Policy Update

CMS Releases CY 2024 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule

On July 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule [CMS-1786-P], which includes proposals to update payment rates and regulations affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings beginning in CY 2024.

For CY 2024, CMS proposes to increase payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System by a factor of 2.8%. Hospitals and ASCs that fail to meet their respective quality reporting program requirements are subject to a 2.0% reduction in the CY 2024 fee schedule increase factor.

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

- CMS proposes to broaden enforcement of the hospital price transparency requirements by requiring hospitals to use a template to submit charge information and by publicizing the enforcement actions it has taken against hospitals.
- CMS outlines plans to implement the Intensive Outpatient Program benefit.
- CMS proposes to not expand the categories of services subject to prior authorization.
- CMS seeks comments from stakeholders on payment alternatives to its current bundling policy for diagnostic radiopharmaceuticals.
- CMS proposes to continue to pay the statutory default rate, average sales price (ASP) plus 6%, for 340B-acquired drugs and biologicals.
- CMS proposes to update the ASC covered procedures list (CPL) by adding 26 dental surgical procedures to the CPL, but proposes no procedure removals from the inpatient only (IPO) list for CY 2024.
- CMS proposes to extend the application of the productivity-adjusted hospital market basket update to ASC payment system rates for an additional two years.
- CMS proposes to maintain its site neutrality policy but proposes to reimburse intensive cardiac rehabilitation provided by an off-campus, non-excepted provider-based department of a hospital at 100% of the OPPS rate.
- CMS solicits feedback via several requests for information, including feedback on what evaluations of health equity should be included in the agency's economic analysis of OPPS and ASC policies, and on establishing additional payments to hospitals for maintaining access to essential medicines.

Comments on the proposed rule are due September 11, 2023.

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

OPPS Major Proposed Policies

Price Transparency

Key Takeaway: CMS proposes to require that hospitals use a template for submitting standard charge information. CMS also proposes to publicize actions taken against hospitals in an effort to increase enforcement provisions.

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.

CMS increased the maximum daily penalties for noncompliance from $300 to between $300 and $5,500, depending on the hospital's number of beds, beginning in 2023. 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.

For CY 2024, CMS proposes to require hospitals to display standard charge information using a machine-readable file template similar to those it made available for voluntary use. CMS proposes to require hospitals to link to this information from their website homepage.

CMS also seeks additions and modifications to its enforcement regulations, including requiring an authorized hospital official to certify the accuracy and completeness of hospital price transparency data; requiring hospitals to acknowledge receipt of warning notices; allowing CMS to notify a health system's leadership of noncompliance by one of its hospitals; and allowing CMS to publicize information related to CMS's assessment of a hospital's compliance, compliance actions taken against hospitals (including the status and outcome of those actions) and notifications sent to health system leadership.

In this rule, CMS requests information on how best to align hospital price transparency requirements with Transparency in Coverage and No Surprises Act requirements.

Hospital price transparency is a topic of significant interest in the 118th Congress. On May 24, 2023, the House Committee on Energy and Commerce voted 49–0 to advance H.R. 3561, the PATIENT Act, and on July 26, 2023, the House Committee on Ways and Means voted 25-16 to advance H.R. 4822, the Health Care Price Transparency Act. Both bills would codify and expand on the current hospital price transparency regulatory requirements.

Prior Authorization Process for Certain Services

Key Takeaway: CMS proposes no additions of service categories to the hospital outpatient prior authorization process for CY 2024.

For CY 2020, CMS finalized a policy through which hospitals must submit a prior authorization request for a provisional affirmation of coverage for select services before the service is furnished to the beneficiary and before the claim is submitted 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, consistent with its approach in CY 2022, CMS proposes no changes to the list of service categories subject to the hospital outpatient prior authorization process, holding steady with the existing categories.

Transitional Pass-Through Payment for Medical Devices

Key Takeaway: CMS reviewed, and requests comment on, six medical devices seeking pass-through payment beginning in CY 2024.

