Policy Update

CMS Releases CY 2024 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule [CMS-1786-FC]. The rule finalizes payment rates and policy changes affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings for CY 2024.

For CY 2024, CMS increased payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System by a productivity-adjusted market basket factor of 3.1%. Hospitals and ASCs that fail to meet their respective quality reporting program requirements will be subject to a 2% reduction in the CY 2024 fee schedule increase factor. For ASCs, this adjustment reflects the extension of the policy to adjust the ASC payment system using the hospital market basket update for two additional years (2024 and 2025).

Based on the finalized policies, CMS estimates that total payments to OPPS and ASC providers (factoring in beneficiary cost-sharing and estimated changes in enrollment, utilization and case-mix) for CY 2024 will be approximately $88.9 billion and $7.1 billion, respectively. This represents an increase of approximately $6 billion and $207 million, respectively, from CY 2023 program payments.

Key takeaways from the CY 2024 OPPS and ASC Payment System Final Rule:

- CMS finalized changes to its hospital price transparency requirements, including requiring hospitals to use a template to submit charge information and requiring hospitals to affirm the accuracy of that information.
- CMS finalized its implementation of the intensive outpatient program benefit, including the coding and billing, payment rates and scope of benefit.
- CMS chose not to finalize proposed changes to its bundling policy for diagnostic radiopharmaceuticals.
- CMS will continue to pay the statutory default rate, average sales price (ASP) plus 6%, for 340B-acquired drugs and biologicals.
- CMS finalized its proposal to add 26 dental codes to the ASC covered procedures list for CY 2024, along with 11 additional procedures identified by commenters, including total ankle and total shoulder replacement surgery.
- CMS finalized proposals to add nine services to, and remove none from, the inpatient only list.
- CMS will continue to use the productivity-adjusted hospital market basket update to increase ASC payment system rates for 2024 and 2025.
- CMS finalized its proposal to assign 229 dental codes, plus 14 additional dental codes identified by commenters, to clinical ambulatory payment classifications (APCs).
- CMS finalized a proposal to create two new comprehensive APCs: 5342 for Level 2 Abdominal/Peritoneal/Biliary and Related Procedures, and 5496 for Level 6 Intraocular Procedures.
- CMS maintained the current list of service categories subject to prior authorization.
- CMS generally maintained its site-neutrality policy, but finalized a proposal to reimburse intensive cardiac rehabilitation provided by an off-campus, non-excepted provider-based department of a hospital at 100% of the OPPS rate.

Following are helpful links related to the final rule:

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

- The fact sheet is available here.

OPPS Major Finalized Policies

Price Transparency

Key Takeaway: CMS finalized its proposal to require that hospitals use a template for submitting standard charge information. CMS will take a phased approach to enforcement.

In CY 2021, CMS began requiring that hospitals publish 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 charges for 300 shoppable services in a consumer-friendly format. Beginning in 2023, CMS increased the maximum daily penalties for noncompliance from $300 to between $300 and $5,500, depending on the hospital's number of beds.

In November 2022, CMS made available several sample templates that hospitals could voluntarily use to make public their standard charge information in a machine-readable format.

In this final rule, CMS finalized its proposal to require hospitals to display standard charge information using a machine-readable file template similar to those it made available for voluntary use in 2022. CMS will require hospitals to link to this information from their website homepage.

CMS also finalized a requirement that each hospital make a good-faith effort to ensure that the information in its machine-readable file is true, accurate and complete. The file must include an affirmation that the hospital, to the best of its knowledge and belief, has included all required standard charge information.

Additions and modifications to enforcement regulations are also finalized in this rule, including the following:

- An authorized hospital official must certify the accuracy and completeness of hospital price transparency data.
- Hospitals are required to acknowledge receipt of warning notices.
- CMS may notify a health system's leadership of noncompliance by one of its hospitals.
- CMS may publicize information related to its assessment of a hospital's compliance, compliance actions taken against a hospital (including the status and outcome of those actions) and notifications sent to health system leadership.

Some stakeholders expressed concern regarding the short implementation period for these policies. In response, CMS finalized the policies with a phased approach. CMS stated that the policies have a January 1, 2024, effective date, but specified a July 1, 2024, and January 1, 2025, effective date for certain requirements as detailed in Tables 151A and 151B of the final rule.

