Policy Update

CMS Releases CY 2021 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule

On December 2, 2020, the Centers for Medicare & Medicaid Services (CMS) released the CY 2021 Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process [CMS-1736-F], which finalizes payment updates and policy changes affecting Medicare hospital outpatient and ambulatory surgical center (ASC) services for CY 2021.

For CY 2021, CMS increased payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment Systems by a factor of 2.4%. Hospitals and ASCs that fail to meet quality reporting program requirements are subject to a 2.0% reduction to the update factor.

CMS estimates, based on the finalized policy changes, that total payments to hospitals and ASCs will be approximately $83.9 billion and $5.42 billion, respectively, for an increase of approximately $7.5 billion and $120 million, respectively, over CY 2020 program payments.

While CMS finalized these slightly higher payment rates, several other policies will be of concern for hospitals and surgery centers. For example, this rule finalizes policies that seek to eliminate the site of service barriers for surgical procedures, and continues to address site neutrality reforms and payments under the 340B drug discount program.

A new Administration may wish to take a fresh look at some of these policies, and may redirect or even reverse course in a few instances.

- The final regulations are available here.
- The press release is available here.
- The fact sheet is available here.

A comparison of the following major provisions as proposed and the finalized policies is presented below:

- **Major OPPS Payment Policies**
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Major OPPS Payment Policies

Proposed Policy	Finalized Policy
Payment for 340B Drugs *For CY 2018, CMS implemented a controversial change whereby Medicare pays for drugs covered and paid under the OPPS and purchased through the 340B Program at Average Sales Price (ASP) minus 22.5%, instead of ASP plus 6%. For CY 2019, CMS extended this policy by also paying ASP minus 22.5% for 340B drugs furnished by non-excepted off-campus provider-based departments. CMS maintained the policy for CY 2020 despite ongoing litigation and several court rulings that CMS exceeded its authority when it implemented these policy changes. Notably, on July 31, 2020, the US Court of Appeals for the District of Columbia Circuit held that CMS does have authority under the Social Security Act to reduce Medicare payment rates for 340B-eligible drugs reimbursed under the OPPS.* **Final Rule Takeaway:** CMS maintained its current policy of paying ASP minus 22.5% for 340B acquired drugs, withdrawing the proposed cut of 28.7%.	
✓ **For CY 2021, CMS proposed a larger reduction to 340B drugs, with a proposed rate of ASP minus 28.7%, which equates to ASP minus 34.7% plus an add-on of 6% of ASP to cover overhead and handling costs.** ✓ **CMS proposed to set payment for 340B-acquired drugs by reducing ASP by the volume-weighted geometric mean discount, excluding "penny priced drugs"—or drugs where the 340B ceiling price falls below $0—and statistical outliers.** ✓ **The proposed new method would utilize data on drug acquisition costs in CYs 2018 and 2019 from the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs to determine volume-weighted geometric mean discount for CY 2021 and beyond.**	✓ **For CY 2021, CMS maintained current payment policy for 340B-acquired drugs, a rate of ASP minus 22.5%.** **Discussion** • CMS indicated that maintaining current policy will provide consistent and reliable payment for 340B-acquired drugs both for the remainder of the public health emergency (PHE) and after its conclusion. • Continuing the current policy also gives CMS time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. • Any future changes to 340B payment policy would be adopted through public notice and comment rulemaking.

Proposed Policy	Finalized Policy
✓ CMS proposed to continue the exemption for rural sole community hospitals, children's hospitals and prospective-payment-system-exempt cancer hospitals, which would continue to be paid at ASP plus 6%. **Rationale for Proposal** • According to CMS, ASP minus 22.5% was a conservative estimate of covered entity drug acquisition costs, and current policy overcompensates covered entity hospitals for drugs acquired under the 340B program and data from the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs supports this perspective. • At the time of the proposed rule's publication, CMS had not made public the 340B survey data, which even if released will not include data on 340B ceiling prices because of statutory confidentiality provisions. Therefore, stakeholders were unable to validate the CMS analysis and calculation methodology. • CMS did hold out the prospect of delaying the cut. The agency solicits comments on an "alternative" proposal under which it would continue the current Medicare payment policy of ASP minus 22.5% for 340B drugs paid under OPPS.	• While considerable questions remain as to whether the "most favored nation" (MFN) drug payment demonstration goes into effect as scheduled, for at least the first two years of the MFN payment adjustments, hospitals subject to 340B payment rates will continue to be paid at the 340B rates under OPPS, rather than the MFN rates. The relationship between the two payment methodologies as the MFN rate is more fully phased in over future years is unclear due to the variability of the international pricing metric used in the MFN calculation.

