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340B Self-Audits: The Best Defense Is A Good Defense

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Federally qualified health centers (FQHCs) participating in the 340B Drug Pricing Program (the "340B Program") are subject to audits by Health Resources and Services Administration (HRSA) and the drug manufacturers who participate in the 340B Program. FQHCs are subject to two types of audits, risked-based and targeted audits. A targeted audit is triggered by allegations of violations of the 340B Program requirements. A risk-based audit is randomly chosen from program types determined to be at higher risk, for such reasons as volume of purchases or use of contract pharmacies. Both the risk-based and targeted audits involve an in-depth review and analysis of the 340B Program's operations and compliance. Targeted audits will include a more thorough review of policies and procedures, auditable records and compliance to prevent duplicate discounts and diversion.

The 340B Program audits involve: (i) reviewing an FQHC's 340B Program policies and procedures and how they are operationalized; (ii) verification of eligibility of the 340B Program; (iii) reviewing 340B Program compliance at the site and contract pharmacies; (iv) verification of internal controls to prevent diversion and duplicate discounts; and (v) testing a sample of 340B Program drug transaction records. The best defense for a 340B Program audit is the performance of on-going internal audits. An internal audit should include a review of the 340B Program policies and procedures, the HRSA 340B Program database, the 340B Program transactions and the 340B Program drug inventory.

The 340B Program policies and procedures should be reviewed and updated to reflect the most recent HRSA publications and best practices. 340B Program policies and procedures should include, but not be limited to those that address the health center's enrollment in the 340B Program, compliance with the 340B Program such as patient eligibility, processes and procedures to avoid duplicate discounts and diversion, the use of contract pharmacies, if applicable, drug inventory procurement and management and staff training. The policies and procedures should be operationalized such that the FQHC is in compliance with those policies and procedures. Also, it is important to maintain records and documentation of compliance with these policies and procedures, as necessary (e.g., documentation of any training completed per the policies and procedures).

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Next, FQHCs should regularly review the HRSA 340B database to ensure that the information it contains is accurate. The database should accurately reflect the FQHC's sites that are enrolled in the 340B Program and the contract pharmacies with which the health center has an agreement to provide 340B Program services. FQHCs using contract pharmacies for their 340B Programs must ensure there are written agreements with every contract pharmacy that include the essential contractual provisions addressing issues such as audits, duplicate discounts, diversion, replenishment of inventory, dispensing fees and regulatory considerations (e. g., the anti-kickback statute). FQHCs also should ensure that the Medicaid exclusion file contains accurate information regarding the FQHC's designation for its use of 340B drugs for Medicaid beneficiaries and ensure that it is billing consistent with such designation. It is recommended that an individual at the FQHC be assigned the responsibility for updating the 340B database, including the Medicaid exclusion file.

FQHCs should, on a regular basis, select a sample of 340B Program transactions to identify any weaknesses or compliance issues in the FQHC's 340B Program. The sample, typically about 25-50 records, should be reviewed for certain information such as patient eligibility, eligible providers, eligible 340B Program drug, appropriate drug pricing (depending on whether the FQHC permits dispensing to Medicaid beneficiaries), and whether the health center pays for, owns and receives reimbursement for 340B Program drugs. The audit also should include a review of the starting inventory for the timeframe of the sample records selected to ensure that 340B Program drugs have not been diverted.

Following an internal audit, the health center should prepare a corrective action plan for any deficiencies identified and a reasonable timeframe for correcting any such deficiencies. The corrective action plan should include a date for re-auditing the deficiency after the plan has been fully implemented to ensure correction of the deficiency and on-going compliance.

340B compliance is crucial to maintaining a 340B Program. A robust 340B compliance program, including on-going internal audits, will increase the health center's success in a HRSA 340B Program audit and ensure the continued operation of the program.

Karen Daley is an attorney with Pullman & Comley LLC, is corporate counsel for one of the largest FQHCs in Connecticut, and is a registered nurse and former director of risk management for two Connecticut hospitals.
