, and those not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not.

CMS is soliciting public comments on the proposed APC and SI assignments for the following codes in this proposed rule: 26 new HCPCS codes established and effective April 1, 2021 and 55 new HCPCS codes established and effective July 1, 2021

These new codes that are assigned to comment indicator "NP" in Addendum B to this proposed rule indicates that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments.

CMS will solicit public comments in the CY 2022 OPPS/ASC final rule on:

- New CPT and Level II HCPCS codes that will be effective October 1, 2021, once released October 2021, in order to finalize the status indicators and APC assignments for the codes in the CY 2023 OPPS/ASC final rule.
- New Level II HCPCS codes that will be effective January 1, 2022 in the CY 2023 OPPS/ASC final rule. Codes are released through the January OPPS quarterly update CRs and via the CMS HCPCS website, therefore CMS is unable to include them in the OPPS/ASC proposed rules. These codes would be incorporated in the January 2022 OPPS quarterly update CR.

The CPT code descriptors that appear in Addendum B of this proposal are short descriptors and do not accurately describe the complete procedure, service, or item for the CPT code. Therefore, CMS is including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2022 CPT codes in Addendum O to this proposed rule (available on the CMS website) for the public to effectively comment on the proposed APCs and SI assignments.

The following related items can be found under these sections of the CY 2022 OPPS/ASC proposed rule and or are available on the CMS website:

- Section XI (page 426)**:** lists the various proposed status indicators used under the OPPS
- Table 5 and Table 6: lists the new HCPCS codes and their long descriptors effective 4/1/21, and 7/1/21
- Table 7**:** summarizes the current process for updating codes through the OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS
- Addendum B, D1, D2 (on the CMS website)**:** complete lists of proposed status indicators and their definitions
- Addendum O (on the CMS website): contains 5-digit placeholder codes for new CPT codes

Proposed OPPS Changes—Variations Within APCs

Ambulatory Payment Classifications (APCs) use Level I (CPT codes) and Level II HCPCS codes (alphanumeric codes) to identify and group the services within each APC. The APCs are organized so each group is identical both clinically and in resource use. CMS established distinct groups of similar services, and developed separate

APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

CMS packaged into the payment for each procedure or service within an APC group the costs associated with those services that are usually ancillary and support the primary diagnostic or therapeutic modality. Therefore, CMS does not make separate payment for these packaged items or services.

Under the OPPS, CMS generally pays for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the service or combination of services is assigned.

For the CY 2022, CMS is proposing that each APC relative payment weight represents the hospital cost of the services included within that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). This is because the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review and revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, technology, new services, new cost data, and other relevant information and factors. The Secretary must also consult with an expert outside the advisory panel composed of an appropriate selection of representatives of providers to review the clinical integrity of the APC groups and the relative payment weights.

The HOP Panel recommendations for specific services for the CY 2022 OPPS update will be discussed in specific sections of the CY 2022 OPPS/ASC final rule with comment period. In addition, section 1833(t)(2) of the Act provides that, items and services within an APC group cannot be considered comparable to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the “2 times rule”).

In determining the APCs with a 2 times rule violation, CMS considers only those HCPCS codes that are significant based on the number of claims. Procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832).

The longstanding definition of when a procedure code is significant for purposes of the 2 times rule selected because a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims used for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832).

For CY 2022, CMS is proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services. For the CY 2022 OPPS update, CMS has

identified APCs with violations of the 2 times rule and propose changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule on the CMS website.

CMS proposes to reassign these procedure codes to new APCs that contain services that are similar in both clinical and resource attributes. Addendum B to this CY 2021 OPPS/ASC proposed rule identifies with a comment indicator "CH" the procedure codes that CMS proposes a change to the APC assignment and/or status indicator, that were initially assigned in the July 1, 2021 OPPS Addendum B Update (available on the CMS website).

Proposed APC Exceptions to the 2 Times Rule

CMS reviewed all the APCs to determine which APCs would not meet the requirements of the 2 times rule with the criteria of resource and clinical homogeneity, hospital outpatient setting utilization, frequency of services, and opportunity for upcoding and code fragments. Based on the CY 2019 claims data available for this CY 2022 proposed rule, CMS discovered 23 APCs with violations of the 2 times rule.

All 23 APCs identified meet the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for this proposed rule. For cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, CMS may accept the HOP Panel's recommendation since it is based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 8 of this proposed rule lists the 23 APCs which CMS proposes to make an exception under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before June 30, 2020, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website

Proposed New Technology APCs

In the CY 2002 OPPS final rule (66 FR 59903), CMS finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. In the CY 2004 OPPS final rule with comment period (68 FR 63416), CMS restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs. These current New Technology APC configurations allow CMS to price new technology services more appropriately and consistently.

For CY 2021, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology - Level 1A ($0-$10)) through the highest cost band assigned to APC 1908 (New Technology - Level 52 ($145,001-$160,000).

These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. The OPPS is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment.

The payment rates reflect the costs that are associated with providing care to Medicare beneficiaries. For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Medicare does not assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment.

CMS noted that in a budget-neutral system, payments may not fully cover hospitals' costs in some circumstances, including those for the purchase and maintenance of capital equipment. As the OPPS acquires claims data regarding hospital costs associated with new procedures, CMS regularly examines the claims data available and new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314).

CMS is proposing payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (available on the CMS website).

Establishing Payment Rates for Low-Volume New Technology Services
Services assigned to New Technology APCs are typically new and do not have sufficient claims history to establish an accurate payment for the services. Establishing New Technology APCs generates sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services have very low annual volume, fewer than 100 claims.

Services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC rate setting calculations and, therefore, are not included in the assessment of the 2 times rule. The CY 2019 OPPS/ASC final rule with comment period (83 FR 58890) listed the concern that the methodology used to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services. In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources.

