340B DRUG PRICING PROGRAM

experience **guidance** // The 340B drug pricing program was created in 1992 to increase eligible patients' access to drugs and expand services by reducing pharmaceutical costs for safety net providers. Through the program's expansion in 2010 by the Affordable Care Act, several types of providers can participate and have arrangements with multiple contract pharmacies. Due to increased participation, the program and Health Resources and Services Administration (HRSA) has been scrutinized by members of Congress, the Government Accountability Office, drug manufacturers and others who claim the program lacks oversight. As a result, HRSA is focusing more on the program's regulation and integrity by investing in additional staffing and auditing participating covered entities. Experience expertise from industry professionals who can help you monitor your 340B drug program compliance.

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HRSA AUDIT RESULTS

During 2012, HRSA conducted 51 audits of covered entities, including 410 outpatient facilities and more than 860 contract pharmacy locations, and many were noncompliant:

- 42 percent of entities subject to Group Purchasing Organization (GPO) prohibition were in violation
- More than one in three hospitals had diversion from drugs dispensed to ineligible individuals
- 24 percent of hospitals had billings violating the Medicaid exclusion file
- More than one in five hospitals had incorrect database records

Only 19 of the 51 covered audited entities had no adverse findings. The 32 entities with adverse findings had their results published on the HRSA website, including a public letter to manufacturers who may be affected by their noncompliance.

In 2013, HRSA conducted 94 audits and is expected to perform almost twice as many in 2014. The results of these audits are being published on the HRSA website as they become available. In addition, HRSA is concerned with contract pharmacy arrangements because transaction types and patient identification can be complicated. Therefore, HRSA expects all covered entities to monitor program compliance through an independent audit or other compliance mechanism.

With HRSA scrutinizing the program and focusing on compliance and integrity, each covered entity should review all program policies and procedures for accuracy and completeness and complete independent audits or reviews.

ORPHAN DRUG EXCLUSION STATUS

On July 23, 2013, HRSA issued a Final Rule regarding the program's orphan drug exclusion that allowed hospitals to purchase orphan drugs at 340B pricing as long as the drugs are used for an indication other than for which the orphan designation was granted. The Final Rule was vacated May 23, 2014, stating that HRSA lacks the statutory authority to engage in such rulemaking. However, HRSA does have authority to interpret statutes; thus, on July 23, 2014, HRSA published an interpretive rule in the **Federal Register** that was consistent with the orphan drug exclusion treatment issued in the Final Rule. Hospitals subject to the orphan drug exclusion should continue monitoring orphan drug purchase compliance.

GPO PROHIBITION & LIMITING WAC EXPOSURE

Certain organizations participating in the 340B program could be subject to the GPO prohibition, which does not allow the purchase of covered outpatient drugs using the

GPO price. If applicable, organizations must purchase these drugs at the wholesale acquisition cost (WAC) for 340B ineligible outpatients. The drugs may have a significantly higher cost than if they were purchased at the GPO price. Organizations have several strategies to limit WAC pricing exposure, such as monitoring WAC purchases for waste or mixed-use inpatient items, Medicaid carve-in versus carve-out, establishing GPO-only areas, managing mixed-use inventory and more. Each organization should incorporate the interpretation of a covered outpatient drug based upon its own operations and document the conclusion in its policies and procedures. Hospitals subject to the GPO prohibition should continuously monitor their GPO and WAC drug purchase compliance.

PROGRAM MONITORING & COMPLIANCE NEEDS

With HRSA's increased scrutiny on the program and its focus on compliance and integrity, each covered entity should review all program policies and procedures for accuracy and completeness. Organizations should have policies that consider their unique circumstances and define eligible and ineligible patient relationships with the covered entity through employed, contracted or referral physicians. The development of robust internal controls is important for overseeing the program and conducting regular self-audits and independent audits to monitor compliance.

The 2012 audits resulted in 32 entities with adverse findings published on HRSA's website.

HOW WE **CAN HELP**

BKD's advisors have a range of industry knowledge from working with thousands of health care providers across the country. We understand the 340B drug pricing program and have the specialized skills to share best practices and offer tailored insight. We also understand the financial demands health care organizations face and believe our assistance in identifying opportunities and providing practical recommendations to help improve an organization's compliance goes beyond the basic service approach.

OUR 340B SERVICES INCLUDE:

- Reviewing policies and procedures specific to each program for accuracy and completeness
- Identifying key risks related to the program
- Summarizing the financial impact of noncompliant transactions
- Analyzing the program's financial performance
- Analyzing contract pharmacy arrangements, financial performance and compliance
- Performing mock audits and readiness preparation for potential HRSA audits

BKD offers timely, efficient and objective services from knowledgeable professionals dedicated to providing **unmatched client service.**

3400 **CLIENTS**

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