Revisions to the Inpatient Only List

Historically, CMS has identified services that are typically provided in an inpatient setting (referred to as the inpatient only (IPO) list) and that thus would not be paid by Medicare under the OPPS or ASC Payment Systems. For CY 2020, there are 1,740 services on this list. Each year, as part of its annual review, CMS seeks to identify services that should be removed from or added to the list based on the most recent data and medical evidence available.

Final Rule Takeaway: CMS will eliminate and transition services off the IPO list over a three-year period.

✓ **The proposed policy would eliminate the IPO list over a three-year transition to be completed by January 1, 2024.**

✓ **For the first phase of the transition, CMS proposed to remove 266 musculoskeletal-related services from the IPO list effective January 1, 2021.**

✓ **CMS also solicited feedback from stakeholders regarding the following policy considerations:**

- Is three years an appropriate timeframe for transitioning to eliminate the IPO list?
- What other services should be considered as candidates for removal from the IPO list for CY 2021?
- In what sequence should CMS remove additional clinical families and services from the IPO list in future rulemaking?

Rationale for Proposal

- Over the years, CMS has received comments, predominantly from surgeons and surgical centers, requesting that CMS eliminate the IPO list and allow physicians to use their clinical judgment to determine the site of service.

✓ **CMS finalized the policy to transition services off the IPO list starting on January 1, 2021.**

✓ **Based on feedback received from stakeholders, including the Medicare Advisory Panel on Hospital Outpatient Payment, CMS will move 298 procedures off the list for CY 2021.**

- CMS provided no insight into the categories of services that CMS intends to remove in CY 2022 and CY 2023.

✓ **To address concerns regarding application of the two-midnight benchmark to services recently removed from the IPO list, CMS implemented an indefinite exemption of recently removed services from the IPO list from medical review activities related to the two-midnight rule.**

- The exemption will be reconsidered when there is sufficient data to support that the procedure is more commonly performed in the outpatient setting.

Further information on the procedures removed from the IPO list for 2021 can be found in Table 48 of the final rule.

• To address concerns regarding beneficiary safety, CMS noted several safeguards in the absence of the IPO list including, but not limited to: o State and local requirements o Accreditation requirements o Hospital conditions of participation o Medical malpractice laws o Other quality and monitoring initiatives	**Discussion** • Eliminating services on the IPO list will likely drive more surgeries to be performed in the outpatient or ASC setting. However, CMS reiterated that the determination of the appropriate site of service should be based on the clinician's judgment, the beneficiary's needs and relevant coverage rules, and that CMS will provide non-binding guidance on the correct care setting. • Many view elimination of the IPO list as another effort to remove payment incentives that drive site of service selection. While CMS has previously stated that it does not expect large volume shifts when procedures are removed from the IPO list, past experience with hip and knee replacements have shown significant volume and payment changes. • The policy may also affect the type of patients that remain in the inpatient setting, potentially leaving the more complex and sick patients as hospital inpatients, while more healthy patients can be treated at ASCs. • Stakeholders should monitor for the potential ripple effects of the phased elimination of the IPO list on actions taken by private payers and Medicare Advantage plans.