Where utilization of services is assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits the ability to assign the service to the appropriate clinical APC.

To mitigate these issues, CMS determined in the CY 2019 OPPS/ASC final rule that it was appropriate to utilize equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how to determine the costs for low-volume services assigned to New Technology APCs. CMS has used this adjustment authority on a case-by-case basis in the past, CMS believes it was appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for

new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, CMS believes it is appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims.

CMS adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which creates a more statistically reliable payment rate. In addition, to better approximate the cost of a low-volume service CMS believes using the median or arithmetic mean rather than the geometric mean could be more appropriate in some circumstances, given the extremely low volume of claims. in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), CMS sought public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. For CY 2022, CMS is proposing to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to four years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC.

CMS is also proposing to utilize the equitable adjustment authority through the proposed universal low volume APC policy described in section X.C. of this proposed rule, which is similar to the current New Technology APC low volume policy, with the difference between the two policies being that the universal low volume APC policy would apply to clinical APCs and brachytherapy APCs, in addition to New Technology APCs, and would use the highest of the geometric mean, arithmetic mean, or median based on up to four years of claims data to set the payment rate for the APC. CMS is proposing to end the separate New Technology APC low volume policy if CMS adopts the proposed universal low volume APC policy, as it also applies to New Technology APCs.

Procedures Assigned to New Technology APC Groups for CY 2022

CMS generally retains a procedure in the New Technology APC to which it is initially assigned until sufficient claims data has been obtained to justify reassignment of the procedure to a clinically appropriate APC. In cases where it is found that the initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), CMS may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with the current policy, for CY 2022, CMS is proposing to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows CMS to reassign a service from a New Technology

APC in less than 2 years if sufficient claims data has not been received. It also allows CMS to retain a service in a New Technology APC for more than 2 years if sufficient claims data has not been obtained upon which to base a reassignment decision (66 FR 59902).

Proposed OPPS APC-Specific Policy
Stromal Vascular Fraction (SVF) Therapy SVF therapy to treat knee osteoarthritis. SVF therapy is currently described by CPT codes 0565T and 0566T. For CY 2021, CPT code 0565T is assigned to APC 5733 (Level 3 Minor Procedures) with a payment rate of $55.66, and CPT code 0566T is assigned to APC 5441 (Level 1 Nerve Injections) with a payment rate of $261.17.

Based on recent information CMS found there is no current FDA-approved autologous cellular product derived from autologous body fat (referred to in CPT code 0565T and 0566T as "autologous cellular implant") associated with SVF therapy. In addition, SVF therapy is currently under clinical trial and has not received CMS approval as investigational device exemption (IDE) studies. IDE studies that have been approved and meet CMS' standards for coverage are listed on the CMS Approved IDE Studies website.

For CY 2022 CMS is proposing not to pay under the OPPS for either code, and is revising the status indicator for CPT code 0565T from "Q1" (conditionally packaged; separately payable) to "E1" to indicate that the code is not payable by Medicare. CMS is also revising the status indicator for CPT code 0566T from "T" (separately payable) to "E1" to indicate that the code is not payable by Medicare and deleting the APC assignment for this code.

Proposed OPPS Payment for Devices
The pass-through payment status of device category C1734, Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable) is set to expire December 31, 2022.

CMS received eight pass-through payment applications for CY 2022. Two applications utilize the alternative pathway for devices achieving FDA Breakthrough Device designation and market authorization. Six applications go through the traditional pass-through payment pathway. None of the applicant devices have orthopaedic indications.

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals (pg. 263)
There are 25 drugs and biologicals whose pass-through payment status will expire during CY 2021. *See Table 27 for the full list.*

CMS is proposing to end pass-through payment status for 26 drugs and biologicals in CY 2022. *See Table 28 for the full list.*

"For 2022, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2022. We propose that a $0 pass-through payment amount would be paid for passthrough drugs and biologicals that are not policy-packaged as described in Section V.B.1.c. under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion

of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0." (pg. 269)

Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

CMS is "proposing to use our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 21 drugs and biologicals whose pass-through payment status will expire on March 31, 2022, June 30, 2022, or September 30, 2022 and six drugs and biologicals and one device category whose pass-through payment status will expire on December 31, 2021. This would ensure that we have a full year of claims data from CY 2021 to use for CY 2023 rate setting and would allow us to avoid using CY 2020 data to set rates for these pass-through drugs, biologicals, and the device category for CY 2022." (pg. 323)
Table 33 provides a list of drugs, biologicals, and device categories for which CMS proposes to provide separate payment for one to four quarters in CY 2022.

Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2022, CMS is proposing to continue with their current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448).

CMS also proposes to continue their payment policy for critical care services for CY 2022. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

CMS is seeking public comments on any changes to these codes that they should consider for future rulemaking cycles. They encourage commenters to provide the data and analysis necessary to justify any suggested changes.

CMS is continuing the clinic visit payment policy for CY 2022 and beyond. They will continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments.

The PFS-equivalent rate for CY 2022 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2022) for the clinic visit service in CY 2022. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

Proposed Services That Would Be Paid Only as Inpatient Services

"In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we significantly adjusted our approach to the IPO list." (pg. 350)

"Accordingly, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized, with modification, our proposal to eliminate the IPO list over the course of three years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a three-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes from the list beginning in CY 2021 and, because we proposed to eliminate the IPO list entirely, the removed procedures were not assessed against our longstanding criteria for removal (85 FR 86094)."

Proposed Changes to the Inpatient Only (IPO) List
CMS is proposing to stop the elimination of the IPO and add the 298 services removed for 2021 back to the IPO for CY 2022. (pg. 351)

CMS proposes to reinstate the five criteria which must be considered for elimination.

