Policy Update

CMS Releases CY 2022 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule

On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule [CMS-1753-F], finalizing payment rates and policy changes affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings for CY 2022.

For CY 2022, CMS increased payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System by a factor of 2%. Hospitals and ASCs that fail to meet their respective quality reporting program requirements will be subject to a 2% reduction.

Based on the finalized policies, CMS estimates that total payments to OPPS and ASC providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization and case-mix) for CY 2022 will be approximately $82.078 billion and $5.41 billion, respectively, for an increase of approximately $5.9 billion and $40 million, respectively, from CY 2021 program payments.

The finalized regulations are available here. The press release and accompanying fact sheet are available here and here, respectively.

Key takeaways from the CY 2022 OPPS and ASC Payment System Final Rule:

- CMS finalized, with modification, the proposal to halt the elimination of the inpatient only (IPO) list and to add back the vast majority of procedures removed from the list in 2021.
- To drive compliance with the recently established hospital price transparency program, CMS will increase the potential size of civil monetary penalties (CMP) for noncompliance.
- The Biden Administration continues to focus on health equity and how to appropriately address it in the hospital quality programs.
- The Radiation Oncology Alternative Payment Model will be effective as of January 1, 2022, unless congressional action further delays the model.

OPPS Major Finalized Policies

Revisions to the Inpatient Only List

Key Takeaway: CMS reversed plans to eliminate the IPO list.

Historically, CMS has identified services that are safely provided only in an inpatient setting and thus would not be paid by Medicare under the OPPS. These services were designated to the IPO list. In the CY 2021 OPPS/ASC Final Rule, CMS announced that it would eliminate the IPO list over the course of three years (85 FR 86084-88). In CY 2021, the first year of the transition, CMS removed 298 codes from the IPO list.

The very next year, CMS proposed to reverse course, and CMS has now finalized its proposal to stop the phased elimination of the IPO list and to add back all but a small number of the 298 codes removed in CY 2021. CMS also finalized a proposal to codify the five longstanding criteria for determining when a service should be placed on the IPO list, and to amend § 419.22(n) to remove reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition.

It is rare to see CMS reverse course on a clinical policy so abruptly, but the about-face likely reflects the change in political leadership earlier this year.

For procedures removed from the IPO list, CMS finalized its policy to exempt these procedures for two years (rather than indefinitely as finalized in the CY 2021 rulemaking cycle) from the two-midnight medical review activities.

Transitional Pass-Through Payment for Medical Devices

Key Takeaway: CMS approved three new devices for transitional pass-through payment and finalized an additional four quarters of eligibility for separate payment for one device whose eligibility for transitional pass-through was scheduled to expire at the end of 2021.

Transitional pass-through payment for new devices is intended to allow for adequate payment of new innovative technology during the interval in which CMS collects the data necessary to incorporate the costs for these devices into the accompanying procedure's payment 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.

Acknowledging the impact of the COVID-19 public health emergency (PHE) on utilization, CMS sought feedback from stakeholders in the CY 2021 rulemaking cycle on the agency's authority to provide separate payment—after pass-through status ends—for devices currently eligible for pass-through payment. This additional period of eligibility would be intended to account for the period of time that device utilization was reduced because of the PHE.

In the CY 2022 final rule, CMS exercised this authority for the device reported under C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads) whose transitional payments were set to expire at the end of CY 2021. CMS has not yet proposed to extend pass-through status for the five devices whose transitional payments are set to expire at the end of CY 2022.

CMS did not propose any changes to the qualification criteria for transitional pass-through payments for medical devices.

As part of its quarterly review cycle, CMS evaluated eight applications for device pass-through payments and approved three devices: RECELL® Autologous Cell Harvesting Device, Shockwave C2 Coronary Intravascular Lithotripsy (IVL) catheter, and AngelMed Guardian® System. Two devices were approved through the alternative pathway for devices with FDA breakthrough designation, and the third was approved through the traditional pathway.

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

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

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. In 2020, CMS implemented the second portion of the payment reduction, a change that reduced payments for these services to 40% of the OPPS rate.

The site-neutral payment policy has been the subject of litigation since it was implemented. In September 2019, a federal district court sided with hospital plaintiffs, ruling that CMS lacked statutory authority to implement the change. However, in July 2020, the US Court of Appeals for the District of Columbia Circuit reversed the lower court 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. The hospital plaintiffs appealed to the Supreme Court of the United States, but the Court announced in June 2021 that it would not take up the case, leaving intact the DC Circuit's ruling upholding CMS's authority.

