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Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

October 25, 2024

Key Takeaways Related to the Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

On August 1, the Centers for Medicare & Medicaid Services (CMS) issued a Final Rule to update payment rates under the Inpatient Prospective Payment System (IPPS) and to advance other policies, including policy to mitigate the impact of drug shortages. This summary focuses on the finalized policies related to drug shortages (pgs. 1057-1097). Generally, CMS finalized as proposed an additional payment opportunity for certain small and independent hospitals (100 beds or fewer) that establish and maintain 6 months of buffer inventory of essential medications.[1] CMS reiterated that the establishment of one or more buffer stock(s) is voluntary on the part of eligible hospitals.

This separate payment (biweekly or lump sum at cost report settlement) will be available under the IPPS for cost reporting periods beginning on or after October 1, 2024. In addition, CMS notes that it is separately seeking comment through the Paperwork Reduction Act (PRA) process on a supplemental cost reporting form for this proposed payment. As of the time of this summary, the supplement cost reporting form and comment opportunity was not yet posted. Lastly, in the Final Rule, CMS notes that if additional changes are needed, it will propose, as needed, appropriate modifications to the policy in future rulemaking.

List of Essential Medicines

To determine which medications are essential, CMS finalized use of the U.S. Department of Health and Humans Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) with the Advanced Regenerative Manufacturing Institute's (ARMI's) list ("ARMI List") of 86 essential medicines.

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[1] In the Final Rule (pg. 2554-2556), CMS provides the final regulatory text for new paragraph (g) under § 412.113 Other payments: (g) *Additional resource costs of establishing and maintaining access to buffer stocks of essential medicines.*
(1) Essential medicines are the 86 medicines prioritized in the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022, and any subsequent revisions to that list of medicines. A buffer stock of essential medicines for a hospital is a supply, for no less than a 6-month period of one or more essential medicines.
(2) The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients or arrange contractually for such a buffer stock to be held by another entity for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves.
(3) For cost reporting periods beginning on or after October 1, 2024, a payment adjustment to a small, independent hospital for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines is made as described in paragraph (g)(4) of this section. For purposes of this section, a small, independent hospital is a hospital with 100 or fewer beds as defined in § 412.105(b) during the cost reporting period that is not part of a chain organization, defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.
(4) The payment adjustment is based on the estimated reasonable cost incurred by the hospital for establishing and maintaining access to buffer stocks of essential medicines during the cost reporting period.

Although CMS requested comment on alternative medicines to include, the agency did not add products to the policy or rely on additional lists that stakeholders suggested in public comments. Should the ARMI List be updated, those medications will also be covered under the finalized policy.

While CMS received comments regarding a potential domestic manufacturing requirement, the agency is not requiring, at this time, that hospitals exclusively establish and maintain buffer stocks of domestically manufactured essential medicines to be eligible for separate payment.

Products in Shortage

In the Final Rule, CMS reiterates that "the appropriate time to establish a buffer inventory of a drug is before it goes into shortage or after a shortage period has ended." If an essential medicine is listed on FDA's Drug Shortages Database as "Currently in Shortage" then, under the Final Rule, a hospital that newly establishes a buffer stock of that medicine while it is in shortage would not be eligible for separate payment for that medicine during the shortage. Alternatively, if a hospital had already established and was maintaining a buffer stock of that essential medicine prior to it being in shortage, then CMS finalized that the hospital would continue to be eligible for the separate payment for that medicine during the shortage.

Also, CMS clarifies that payment eligibility would be maintained for the medicine during the shortage as the hospital draws down its established buffer stock of the medicine in shortage. Although CMS requested comment in the Proposed Rule regarding whether it should stop providing a separate payment if a product is on the shortage for a certain period of time (e.g., six months), CMS agreed with stakeholders, like Vizient, that it should not limit the amount of time that it will continue to pay for the reasonable costs of maintaining the buffer stock after an essential medicine is listed as "Currently in Shortage".

In addition, CMS acknowledged stakeholder comments requesting that CMS continue to allow payment for buffer stocks of drugs regardless of shortage status (e.g., allowing payment when hospitals newly establish buffer stocks for medicines in shortage). CMS disagreed with commenters and as noted above, finalized the proposal that separate payment is available only where the buffer stock is established prior to an essential medicine entering shortage.

Lastly, CMS acknowledged stakeholder concerns regarding use of the FDA's Drug Shortage Database to identify products in shortage. While CMS declined to consider other sources of information, it indicates that in conjunction with this final policy, CMS will conduct provider outreach on a quarterly basis regarding essential medicines that are currently in shortage. CMS further notes that it intends to make it clear to hospitals on or about the start date of each calendar quarter which drugs are or are not in shortage.

Update: In September 2024, CMS launched a new website, "Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines," where CMS will post a file each quarter at the National Drug Code (NDC) level so that hospitals will know what NDCs are considered in shortage for that quarter for purposes of determining whether or not Medicare will pay for a newly established buffer stock of that NDC.