Physician-Owned Hospitals

Under the federal physician self-referral proscription, commonly known as the Stark Law, a physician is prohibited from making referrals for certain specified services to any entity in which the physician (or an immediate family member of the physician) has a financial relationship (including a direct or indirect ownership or investment interest). Penalties for violating the law include steep civil monetary penalties and possible exclusion from the Medicare and Medicaid programs. Despite this self-referral prohibition, until 2010, physicians could make referrals to hospitals that they owned through exceptions to the law. In 2010, after almost a decade of rapid growth in both physician-owned hospitals and corresponding policy scrutiny, Congress enacted provisions in the Affordable Care Act severely restricting new physician-owned hospitals and limiting growth of existing facilities.

Final Rule Takeaway: CMS removed certain expansion limitations on physician-owned hospitals for "high Medicaid facilities."

✓ **The proposed policy would implement the following flexibilities applicable to only "high Medicaid facilities":**

- Hospitals can request an exception to the prohibition of expansion at any time, provided that the facility has not submitted another exception request that is pending a CMS decision. This proposal would eliminate the restriction that exceptions can only be submitted every two years to Medicaid hospitals.
- If CMS approves a hospital's request for expansion, the hospital can exceed 200% of its baseline number of beds, operating rooms and procedure rooms.
- Requests for expansion may include facilities that are not located on the hospital's main campus.
- A bed counts toward a hospital's baseline number if the bed is considered licensed for purposes of state licensure.

✓ **A hospital qualifies as a "high Medicaid facility" when the hospital meets all of the following criteria:**

- It is not the only hospital in a county.

✓ **CMS finalizes its proposed flexibilities for "high Medicaid facilities."**

- CMS removed the cap on the number of additional operating rooms, procedure rooms and beds that can be approved in an exception.
- Expansion can occur beyond the hospital's main campus.
- Additional requests for expansion can be made more than once every two years, provided that the facility has not submitted another exception request that is pending a CMS decision.

Discussion

- CMS stated that these changes provide flexibility and remove administrative burden for high Medicaid facilities, which serve more Medicaid inpatients, despite comments from hospital groups that largely opposed the policy, citing fraud and abuse as well as other concerns.
- CMS also estimates that only one physician-owned hospital per year will request an expansion exception on the grounds that it is a high Medicaid facility.
- These changes are not likely to materially alter the status quo in most communities with physician-owned hospitals,

• Its annual percentage of total inpatient admissions under Medicaid is estimated to be greater than any other hospital located in the county in which the hospital is located for the three most recent 12-month periods. • It does not discriminate against beneficiaries of federal healthcare programs, and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.	but it is notable that this debate has re-emerged after almost a decade of dormancy, and it might signal the potential for more proposed changes in the future.

Prior Authorization Process for Certain Services

For CY 2020, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. The change applied as of July 1, 2020, to five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

Final Rule Takeaway: CMS finalized a proposal to add two new service categories to the list of outpatient procedures requiring prior authorization.

✓ **CMS proposed the addition of two new service categories to the list of outpatient hospital services that would require prior authorization, effective July 1, 2021:** 1. Cervical Fusion with Disc Removal • **22551** Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial • **22552** Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck, anterior approach, each additional interspace 2. Implanted Spinal Neurostimulators • **63650** Implantation of spinal neurostimulator electrodes, accessed through the skin • **63685** Insertion or replacement of spinal neurostimulator pulse generator or receiver	✓ **CMS finalized the addition of these two service categories and five CPT codes as proposed. With the addition of these new service categories, a total of seven service categories will require prior authorization effective July 1, 2021:** 1. Blepharoplasty 2. Botulinum toxin injections 3. Panniculectomy 4. Rhinoplasty 5. Vein ablation 6. Cervical Fusion with Disc Removal 7. Implanted Spinal Neurostimulators

• **63688** Revision or removal of implanted spinal neurostimulator pulse generator or receiver For more information on the Outpatient Department Prior Authorization process, see our summary of the CY 2020 OPPS/ASC final rule.	• **CMS will monitor both MAC timeliness in processing prior authorization requests and impacts on beneficiary access to services.** **Discussion** • Prior authorization remains at the forefront of the policy debate on Capitol Hill and with the Administration, with policies introduced in the past year intended to both curtail (*e.g.*, COVID-19 related policies) and expand the use of prior authorization (*e.g.*, the expansion of prior authorization for Repetitive, Scheduled Non-Emergent Ambulance Transport). • Prior authorization is likely to continue as a hot topic on the Hill next year. The level of administrative interest in the topic may change with new leadership at CMS and the US Department of Health and Human Services.

