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Kenneth Maxik

Craig Kimble

Alberto Coustasse

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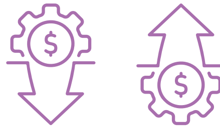

Consider Real Costs Before Implementing a 340B Program

Proposed CMS Changes Could Hurt Many Health Systems That Are Already Struggling Due to COVID-19 Pandemic

BY KENNETH MAXIK, MBA, MBB; CRAIG KIMBLE, PHARMD, MBA, MS, BCACP, AND ALBERTO COUSTASSE, DRPH, MD, MBA, MPH

KENNETH MAXIK, MBA, MBB

CRAIG KIMBLE, PHARMD, MBA, MS, BCACP

ALBERTO COUSTASSE, DRPH, MD, MBA, MPH

The 340B drug pricing program was created to improve access to outpatient medications for low-income and underinsured or uninsured patients.[1,2]

The program grants reduced pricing on biologics, FDA-approved prescription drugs, insulins, and some OTC drugs with a prescription.[3] Originally, this program was limited to about 90 safety-net hospitals known as qualified "covered entities." Through the passage of the Affordable Care Act, these entities expanded to include cancer centers, critical access hospitals, federally qualified health centers, rural referral centers, sole community hospitals, and other settings.[3]

The program has exponentially grown with the expansion of the definition of a covered entity and the change to allow multiple contract pharmacies. Still, there are debates about the program's financial impact and whether the discounts are passed along to enough underinsured or uninsured patients.[4] The Health Resources and Services Administration predicted that covered entities saved $3.8 billion on outpatient drugs through the program in 2013 and estimated that covered entities applying the 340B program reached more than $16 billion in 2016.[5] Hospitals have claimed that they have expanded services and reduced overall costs to patients.[6] However, the Centers for Medicare & Medicaid Services (CMS) has contended that financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among patients.[7,8]

In 2018, the US Department of Health & Human Services (HHS) amended the program by cutting Medicare Part B outpatient drug payments to 340B hospitals by 28.5%, seeking to close a gap between those prices and Medicare Part B payments.[9] Proposed amendments would further reduce the payment to certain covered entities by an estimated $1.6 billion.[10] As a result, a lawsuit was filed by the American Hospital Association, the Association of American Medical Colleges, Eastern Maine Healthcare Systems, Fletcher Hospital, and Henry Ford Health System.

The most recent decision was from the US Court of Appeals for the District of Columbia Circuit on July 31. The court decreed in favor of HHS, allowing the lower 340B program reimbursement.[9] Hospitals have continued to challenge the rule and have argued dire financial consequences resulting from this policy change that includes an increased impact on small community hospitals without a significant financial cushion.[9,11] All covered entities, hospitals, and those affected by these cuts to the program should provide comments by October 5 on this new rule.[12]

Additionally, on August 4, CMS recommended a shift to the Medicare Hospital Outpatient Prospective Payment System methodology. If enacted, this change would mean that certain covered entities would have a change in reimbursement from the average sale price (ASP) plus 6% to ASP minus 28.7% for separately payable drugs or biologicals acquired through the 340B program. It was also requested to continue the Medicare payment policy of paying an ASP of 22.5% for 340B-acquired drugs for calendar year 2021 and subsequent years.[10] This would add to previous cuts to total an estimated $2 billion to $2.5 billion reduction of 340B-covered medications.[12]

If these proposed CMS changes are implemented, affected covered entities must be ready and understand the direct impact on the organization, which could be critical.[13]

Explanation and Next Steps

Facilities designated as disproportionate

share hospitals or rural referral centers will receive reduced payment for certain separately payable drugs or biologicals specified by CMS purchased under the program and furnished to a Medicare beneficiary.[13]

When determining the organizational cost of maintaining the 340B program rules, consider the cost of any employees added, such as individuals to the revenue integrity area to monitor the program or a purchasing agent position. Alternatively, additional expenses could occur in the internal auditing department to maintain compliance with the program, as many organizations have used third-party consultants to conduct annual program audits and reviews.

Additionally, staff members must be trained in the program, increasing the cost, and administrative costs associated with the program include planning, audit and meeting preparation, audit review, and response. Some other items to consider are the potential loss of goodwill related to the public release of the 340B audit findings and the hardware and software needed to maintain the split billing program and contract pharmacy compliance. Those entities subject to the group purchasing prohibition will also have a cost increase based upon the requirement to purchase medications at the wholesale acquisition cost.

Conclusion

Hospitals must take a systematic approach and undertake financial calculations to ensure a clear understanding of the program's real cost. Many hospitals have financially struggled during the COVID-19 pandemic and this reduction without a significant increase in outpatient payments (proposed just 6%) aggregate on handling and overhead costs[14] adds another hurdle for these organizations.

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ABOUT THE AUTHORS

Kenneth Maxik, MBA, MBB, is vice president of operations support CompleteRx in Houston, Texas.

Craig Kimble, PharmD, MBA, MS, BCACP, is director of experiential learning, manager of clinical support services, and associate professor of pharmacy practice, administration, and research at Marshall University School of Pharmacy in Huntington, West Virginia.

Alberto Coustasse, DrPH, MD, MBA, MPH, is a professor of health care administration at the Management and Healthcare Administration Division at Lewis College of Business at Marshall University.