Hospital Eligibility

CMS finalized limiting eligibility for the separate payment to small, independent hospitals that are paid under the IPPS. More specifically, CMS finalized the following as proposed:

- *Small hospital* means one with not more than 100 beds.[2] CMS did not expand the definition of small hospital in the Final Rule.
- *Independent hospital* is one that is not part of a chain organization, as defined for purposes of hospital cost reporting. A chain organization is defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.[3]

CMS acknowledged stakeholders' comments to broaden the scope of eligible hospitals but declined to do so. Among other reasons, CMS notes that is lacks actual experience under the policy and that expansion of the policy to other providers could risk inducing or exacerbating drug shortages. However, the agency provided the following comment in response to stakeholders' comments related to children's hospitals' eligibility: "Children's hospitals are exempt from the IPPS and paid according to a hospital-specific target amount updated for inflation with the option to apply for a temporary or permanent adjustment to their target amount for the reasonable costs their incur in furnishing inpatient care to Medicare beneficiaries, including those costs attributable to buffer stocks of essential medicines."

Size of the Buffer Stock

CMS finalized that the size of the buffer stock must be sufficient for no less than a 6-month period for each of one or more essential medicines. While CMS acknowledged stakeholder concerns (including phasing up from 3 to 6 months) CMS reiterated its belief that a 6-month buffer stock is generally more effective than a 3-month buffer stock. However, CMS notes that as it gains experience under this policy, including the extent to which the size of the buffer stock impacts hospital participation and also a potential cap on the size of the buffer. CMS may revisit these topics in future rulemaking.

Proposed Separate Payment Under IPPS

CMS finalized that for purposes of the proposed separate payment under the IPPS to small, independent hospitals, those costs associated with establishing and maintaining access to 6-month buffer stocks either directly or through contractual arrangements with pharmaceutical manufacturers, intermediaries (e.g., group purchasing organizations), or distributors would be eligible for additional payment under this policy. These costs do not include the cost of the medicines themselves[4], which would continue to be paid in the current manner. CMS also notes that the payment is only for the IPPS share of the costs of establishing and maintaining access to buffer stock(s) of one or more essential medicine(s). Participating hospitals would report the IPPS share of the costs on a forthcoming supplement cost reporting worksheet, as described below under "Hospital Reporting". In the Final Rule, CMS clarifies that the Medicare inpatient share of costs under this policy does not include Medicare Advantage.

In addition, CMS notes that payment could be provided as a lump sum at cost report settlement or biweekly as interim lump-sum payments to the hospital, which would be reconciled at cost report settlement. If a provider requests biweekly interim lump sum payments for an applicable cost reporting period,[5] then these payment amounts would be determined by the Medicare Administrative Contractor (MAC) consistent with existing policies and procedures. CMS clarifies that the MACs would determine the interim lumpsum payments based on the data the hospital may provide that reflects the information that would be included on the new supplemental cost reporting form. CMS

[2] CMS notes that this definition is consistent with the definition of a small hospital used for Medicare-dependent, small rural hospitals (MDH) in section 1886(d)(5)(G)(iv)(II) of the Act and consistent with the MDH regulations at § 412.108(a)(1)(ii).
[3] CMS notes that the proposed definition is the definition of chain organization in CMS Pub 15-1, Provider Reimbursement Manual, Chapter 21, Cost Related to Patient Care §2150: "Home Office Costs – Chain Operations" and used by a hospital when completing its cost report.
[4] In the Final Rule, CMS clarifies that the cost of compounding (e.g., internal compounding) would not be included in the cost for establishing and maintaining a buffer stock of an essential medicine.
[5] As provided under 42 CFR 413.64 – Payments to providers: Specific Rules

reiterated that it is separately seeking comment through the PRA process on a supplemental cost reporting form that would be used for this purpose. Lastly, CMS clarifies that the policy is not budget neutral, meaning payments made to hospitals are not offset with payment reductions elsewhere.

Hospital Reporting

CMS finalized, for cost reporting periods beginning on or after October 1, 2024, that payment adjustments will be based on the reasonable cost incurred by the hospital for establishing and maintaining access to a 6-month buffer stock of one or more essential medicines during the cost reporting period. To calculate the essential medicines payment adjustment for each eligible cost reporting period, CMS indicates it will create a new supplemental cost reporting form that will collect the additional information from hospitals.

In the Final Rule, CMS clarifies, "the new cost reporting worksheet will collect the costs of a hospital that voluntarily requests separate payment under this policy for the costs associated with establishing and maintaining access to its buffer stock of one or more essential medicines. This new information will include the costs associated with contractual arrangements to establish and maintain access to buffer stock(s) of essential medicine(s) as well as the costs associated with directly establishing and maintaining buffer stock(s) of essential medicine(s) such as (but not limited to) utilities like cold chain storage and heating, ventilation, and air conditioning, warehouse space, refrigeration, management of stock including stock rotation, managing expiration dates, and managing recalls, administrative costs related to contracting and recordkeeping, and dedicated staff for maintaining the buffer stock(s)." CMS also notes that information from the new cost reporting worksheet will be used in addition to information already collected on the Hospitals and Health Care Complex Cost Report (Form CMS-2552-10)[6] to calculate the IPPS payment adjustment amount.