Laboratory Date of Service Policy

The date of service for a laboratory test may affect payment for patients seen in a hospital outpatient department, because if the date of service falls during an outpatient encounter, payment for the laboratory test usually is bundled with the hospital service. For most laboratory tests, the date of service is typically the date of specimen collection, unless the specimen was archived (held for more than 30 days) before testing, in which case the date of testing is the date of service. In prior rulemakings, CMS developed exceptions to this date of service policy for some tests.

Final Rule Takeaway: CMS extended the date of service exception to apply to cancer-related protein-based multianalyte algorithmic assays (MAAAs).

✓ **CMS proposed to create an exception for cancer-related protein-based MAAAs from the OPPS packaging policy via an exception to the laboratory date of service rule. CMS indicated that the following codes were cancer-related protein based MAAAs:** • 81500 Onco (ovar) two proteins	✓ **CMS finalized the proposal with modification.** • CMS expanded the laboratory DOS exception to include cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536 and 81539. This exception is not limited to the current MAAAs and will apply to MAAAs that are developed in the future.

• 81503 Onco (ovar) five proteins • 81535 Oncology gynecologic • 81536 Oncology gynecologic • 81538 Oncology lung* • 81539 Oncology prostate prob score *A DOS exception already applied to the test described by code 81538 due to its status as an advanced diagnostic laboratory test.	• In response to stakeholder feedback, CMS also finalized an exception to the DOS policy for the test described by the CPT code 81490, a test for rheumatoid arthritis. • The DOS exception will not apply to PLA codes that seem MAAA-like, but CMS may revisit this policy in the future when patterns of utilization are better understood. **Discussion** • CMS continues to re-evaluate the DOS policy and is open to considering further revisions to the laboratory date of service exception at 42 CFR 414.510(b)(5) in future rulemaking.

Transitional Pass-Through Payment for Medical Devices

Transitional pass-through payment for devices allows for adequate payment of new innovative technology during the interval in which CMS collects the data necessary to incorporate costs for these devices into the procedure APC rate. Devices that meet the requisite qualification criteria are eligible to receive transitional pass-through payment. CMS also has established an alternative pathway for devices approved under the US Food and Drug Administration (FDA) Breakthrough Device Program. The period for which a device category is eligible for transitional pass-through payments is at least two years but no more than three years, depending upon the quarter in which the device was approved.

Final Rule Takeaway: CMS will consider extension of the transitional pass-through period in future rulemaking.

✓ **CMS solicited comments on its authority to provide separate payment following the end of the pass-through period for medical devices with reduced utilization during the PHE.** • Rulemaking on this issue would be included in the CY 2022 OPPS/ASC proposed rule.	✓ **CMS took no action in this rulemaking cycle on the extension of the transitional pass-through period for devices whose utilization may have been affected during the PHE.** • CMS will consider extension of the pass-through period in the CY 2022 rulemaking cycle, as none of the eligible devices have their pass-through periods ending in CY 2020. • Currently, seven devices are eligible for transitional pass-through payment with expirations dates varying from

