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August 23, 2018

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-1850

Attention:  
Docket CMS-1695-P  
Proposed Rule for Changes to Hospital Outpatient Prospective Payment System for Off-Campus Sites

### Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit, organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in the federal government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW was established to follow up on the work of the President's Private Sector Survey on Cost Control, also known as the Grace Commission.

The 340B drug discount program was created in 1992 and expanded under the Patient Protection and Affordable Care Act (ACA). The program requires pharmaceutical manufacturers that want to participate in Medicaid to provide heavily discounted outpatient drugs to certain "[covered entities](#)," including disproportionate share hospitals (DSH); critical access hospitals; children's hospitals; and, other safety-net providers, such as federally-qualified health centers, which serve uninsured, low-income people who do not qualify for Medicaid or Medicare.

Since the implementation of ACA, the 340B program has strayed from its original mission to help the uninsured poor get access to low-cost pharmaceuticals, and sales under the program have skyrocketed. A June 28, 2018 Government Accountability Office (GAO) [report](#), "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," added to the growing evidence that the discount program is out of control and needs to be reformed. Hospitals and their contract pharmacies are making huge profits from the program and in many instances are not passing along the discounts to their patients. GAO examined 55 entities, of which 28 were hospitals; 16 hospitals, or 57 percent, did not pass along the discounted price to low-income, uninsured patients.

### Comments

CAGW was pleased when on November 13, 2017, the Centers for Medicare and Medicaid Services (CMS) approved the final rule to revise the Medicare Hospital Outpatient Prospective Payment System (HOPPS) for outpatient drugs purchased under the 340B program. CAGW

agreed with CMS that changing the Medicare Part B payment rate for 340B-acquired drugs from the Average Sales Price (ASP) plus 6 percent to the ASP minus 22.5 percent for certain hospitals would be of great benefit to Medicare beneficiaries and taxpayers. The rule change is justified because a Medicare Payment Advisory Commission (MedPac) estimated in a May 2015 [report](#) to Congress that hospitals receive a minimum of a 22.5 percent discount of the ASP and a March 2016 MedPac [report](#) wrote that all 340B providers receive an aggregate 34 percent discount of the ASP.

CMS has estimated this payment change for drugs purchased under the 340B discount program will save Medicare beneficiaries \$320 million on copayments in 2018. Taxpayers will benefit because the monetary savings of \$1.6 billion will be reallocated equally to all hospitals paid under the HOPPS and help reduce future spending.

With respect to this proposed rule, CAGW is pleased to see that CMS responded to commenter concerns about the November 2017 final rule that the payment change to ASP minus 22.5 percent would not apply to certain off-campus provider-based departments (PBDs). Not addressing this discrepancy would have encouraged hospitals to shift services to off-campus sites to take advantage of the ASP plus 6 percent reimbursement rate and allow them to continue to misuse the 340B program, thus negating much of what CMS is trying to accomplish. This proposed rule adopts the ASP minus 22.5 percent rate for drugs purchased under the 340B discount program by non-excepted, off-campus PBDs. It is expected this new change will save an additional \$48.5 million in lower copayments for beneficiaries and reduce future spending.

Despite these positive changes, much more needs to be done to reform the 340B program to return it to its original intent of helping low-income, uninsured Americans get access to low-cost pharmaceuticals. While some reforms can be implemented by agencies within the Department of Health and Human Services, other reforms will require congressional action. Reforms should include a clear definition of a 340B-eligible patient; a well-defined depiction of what constitutes charity care; a new disproportionate share hospital adjustment formula to determine qualification for the 340B drug discount program, such as one that is not based on the number of inpatient days for individuals who are on Medicare and Medicaid; and, a requirement that safety-net hospitals report how the savings obtained under the 340B drug discount program are utilized.

Endorsement of this payment change is not an expression of support for government price controls. Private-sector solutions are preferred for the Medicare and Medicaid programs, but under the current circumstances, the proposed rule change for reimbursement of Medicare Part B drugs purchased under the 340B program is an appropriate solution.

Sincerely,

The image shows a handwritten signature in black ink that reads "Thomas Schatz". The signature is written in a cursive, slightly slanted style.