CMS indicates that the new cost report worksheet may be submitted by a provider of service as part of the annual filing of the cost report and the provider should make available to its contractor and CMS, documentation to substantiate the data included on this Medicare cost report worksheet.[7]

In the Final Rule, CMS indicates that information on which hospitals receive separate payment under this policy will be publicly available as part of the cost report information reported by hospitals.

Buffer Stock Clarification: Shared vs Separately Established

In the Final Rule, CMS acknowledges requests that CMS clarify if eligible hospitals will be permitted to establish a shared buffer stock, or if each hospital will have to separately establish and maintain their respective buffer stock(s). In response, CMS notes that eligible hospitals that elect to maintain a shared buffer stock of essential medicines with other hospitals may receive separate payment only if all of the requirements for payment under this policy are met independently by each hospital (e.g., there is sufficient buffer stock that each hospital has access to a 6-month supply for itself if all hospitals begin to access the buffer stock at the same time), and the costs associated with establishing and maintain the shared buffer stock are reasonably allocated to each hospital without duplication of those costs across the hospitals establishing and maintaining the shared buffer stock.[8]

Also, in the Final Rule, CMS notes that it anticipates that when a hospital contracts with one or more manufacturers or wholesalers or other intermediaries to establish and maintain 6-month buffer

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[6] Approved under OMB control number 0938-0050

[7] The documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

[8] In the Final Rule, CMS notes the following example regarding the reasonable allocation of costs: "the total costs reported to Medicare – in accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR §413.9—across the hospitals for establishing and maintaining that shared buffer stock must equal the total costs of establishing and maintaining that buffer stock).

stocks of one or more essential medicines, it would need to ensure that a discrete buffer stock is maintained for that hospital.

Administrative Burden

In the Final Rule, CMS acknowledges stakeholder comments regarding the administrative burden and staffing requirements associated with the policy as proposed (e.g., costs associated with establishing and maintaining buffer tracking and maintaining buffer stock(s) of essential medicines, including staff costs of tracking shortage status of essential medicines.) In addition, CMS notes that commenters opposed the use of a supplemental cost reporting form and instead requested that contract manufacturers, distributors and intermediaries be permitted to directly report the costs associated with establishing and maintaining a buffer stock to CMS or to base payment to hospitals based on attestations from contracted manufacturers, distributors or intermediaries. In response, CMS indicates that it continues to believe that the Medicare cost report is the most feasible and least burdensome method of collecting and being able to audit cost information.

In the Final Rule, in response to burden concerns related to tracking drug shortages, CMS indicated that MACs will inform hospitals of all eligible medicines and their associated shortage status on a calendar quarter basis on or about the start of each quarter. The shortage status information that the MACs will provide to the hospital will be based on the shortage status of each essential medicine(s) as reported by the FDA's Drug Shortage Database.[9]

Estimated Effects of the IPPS Payment Adjustment for Establishing and Maintaining Access to Essential Medicines

In the Final Rule, CMS estimates the effects of this policy (pg. 2891-2894). For example, to estimate spend per hospital on its applicable essential medicines, CMS assumed that the cost of a given hospital's essential medicines will be 1 percent of its total Drug Charged to Patients costs,[10] a multiplicative factor of 50 percent to estimate the total costs of the essential medicines that are in the 6-month buffer stocks and assumed costs of carrying essential medicines. Also, CMS assumed that the cost of carrying essential medicines is 20 percent of the cost of the essential medicines themselves and that this amount would apply to any size of buffer stock of essential medicines. In the Final Rule, CMS estimates that the total annual costs for eligible hospitals to establish and maintain buffer stocks of essential medicines would be approximately $2.8 million and the mean cost per eligible hospital would be approximately $5,610. The IPPS payments under this finalized policy represent approximately 11 percent of that amount (i.e., $0.3 million).

What's Next?

Vizient's Office of Public Policy and Government Relations will be monitoring CMS activity regarding implementation of the Final Rule, including information related to the supplemental cost reporting form. Vizient encourages hospitals to review the Final Rule to determine eligibility for the payment adjustment, including determining whether buffer stock programs that they may participate in would meet the Final Rule's requirements. Vizient notes that the fees associated with Novaplus Enhanced Supply include maintaining and running the buffer inventory program, however, Vizient cannot advise individual members how to report those fees on their cost reports. If you have any questions or would like to share feedback, please reach out to Jenna Stern, Associate Vice President, Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.

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[9] In the Final Rule, CMS provides the following example: "hospitals will be informed by the MACs on or about January 1st each year which essential medicines are considered in shortage for purposes of this policy for the calendar year quarter starting January 1st. The MACs will similarly provide this information for the calendar year quarters beginning April 1st, July 1st, and October 1st.

[10] Per CMS, the total Drugs Charged to Patients cost center is found on Worksheet B, Part 1, line 73, column 26 on Form CMS-2552-2010.