Rationale for Proposal • CMS responded to stakeholders' comments that volume has declined for some services that may be considered elective, as well as new technology devices used in those services. • Claims data that are used to calculate appropriate payment for these services once the transitional payment period is over may be affected.	December 31, 2021, to June 30, 2023, and thus are directly affected by this circumstance. • While extension of the pass-through period was only discussed in the context of devices, CMS expressed openness to considering expansion of the pass-through extension to drugs in future rulemaking. **Discussion** • CMS has not committed to the extension of the pass-through period but has agreed to consider it in future rulemaking. Stakeholders, particularly organizations that are directly affected, should continue to engage with CMS on this topic and, to the extent possible, should seek to quantify the PHE's effect on device utilization.
Final Rule Takeaway: CMS approved five device applications for transitional pass-through payment.	
✓ **CMS evaluated five applications for device pass-through payments and preliminarily approved two: CUSTOMFLEX® ARTIFICIALIRIS and EXALT™ Model D Single-Use Duodenoscope.** ✓ **CMS did not propose any changes to its qualification criteria for transitional pass-through payments for medical devices.**	✓ **CMS approved five device applications for transitional pass-through payments.** • Three devices received approval through the alternative pathway for devices receiving FDA Breakthrough Device designation and FDA premarket approval. o CUSTOMFLEX® ARTIFICIALIRIS o EXALT™ Model D Single-Use Duodenoscope o BAROSTIM NEO™ • CMS approved two devices through the "traditional" pass-through application process (*i.e.*, these devices must also demonstrate substantial clinical improvement). o Hemospray® Endoscopic Hemostat o SpineJack® Expansion Kit

	✓ **While CMS did not propose any changes to its qualification criteria for transitional pass-through payments for medical devices, CMS did clarifiy that devices pursuing the alternative pathway for certain transformative devices must not only be a part of the FDA Device Breakthrough program but must also have FDA marketing authorization for the specific indication covered by the breakthrough designation.** **Discussion** • This is the first year in at least four rulemaking cycles where CMS approved all transitional pass-through applications. Historically, "traditional" applications have struggled to meet the substantial clinical improvement criteria.

Site Neutral Payments for Clinic Visits at Off-Campus Provider-Based Departments

Beginning in 2019, CMS implemented a policy that reduced OPPS payments for clinic visits described by HCPCS code G0463 and furnished at off-campus provider-based outpatient departments that previously were excepted or grandfathered from site-neutral payment policies. CMS phased in the payment reduction over two years. For 2020, CMS implemented the second portion of the payment reduction, a change that reduced payments for these services to 40% of the OPPS rate.

Final Rule Takeaway: CMS will continue to pay clinic visits provided by off-campus hospital outpatient departments at 40% of the OPPS rate.

✓ **CMS proposed to continue to pay clinic visits provided by off-campus hospital outpatient departments at 40% of the OPPS rate.** **Rationale for Proposal** • This policy is controversial and is the subject of litigation. In September 2019, a federal district court sided with hospital plaintiffs, ruling that CMS lacked statutory authority to	✓ **CMS maintained current payment policy as proposed.** **Discussion** • Subsequent to the July 17, 2020, ruling, the American Hospital Association and the Association of American Medical Colleges announced that they would seek a rehearing and push to reverse the ruling. Insofar as the hospital plaintiffs won at the district court level and

implement the change. However, on July 17, 2020, the US Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that the agency's regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. • In light of this court victory, CMS proposed to continue the site neutral policy in 2021.	further legal action is being pursued, CMS's site-neutrality policy is not yet secure.

Other Major Payment Policy

Finalized Policy	Revised Policy

Radiation Oncology Model

In September 2020, CMS finalized two Center for Medicare and Medicaid Innovation demonstration models: the Radiation Oncology (RO) Model and the End Stage Renal Disease Treatment Choice Model. The RO Model is a mandatory nationwide demonstration model encompassing approximately 30% of eligible radiation oncology episodes. The model pays a prospective payment on a site neutral basis, and the rate does not vary based on the modality of treatment.

Final Rule Takeaway: CMS delayed the beginning of the RO Model performance period and made other conforming changes based on this delay.