CMS wants "…to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above, we believe that the IPO list is a necessary safeguard that considers the broader Medicare population." (pg. 354)

"Separately, we also acknowledged the numerous challenges that providers are facing due to the COVID-19 PHE (85 FR 86089). After further experience with the PHE and its impact on provider and beneficiary behavior, we recognize that the COVID-19 PHE has likely reduced providers' ability to prepare to furnish these services in the outpatient setting in the manner they would absent the PHE. We recognize that the COVID-19 PHE may have negatively impacted the time and resources that providers have to adapt to the removal of these procedures from the IPO list— making it more difficult for providers to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS. We also recognize that the COVID-19 PHE has negatively impacted clinical staff and providers' opportunity to develop the comprehensive patient selection criteria and other protocols necessary to identify whether a Medicare beneficiary could safely have these procedures performed in the outpatient setting while guaranteeing them appropriate quality of care." (pg. 355)

CMS believes "…that with additional time stakeholders can provide supportive evidence to aid in the evaluations of each individual procedure's assignment to the IPO list, and where appropriate the APC assignment and corresponding payment for any codes as well, including but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols." (pg. 356)

"An initial review of 2021 billing data through May 21, 2021, supports our proposal to halt the elimination of the list, revealing that 131 of the 298 codes removed from the IPO list in last year's final rule appeared on either zero or one OPPS claims and 269 of the 298 codes appeared on fewer than 100 claims. These data indicate that fewer than 3 percent of the services removed from the IPO list in 2021 have seen notable volume in the outpatient setting following their removal from the IPO list."

"For perspective, we also note that even before we removed these codes from the IPO list, it was not uncommon to see at least some volume for these codes in the claims data. In CY 2020, when these codes were still not payable under the OPPS, 188 of the codes had at least one outpatient claim and 18 codes had greater than 100 claims, for reasons undetermined. As a result, it is likely that not all of the reported claims represent services provided in the outpatient setting due to these services being removed from the IPO list in CY 2021." (pg. 357)

"Below we solicit comments on the potential future elimination of the IPO list and what commenters believe the effects of that elimination would be. We also solicit comment on if CMS should maintain the IPO list but continue to systematically scale back the list by looking at groups of services that can safely and effectively be performed in the outpatient setting. Specifically, CMS is requesting comments on whether CMS should maintain the longer-term objective of eliminating the IPO list and if so, suggestions for a reasonable timeline for the elimination and what method should be employed to evaluate procedure removal. We request that commenters submit evidence on what effect, if any, they believe eliminating or scaling back the IPO list will have on beneficiary quality of care and what effect, if any, would the elimination or scaling back of the IPO list have on provider behavior, incentives, or innovation. We are also interested in stakeholders' viewpoints on the clinical, financial, and administrative impact of removing services from the IPO list. Additionally, we are interested in stakeholders' suggestions for refining the approach to inpatient only code evaluation to keep pace with advances in technology and surgical techniques that allow for more services to appropriately take place in the outpatient setting if we were to retain the IPO list." (pg. 357)

"Some commenters were able to review the individual services and requested that specific CPT codes remain payable in the inpatient setting only, including CPT codes 27280 (Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed) and 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar) due to concerns about the safety of these procedures if they are performed in the outpatient setting." (pg. 360)

"In light of ongoing stakeholder feedback, we have now, for CY 2022, reviewed each of the procedures removed from the IPO list in CY 2021 to determine whether they individually meet the longstanding criteria for removal from the list. Our review considered the clinical intensity and characteristics of the service, the underlying condition of the beneficiary who would require the service, peer-reviewed medical literature, case reports, clinical criteria sets, and utilization data. This review determined that none of the services removed in CY 2021 have sufficient supporting evidence that the service 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." (pg. 361)

"In particular, we found that the simplest procedures described by the codes for these services cannot be furnished safely in most outpatient departments, most outpatient departments are not equipped to provide these services to the Medicare population, and the procedures are not being performed in numerous hospitals on an outpatient basis. We also do not believe the services can be appropriately and safely furnished in an ASC." (pg. 362)

"As mentioned above, the services that we are proposing to add back to the IPO list reflect those services that we believe may pose increased safety risk to the typical Medicare beneficiary. However, we recognize that there may be a subset of Medicare beneficiaries who, on a case by case basis, may nonetheless be appropriate to treat in the outpatient setting and we seek comment below on whether any services that were removed in CY 2021, but are being proposed to be added back to the IPO for CY 2022, should in fact, remain off the IPO list." (pg. 363) ***See table 35.***

"In addition to our proposal to halt the elimination of the IPO list and return services summarily removed from the IPO list last year that our clinicians have determined do not meet the criteria for removal from the IPO list, as provided in Table 35, we are also interested in feedback from stakeholders on whether CMS should maintain the longer-term objective of eliminating the IPO list or if CMS should maintain the IPO list but continue to systematically scale the list back to so that inpatient only designations are consistent with current standards of practice. Specifically, CMS is requesting comments on the following:

- Should CMS maintain the longer-term objective of eliminating the IPO list? If so, what is a reasonable timeline for eliminating the list? What method do stakeholders suggest CMS use to approach removing codes from the list?

- Should CMS maintain the IPO list but continue to streamline the list of services included on the list and, if so, suggestions for ways to systematically scale the list back to allow for the removal of codes, or groups of codes, that can safely and effectively be performed on a typical Medicare beneficiary in the hospital outpatient setting so that inpatient only designations are consistent with current standards of practice?

- What effect do commenters believe the elimination or scaling back of the IPO list would have on safety and quality of care for Medicare beneficiaries?

- What effect do commenters believe elimination or the scaling back of the IPO list would have 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's 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 stakeholders believe 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?" (pg. 379)

Proposed Nonrecurring Policy Changes

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

*"*In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-Midnight rule within the 2 calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for "patient status."