Hospital price transparency remains a topic of significant interest in the 118th Congress. Language to codify and extend hospital price transparency requirements is included in the bipartisan Lower Costs, More Transparency Act advanced by the US House of Representatives Energy and Commerce, Ways and Means, and Education and the Workforce Committees.

Prior Authorization Process for Certain Services

Key Takeaway: CMS maintained its current list of service categories subject to the hospital outpatient prior authorization process, adding no new categories for CY 2024.

For CY 2020, CMS finalized a policy that hospitals must submit a prior authorization request for a provisional affirmation of coverage for select services before furnishing them to the beneficiary and before submitting the claim for processing. The change applied initially to only five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

For CY 2021, CMS expanded the services subject to prior authorization, adding cervical fusion with disc removal and implanted spinal neurostimulators for dates of service on or after July 1, 2021. CMS did not change the list of services subject to prior authorization in CY 2022, holding steady with the previously established seven categories. In the CY 2023 rulemaking cycle, CMS again expanded the services subject to this requirement, adding facet joint injections, medial branch blocks and facet joint nerve destruction.

For CY 2024, CMS made no changes to the list of service categories subject to the hospital outpatient prior authorization process.

Transitional Pass-Through Payment for Medical Devices

Key Takeaway: CMS evaluated applications for six medical devices seeking pass-through payment beginning in CY 2024.

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.

In the CY 2021 rulemaking cycle, CMS acknowledged the impact of the COVID-19 public health emergency (PHE) on utilization and sought stakeholder feedback on whether the agency should use its authority to provide separate payment for an undefined period after pass-through status ends for these device categories to account for the period that device utilization was reduced. In CY 2022, CMS exercised its equitable adjustment authority to extend transitional pass-through status for one device whose eligibility was to end December 31, 2021, because of the impact of the COVID-19 pandemic. For CY 2023, CMS returned to the "regular update process" and did not exercise this authority. However, Congress intervened through the Consolidated Appropriations Act, 2023 (CAA, 2023), which extended the transitional pass-through status for one additional year for the five medical devices whose status would have ended on December 31, 2022. Pass-through status for these five medical devices began on January 1, 2020, and will now end on December 31, 2023. Pass-through status for three additional medical devices that began on January 1, 2021, but was not subject to the one-year extension under the CAA, 2023, will also end on December 31, 2023. Pass-through status for an additional seven medical devices will continue into 2024 or through 2025. See Table 84 for devices with pass-through status expiring in the fourth quarter of 2023, in 2024 or in 2025.

As part of its quarterly review cycle, CMS evaluated six applications for device pass-through payments—two through the alternative pathway for breakthrough designated devices and four through the traditional pathway. The agency approved four devices, including the two with breakthrough device designation, for transitional pass-through. The remaining two were denied, one for not meeting the transitional pass-through eligibility criteria and the second for failing to meet the substantial clinical improvement criteria.

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

Revisions to the Inpatient Only List

Key Takeaway: CMS finalized proposals to add nine services to, and remove none from, the inpatient only (IPO) list.

Historically, CMS has identified services that it believes are safely provided only in an inpatient setting and thus will not be paid by Medicare under the OPPS. These services are designated to the IPO list.

While CMS received requests to remove procedures from the list, the agency found that none of the proposed services met the criteria for removal. CMS finalized its proposal to add to the IPO list nine services that were newly defined by the American Medical Association CPT Editorial Panel for CY 2024. See Table 103 in the final rule for the new codes added to the IPO list for CY 2024.

Payment for 340B Drugs and 340B Modifiers

Key Takeaway: CMS will continue to pay the statutory default rate, ASP plus 6%, for 340B-acquired drugs and biologicals. CMS also finalized its proposal to use a single modifier to identify drugs and biologicals acquired through the 340B program. All 340B covered entity hospitals paid under the OPPS are required to report the TB modifier effective January 1, 2025.

