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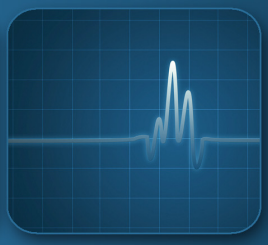


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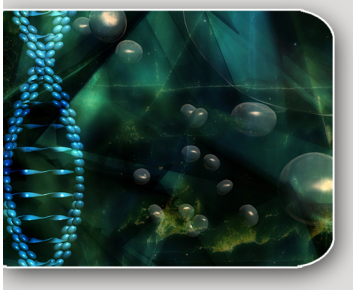

340B Drug Pricing Program Experiencing Unprecedented Compliance Scrutiny

A Polsinelli Shughart Update

Participants in the 340B Drug Pricing Program (340B Program) should be aware that over the last several months, the 340B Program has witnessed an unprecedented focus on oversight, integrity and enforcement. Although the 340B Program was enacted as part of the Veterans Health Care Act of 1992, its expansion of the types of providers that were made eligible in Patient Protection and Affordable Care Act of 2010 (ACA) has ignited recent scrutiny by Congress, federal government agencies and the pharmaceutical industry to verify participants' compliance with the 340B Program.

The 340B Program requires drug companies to give discounts on outpatient drugs to certain health care providers (Covered Entities) who serve patients who have little or no insurance coverage. From 2001 to 2011, the number of Covered Entities almost doubled, reaching slightly more than 16,500, and, under ACA, additional types of providers were made eligible further expanding the pool of providers to receive the drug discounts. Providers eligible to be Covered Entities under the 340B Program include federal grantees, federally-qualified health center look-alikes and qualified hospitals.

Catalysts of the Compliance Environment

Recently, two government reports have catalyzed increases in enforcement and oversight of the 340B Program, which is administered by Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). Under the 340B Program guidelines, Covered Entities may not accept a discount for a drug that would also generate a Medicaid rebate (duplicate discount) and may not sell discounted drugs to persons who are not patients of the hospital (drug diversion).

In June of 2011, the Department of Health and Human Services, the Office of Inspector General, released a report questioning the effectiveness of federal and state guidance on Medicaid-related billing from 340B participants. Additionally, the Government Accountability Office released a report in September of 2011 pointing out the government's overreliance on participating providers self-policing of their actions. The GAO report recommended greater government oversight and enforcement.

In addition to these reports, in March and May of 2012, members of Congress requested information from various 340B Program stakeholders including two drug industry groups, a hospital group, the nonprofit contractor that serves as the 340B program's prime vendor and two health care providers. The congressional inquiries request information pertaining to each stakeholder's role in the 340B program, following the 2011 reports of insufficient oversight and calling for transparency in the 340B Program.

HRSA Program Integrity Response

Stemming from provisions in the ACA, HRSA has begun to conduct audits to address compliance issues concerning Covered Entity drug diversion and duplicative discounting practices. In a February 2012 letter to 340B Program Participants, HRSA highlighted the importance of strengthening oversight of both participating Covered Entities and manufacturers to ensure compliance and outlined several key components of HRSA's program integrity efforts. In a March 2012 policy release, HRSA clarified its intent and procedure to audit Covered Entities. HRSA stated the purpose of the audits is to help HRSA and participating Covered Entities identify and mitigate program risk as well as identify best practices regarding 340B Program compliance. HRSA explains it will conduct both random and targeted Covered Entity audits.

According to the release, HRSA's random audits of higher risk programs are to be conducted first, and then HRSA's focus will shift lesser risk programs. HRSA looks at various criteria to determine whether a Covered Entity's program is high risk, including volume of purchases, complexity of program administration, and use of contract pharmacies. Hospitals generally have higher risk programs because they involve most of these components and serve both 340B and non-340B patients. Targeted audits can be triggered by allegations of violations of 340B requirements from whistleblowers, manufacturers, hospital self-reporting, or other source and include a more thorough investigation of policies and procedures, review of auditable records, and system compliance to prevent diversion and duplicate discounts. HRSA has stated that non-compliance issues uncovered in its audit may be used to refer matters to the Office of Inspector General or Department of Justice.

On June 19, 2012, the OPA published additional guidance regarding the scope and process of HRSA's Covered Entity audits. The document is meant to increase Covered Entity and manufacturer understanding of HRSA's audit objectives by providing a short summary of HRSA's pre, onsite and post audit procedures. Pre-audit protocols include general information requests from HRSA. Onsite audit procedures are composed of various investigations, including a review of contract pharmacy compliance and a sample testing of 340B drug transaction records. Post audit, HRSA forwards its findings to the OPA, and the OPA works directly with the Covered Entity to address concerns, remedies and any necessary corrective action. Finalized reports summarizing the audit findings and the Covered Entity's response will be posted on the OPA's website.

On the Horizon: ACA's Addition of Section 340B(d) Improvements in Program Integrity

Under the ACA, HRSA was granted authority to impose sanctions in the form of civil monetary penalties against Covered Entities. In addition to the penalties to which Covered Entities are already subject under Section 340B(a)(5)(D), HRSA will have the authority to require Covered Entities to pay monetary penalties to manufacturers in the form of compounded interest for knowing and intentional violations of diversion and/or removing and disqualifying the covered entity from the 340B Program for a designated period of time as penalty when diversion violations are found to be systematic and egregious. Notably, however, HRSA stated that due to funding limitations these new authorities and responsibilities have *not* yet been fully implemented.

What Covered Entities Should Do Now

Participating Covered Entities should stay abreast of HRSA's increased program enforcement and be aware of the increasing oversight. Covered Entities should make sure to maintain auditable records available in case of a HRSA or manufacturer audit. Policies and procedures preventing diversion and duplicate discounting and describing implemented compliance safeguards should be reviewed and fine-tuned as required. Verification of Covered Entity eligibility and a review of contract pharmacy compliance is also encouraged. By effectively monitoring its 340B program while ensuring compliance with HRSA guidelines, a Covered Entity can take a proactive role in managing its 340B program in this heightened compliance environment.

For More Information

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