For CY 2022, CMS will continue the policy of paying the Physician Fee Schedule-equivalent rate of 40% of the OPPS payment rate for hospital outpatient clinic visits coded under HCPCS G0463 when delivered by a previously excepted off-campus provider-based department. Given the result of the litigation and the Supreme Court's decision not to review the case, it is unlikely that this policy is susceptible to legal challenges.

Price Transparency

Key Takeaway: CMS will increase penalties for larger hospitals.

The Affordable Care Act requires hospitals to publish standard charges for items and services provided, and to update this published information annually.

In the CY 2020 OPPS Final Rule, CMS substantially revised this policy to require hospitals to publish more detailed price information in a machine-readable format (including gross charges, discounted cash prices, payer-specific negotiated charges, and minimum and maximum negotiated charges for items and services provided by the hospital) and display of the charges for a hospital's 300 most shoppable services in a consumer-friendly format. This requirement went into effect on January 1, 2021, despite opposition and legal challenges from hospital associations. Originally, failure to comply would subject a hospital to CMP of up to $300 a day.

CMS proposed to substantially increase those penalties for CY 2022, and in the final rule the agency finalized its proposal to increase the amount of a CMP by a scaling factor based on hospital bed count, as specified in the most recently available hospital cost report data submitted to CMS.

Larger hospitals could incur a penalty of $10/bed/day, not to exceed a maximum daily penalty amount of $5,500. The rule would maintain a minimum CMP of $300/day for smaller hospitals (those with 30 or fewer beds). Under this approach, the total penalty amount for a full calendar year of noncompliance would range from a minimum of $109,500 for small hospitals to a maximum of $2,007,500 for larger hospitals.

Application of CMP Daily Amounts for Hospital Noncompliance for CMP Assessed in CY 2022 and Subsequent Years

Number of Beds	Penalty Applied per Day	Total Penalty Amount for Full Calendar Year of Noncompliance
30 or fewer	$300 per hospital	$109,500 per hospital
31 to 550	$310 to $5,500 per hospital (number of beds x $10)	$113,150 to $2,007,500 per hospital
More than 550	$5,500 per hospital	$2,007,500 per hospital

Source: Table 76 in the CY 2022 OPPS and ASC Payment System Final Rule

The agency also added new requirements that machine-readable files must be accessible without barriers, allowing automated searches and direct file downloads. Lastly, CMS noted that it is seeking input on how to align the hospital price transparency requirements with new regulations that will require a good faith estimate for scheduled services under the No Surprises Act related to surprise medical bills.

Prior Authorization Process for Certain Services

Key Takeaway: CMS will not broaden the list of outpatient procedures subject to prior authorization under OPPS for CY 2022.

CMS previously established a process through which hospitals must request prior authorization before a covered outpatient service is furnished to a beneficiary and before a claim is submitted for five categories of services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation) starting July 1, 2020. For 2021, CMS expanded the list of services subject to the prior authorization requirement to include cervical fusion with disc removal and implanted spinal neurostimulators effective July 1, 2021.

CMS did not propose to supplement or otherwise change the list of services subject to prior authorization in this rulemaking for 2022.

Prior authorization is likely to continue as a hot topic next year as new CMS leadership gets settled in.

Payment for 340B Drugs

Key Takeaway: CMS will maintain payment for 340B drugs furnished to hospital outpatients at average sales price (ASP) minus 22.5%.

The 340B program allows certain providers to purchase specified drugs administered in hospital outpatient departments at a discount from drug manufacturers. Prior to 2018, Medicare reimbursed 340B drugs through the Part B benefit at ASP plus 6%. The discounted purchase price combined with the higher reimbursement rate allowed hospitals to realize significant savings on high-cost drugs, which in turn would support uncompensated care costs and other safety net programs.

Beginning in 2018, CMS reduced the reimbursement rate to ASP minus 22.5%. Because OPPS policies must be budget neutral, these cuts had implications for all hospitals. CMS chose to redistribute the savings

achieved by the reimbursement reduction among all hospitals, including those that do not participate in the 340B program, thereby dividing hospital interests in this policy change. Hospitals with substantial 340B programs typically experienced reimbursement reductions, while hospitals with no or small 340B programs might have seen an increase in OPPS reimbursement.

Immediately following the policy change, the American Hospital Association (AHA) led a group of plaintiffs challenging this rule in federal district court, where they initially prevailed in arguing that the government lacked the authority to implement these cuts. The government appealed the district court decision, and a federal appeals court overturned the district court ruling, siding with the government. The plaintiffs petitioned the Supreme Court to review, and in July 2021, the Supreme Court announced that it would review the case, now styled *AHA, et al. v. Becerra, et al.* This case will determine whether the US Department of Health and Human Services has the authority to calculate and adjust the 340B reimbursement rate in the manner that it did. Oral argument will be heard on November 30, 2021.