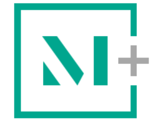
Transitional pass-through payment for new devices is intended to allow for adequate payment of new innovative technology during the interval in which CMS collects the data necessary to incorporate the costs for these devices into the accompanying procedure's payment rate. Devices that meet the requisite 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 of time after pass-through status ends for these device categories to account for the period of time that device utilization was reduced. In CY 2022, CMS exercised its equitable adjustment authority to extend the transitional pass-through for one device whose eligibility was slated 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 for the upcoming calendar year. However, Congress intervened and in the Consolidated Appropriations Act, 2023 (CAA, 2023), 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 six medical devices will continue into 2024 or through 2025. See Table 28 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 did not approve any devices during the quarterly cycle review.

CMS does 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 proposes to add nine services and remove no procedures from 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 are designated to the IPO list.

For CY 2024, CMS proposes to remove no procedures from the IPO list. CMS proposes to add nine services that were newly defined by the American Medical Association CPT Editorial Panel for CY 2024 to the IPO list. These new services are described by the placeholder CPT codes X114T, 2X002, 2X003, 2X004, 619X1, 7X000, 7X001, 7X002 and 7X003. Table 47 in the proposed rule outlines the proposed changes to the IPO list for CY 2024.

Payment for 340B Drugs

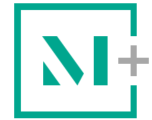
Key Takeaway: CMS proposes to continue to pay the statutory default rate, ASP plus 6%, for 340B-acquired drugs and biologicals. CMS also proposes to use a single modifier to identify drugs and biologicals acquired through the 340B program. All 340B covered entity hospitals paid under the OPPS would be 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 an adjusted amount of ASP minus 22.5% for certain separately payable drugs or 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. This decision ruled in favor of hospitals opposing the CY 2018 payment adjustment, and against the CMS policy.

As a result of this decision, CMS was compelled to restore payments to the original ASP plus 6%. CMS restored these payments in the CY 2023 OPPS final rule. In the CY 2024 OPPS proposed rule, CMS proposes to continue this statutory default rate of ASP plus 6%.

CMS recently released a separate proposed rule, Hospital Outpatient Prospective Payment System: Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022, providing a remedy for the reduced 340B payments hospitals received from 2018 through September 27, 2022 (the date on which CMS restored reimbursement for 340B drugs to the full OPPS rate). In that proposed rule, CMS proposes 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 would be $9 billion. For our complete summary of the 340B remedy proposed rule, click here.

In the CY 2024 OPPS proposed rule, CMS also proposes 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" modifiers to identify drugs and biologicals acquired through the 340B program. CMS states that "utilizing a single modifier will allow for greater simplicity," while also 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 proposes that all 340B covered entity hospitals paid under the OPPS would report the "TB" modifier effective January 1, 2025, even if the hospital previously reported the "JG" modifier. If this proposal is finalized, all hospitals using "JG" modifiers would need to switch to use "TB" modifiers by January 1, 2025.



Changes in APC Groupings or Comprehensive APCs

Key Takeaway: CMS proposes to create two new comprehensive ambulatory payment classifications (APCs) for 2024 and to set outpatient payment rates for 229 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 2024, CMS proposes 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. This would require renaming the previously existing Levels 3, 4 and 5 Intraocular APCs (5493, 5494, 5495) to be 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 to allow 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 now proposes to assign 229 additional dental codes to clinical APCs. The full list of those codes can be found in table 53 of the OPPS proposed rule.

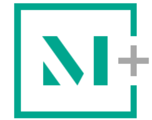
CMS reiterates that assignment of a drug, device, procedure or service to an HCPCS and APC does not imply coverage by the Medicare program, but instead shows how the procedure or service would be paid through the OPPS if covered by the Medicare program. Medicare Administrative Contractors are responsible for determining when the conditions are met for coverage and payment for the 229 dental codes assigned to clinical APCs.

