Long-Awaited 340B Proposed Regulations Now Under OMB Review

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Regulations providing formal guidance on certain key aspects of the federal 340B Drug Pricing Program have been anticipated for some time. On April 9, 2014, proposed regulations were sent to the Office of Management and Budget (OMB) for its vetting prior to publication. Covered entities and pharmaceutical manufacturers will need to carefully review their 340B policies and procedures in light of the proposed regulations once they come out, possibly by June 2014, to ensure compliance with final regulations once they go into effect sometime later. This is the first in a series of articles that will discuss various aspects of the proposed regulations.

Background

The federal 340B Drug Pricing Program is administered by the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs, which is housed within the U.S. Department of Health and Human Services. The 340B Program requires pharmaceutical manufacturers to discount outpatient drugs to qualifying healthcare organizations, known as "covered entities," which include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics.[1] The goal of the 340B Program is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

The 340 Program was established in 1992 under the Veterans Health Care Act and followed the Medicaid Drug Rebate Program (MDRP), established under the Omnibus Budget Reconciliation Act of 1990, largely in response to disincentives for drug manufacturers to provide voluntary discounts to safety-net providers, which has been seen as an unintended consequence of the MDRP. The Patient Protection and Affordable Care Act (PPACA) subsequently amended the 340B Program. PPACA increased the scope of covered entities to now include certain critical-access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. PPACA also introduced various measures designed to ensure program integrity and compliance.

Criticism of 340B Program Oversight by HRSA

PPACA also mandated that the Government Accountability Office (GAO) conduct a study of the 340B Program. The GAO released its findings in a September 2011 report to Congress.[3] In its report, the GAO criticized HRSA's oversight of the 340B Program, noting that this has mostly been left to self-policing by covered entities and drug manufacturers. For example, the GAO indicated that HRSA's lack of guidance on key 340B program requirements has allowed for inconsistent interpretations that impact program compliance. One example is the definition of a qualifying patient. Under the 340B Program, covered entities are not permitted to provide drugs purchased at 340B prices to individuals who do not meet HRSA's patient definition (generally speaking, these are patients who receive healthcare services other than drugs from the covered entity).[4] The GAO

1 To see the complete list of eligible organizations/covered entities, *see* http://www.hrsa.gov/opa/eligibilityandregistration/index.html.

2 *See* description available at HRSA's 340B Program website, at http://www.hrsa.gov/opa.

3 *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. GAO-11-836 (Sept. 23, 2011).

4 To access full definition, *see* http://www.hrsa.gov/opa/eligibilityandregistration/index.html.

criticized HRSA for not having provided formal guidance on what many have regarded as a definition lacking necessary specificity. The GAO also criticized HRSA for its lack of guidance on how nonpublic hospitals may qualify for 340B Program participation. Accordingly, GAO's recommendations included that HRSA issue specific guidance on these program requirements.

HRSA's Response

On January 8, 2014, HRSA posted a 340B Program update indicating that it was in the process of drafting regulations to provide formal guidance on the definition of an eligible patient and hospital-eligibility criteria, as well as compliance requirements for contract pharmacy arrangements and eligibility of offsite facilities. HRSA indicated that it expected to publish the proposed regulations by June 2014, for public comment. On April 9, 2014, the proposed regulations were sent to the OMB for its review as the next step toward publication (for more information, please click here).[5]

Conclusion

These developments are occurring in an environment of continuing scrutiny of the 340B Program stemming from the OIG report. Once these proposed regulations are released, covered entities and drug manufacturers will be well advised to carefully review their 340B policies and procedures to determine if they are consistent the way the proposed regulations define key program requirements.

5 http://www.reginfo.gov/public/do/eoPackageMain.

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