*"*We explained that during this 2-year period, BFCC-QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A." (pg. 382)

"In CY 2021 we proposed to continue the 2-year exemption from site-of-service claim denials, BFCC-QIO referrals to RACs, and RAC reviews for "patient status" (that is, site-of service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. However, we finalized our proposal with modifications in the CY 2021 OPPS/ASC final rule with comment period. Instead of the 2-year exemption, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC-QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for "patient status" (that is, site-of-service)." (pg. 382)

"We stated that this exemption would last until we have 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 we would need to have Medicare claims data indicating that the procedure was performed more than 50 percent of the time in the outpatient setting. We stated that we would revisit in rulemaking whether an exemption for a procedure should be ended or whether we may consider additional metrics in the future that could assist us in determining when the exemption period should end for a procedure."

"Even during this exemption period, the BFCC-QIOs retain the authority to review such claims in order to provide education for practitioners and providers regarding compliance with the 2- Midnight rule, but claims identified as noncompliant will not be denied with respect to the site of-service under Medicare Part A.

Additionally, we stated that we may still conduct medical review in cases in which we believe there is potential fraud or abuse occurring. We explained that the elimination of the IPO list was a largescale change that created brand new considerations in determining site-of-service for providers and beneficiaries." (pg. 383)

"...In the CY 2021 OPPS/ASC final rule with comment period we amended 42 CFR 412.3 to clarify when a procedure removed from the IPO is exempt from certain medical review activities. We stated that for those

services and procedures removed between January 1 and December 31, 2020, this exemption will last for 2 years from the date of such removal. For those services and procedures removed on or after January 1, 2021, this exemption will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting." (pg. 384)

"As stated earlier in this section, services on the IPO list are not subject to the 2-Midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-Midnight rule is applicable once services have been removed from the IPO list. Outside of the exemption periods discussed above, services that have been removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC-QIOs." (pg. 384)

"Regardless of the status of the IPO list, we believe that the 2-Midnight benchmark remains an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. As technology advances and more services may be safely performed in the hospital outpatient setting and paid under the OPPS, it is increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case by case basis." (pg. 385)

"As in previous years, any services that are removed from the list in the future will be subject to the 2-Midnight benchmark and 2-Midnight presumption. This means that for services removed from the IPO list, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission will be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. Additionally, under the 2-Midnight benchmark, services formerly on the IPO list will be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation." (pg. 385)

"However, should we finalize our proposal to halt the elimination of the IPO list, there will no longer be an unprecedented volume of procedures removed from the IPO list at once, and thus the indefinite exemption may no longer be appropriate. As we explained in the CY 2021 OPPS/ASC final rule with comment period, the indefinite exemption was necessary given the magnitude of the change for providers. Now, however, we are proposing to move toward a much smaller volume of procedures becoming subject to the 2-Midnight rule at one time. We believe that, in the event that we finalize the proposed halt in the elimination of the IPO list, an indefinite exemption from medical review activities related to the 2-Midnight rule will no longer be warranted." (pg. 387)

"As with the previous 2-year exemption period for services removed from the IPO list between January 1 and December 30, 2020, applying a 2-year exemption period to services removed from the IPO list on or after January 1, 2021, would allow providers time to gather information on procedures newly removed from the IPO list to help inform education and guidance for the broader provider community, develop patient selection

criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures, and to develop related policy protocols. We believe that this exemption period would aid in compliance with our payment policy for inpatient admissions." (pg. 388)

"It is important to note that whether there is a limited timeframe or an indefinite exemption from the specified medical review activities, providers are still expected to comply with the 2-Midnight rule. It is also important to note that the 2-Midnight rule does not prohibit procedures from being performed or billed on an inpatient basis. Whether a procedure has an exemption or not does not change what site of service is medically necessary or appropriate for an individual beneficiary. Providers are still expected to use their complex medical judgment to determine the appropriate site of service for each patient and to bill in compliance with the 2- Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and site-of-service claim denials." (pg. 388)

"In summary, for CY 2021 and subsequent years, we propose to return to the 2-year exemption from site-of-service claim denials, BFCC-QIO referrals to RACs, and RAC reviews for "patient status" (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS on January 1, 2021 or later. Under this proposal, services removed beginning on January 1, 2021 would receive the same 2-year exemption from 2-Midnight medical review activities as currently applies to services removed between January 1 and December 30, 2020, and not the indefinite exemption finalized in the CY 2021 OPPS/ASC final rule with comment period. We encourage BFCC-QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis." (pg. 389)

Low Volume Procedures

"While we believe that the policies we have adopted to calculate payment rates for low-volume procedures have mitigated concerns regarding payment rates for new technologies and device-intensive procedures, we also believe 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, we believe 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 our low-volume policies for device-intensive procedures and New Technology APCs." (pg. 399)

"... due to the payment volatility and low volume nature of these products, we believe that choosing the methodology that yields the highest rate will ensure that these products receive sufficient payment and that payment is not a barrier to access for these procedures." (pg. 401)

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

CMS proposes establishing a Low Volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs. The threshold for the low volume APC designation would be fewer than 100 single claims per year for the APC and four years of claims data would be used to determine payment rates. CMS proposes using of the highest of the geometric mean, median, and arithmetic mean to determine the payment rate for these low volume APCs. (pg. 397)

Comment Solicitation on Temporary Policies to Address the COVID-19 PHE
CMS is "seeking comment on the extent to which stakeholders utilized the flexibilities available under these waivers, as well as whether stakeholders believe certain of these temporary policies should be made permanent to the extent possible within our existing authority. Specifically, we are seeking comment on stakeholders' experience with hospital staff furnishing services remotely to beneficiaries in their homes through use of communications technology." (pg. 406)

Proposal to Provide Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals with Transitional Pass-Through Payment Status Expiring between December 31, 2021 and September 30, 2022
"... we propose a one-time equitable adjustment under section 1833(t)(2)(E) to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. We have consistently explained that transitional pass-through payment for drugs, biologicals, and devices is intended as an interim measure to allow for adequate payment of certain new technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate." (pg. 423)

CMS believes that it is "an equitable adjustment to continue separate payment for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 is necessary to ensure that we have full claims data from CY 2021 with which to set payment rates beginning in CY 2023. We also believe it is necessary to pay separately for these products in CY 2022 in a manner that mimics continued pass-through status, rather than having to set rates and make APC assignments and packaging decisions for these products for CY 2022 based on data from CY 2020, which we do not believe is the best available data for this purpose." (pg. 423)

"One device category, HCPCS code C1823 (Generator, neurostimulator (implantable), non rechargeable, with transvenous sensing and stimulation leads), would receive adjusted payment equivalent to an additional four quarters of device pass-through status. There are 27 drugs and biologicals whose pass-through payment status expires between December 31, 2021 and September 30, 2022."

