Schaeffer Initiative on Health Policy at BROOKINGS

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850
[CMS-1786-P]

Re: Potential Payment under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines (Docket No. RIN 0938-AV09)

Dear Administrator Brooks-LaSure,

We appreciate the opportunity to comment on CMS's proposal for potential IPPS payment for Establishing and Maintaining Access to Essential Medicines. We commend CMS for proactively engaging in the drug shortage crisis affecting highly vulnerable hospital patients.

We agree that maintaining sufficient inventory is one way to make drug supply chains more resilient to shocks. We are concerned, however, that the proposal will not have the effect on shortages where it is most needed. In addition, some provisions may inadvertently result in increased levels of waste, fraud, and abuse.

Our comments are based on over a decade experience studying drug shortages. One of us is a healthcare economist focusing on economic drivers of drug shortages, the other one is an industrial engineer who studies vulnerabilities of drug supply chains, including vulnerabilities in inventory systems.

In this comment letter, we explain our concerns about the CMS buffer inventory proposal and identify improvements to some elements of that proposal. We propose to extend the buffer to six months, narrow down the proposal to third-party options only, switch from a submit-a-bill to a fixed payment, and be more explicit when inventories are to be build up and drawn down.

We are, however, unable to provide a CMS solution to the drug access disparities that we expect will continue to exist under any proposal that does not explicitly tackle panic buying. We do think mechanisms like that exist, but within powers of other HHS Agencies. In turn, we believe that CMS's greatest contribution would be in encouraging hospitals to buy from reliable manufacturers.

The buffer inventory proposal may not have impact where it is needed most

According to the proposed rule, CMS looks to establish an IPPS payment for the IPPS share of the reasonable costs of establishing and maintaining access to a three-month buffer stock of one of more of the 86 essential medicines on the ASPR list. There are three options that CMS offers: maintaining inventory directly at the hospitals, arranging contractually for a distributor or wholesaler to hold, or arranging contractually for a manufacturer to hold. The cost of establishing or maintaining inventory would not include the costs of the medicine itself.

To assess whether this proposal would be an effective buffer, it is important to understand what drives current shortages, how hospitals currently respond to shortages, and how that response

differs across hospital types. This will give indication of the likely impact of creating incentives for a buffer inventory.

Currently, most shortages of the generic sterile injectable drugs heavily used in hospitals are caused by manufacturing quality problems that lead to production disruptions. When supply shocks occur, shortages are then exacerbated by panic buying by hospitals. When panic buying, hospitals try to rapidly purchase as much of the product as they can find. Once a shortage hits, it can last many months or even several years.

In response to repeated shortages, many major health systems have taken steps to secure more reliable sources of product and – relevant to this proposal – to secure buffer inventories either through organizations such as CivicaRx, through private label GPO programs, or wholesaler programs. Many health systems also have staff dedicated to monitoring shortage risk. Those health systems are first out of the gate at any sign of potential shortage, allowing them to secure supply for their patients, likely at the expense of slower-reacting hospitals.

The proposed program would compensate well-resourced hospitals for doing a great job providing for their patients. This is a good thing.

We are concerned, however, that the proposed policy will provide help to the hospitals that least need it and will overlook those that are most vulnerable to the appearance of shortages. The vulnerable facilities may typically include small hospitals, often in rural or other low-income areas.

One reason the proposal is unlikely to help hospitals most vulnerable to shortages is because the proposal only covers a small fraction of the total cost of an effective buffer. Covering only the IPPS share of the inventory holding costs means that less than half the costs will be covered for most hospitals. More importantly, the proposed payment does not include the cost of the drugs, which we expect to be the overwhelming majority of the cost.

Another reason the proposal is unlikely to help hospitals most vulnerable to shortages is because the proposal does not account of the existing divergence in how hospitals respond to information on emerging shortages. As we noted earlier, currently the well-resourced hospitals can quickly place large orders through multiple accounts, building buffer stock before a shortage hits. A three-month buffer is small relative to the length of most shortages and therefore likely to be insufficient, suggesting that panic behavior will continue to occur in participating hospitals.

Even if drugs are not currently in shortage, the proposal as written has the potential to cause shortages. If many participating health systems attempt to establish buffer inventory, this will be a large demand-side shock. It is likely that manufacturers will not be able to fulfill these orders, true demand based on patient need may not be met, and panic buying may ensue in response to unfilled orders.