In the CY 2018 OPPS final rule, CMS implemented a controversial policy that changed reimbursement to hospitals for 340B-acquired drugs and biologicals. CMS changed payment from the traditional ASP plus 6% to ASP minus 22.5% for certain separately payable drugs and biologicals acquired through the 340B program. Hospitals led by several national hospital associations immediately sued to invalidate this change, and on June 15, 2022, the Supreme Court of the United States ruled unanimously that the US Department of Health and Human Services may not vary payment rates for drugs and biologicals among groups of hospitals without having conducted a survey of hospitals' acquisition costs. As a result, CMS was compelled to revert to the original ASP plus 6%. CMS restored these payments in the CY 2023 OPPS final rule and will continue to pay ASP plus 6% in CY 2024.

On the same day that CMS published this final rule, the agency also finalized the rule Medicare Program: Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022, which provides an approach for refunding 340B payments withheld from hospitals from 2018 through September 27, 2022 (the date on which CMS restored reimbursement for 340B drugs to the full OPPS rate). In that companion rule, CMS finalized its proposal to refund hospitals that had payments reduced with a one-time lump sum payment intended to account for the difference in what was paid to the hospitals and what should have been paid had the cut not been implemented. CMS estimates that the total remedy payments to 340B hospitals will be $9 billion. CMS also finalized its proposal to make this remedy payment budget neutral. CMS will offset the payments by adjusting the OPPS conversion factor by -0.5% starting in CY 2026. CMS expects to apply this adjustment for 16 years to slowly phase in the budget-neutral aspect of this substantial one-time outlay. For more information, see our +Insight on the 340B remedy.

In the CY 2024 OPPS final rule, CMS also finalized a proposal to use only a single modifier to identify separately payable drugs and biologicals acquired under the 340B program. Currently, 340B hospitals report the JG or TB modifier to identify drugs and biologicals acquired through the 340B program. CMS states that "utilizing a single modifier will allow for greater simplicity" while continuing to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability. CMS requires all 340B covered entity hospitals paid under the OPPS to report the TB modifier effective January 1, 2025, even if the hospital previously reported the JG modifier. All hospitals using the JG modifier therefore must switch to the TB modifier by January 1, 2025.

Changes in APC Groupings or Comprehensive APCs

Key Takeaway: CMS finalized its proposals to create two new comprehensive APCs for 2024 and to set outpatient payment rates for 243 dental codes by assigning them to clinical APCs.

Under the OPPS, CMS assigns items, services and procedures to APCs that are used to set payment rates. The APCs are organized such that each group is intended to be homogeneous both clinically and in terms of resource use. Starting in 2015, CMS began implementing comprehensive APCs (C-APCs) that include a primary service and all adjunctive services provided to support the delivery system of the primary service.

For CY 2024, CMS finalized a proposal to create two new C-APCs:

- Splitting the existing Level 2 Intraocular C-APC 5492 into Level 2 and Level 3 Intraocular C-APC 5493, which requires renaming the previously existing Levels 3, 4 and 5 Intraocular APCs (5493, 5494, 5495) to Levels 4, 5 and 6, respectively (APCs 5494, 5495, 5496)
- Creating C-APC 5342 for Level 2 Abdominal/Peritoneal/Biliary and Related Procedures to improve the clinical and resource homogeneity in the Level 1 Abdominal/Peritoneal/Biliary and Related Procedures APC (5341).

In 2023, CMS began allowing payment for dental services that are inextricably linked to, and substantially related and integral to, the clinical success of other covered medical services. This policy change allows payment for certain dental services performed in outpatient settings when OPPS coverage and payment conditions are met. To ensure that CMS can pay for dental services under OPPS, the agency proposed to assign 229 additional dental codes to clinical APCs. After consideration of public comments, CMS decided to finalize its proposal to add those 229 dental codes to clinical APCs and to include an additional 14 dental codes identified by commenters. Table 111 identifies the 243 dental codes assigned to clinical APCs for 2024.

CMS reminds stakeholders in the final rule that assignment of a code to an APC is not a determination of Medicare coverage or payment. Assignment to a clinical APC shows how the procedure or service would be paid through the OPPS *if covered* by the Medicare program. Medicare Administrative Contractors are responsible for determining when the conditions are met for coverage and payment of the dental codes assigned to clinical APCs.

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 to a rate equivalent to the physician fee schedule (PFS) rate for clinic visits described by HCPCS code G0463 and furnished at off-campus provider-based outpatient departments (PBDs) that previously were excepted or grandfathered from site-neutral payment policies. The PFS-equivalent rate is 40% of the OPPS payment. Beginning in 2023, CMS implemented a policy that excepted off-campus PBDs of rural sole community hospitals from this clinic visit payment policy.