CMS requests comments from stakeholders regarding the APC assignments for those dental codes, and whether any of the 229 dental codes do not meet the requirements for payment under the 2023 Medicare Physician Fee Schedule (PFS) final rule and § 411.15(i)(3)(i).

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 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 proposes 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 would be paid at 100% of the OPPS rate (which is also 100% of the PFS rate) rather than at 40% of the OPPS rate. CMS solicits comment on whether there are other services for which the OPPS rate is unconditionally used under the PFS, such that these services should be treated similarly for purposes of payment to off-campus, non-excepted PBDs of hospitals.

Rural Emergency Hospitals

Key Takeaway: CMS proposes to allow Indian Health Service (IHS) and Tribal hospitals to convert to rural emergency hospitals (REHs).

The Consolidated Appropriations Act, 2021, included a provision that allows critical access hospitals and small rural hospitals (those with fewer than 50 beds) to convert to a new Medicare provider type called REHs starting on January 1, 2023. Once established, REHs receive enhanced reimbursement under Medicare, but they cannot provide any 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. In the CY 2024 proposed rule, CMS proposes 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. Thus, CMS proposes to allow tribal and IHS hospitals to convert to REHs. These IHS-REHs would receive the REH monthly facility payment consistent with how this payment is made to REHs that are not tribally or IHS operated. CMS also believes that from a claims processing perspective, it would be most efficient for the IHS-REHs to process their claims separately from other REHs and continue billing separately under the all-inclusive rate.

Radiopharmaceuticals

Key Takeaway: CMS solicits comments on five payment alternatives for 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 paid under the OPPS. Stakeholders have commented that the packaged payment rate is often inadequate, especially in cases where the 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.

CMS now seeks comments on potential modifications to its packaging policy for diagnostic radiopharmaceuticals. CMS also requests 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 for which it is only clinically appropriate to use the more expensive diagnostic radiopharmaceutical, rather than a lower cost alternative, as well as clinical scenarios in which the only diagnostic modality is a high-cost radiopharmaceutical.

Finally, CMS solicits 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.

While CMS does not propose a specific option, based on feedback received, CMS may potentially adopt one or more alternative payment mechanisms for radiopharmaceuticals in the CY 2024 OPPS final rule.

ASC Major Proposed Policies

ASC Covered Procedures List

Key Takeaway: CMS proposes to add 26 dental codes to the ASC CPL for CY 2024.

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. In evaluating procedures for inclusion on the CPL, CMS examines these procedures 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, were not currently on the ASC CPL and met the criteria for inclusion on the CPL. Based on this assessment, CMS proposes to add 26 dental surgical procedure codes to the CPL in CY 2024. These procedures can be found in Table 61 in the proposed rule.

Consistent with its assignment of dental procedures to clinical APCs under OPPS, CMS reminds stakeholders that assignment of a drug, device, procedure or service to an HCPCS and APC does not imply coverage by the Medicare program, but instead 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 for the 26 dental codes proposed as additions to the CPL.

ASC Rate Update Based on the Hospital Market Basket

Key Takeaway: CMS proposes to extend the application of the productivity-adjusted hospital market basket update to ASC payment system rates for an additional two years.

For CY 2019, CMS finalized a policy to apply the productivity-adjusted hospital market basket update to 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 the performance of procedures from the hospital setting to the ASC setting, or any unintended consequences.

However, CMS notes the impact of the COVID-19 PHE on healthcare utilization, in particular in CY 2020 and with respect to elective surgeries. CMS states that it is almost impossible to disentangle the effects of the COVID-19 PHE from its analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. In this rule, CMS proposes to extend the five-year interim period for which the productivity-adjusted hospital market basket update would apply to the ASC payment system rates for an additional two years, CY 2024 and CY 2025.

OPPS and ASC Quality Proposed Policies

Hospital Outpatient, ASC and REH Quality Reporting Programs

Key Takeaway: CMS proposes to codify the quality reporting program for REHs and codify specific policies within the Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs. CMS also proposes to add, modify and remove measures from the three programs.