"Based on the CY 2020 data, payment for three of the 27 drugs and biologicals would otherwise be packaged after the expiration of their pass-through status. The remaining 24 drugs and biologicals would be paid separately and would otherwise receive reduced payment at the proposed rate of ASP minus 22.5 percent when they are acquired under the 340B program."

"There are currently six drugs and one device category whose pass-through payment status will expire on December 31, 2021, nine drugs and three biologicals whose pass-through status will expire on March 31, 2022, seven drugs whose pass-through status will expire on June 30, 2022, and two drugs whose pass-through payment status will expire on September 30, 2022. Because pass-through status can expire at the end of a quarter, the proposed adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the device category, drug, or biological."

"In particular, separate payment would be made a full year for the device category and 6 drugs for which pass-through status will expire on December 31, 2021, three quarters for the 12 drugs and biologicals for which pass-through status will expire on March 31, 2022, two quarters for the 7 drugs for which pass-through status will expire on June 30, 2022, and one quarter for the 2 drugs for which pass-through status will expire on September 30, 2022." (pg. 424) ***See Table 38***

Proposed CY 2021 OPPS Payment Status and Comment Indicators
For CY 2022, CMS is not proposing to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2021 OPPS/ASC final rule with comment period available on the CMS website at: https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

CMS is requesting public comments on the proposed definitions of the OPPS status indicators for CY 2022. The complete list of the proposed payment status indicators and their definitions that would apply for CY 2022 is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/index.html.

The proposed CY 2022 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/index.html.

Proposed CY 2021 Comment Indicator Definitions
CMS is proposing to use four comment indicators for the CY 2022 OPPS. These comment indicators, "CH", "NC", "NI", and "NP", are in effect for CY 2021 and we propose to continue their use in CY 2022. The proposed CY 2022 OPPS comment indicators are as follows:
● "CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
● "NC"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
● "NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
● "NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.
The definitions of the proposed OPPS comment indicators for CY 2022 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/index.html.

Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
Under Medicare regulations (§§ 416.2 and 416.166), covered surgical procedures in an ASC are surgical

procedures that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15. CMS notes these are subject to certain exclusions. In previous years, CMS identified surgical procedures as those described by Category I CPT in the surgical range from 10000 through 69999 as well as Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that they have determined do not pose a significant safety risk, that CMS would not expect to require an overnight stayed when performed in the ASC setting, and that are separately paid under the OPPS. Covered ancillary services (specified in § 416.164(b) and as previously stated) are eligible for separate ASC payment.

CMS makes separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures:

- brachytherapy sources;
- certain implantable items that have pass-through payment status under the OPPS;
- certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue;
- certain drugs and biologicals for which separate payment is allowed under the OPPS;
- certain radiology services for which separate payment is allowed under the OPPS; and
- non-opioid pain management drugs that function as a supply when used in a surgical procedure.

Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure. The lists of and payments rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system.

CMS bases ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies and uses quarterly change requests to update services paid for under the OPPS. Quarterly change requests for ASC covered surgical procedures and ancillary services are provided in January, April, July, and October.

CMS releases new and revised Category I, Category III, and Level II HCPCS codes as they become effective by the American Medical Association in coordination with CMS' quarterly updates.

Definitions

CMS defines a surgical procedure under the ASC payment systems as any procedure described within the range of Category I CPT codes that the AMA CPT Editorial Panel defines as "surgery" (CPT codes 10000-69999) as well as procedures that are described by Level II HCPCS codes (or by Category I CPT codes or Category III CPT codes that directly crosswalk or are clinically similar).

In CY 2021, CMS revised the definition of covered surgical procedures to surgical procedures specified by the Secretary that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153).

Proposed ASC Treatment of New and Revised Codes

July 2021 HCPCS and Codes for Which CMS Are Soliciting Public Comments in this Proposed Rule

CMS added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Below is a list of some of the new HCPCS codes, effective July 1, 2021.

- J7168, Prothrombin complex concentrate (human), kcentra, per I.u. of factor ix activity
- J9348, Injection, naxitamag-gqgk, 1 mg
- *J9353, Injection, margetuximab-cmkb, 5 mg*
- *Q4201, Matrion 1 sq cm*
- *Q5123, Injection, rituximab-arrx, biosimilar, (riabni), 10 mg*

The proposed payment indicators for these Level II HCPCS codes can be found on Table 40. CMS is inviting public comment on the proposed comment indicators and payment indicators. They are proposing to finalize the proposed payment indicators in the CY 2022 OPPS/ASC final rule.

October 2021 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule with Comment Period

For CY 2022, CMS is proposing that the Level II HCPCS codes that will be effective October 1, 2021 would be flagged with comment indicator "NI" in Addendum B to the CY 2022 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2022. They are inviting public comments in the CY 2022 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

Addendum B can be found here: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1753-p

Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

"Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or non office-based, after taking into account updated volume and utilization data." (pg. 444)

"For CY 2022, we propose to designate two new CY 2022 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures listed in Table 44 would be predominantly performed in physicians' offices." **(pg. 445) See Table 44**

"The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2022, are assigned payment indicator "J8" and are included in ASC Addendum AA to this proposed rule (which is available via the Internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2022 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because

the procedure is designated as device-intensive are also included in Addendum AA to the proposed rule (which is available via the Internet on the CMS website)." (pg. 450)

"... for CY 2022 and subsequent years, we are proposing to assign device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard rate setting methodology, even if the procedure is not designated as device intensive under the OPPS." (pg. 451)

"Therefore, for CY 2022 and subsequent years, we are proposing that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC rate setting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent." (pg. 452)

"Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device."