While the case proceeds, CMS will continue reimbursing drugs and biologics purchased under the 340B program at ASP minus 22.5% or wholesale acquisition cost (WAC) minus 22.5% for WAC-priced drugs.

ASC Major Finalized Policies

ASC Covered Procedures List

Key Takeaway: CMS will halt expansion of the ASC covered procedures list (CPL), consistent with the change to the IPO list transition.

CMS maintains a list of procedures eligible for reimbursement in the ASC setting. Each year, CMS reviews the ASC CPL to determine if there are services that should be added or removed. Historically, stakeholder requests and feedback have driven changes to the list. In the 2021 rulemaking cycle, CMS finalized a policy to eliminate a subset of the exclusion criteria for adding surgical procedures to the ASC CPL. Pursuant to this change, CMS added 267 surgical and surgical-like procedures to the CPL, giving providers additional flexibility and more responsibility in determining whether a surgical procedure can be safely performed in an ASC setting.

Beginning in 2022, CMS will restore the ASC CPL criteria that were in place prior to 2021, and will remove 255 of the 267 procedures added to the ASC CPL in 2021 under the revised criteria. A key factor driving these proposed changes is concern that many procedures added as part of last year's rulemaking cycle are only appropriate for healthier Medicare beneficiaries, and that these procedures may pose a significant safety risk and require active medical monitoring and overnight care for a typical Medicare beneficiary when performed in the ASC.

CMS also finalized a proposal to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. Under this policy change, stakeholders can nominate procedures to be added to the ASC CPL by March 1 for consideration in the upcoming rulemaking cycle. CMS will then evaluate the nominated procedures based on the applicable statutory and regulatory requirements for ASC covered surgical procedures, and will allow for public comment in the proposed rule. CMS will then finalize which procedures would be added to the ASC CPL, or possibly defer making a decision for a nominated procedure to later rulemaking. CMS will provide greater detail on how procedures can be nominated in early 2022.

OPPS and ASC Finalized Quality Policies

Hospital Outpatient Quality Reporting Program

Key Takeaway: CMS finalized proposals to update existing measures and modify other policies with the intent to reduce provider burden and improve processes.

The Hospital Outpatient Quality Reporting (OQR) Program is a pay for reporting program for Medicare hospital outpatient departments. Hospitals that fail to meet program requirements are subject to a 2% reduction in OPPS payments.

CMS finalized several modifications to the Hospital OQR Program including measure removals and additions, revisions to reporting requirements and updates to other policies. These changes are consistent with CMS's other priorities related to COVID-19, reduction of quality reporting burdens, Meaningful Measures goals and use of measures with greater applicability.

Measure Removal/Replacement

CMS finalized a proposal to remove two chart-abstracted measures beginning with the CY 2023 reporting period:

- Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP-2)
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3).

Beginning in the CY 2023 reporting year, CMS will replace the above two measures with ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM), which the agency describes as a more broadly applicable measure. The STEMI measure is also an electronic measure, whereas the OP-2 and OP-3 are more administratively burdensome chart-abstracted measures.

Measure Additions

CMS finalized a proposal to add three measures to the Hospital OQR Program:

- COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period
- Breast Cancer Screening Recall Rates measure, beginning with the CY 2022 reporting period
- STEMI eCQM, beginning as a voluntary measure for the CY 2023 reporting period, and as a mandatory measure for the CY 2024 reporting period.

The HCP measure will assess the proportion of a hospital's healthcare workforce that has been vaccinated against COVID-19. This assessment will help the agency determine whether facilities are taking steps to limit the spread of COVID-19 among their staff, putting facilities in a better position to serve their local communities during and after the PHE. The Breast Cancer Screening measure will fill the gap in women's health and oncology care left following the removal of the Mammography Follow Up Rates measure (OP-9), finalized in the 2019 OPPS Final Rule.

Measure Modifications

CMS will add back two measures previously removed from the program, with modifications that the agency believes address previous concerns.

- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37-a-e) (voluntary for CY 2023 reporting period and mandatory for CY 2024 reporting period)
- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (CY 2025 reporting period).

Transition from Inpatient to Outpatient Setting

As discussed above, CMS finalized a proposal to maintain the IPO list. The agency noted a trend of procedures transitioning from the inpatient to the outpatient setting, and acknowledged that the agency must have a means to measure the quality of these services when provided in the outpatient setting. In the proposed rule, CMS sought comments on quality measures that address the transition from the inpatient to the outpatient setting.