For CY 2024, CMS will continue to pay clinic visits provided by off-campus hospital outpatient departments at 40% of the OPPS rate. Excepted off-campus PBDs of rural sole community hospitals will continue to be exempt from the policy.

CMS also finalized its proposal that, beginning in CY 2024, intensive cardiac rehabilitation services (HCPCS codes G0422 and G0423) provided by an off-campus, non-excepted PBD of a hospital will be paid at 100% of the OPPS rate (which is also 100% of the PFS rate) rather than at 40% of the OPPS rate. This policy change addresses an unintended impact on the payment rate for intensive cardiac rehabilitation services in

the hospital setting as a result of this site-neutral policy. CMS stated that it will consider for future rulemaking commenters' suggestions for additional services that should similarly be excluded from the 40% PFS adjustment.

Rural Emergency Hospitals

Key Takeaway: CMS finalized a proposal to allow Indian Health Service (IHS) and tribal rural emergency hospitals to convert to rural emergency hospitals (REHs).

The Consolidated Appropriations Act, 2021, allowed critical access hospitals and small rural hospitals (those with fewer than 50 beds) to convert to a new Medicare provider type called REHs starting January 1, 2023. REHs receive enhanced reimbursement under Medicare, but they cannot provide inpatient services and must be able to provide emergency services 24 hours a day, seven days a week, as well as other outpatient services.

CMS established conditions of participation and payment and structural requirements for REHs in the CY 2023 OPPS final rule. For CY 2024, CMS proposed to allow IHS and tribal hospitals to convert to REHs. Tribal and IHS hospitals are excluded from payment under the OPPS and instead are paid for hospital outpatient services under an all-inclusive rate. However, CMS believes that it is feasible for these facilities to provide the types of services that are delivered in REHs. After consideration of public comments, CMS will allow tribal and IHS hospitals to convert to REHs, but these hospitals will continue to receive payment using the IHS all-inclusive rate.

Diagnostic Radiopharmaceuticals

Key Takeaway: CMS received comments on five payment alternatives but did not finalize any changes to the current bundling policy for diagnostic radiopharmaceuticals.

CMS packages several categories of non-pass-through drugs, biologicals and radiopharmaceuticals, regardless of the cost of the products. Many stakeholders have recommended that CMS pay separately for diagnostic radiopharmaceuticals under the OPPS. Stakeholders have commented that the packaged payment rate is often inadequate, especially where a diagnostic radiopharmaceutical is high-cost and has low utilization. CMS has previously heard from interested parties regarding alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold and creating separate APC payments for diagnostic radiopharmaceuticals with a per-day cost greater than $500. Stakeholders have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries.

In the CY 2024 proposed rule, CMS invited comments on potential modifications to its packaging policy for diagnostic radiopharmaceuticals. CMS requested information on specific cost-prohibitive diagnostic radiopharmaceuticals that commenters believe are superior to alternative diagnostic modalities. CMS is interested to learn about specific clinical scenarios where only the more expensive diagnostic radiopharmaceutical is clinically appropriate, rather than a lower cost alternative, as well as clinical scenarios in which the only diagnostic modality is a high-cost radiopharmaceutical.

CMS sought comments on the following payment alternatives:

- Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140
- Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold

- Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals
- Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials
- Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

CMS ultimately chose not change its policy for this upcoming year. While stakeholders were supportive of changes to the existing policy, there was no clear consensus on the best payment alternative. Given the issue's complexity, CMS determined that it would not finalize any changes this year and instead will consider stakeholder feedback in future rulemaking.

ASC Major Proposed Policies

ASC Covered Procedures List

Key Takeaway: CMS finalized its proposal to add 26 dental codes to the ASC covered procedures list (CPL) for CY 2024 along with 11 additional procedures.

CMS maintains a list of procedures eligible for reimbursement in the ASC setting. Each year, CMS reviews the ASC CPL to determine if any services should be added or removed. In evaluating procedures for inclusion on the CPL, CMS examines them against their regulatory safety criteria, which remain unchanged for CY 2024. CMS notes that following the CY 2023 OPPS final rule, the agency received requests for the inclusion of dental procedures on the ASC CPL.