- ✓ **CMS previously finalized the RO Model to begin on January 1, 2021, with a five-year performance period.**
- ✓ **The payment rates that each individual would receive for the relevant episode of care would depend on several factors, including but not limited to:**
  - Trend rates
  - Historical experience adjustments
  - Quality and incorrect payment withholds
- ✓ **The model implemented quality measures and clinical data collection requirements starting in Performance Year (PY) 1.**
- ✓ **Based on its design, the RO Model qualified as an Advanced Alternative Payment Model (APM), and qualified participants were eligible for the 5% APM Incentive Payment in PY 1.**

- ✓ **In response to stakeholder feedback, CMS delayed the start of the RO Model by six months, with an effective date of July 1, 2021. CMS will maintain the model end date of December 31, 2025, thereby shortening the performance period to 4.5 years.**
- ✓ **With the change in the effective date, CMS implemented other changes in the model for PY 1:**
  - Quality reporting will not begin until PY 2 (CY 2022). Given that no quality reporting will occur in PY 1, CMS eliminated the 2% quality withhold for professional participants. In addition, the RO Model will not meet the criteria of an Advanced APM or MIPS APM for PY 1.
  - Collection of clinical data elements will not begin until January 1, 2022, with the initial submission due in July 2022.

Finalized Policy	Revised Policy
For more information on this model, see our RO Model Executive Summary.	**Discussion** • Many stakeholders have expressed concerns regarding the design of the RO Model and its impact on participants, particularly during the COVID-19 PHE as resources are strained. Continued pressure on Congress and the Administration is likely, as participants and key medical societies seek additional changes to the model design and further delays of the implementation date. The change in Administration could bring additional opportunities to modify this model.

Major ASC Payment Policies

Proposed Policy	Finalized Policy
ASC Covered Procedures List *Similar to the IPO list, CMS maintains the ASC Covered Procedures List (CPL) and reviews it annually to determine if services should be added to or removed from the list. Historically, stakeholder requests and feedback have led to additions to the list.* **Final Rule Takeaway:** CMS revised the criteria under which surgical procedures are added to the ASC CPL.	
✓ **As part of its annual review, CMS proposed to add 11 procedures, including total hip arthroplasty, to the CPL.** ✓ **CMS sought feedback on two alternative processes for identifying procedures that should be added to the ASC CPL.** • *Alternative 1*. Stakeholders would nominate procedures for consideration to be added to the ASC CPL. Any procedures recommended to CMS would be reviewed as part of the annual rulemaking cycle, with CMS summarizing the recommendations and the justification for inclusion or exclusion. Final decisions would be published in each year's final rule. CMS would also modify a subset of the criteria used to evaluate the inclusion of a service on the ASC CPL. The nomination process would begin in CY 2021 for CY 2022. • *Alternative 2*. CMS would use the existing process for annually reviewing services for consideration, but would eliminate five of the current eight general exclusion criteria for adding surgical procedures to the ASC CPL: o Generally result in extensive blood loss o Require major or prolonged invasion of body cavities o Directly involve major blood vessels	✓ **CMS added total hip arthroplasty and 10 other procedures to the ASC CPL.** ✓ **CMS will proceed with Alternative 2 as the approach for identifying procedures to add to the ASC CPL. Under this process, CMS will consider eligible procedures on annual basis but against a smaller set of criteria.** • An additional 267 surgical and surgical-like procedures will be added to the ASC CPL. With this approach, physicians have a greater role and responsibility in determining whether a surgical procedure can be safely performed in an ASC setting. Further information on the procedures added to the ASC CPL for 2021 can be found in Tables 59 and 60 of the final rule.

Proposed Policy	Finalized Policy
o Are generally emergent or life-threatening in nature o Commonly require systemic thrombolytic therapy. Under this approach, CMS identified 270 procedures that could be added to the ASC CPL for CY 2021. **Rationale for Proposal** • The COVID-19 pandemic has had a significant impact on healthcare facilities and has highlighted the need for additional healthcare access points for beneficiaries across the United States. Many ASCs have either temporarily or permanently closed, or temporarily enrolled as hospitals during the PHE. To ensure continued access to care during and after the PHE, CMS seeks to give physicians and patients greater flexibility to choose ASCs as a site of care for covered surgical procedures. • CMS has existing protocols and exclusion criteria in place against which any proposed services are evaluated for addition to the CPL. • With the proposed elimination of the IPO list, any proposed approach would exclude procedures designated as requiring inpatient care as of December 31, 2020.	**Discussion** • The changes in the ASC CPL and the process for adding procedures to this list are consistent with the changes to the IPO list. CMS seeks to have payment incentives play a smaller role in site of service selection, placing the responsibility and burden on the physicians to determine the appropriate setting based on the individual beneficiary's needs. • CMS's plans to eliminate the IPO list over three years will likely accelerate the number of procedures added to the ASC CPL annually.