In a summary of stakeholder comments, CMS stated that commenters urged the agency to:

- Identify measures that would apply across care settings
- Focus on developing patient reported outcome measures and patient experience measures to gather feedback directly from the patient without interpretation from a third-party source
- Adopt measures that are in the current Medicare ASC quality program
- Consider measures that focus on access to surgical care.

CMS did not make changes at this time but indicated that this feedback may inform future rulemaking around the Hospital OQR Program.

Advancement of Digital Quality Measures

Key Takeaway: CMS discussed stakeholder feedback on digital quality measures but stopped short of implementing any policy proposals.

CMS previously announced that by 2025 it plans to move fully to digital quality measures for the quality reporting and value-based purchasing programs. This initiative would require significant modifications to individual measures and programmatic changes across the board.

As part of this rulemaking cycle, CMS issued a request for information (RFI) to gather feedback on the planning and implementation of such an endeavor. Any changes to a specific program would be pursued through rulemaking.

CMS proposed changes in four areas over the next four years:

- Digital data standards
- Redesign of quality measures to be self-contained tools
- Better support around data aggregation
- Alignment of measure requirements across CMS and other federal or private sector programs.

CMS did not make any policy changes in the final rule. Instead, the agency committed to considering stakeholder input in future rulemaking as it continues to build upon its digital quality measures strategy.

Potential Future Efforts to Address Health Equity in the Hospital OQR Program

Key Takeaway: CMS noted that commenter feedback would be incorporated and considered in future RFIs and program design. CMS recognized commenter concerns about indirect estimation methods and privacy, and stated that it would begin confidential reporting for the six proposed priority measures stratified by dual eligibility status, assuming doing so proves feasible and reliable.

Consistent with the Biden Administration's commitment to advancing health equity and the president's Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, CMS has issued RFIs and proposed health equity initiatives in recent rules. In the proposed rule, CMS solicited comments on potential future efforts to address equity in the Hospital OQR Program, relying on the executive order's definition of "equity."

Expansion and Stratification of Disparity Methods Measures

CMS's strategies to help drive more equitable health outcomes across different care delivery settings include the CMS Disparity Methods, which were finalized in the 2018 and 2020 Inpatient Prospective Payment System Rules. The Disparity Methods fall into two main categories: the Within-Hospital Disparity Method (WHDM) and the Across-Hospital Disparity Method (AHDM). The WHDM "promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors," while the AHDM "assesses hospitals' outcome rates for patients with a given risk factor, across facilities, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors."

In the proposed rule, CMS seeks comment on stratifying performance results by dual Medicare-Medicaid eligibility (a proxy for social risk) in the outpatient setting for the following six priority measures in the Hospital OQR Program:

- 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 will request input on confidentially reporting these measures on Care Compare in the future, and seeks input on other potential future measures stratified by dual eligibility status as a means of advancing health equity.

Additional Social Risk Factors

CMS has attempted to improve race and ethnicity data using "indirect estimation," which uses an algorithm to predict the race and ethnicity at the population level for beneficiaries based on a combination of other data sources. The agency has also tried Medicare Bayesian Improved Surname Geocoding, which attempts to use other data points and statistical analysis to estimate the likelihood of belonging to one of six ethnic groups. The agency believes the latter approach runs a relatively low risk of unintentional bias, especially compared to bias that currently exists in administrative data. In the long run, CMS hopes to move to self-reported race and ethnicity data.

CMS requested comments on potential benefits and challenges related to using indirect estimation to assess facility equity. Specifically, the agency wants information on how facilities currently capture demographic data, such as race, ethnicity, sex, sexual orientation and gender identity, primary language and disability status. The agency believes that a minimum data set that includes demographic data that is used in quality measures could help better identify disparities. However, CMS solicited comments on challenges associated with the use of such a data set on day of service.

This request for comment was complementary to CMS's policy changes in the FY 2022 Inpatient Prospective Payment System rule and CY 2022 Physician Fee Schedule rule, and

illustrates how CMS is seeking to advance equity across inpatient and outpatient settings by improving data collection practices and by building out ways to identify disparities using existing systems.

Other Major Payment Policies

Radiation Oncology Alternative Payment Model

Key Takeaway: CMS will begin implementation of the previously delayed Radiation Oncology (RO) Model as of January 1, 2022.

In September 2020, CMS finalized two Innovation Center demonstration models: the 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. CMS had intended to implement the RO Model effective January 1, 2021, but the model was delayed to January 1, 2022, because of the pandemic.

In the final rule, CMS announced that it will proceed with implementation on January 1, 2022. CMS denied requests for further delay because the agency believed felt that participants had sufficient time to prepare for this new model, with the original model finalized in September 2020.