OQR and ASCQR Programs

The Hospital OQR and ASCQR Programs are pay-for-reporting quality programs that require providers to meet quality reporting requirements or receive a 2.0% reduction in their annual payment update.

CMS proposes to modify 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 also proposes the adoption of the following measures:

- Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty measure (separate measures in OQR and ASCQR)
- Hospital Outpatient/ASC Facility Volume Data on Selected Outpatient Surgical Procedures (separate measures in OQR and ASCQR)
- Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults electronic clinical quality measure (OQR measure only).

Finally, CMS proposes to remove the Left Without Being Seen measure from the OQR Program, as the agency believes it does not provide sufficient detail to improve quality and, subsequently, patient outcomes.

The agency also solicits comments in the measure topic areas of patient safety and sepsis, behavioral health (including mental health and suicide risk) and telehealth.

REHQR Program

CMS proposes to codify the REH Quality Reporting (REHQR) Program, the quality reporting program for REHs. CMS also proposes to add four quality measures to the program, all of which have been previously endorsed by a consensus-based entity 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.

CMS believes that these measures strike a balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. CMS also assessed whether these facilities have successfully reported the proposed measures within the context of the Hospital OQR Program with sufficient volume to meet CMS case number thresholds for data to be publicly reported. CMS found that services targeted by the proposed measures are relevant for hospitals that may participate in the REHQR Program, as these hospitals are currently providing the services assessed by the selected measures with case volumes sufficient to meet thresholds to allow public reporting of the collected data.

CMS proposes policies for retaining, adding, modifying and removing measures from the REHQR program based on the processes used in the Hospital OQR and ASCQR Programs. CMS also seeks comment on the use of electronic clinical quality measures and care coordination measures, including telehealth measures, in the REHQR program going forward. CMS seeks public comment on the implementation of a tiered quality measure approach in the REHQR Program, considerations in designing the structure of a tiered framework, the number of measures in each tier and considerations for designating measures for tiers of such a framework. Finally, CMS proposes to make measure scores for claims-based measures proposed for the REHQR Program measure set publicly available beginning with measure data submitted for services provided in CY 2024. CMS proposes processes, deadlines and exceptions for REHs with respect to reporting data that would be publicly reported.

Other Major Payment Policies

Intensive Outpatient Program

Key Takeaway: CMS proposes 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 of psychiatric services provided for individuals who have an acute mental illness, including conditions such as depression, schizophrenia and substance use disorders.

In this rule, CMS proposes the payment and program requirements for the new IOP benefit. The proposed rule includes the scope of benefits, physician certification requirements, coding and billing,

and payment rates under the IOP benefit. CMS proposes 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 seeks feedback on what evaluations of health equity should be included in its economic analysis of OPPS and ASC policies.

To gain insight into how OPPS and ASC policies affect health equity, CMS is considering adding elements to its economic analysis that would detail how OPPS and ASC policies impact particular beneficiary populations that are typically underserved by the healthcare system. Currently, OPPS impacts are presented by provider type, rural versus urban area, geographic region, teaching status and ownership type.

CMS seeks comment about structuring an impact analysis that addresses how OPPS and ASC changes may impact beneficiaries of different groups. CMS requests input on what health equity questions should be examined, what categories or measures should be included (such as using the area deprivation index as a proxy for disparities related to geographic variation), and any other feedback on ways to continue building an OPPS health equity framework.

Potential Payments for Cost of Maintaining Access to Essential Medicines

Key Takeaway: CMS seeks comments on establishing additional payments to hospitals for maintaining access to essential medicines.

Citing the persistence and severity of shortages for critical medical products and the additional time, labor and resources required to navigate them, in this rule CMS describes 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 one of the 86 medicines prioritized in the 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, whether those payments are bundled with other items and services or separately paid. Noting the challenge of quantifying the additional resource costs, CMS suggests initially basing IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock, which it 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 a potential IPPS payment is discussed in depth, CMS notes that with respect to the OPPS, a payment adjustment could be considered for future years.

In addition to essential medicines, CMS notes 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.

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