"To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. We are not proposing any other changes to our policies related to no/cost full credit or partial credit devices." (pg. 455)

Additions to the ASC CPL

Prior to 2021, the "...general exclusion criteria provided that covered surgical procedures do not include those surgical procedures 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 § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15." (pg. 456)

"In the CY 2021 OPPS/ASC Final Rule, we significantly revised our policy for adding surgical procedures to the ASC CPL. We revised the definition of covered surgical procedures at 42 CFR 416.166(a) and (b) to add new subparagraphs to provide that, for services furnished on or after January 1, 2021, covered surgical procedures for purposes of the ASC CPL are surgical procedures specified by the Secretary and published in the Federal Register and/or via the internet on the CMS website that: are separately paid under the OPPS; and are not:

designated as requiring inpatient care as of December 31, 2020; only able to be reported using a CPT unlisted surgical procedure code; or otherwise excluded under § 411.15." (pg. 456)

"..., on or after January 1, 2021, we add surgical procedures to the list of ASC covered surgical procedures either when we identify a surgical procedure that meets the requirements of paragraph (b)(2) or we are notified of a surgical procedure that could meet the requirements of paragraph (b)(2) and we confirm that such procedure meets those requirements. We added 267 surgical procedures to the ASC CPL that met the revised criteria for covered surgical procedures beginning in CY 2021." (pg. 457)

"Since the CY 2021 OPPS/ASC final rule was published, we have reexamined our ASC CPL policy and the public comments we received in response to the CY 2021 OPPS/ASC proposed rule, considered the concerns we received from stakeholders since the final rule was published, and conducted an internal clinical review of the 267 procedures we added to the ASC CPL under our revised policy beginning in CY 2021. After examining our revised policy and the feedback we have received, and reviewing the procedures we added to the ASC CPL under our revised policy, we have reconsidered our policy and believe that the policy may not appropriately assess the safety of performing surgical procedures on a typical Medicare beneficiary in an ASC, and that the 258 surgical procedures we added to the ASC CPL beginning in CY 2021 under our revised policy may not be appropriate to be performed on a typical beneficiary in the ASC setting." (pg. 458)

"We recognize that appropriate patient selection and physicians' complex medical judgment could help mitigate risks for patient safety. But while we are always striving to balance the goals of increasing physician and patient choice, and expanding site neutral options with patient safety considerations, we nonetheless believe the current policy could be improved with additional patient safety considerations in determining whether a surgical procedure should be added to the ASC CPL." (pg. 458)

"After evaluating the 267 surgery or surgery-like codes that were added 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." (pg. 459)

"In light of these concerns, in this CY 2022 OPPS/ASC proposed rule, we propose to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulation text that were in place in CY 2020. While this approach is a departure from the revised policy we adopted for CY 2021, it is consistent with our policy from CY 2008 through CY 2020 where we gradually expanded the ASC CPL while giving careful consideration to safety concerns and risks to the typical beneficiary. This approach would also continue to support our efforts to maximize patient access to care by, when appropriate, adding procedures to the ASC CPL to further increase the availability of ASCs as an alternative, lower cost site of care." (pg. 460)

"As stated above, we are proposing to remove 258 procedures from the ASC CPL for CY 2022 that were added to the ASC CPL in CY 2021 that we believe do not meet the proposed revised CY 2022 ASC CPL criteria, listed in Table 45." (pg. 462) ***See Table 45.***

"For CY 2022, we propose to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. We propose that external parties, for example, medical specialty societies or other members of the public, could nominate procedures to be added to the ASC CPL." (pg. 462)

"Specifically, for the OPPS/ASC rulemaking for a calendar year, we 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 January 1, 2023. We would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures. We propose to address nominated procedures beginning in the CY 2023 rulemaking cycle. We would address in rulemaking nominated procedures for which stakeholders have provided sufficient information for us to evaluate the procedure." (pg. 463)

"Therefore, we are seeking comments as to how CMS should prioritize nominations. For example, whether we would prioritize the nominations that have codes nominated by multiple organizations or individuals, codes recently removed from the IPO list, codes accompanied by evidence that other payers are paying for the service on an outpatient basis or in an ASC setting, or a variety of other factors." (pg. 464)

Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services
In alignment with their proposal to eliminate the OPPS payment rate for low-volume device-intensive procedures and instead implement a low-volume APC payment rate (i.e. the universal low volume APC policy described in Section X.C), CMS is proposing to limit the ASC payment rate for services assigned to low-volume APCs to a rate equal to the OPPS payment rate. (pg. 484)

No changes being proposed for how payment rates for ASC covered surgical procedures and covered ancillary services are calculated.

Proposed ASC Payment and Comment Indicators
CMS is proposing that Category I and III CPT codes that are new and revised for CY 2022 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2022, compared to the CY 2021 descriptors, be included in ASC Addenda AA and BB to this proposed rule and labeled with proposed comment indicator "NP" to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed comment indicator "NP" meant a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to the current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

CMs will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2022 OPPS/ASC final rule with comment period. Readers are referred to Addenda DD1 and DD2 of this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2022 update. Addenda DD1 and DD2 to this proposed rule contain the complete list of ASC payment and comment indicators for CY 2022 and can be

found on the CMS website at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1753-p

Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor
CMS is using CY 2019 claims data to be consistent with the OPPS claims data for the CY 2022 OPPS/ASC proposed due to concerns with the CY 2020 claims data as a result of the PHE. CMS proposes to scale the CY 2022 relative payment weights for ASC's according to the following method:

- Compare the total payment using the CY 2021 ASC relative payment weights with the total payment using the CY 2022 ASC relative payments weights to take into account the changes in the OPPS relative payment weights between CY 2021 and CY 2022 (while holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2019).
- Use the ratio of CY 2021 to CY 2022 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2022.
- The proposed CY 2022 ASC weight scalar is 0.8591

For CY 2022, CMS calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2022 ASC wage indexes.