Foundational aspects of the RO Model remain intact:

- The model is still mandatory and will run for five years.
- Participation will be based on selected geographic areas, representing approximately 30% of eligible episodes.
- The model will use site- and modality-neutral payment based on a 90-day episode of care for selected modalities.
- Payment rates will be based on case mix, historical experience and efficiency.

CMS's changes to the model include, but are not limited to, the following:

- Removing brachytherapy as an included modality and liver cancer as an included indication
- Lowering the discount factors for professional and technical components from 3.75% and 4.75% to 3.5% and 4.5%, respectively
- Qualifying the RO Model as an Advanced Alternative Payment Model or Merit-Based Incentive Payment System Alternative Payment Model in Performance Year 1 (as opposed to Performance Year 2)
- Invoking CMS's authority under the extreme and uncontrollable circumstances policy to make three requirements (quality and clinical data element reporting, engagement with an AHRQ-listed safety organization, and peer review requirements) optional for PY 1.

Temporary COVID-19 Policies

Key Takeaway: CMS did not make any decision regarding continuation of flexibilities after the conclusion of the PHE but will consider stakeholder input in future rulemaking.

Prior to the PHE, CMS generally required that hospital outpatient services be delivered to patients physically present in the hospital outpatient department by clinical staff who were also physically present. During the PHE, CMS implemented hundreds of waivers and flexibilities to mitigate the risks of SARS-CoV-2 spread and to accommodate the precautions necessary to treat patients suspected of having COVID-19. In the CY

2022 proposed rule, CMS sought comments from stakeholders to understand the impact on care delivery related to three specific flexibilities granted during the PHE:

- Mental health services furnished remotely by hospital staff to beneficiaries in their homes
- Direct supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services by audio visual virtual communications technology
- Payment for COVID-19 specimen collection in hospital outpatient departments.

While CMS did not make any of these flexibilities permanent in the final rule, comments could inform future policies regarding outpatient hospital care. In particular, CMS stated its intention to explore how hospital payment for virtual services, such as mental health services, could support access to care in underserved and/or rural areas. CMS also appears to be considering a service-level modifier to monitor utilization of virtual direct supervision of allowed services. CMS's willingness to consider extending or making permanent these payment policies appears to reflect a broader effort to reform Medicare to create reimbursement options for modernized care delivery that takes advantage of advances in technology and integrates changes in practice patterns accelerated by the pandemic.

Removal of Non-Opioid Drugs Used for Perioperative Pain Relief from Payment Packaging Policies

Key Takeaway: CMS finalized its policy for separate payment for non-opioid drugs.

Over the past decade, opioid addiction has been recognized as a serious health problem. In 2017, the president established a commission on combating drug addiction and opioid crises, and in 2018 Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act by overwhelming majority. Based on these directives, CMS has had an interest in reviewing payment policies and minimizing economic incentives to use opioids instead of non-opioid pain relief, which has resulted in modifications to Medicare's surgical packaging policies.

Reimbursement for surgical care, which may require opioids for pain relief, often uses packaging policies in order to not pay additionally for drugs used as supplies during surgery. As a result of packaging policies, CMS had not paid separately for Exparel®, a non-opioid drug for perioperative pain relief. While the agency saw an increased utilization of Exparel in the hospital outpatient department setting, it found a decreased utilization of Exparel in the ASC setting. In response, CMS finalized a policy in 2019 to remove Exparel from packaging policies in the ASC setting, thereby allowing separate payment and theoretically creating incentives for use. CMS did not implement such a change in the hospital outpatient setting, however. A second drug, Omidria®, was excluded from packaging policies in the ASC setting in the 2021 rule.

Against this background, CMS finalized two new policy changes in the CY 2022 final rule:

- Expanding the ASC policy of allowing separate payment for non-opioid paid medications used as surgical supplies to the hospital outpatient setting
- Developing criteria for eligibility for separate payment under the ASC Payment System, which would require that a drug has FDA approval for pain management or analgesia, and that it meets a cost threshold requirement.

Conclusion

While this rule finalizes several policy proposals, there are two overarching takeaways. First, the Administration continues to be sensitive to the burden of the PHE and its lingering effects on healthcare providers, particularly hospitals and ASCs. It continues to solicit feedback and explore ways to create flexibilities during and following the PHE. Second, this rule reflects the change in CMS leadership as it reverses course on several major policies finalized last year. More changes are likely in future rulemakings as this Administration gains its footing.

This rule is also notable for what is not included. Several areas that were subject to policy change in recent years, including policies concerning skin substitutes, the laboratory date of service rule and comprehensive Ambulatory Payment Classifications, were not revisited in this rulemaking.

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