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Vizient Office of Public Policy and Government Relations

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

April 16, 2024

Key Takeaways

On April 10, the Centers for Medicare & Medicaid Services (CMS) issued a Proposed 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 agency's proposals related to drug shortages. Specifically, CMS proposes to provide a payment adjustment to small and independent hospitals (defined further below) that establish and maintain 6 months of buffer inventory of essential medications.

Comments are due June 10, 2024 by 5pm, and the final rule is expected to be released by early August. Vizient looks forward to working with members to help inform our letter to the agency.

Major Proposals Related to Drug Shortages

Separate IPPS payment for establishing and maintaining access to essential medicines

CMS proposes to establish separate payments (biweekly or lump sum at cost report settlement) under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of at least one essential medicine (for cost reporting periods beginning on or after October 1, 2024).

Proposed List of Essential Medicines

To determine which medications are essential, CMS proposes to use 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, including any subsequent revision to the list.[1] The ARMI List is a prioritized list of 86 medicines that are either critical for minimum patient care in acute settings or important for acute care with no comparable alternatives available.

CMS seeks comments on products excluded from the ARMI List (e.g., blood and blood products) due to supply chain differences or other categories not needed for routine/typical acute patient care. Also, CMS seeks comment on whether oncology drugs or other types of drugs not currently on the ARMI List should be eligible for this separate payment. In addition, to the extent that other medicines or lists are identified for eligibility in future iterations of this policy, CMS seeks comments on the potential mechanism and timing for incorporating those updates.

[1] In the Proposed Rule, CMS clarifies that if the ARMI List is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment for the IPPS share of the buffer inventory as of the date the updated ARMI List is published

Products in Shortage

In the Proposed Rule, CMS indicates 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 CMS proposes that 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 proposes 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 even if the buffer drops below 6 months as the hospital draws on buffer stock.

However, if the buffer drops below a 6-month supply for a reason other than it being on FDA's shortage list, then any separate payment to a hospital under this policy would be adjusted based on the proportion of the cost reporting period for which the hospital did maintain the 6-month buffer stock of the essential medicine. In the Proposed Rule (pg. 709), CMS provides an illustrative example of this scenario.

CMS requests comments on the duration that CMS should continue to pay hospitals for maintenance of less than 6-month buffer stock of the essential medicine if it is "Currently in Shortage". In addition, CMS requests comments on if there is a quantity or dosage minimum floor where CMS should no longer pay to maintain a 6-month buffer stock of the essential medicine if it is "Currently in Shortage" (e.g., a hospital has one remaining dose of a drug "Currently in Shortage" and that drug remains in shortage on the FDA Drug Shortage Database for 5 years, should there be limits on how much and for how long CMS would pay a hospital for a 6-month buffer stock?).

CMS also clarifies that hospitals would be permitted to use multiple contracts to establish and maintain at least a 6-month buffer stock for any given essential medicine.

Hospital Eligibility

CMS proposes to limit eligibility for the separate payment to small, independent hospitals that are paid under the IPPS. CMS also notes that many of these hospitals are located in rural areas, so this policy also supports rural hospitals.

CMS proposes to that small hospital, for this policy, means one with not more than 100 beds.[2] CMS seeks comment on using other criteria (other than Medicare-dependent, small rural hospitals (MDH) bed size) to identify small hospitals. CMS proposes that an 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] Based on these criteria, CMS identified 493 potentially eligible hospitals based on FY 2021 cost report data. CMS seeks comment on proposed eligibility requirements.

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[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. Consistent with the MDH regulations at § 412.108(a)(1)(ii). CMS further clarifies that the hospital would need to have 100 or fewer beds as defined in §412.105(b) during the cost reporting period for which it is seeking the payment adjustment to be considered a small hospital for purposes of this payment adjustment.

[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. To operationalize the agency's proposed separate payment policy, CMS proposes that any hospital that appropriately answers "yes" (denoted "Y") to line 140 column 1 or fills out any part of lines 141 through line 143 on Worksheet S-2, Part I, on Form CMS-2552-10 is considered to be part of a chain organization and not independent, and therefore not eligible for separate payment under this proposal.