CMS proposes to adjust the CY 2021 ASC conversion factor ($48.592) by the proposed wage index budget neutrality factor of 0.9993 in addition to the productivity-adjusted hospital market basket update of 2.3 percent. This results in a proposed ASC conversion factor of $50.043 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2021 ASC conversation factor by the proposed wage index budget neutrality factor of in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.3 percent. This results in a proposed CY 2022 ASC conversion factor of $49.064.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs – Request for Information (pg. 504)
In alignment with the 2022 Inpatient Prospective Payment System Proposed Rule & 2022 Medicare Physician Fee Schedule Proposed Rule, CMS is issuing an RFI on Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) within the scope of the Outpatient Quality Programs.

Proposed Requirements for the Hospital Outpatient Quality Reporting (OQR) Program (pg. 521)
Proposed Hospital OQR Program Quality Measures
In the Hospital OQR Program measure set, CMS is proposing to remove two measures, (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)) beginning with the CY 2023 reporting period due to the availability of a more broadly applicable measure, the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM).

CMS is proposing the following additions to the Hospital OQR Program measure set:

- **COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period**
- **This measure assesses the proportion of a hospital's health care workforce that has been vaccinated against COVID-19. Measure specifications are described on pg. 531.**
- **Hospitals would be required to report this measure quarterly due to the immediacy of the COVID-19 pandemic.**
- Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period
- STEMI eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period.

CMS is renewing its effort to include OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures in the Hospital OQR Program.

They are proposing voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

CMS requests comment on "the potential future adoption of measures for our consideration that address care quality in the hospital outpatient setting given the transition of procedures from inpatient settings to outpatient settings of care." (pg. 562)

As they did in the FY 2022 IPPS/LTCH PPS Proposed Rule, CMS is soliciting comment on including a re-specified version of the Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) measure (NQF #3559) in future years of the Hospital OQR Program. The measure would need to be adapted to the outpatient setting.

Specifically, CMS requests public feedback on the following questions:

- "Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO-PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a hospital that performs both inpatient and outpatient elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the hospital outpatient setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach." (pg. 565)

Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program (pg. 565)

To expand efforts to promote health equity, CMS seeks comment on the idea of stratifying performance results of six priority measures by dual eligibility. These six priority measures are:

- **MRI Lumbar Spine for Low Back Pain (OP-8)**
- **Abdomen CT – Use of Contract Material (OP-10)**

- **Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13)**
- **Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32)**
- **Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35)**
- **Hospital Visits after Hospital Outpatient Surgery (OP-36)**

CMS is seeking public comment on potential future confidential reporting of these six measures stratified by dual eligibility status.

CMS is exploring the idea of using dual eligibility as a proxy for social risk in Facility-Specific Reports and on the Care Compare website.

Form, Manner, and Timing of Data Submitted for the Hospital OQR Program
CMS is proposing to discontinue the option for hospitals 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. Hospitals would be required to submit only electronic files (i.e. PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process). CMS would continue to reimburse hospitals at $3.00 per chart.

To provide more timely feedback, CMS proposes reducing the amount of time hospitals have to submit medical records for validation from 45 days to 30 days.

Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2021 Payment Determination
For hospitals that fail to meet the Hospital OQR program requirements the proposed reduced conversion factor for CY 2022 is 82.810.

Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program (pg. 611)
Proposed ASCQR Program Quality Measures

As with the Hospital OQR Program, CMS proposes adding the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure to the ASCQR Program beginning with the CY 2022 reporting period. Measure specifications can be found on page 618.

CMS proposes requiring reporting of the following previously suspended measures beginning with the CY 2023 reporting period. (pg. 628)

- **ASC-1: Patient Burn**
- **ASC-2: Patient Fall**
- **ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant**
- **ASC-4: All-Cause Hospital Transfer/Admission**

Similar to proposals in the Hospital OQR program, CMS wants to resume implementation of ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS

CAHPS) Survey-Based Measures. CMS proposes voluntary submission beginning with the CY 2023 reporting period and transitioning to mandatory reporting beginning with the CY 2024 reporting period.
Table 52 lists the ASCQR Program Measure Set proposed for the CY 2022 reporting period.

CMS makes similar requests for comment on how to address the transition of procedures to the ASC in the ASCQR Program and the future inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA).
From analysis of CY 2019 and CY 2020 Medicare claims data, CMS sees pain management surgical procedures as a significant portion of procedures performed in the ASC setting. Thus, they seek feedback on the future development and inclusion of a pain management measure in the ASCQR Program measure set. (pg. 648, Table 55)

Request for Information on Rural Emergency Hospitals
"There has been a growing concern that closures of rural hospitals and critical access hospitals (CAHs) are leading to a lack of services for people living in rural areas, including access to emergency care. Section 125 of the Consolidated Appropriations Act of 2021 (CAA) established a new provider type called Rural Emergency Hospitals (REHs), effective January 1, 2023.
REHs are facilities that convert from either a CAH or a rural hospital, under section 1886(d)(8)(E) of the Social Security Act) with less than 50 beds, and that do not provide acute care inpatient services with the exception of skilled nursing facility services furnished in a distinct part unit. REHs will be required to furnish emergency department services and observation care and may provide other outpatient medical and health services as specified by the Secretary."