Major Quality Proposals

Proposed Policy	Finalized Policy
Overall Quality Star Ratings *The Overall Hospital Quality Star Ratings rate hospital quality on a scale from one to five stars and are based on data from the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting (OQR) Program. Ratings are publicly available to Medicare beneficiaries online. Although CMS periodically updates the Star Ratings methodology, over the years the methodology has been criticized for being flawed and for not capturing a comprehensive assessment of a hospital's performance.* **Final Rule Takeaway:** CMS finalized a modified proposal to update Star Ratings methodology.	
✓ **CMS proposed changes to the Star Rating Methodology with an eye towards simplification, burden reduction and increased comparability. These changes would begin starting in 2021.** • Proposed changes include: o Combining three existing process measure groups into one new Timely and Effective Care group, reducing the total number of measure groups to five o Using a simple average methodology to calculate measure group scores instead of the current statistical Latent Variable Model o Stratifying the Readmission measure group only by hospitals' proportion of dual-eligible patients to align with the Hospital Readmissions Reduction Program o Making changes to reporting thresholds for measure groups o Applying a peer grouping methodology	✓ **CMS finalized a modified proposal to update Star Ratings methodology.** • CMS did not finalize the stratification of the Readmissions group by dual-eligible patients for several reasons: o Continued stakeholder concerns regarding the dual-eligibility variable o Concerns that stratification may be confusing to patients o Analyses that indicate stratification of the Readmission measure group would not have the intended effect o Recent report to Congress from Assistant Secretary of Health and Human Services for Planning and Evaluation that did not recommend adjusting quality measure for social risk in public reporting

Proposed Policy	Finalized Policy
✓ **CMS proposed to allow the voluntary participation of critical access hospitals beginning in CY 2021 and participation of Veterans Health Administration hospitals beginning in CY 2023.**	✓ **CMS finalizes as proposed its proposal for critical access hospitals and Veterans Health Administration hospitals.**
Hospital Outpatient Quality Reporting and ASC Quality Reporting Programs *Hospitals and ASCs have separate quality reporting programs. In recent years, CMS has sought to reduce the reporting burden and redundancy across the various CMS quality reporting programs through the Meaningful Measures Framework and other similar initiatives. CMS believes greater alignment between quality programs not only reduces burden but also can improve the robustness of the data collected.* **Final Rule Takeaway:** CMS finalized its proposal to increase alignment between hospital and ASC quality programs.	
✓ **CMS proposed changes to align the Hospital Outpatient Quality Reporting (OQR) and the ASC Quality Reporting (ASCQR) Programs.** • CMS previously finalized that hospitals sharing the same CMS Certification Number must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. For CY 2021, CMS proposed to codify this policy by adding language to regulation text. • CMS also proposed to codify an expanded review and corrections process to further align the Hospital OQR and ASCQR Programs while clarifying program requirements. • CMS solicited comments on new measures for consideration that address care quality in the ASC setting,	✓ **CMS finalized changes to better align the Hospital OQR and ASCQR programs.** • While CMS had solicited feedback from stakeholders on additional measures to improve comparison of care provided in both the hospital and ASC settings, it did not propose any new measures for either program. • Changes to the program are primarily operational in nature, finalizing selected administrative procedures and codifying established processes and regulations. **Discussion**

Proposed Policy	Finalized Policy
and on additional measures that could facilitate comparison of care provided in ASCs and hospitals. • CMS did not propose any measure additions or measure deletions in this rulemaking cycle.	• With the increase in procedures and services that can be performed in both the outpatient and ASC settings, stakeholders should expect continued alignment and harmonization of measures to allow beneficiaries to compare across setting.

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