CMS clarifies that since critical access hospitals (CAHs) are paid for inpatient and outpatient services at 101% of Medicare's share of reasonable costs, that this would include Medicare's share of reasonable costs of establishing and maintaining access to buffer stocks of medicines. CMS seeks comment on the use of buffer stocks by CAHs, whether CAHs tend to contract out this activity, and any barriers that CAHs may face in establishing and maintaining access to buffer stocks.

Size of the Buffer Stock

CMS proposes 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. However, CMS seeks comment on whether a phase-in approach to build towards a 6-month buffer would be appropriate. For example, CMS seeks comment on whether it should provide separate payment for establishing and maintaining access to a 3-month supply for the first year in which the policy is implemented and then to require a 6-month supply for all subsequent years. CMS clarifies that in estimating the amount of buffer stock needed for each essential medicine, the hospital should consider that the amount needed to maintain a buffer stock could vary month to month and throughout the applicable months of the cost reporting period (e.g., a hospital's historical use of a medicine may indicate that it is typically needed more often in January than June).

Proposed Separate Payment Under IPPS

CMS proposes 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, which would continue to be paid in the current manner. CMS also notes that the proposed 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. More information regarding hospital reporting is noted below.

In the Proposed Rule, CMS indicates the costs associated with directly establishing and maintaining a buffer stock may include 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 record-keeping, and dedicated staff for maintaining the buffer stock(s). CMS requests comments on other types of costs intrinsic to directly establishing buffer stocks of essential medicines that should be considered eligible for purposes of separate payment under this policy. CMS also requests comment regarding whether labor costs would increase with the number of essential medicines in buffer stock, and whether there would be efficiencies if multiple hospitals elect to establish buffer stocks of essential medicines with the same pharmaceutical manufacturer, intermediary, or distributor.

Lastly, CMS clarifies that the proposed policy would not be budget neutral, meaning that any payments made to hospitals would not need to be offset with payment reductions elsewhere.

Hospital Reporting

If buffer stock is established and maintained through contractual arrangements, CMS provides that the hospital would be required to disaggregate the costs specific to establishing and maintaining the buffer stock from the remainder of the costs on the contract for purposes of reporting these disaggregated costs under this proposed policy. This disaggregated information, reported by the

hospital on a new supplemental cost reporting worksheet[4], along with existing information already collected on the cost report, would be used to calculate a Medicare payment for the IPPS share of the hospital's costs of establishing and maintaining access to the buffer stock(s) of essential medicine(s). CMS also provides that the policy would be in place for cost reporting periods beginning on or after October 1, 2024.

CMS provides the following, simplified example to further detail this policy:

> "…suppose a hospital has a $500,000 contract with a pharmaceutical wholesaler. The contract is for pharmaceutical products, 50 of which are qualifying essential medicines. Additionally, the contract contains a provision for the wholesaler to establish and maintain 6-month buffer stocks of those 50 essential medicines on the hospital's behalf. The contract further specifies that $10,000 of the $500,000 is for the provision of the contract that establishes and maintains the 6-month buffer stocks of those 50 essential medicines. This $10,000 amount does not include any costs to the hospital for the drugs themselves which, as previously noted, would continue to be paid in the current manner. Under this proposal, the hospital would report the $10,000 cost for establishing and maintaining the 6-month buffer stocks of the 50 essential medicines on the supplemental cost reporting worksheet. That $10,000 cost, in addition to other information already existing on the cost report, would be used to calculate the additional payment under this policy including the hospital-specific Medicare IPPS share percentage of this cost, expressed as the percentage of inpatient Medicare costs to total hospital costs. On average for the small, independent hospitals that are eligible for this policy, the Medicare IPPS share percentage is approximately 11 percent."

Based on the agency's estimates (Proposed Rule pg. 1811-1812), CMS estimated that the total costs for eligible hospitals to establish and maintain buffer stocks of essential medicines would be approximately $2.8 million, and the average cost per eligible hospital would be approximately $5,610. The IPPS payments under this proposed policy represent approximately 11 percent of that amount, or $0.3 million. CMS seeks comments on the assumptions and estimates included in the Proposed Rule.

What's Next?

Vizient's Office of Public Policy and Government Relations will be commenting to CMS regarding the Proposed Rule. 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.

[4] CMS indicates that it will seek separate comment regarding the supplemental cost reporting form.