For CY 2024, CMS reviewed dental procedures that were reimbursable in the hospital outpatient setting and were not currently on the ASC CPL, and that met the criteria for inclusion on the CPL. Based on this assessment, CMS will add 26 dental surgical procedure codes to the ASC CPL in CY 2024.

As noted, assignment of a procedure to an HCPCS and APC does not imply coverage by the Medicare program, but instead shows how the procedure would be paid through the OPPS if covered by the Medicare program. Medicare Administrative Contractors are responsible for determining when the conditions are met for coverage and payment for the 26 dental codes added to the CPL. Similar to its position in the hospital outpatient setting, CMS reiterated that adding dental procedures to the ASC CPL does not serve as a coverage determination for dental services under general anesthesia.

CMS received more than 200 procedure recommendations for the CPL. After individually assessing each recommendation, the agency concluded that 11 other procedures—including total ankle and total shoulder replacement surgeries—could also be safely performed in the ASC setting, and added them to the ASC CPL. The 37 procedures added for CY 2024 can be found in Table 123 of the final rule.

ASC Rate Update Based on the Hospital Market Basket

Key Takeaway: CMS will continue to use the productivity-adjusted hospital market basket update to increase ASC payment system rates for an additional two years.

For CY 2019, CMS finalized a policy to use the productivity-adjusted hospital market basket update to increase ASC payment system rates for an interim period of five years (CY 2019 through CY 2023). CMS stated that it would use this period to assess whether there was migration of procedures from the hospital setting to the ASC setting, or any unintended consequences.

Because CMS found it difficult to disentangle the effects of the COVID-19 PHE from its analysis of whether the higher update factor for the ASC payment system caused migration of procedures to the ASC setting,

CMS extended the five-year interim period for which the productivity-adjusted hospital market basket update will apply to the ASC payment system rates for an additional two years, CYs 2024 and 2025.

OPPS and ASC Finalized Quality Policies

Hospital Outpatient, ASC and REH Quality Reporting Programs

Key Takeaway: CMS updated measures for the Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs and codified the quality reporting program for REHs.

OQR and ASCQR Programs

The Hospital OQR and ASCQR Programs are pay-for-reporting quality programs. Providers must meet quality reporting requirements or receive a 2% reduction in their annual payment update.

CMS will add a new measure, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty, to both the OQR and ASCQR Programs. This measure will have a voluntary reporting period of three years before becoming mandatory for the CY 2028 reporting period/CY 2031 payment determination.

CMS finalized, with modification, an additional measure in the Hospital OQR Program to promote patient safety: the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults. CMS modified its policy by extending the voluntary reporting for two years before requiring mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

CMS also finalized modifications to three measures in both the OQR and ASCQR Programs:
- COVID-19 Vaccination Coverage Among Healthcare Personnel measure, to align with the updated Centers for Disease Control and Prevention National Healthcare Safety Network measure specifications
- Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument, to further standardize data collection and reduce facility burden
- Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, to align with updated clinical guidelines.

CMS will not re-adopt the Hospital Outpatient/ASC Facility Volume Data on Selected Outpatient Surgical Procedures measure, after consideration of commenter feedback. Commenters requested that CMS reconsider what data is collected for this measure and reassess how the volume data is publicly displayed.

CMS also will not remove the Left Without Being Seen measure, because of a recent increase in these rates that the agency believes warrants further review.

Finally, the rule outlines comments on measure topic areas of patient safety and sepsis, behavioral health (including mental health and suicide risk) and telehealth.

REHQR Program

CMS codified the new REH Quality Reporting (REHQR) Program.

For the program, CMS adopted all four of the proposed quality measures, which a consensus-based entity previously endorsed for use in the OQR Program. The measures are as follows:
- Abdomen Computed Tomography – Use of Contrast Material
- Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients

- Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
- Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery.

Additional quality measures for the REHQR Program will be considered through future notice-and-comment rulemaking.

Other Major Finalized Payment Policies

Intensive Outpatient Program

Key Takeaway: CMS finalized the payment and program requirements to implement the intensive outpatient program (IOP) benefit under Medicare.

Section 4124(b) of the CAA, 2023, established Medicare coverage for intensive outpatient services beginning in CY 2024. Intensive outpatient services are furnished under IOPs, which are distinct and organized outpatient programs for psychiatric services provided to individuals who have an acute mental illness, including depression, schizophrenia and substance use disorders.