Solicitation of Public Comments
"CMS has included a Request for Information (RFI) to seek public input on a broad range of issues that should be considered in establishing this new provider type. Specifically, CMS is interested in feedback on the health and safety standards, payment policies, and quality measures for REHs. Public comment on these areas will help inform proposed rulemaking for CY 2023."

Radiation Oncology Model
"In September 2020, the Center for Medicare and Medicaid Innovation (the Innovation Center) published a final rule that established the Radiation Oncology (RO) Model with a start date of January 1, 2021. The RO Model will test whether making site-neutral, modality agnostic, prospective episode-based payments to Hospital Outpatient Departments (HOPDs) and physician group practices (including freestanding radiation therapy (RT) centers) for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing or maintaining Medicare spending."

"As a result of the ongoing COVID-19 PHE, CMS included an interim final rule with comment period (IFC) in the CY 2021 OPPS/ASC Final Rule to delay the start of the RO Model until July 1, 2021. Subsequently, the Consolidated Appropriations Act, 2021, included a provision that prohibits implementation of the RO Model prior to January 1, 2022, effectively delaying the start date by at least 6 months. CMS is making proposals to address necessary changes as a result of the legislatively mandated delay and additional proposed modifications to the model design."

"The CY 2022 OPPS and ASC Payment System proposed rule includes the following proposals to modify the RO Model's timing and design:

- To begin the RO Model on January 1, 2022, with a 5-year Model performance period (ending December 31, 2026).
- To change the baseline period from 2016-2018 to 2017-2019.
- To lower the discounts to 3.5 percent (Professional Component) and 4.5 percent (Technical Component).
- To remove brachytherapy from the list of included modalities under the RO Model so that it would still be paid FFS.
- To revise the cancer inclusion criteria under the RO Model.
- In cases where a beneficiary switches from traditional Medicare to Medicare Advantage during an episode before treatment is complete, CMS would consider this an incomplete episode and RT services would be paid the traditional Medicare rate instead of being paid under the RO Model.
- To adopt an extreme and uncontrollable circumstances policy. This policy would provide flexibility to reduce administrative burden of Model participation, including reporting requirements, and/or adjust the payment methodology as necessary when extreme and uncontrollable circumstances exist.
- To exclude hospital outpatient departments participating in the Community Transformation track of the CHART Model from participation in the RO Model. For the CHART ACO Transformation track, we would follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs.
- That only hospital outpatient departments that are participating in the Pennsylvania Rural Health Model (PARHM) would be excluded from the RO Model, rather than those that are eligible to participate in PARHM.
- To remove liver cancer from the RO Model as it does not satisfy the model's cancer inclusion criteria.

Finally, CMS includes clarifications to help address questions from stakeholders and future RO participants related to the interaction between the RO Model and the Quality Payment Program."

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

"Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled "Bringing Down the Cost of Health Care Coverage," requires each hospital operating within the United States (U.S.) for each year to establish (and update) and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act). Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services (Secretary) to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties." (pg. 731)

"We are proposing to amend several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance. For the reasons explained in this section of the preamble, we are proposing to: (1) increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count; (2) deem state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) prohibit certain conduct that we have concluded are barriers to accessing the standard charge information." (pg. 732)

Proposal to Increase the Civil Monetary Penalty Using a Scaling Factor
Due to noncompliance with the hospital price transparency requirements implemented on January 1, 2021 CMS is proposing to implement a civil monetary penalty using a scaling factor to set the penalty rate for each noncompliant hospital.

"First, this would allow us to penalize a hospital on a sliding scale in a manner that generally correlates to the hospital's characteristics, such as using the hospital's number of beds as a proxy for the size of the patient population it serves. Second, in the previous rulemaking, commenters suggested using a scaling factor as an alternative to a uniform CMP amount so as to not overly penalize smaller hospitals, while also providing a sufficient incentive for hospitals to comply. Third, other Federal programs use scaling factors in determining a CMP amount, in particular by taking into consideration the size of the entity subject to the penalty, or calculating the penalty based on the number of enrollees affected. Fourth, since finalization of the CY 2020 Hospital Price Transparency final rule, we have had the opportunity to evaluate and determine a reliable source of data that could be used to establish a CMP amount across most institutions that meet the definition of 'hospital' as defined at § 180.20." (pg. 736)

"We propose the following approach to scaling the CMP amount based on the hospital's number of beds, and as summarized in Table 63: ***See Table 63***

● For a noncompliant hospital with a number of beds equal to or less than 30, the maximum daily dollar CMP amount would be $300, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
● For a noncompliant hospital with a number of beds between 31 and 550, the maximum daily dollar CMP amount would be the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.

● For a noncompliant hospital with a number of beds greater than 550, the maximum daily dollar CMP amount would be $5,500, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180." (pg. 739)

"Given that the requirements in 45 CFR part 180, as established by the CY 2020 Hospital Price Transparency final rule, were effective January 1, 2021, and because of the proposed effective date of January 1, 2022, for the modifications to the CMP amounts in this proposed rule, we would apply the cost-of-living adjustment multiplier determined by OMB, in calculating CMP amounts for hospital noncompliance with the requirements in 45 CFR part 180, beginning in CY 2023 and subsequent years." (pg.742)

Additional Hospital Inpatient Quality Reporting (IQR) Program Policies (pg. 760)
Safe Use of Opioids - Concurrent Prescribing eCQM (NQF # 3316e) and eCQM Reporting Requirements in the Hospital IQR Program – Request for Information (pg. 761)

"The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 for reendorsement consideration as part of the measure maintenance process. The purpose of this RFI is to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids – Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure."

Additional Medicare Promoting Interoperability Program Policies
CMS makes a similar RFI on Safe Use of Opioids - Concurrent Prescribing eCQM (NQF # 3316e) and eCQM reporting requirements as it relates to the Medicare Promoting Interoperability Program. (pg. 766)