The buffer inventory proposal has waste, fraud, and abuse potential

The current version of the proposal has an inadvertent potential for waste, fraud, and abuse.

Allowing hospitals to choose between the three options (i.e., hold at hospital, distributor/wholesaler, or manufacturer) could be wasteful because hospitals may not choose the most cost-effective option. Because space is the biggest driver of inventory costs, it would be wasteful for Medicare to pay a hospital in Manhattan to store drugs on its premises rather than in an off-site warehouse from which the hospital gets daily deliveries of other products.

As designed, the payment may also be easily gamed because of bundling. Holding inventory with wholesalers or manufacturers is either already bundled with other offerings or could be

easily bundled. Given the bundling opportunities, it would be in the interest of the hospital and the third party to have the hospital be charged a higher inventory holding cost, while giving the hospital a cut on some other bundled services on the back end.

We also expect oversight costs for proper oversight to vary between the three options. In particular, we expect oversight of hospital-based inventories to be very resource intensive because each inventory would be hospital-specific, in contrast to being tied to a wholesaler program, which would be easier to oversee.

More generally, it is not clear what compliance would look like in this program and what mechanisms would be put in place to assure compliance.

Some but not all problems can be addressed through program modifications

Some of the elements we are concerned about could be addressed with changes to the proposal.

On the impact side, we propose to increase the size of the buffer to at least six months. We caution, however that even a six-month buffer may not be sufficient to slow down panic buying, given that many shortages last much longer than that and hospitals lack insight into how long a given shortage might last.

To reduce the potential for the policy to cause shortages, we recommend that policy implementation is staggered to reduce the demand shocks of increased orders to establish inventory buffers. We recommend CMS coordinate with manufacturers and the FDA throughout plans and implementation. This would include notification of drugs for which to consider increasing manufacturing capacity and an evaluation of the potential for cascading shortages to other types of drugs if manufacturing capacity is reallocated. Further, we recommend that the policy be clarified to not allow for the establishment of buffers for drugs in active shortage.

We also recommend that CMS consider ways to incentivize hospitals to draw down inventory in shortage. The latter might require more onerous reporting requirements from hospitals where they can show their inventory changes. This setup may be possible for large health systems, especially for DSH hospitals that have software to help keep track of 340B inventory. These are the hospitals that already have the incentive to create buffers, so increasing reporting requirements on them may not have as an adverse effect as it would have on small rural hospitals.

To address some waste, fraud, and abuse concerns, we recommend that CMS eliminate the hospital-based holding cost option. We also propose that CMS move from submit-a-bill approach to one where CMS establishes a fixed payment for holding inventory off site. This fixed payment should reflect differences in physical volume (paying more for storing bags than vials) and in special handling requirements (paying more for drugs that need to be refrigerated or stored in controlled substance vaults).

CMS should focus its efforts on having hospitals buy from reliable manufacturers

We believe that buffer inventories can be an effective method for preventing a supply disruption from turning into shortage. However, the confines of this proposal make it challenging to develop an effective buffer for all types of hospitals. In particular, given the disparities in hospital resources to prepare and respond to shortages and corresponding disparities in patient impact, a policy approach should focus first on those at the greatest disadvantage.

To address the underlying resource disparity that appears during panic buying, it is important that a proposal has allocation mechanisms in place. This could be accomplished with a targeted first-in-first out buffer inventory at the wholesaler or manufacturer level, coupled with predetermined, automatic allocation schemes. Those allocation schemes could be historical, could be adjusted to uneven demand or supply shocks, or adjusted from historical usage to where the shorted drug may be needed most, such as when a drug may not have pediatric alternatives.

CMS authorities do not appear to enable such a program, which is better suited for HHS ASPR.

Where we think CMS could be particularly effective is changing how hospitals procure drugs, specifically selecting vendors that are less likely to experience production disruptions. The approach we propose CMS take is laid out in detail in The Hamilton Project proposal found here. We attach the proposal's overview.

We are fully aware that both the ASPR buffer inventory and CMS reliable manufacturer programs would require Congressional support, but we are hopeful that the current focus on the shortage problem will motivate constructive Congressional action.

We thank CMS for their efforts to address the on-going drug shortage crisis.

Respectfully,

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