In this rule, CMS finalized the payment and program requirements for the new IOP benefit. The final rule includes the scope of benefits, physician certification requirements, coding and billing guidelines, and payment rates under the IOP benefit. CMS finalized its proposal that IOP services may be furnished in hospital outpatient departments, community mental health centers, federally qualified health centers and rural health clinics.

Health Equity Comment Solicitation

Key Takeaway: CMS will take into consideration the many suggestions it received for advancing equity in OPPS and ASC policies, such as engaging beneficiaries from minoritized groups, using the National Committee for Quality Assurance health equity framework, and considering hospital performance and the proportion of vulnerable populations served.

In the proposed rule, CMS requested information on advancing health equity efforts using the OPPS and ASC and continuing to build a framework that allows for further development of policies that enhance health equity. The agency sought comment on how to structure an impact analysis to address how changes may impact beneficiaries of different groups. CMS also sought comment on the possibility of adding new categories or measures of health equity to impact analyses, such as using the area deprivation index as a proxy for disparities related to geographic variation.

CMS received a range of suggestions from stakeholders, including the following:

- Engaging with interested parties or beneficiaries to identify instances where payment policy negatively impacts beneficiary care and to determine which health equity elements should be included in impact analyses
- Adding elements that address policy impacts on social drivers of health, racial and ethnically minoritized groups, the LGBTQIA+ community, those living with disabilities and other underserved populations
- Using health equity accreditation programs or the National Committee for Quality Assurance health equity framework to examine whether payment adjustments worsen health disparities or produce unintended results
- Conducting research to better understand how beneficiaries are made aware of outpatient services and whether this leads to disparities in accessing outpatient services
- Assessing whether utilization by geographic areas is skewed by socioeconomic circumstances or inequities that pose barriers to beneficiaries accessing and utilizing services

- Outlining specific health equity goals for providers
- Adopting the Office of the National Coordinator for Health Information Technology certification requirements as a model for embedding health equity in all components of data measurement
- Adopting payment policies that recognize the unique role of essential hospitals in promoting health equity
- Considering hospital performance and the proportion of vulnerable populations served by the hospitals in any health equity framework
- Continuing efforts to advance interoperable data systems that collect health equity data.

CMS will take commenters' feedback into consideration in future rulemaking.

Potential Payments for Cost of Maintaining Access to Essential Medicines

Key Takeaway: CMS sought comments on establishing additional payments to hospitals for maintaining access to essential medicines but did not finalize any policies in this final rule.

Citing the persistence and severity of shortages for critical medical products and the additional time, labor and resources required to address them, CMS described in the final rule how it could make payments to hospitals under the Inpatient Prospective Payment System (IPPS) for establishing and maintaining access to a buffer stock of essential medicines. "Essential medicines" would be defined as the 86 medicines prioritized in the Administration for Strategic Preparedness and Response report "Essential Medicines Supply Chain and Manufacturing Resilience Assessment."

Payment under the IPPS would not be budget neutral and could be made for cost reporting periods beginning as early as January 1, 2024. The payments would be in addition to payments for the essential medicines themselves, regardless of whether those payments are bundled with other items and services or separately paid. Noting the challenge of quantifying the additional resource costs, CMS suggested initially basing IPPS payment on the IPPS shares of a hospital's additional reasonable costs to establish and maintain access to its buffer stock, which CMS notes would be consistent with the use of these shares for the payment adjustment for N95 respirators. These payments could be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement.

While the final rule discussed a potential IPPS payment in depth, CMS noted that with respect to the OPPS, a payment adjustment could be considered for future years.

In addition to essential medicines, CMS noted that it may consider expanding a potential Medicare payment policy in future years to include critical medical devices once the FDA's Critical Medical Device List becomes available. CMS seeks comment on all aspects of this potential policy, and specifically on making payments under the IPPS for establishing and maintaining a three-month buffer stock of one or more essential medicines.

For more information, contact Jeff Davis, Leigh Feldman, Deborah Godes, Kayla Holgash, Rachel Hollander, Marie Knoll, Kristen O'Brien, Devin Stone, Katie Waldo or Eric Zimmerman.