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Securing the safety net: Current compliance issues in Federally Qualified Health Centers

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Federally Qualified Health Centers (FQHC) are a crucial component of the nation's healthcare safety net, providing structured access to primary and specialty care in underserved communities. Operating an FQHC is a uniquely challenging endeavor. FQHCs are eligible for numerous federal and state benefits, such as grant funding under Section 330 of the Public Health Service Act, discounted drug pricing under the 340B Drug Discount Program (340B Program), enhanced Medicare payment under the Centers for Medicare & Medicaid Services (CMS) FQHC Prospective Payment System, cost-based reimbursement under the Medicaid program, protections from Anti-Kickback Statute restrictions, and access to various federal and state practitioner recruitment programs. Of course, in exchange for access to these benefits, an FQHC agrees to comply with a wide array of statutory and regulatory obligations.

This article describes contemporary hot topics in FQHC compliance with the goal of helping FQHC executives and compliance professionals update their compliance work plans to identify potential trouble spots before they develop into significant compliance concerns. Each section describes practical steps that a compliance professional can take to address these concerns.

340B Drug Discount Program

FQHCs can secure substantial savings on prescription drugs provided to patients in the office and through third-party retail pharmacies by enrolling in the 340B Program,[1] but doing so carries with it significant compliance obligations. One common challenge to 340B Program compliance is that oftentimes, shifts in program compliance are communicated through nonpublic audit findings rather than publicly available resources. Compliance professionals should be aware of three particular issues that have become prevalent in recent years: tracking of drugs purchased under the 340B Program; enrollment of FQHC-affiliated pharmacies; and ensuring that patients referred to other providers, through FQHC referral arrangements or otherwise, are appropriately accounted for.

A full description of the 340B Program is outside the scope of this article, but certain key concepts are important to the discussion that follows. Under the 340B Program, safety net providers such as FQHCs are eligible to purchase certain drugs at a significant discount. Participation in the 340B Program is elective, and entities that participate (called "covered entities") are required to attest to 340B Program compliance on an annual basis. 340B covered entity status does not encompass all of a participating provider's operations; instead, a covered entity is only permitted to dispense covered outpatient drugs[2] to eligible patients.[3] Dispensing or transferring a 340B-purchased drug to any other person or entity is considered diversion, which can lead to significant penalties for the FQHC.

Diversion and floor stock

In recent years, some FQHCs participating in the 340B Program have struggled to document that "floor stock" (i.e., drugs that are stored outside of a central licensed pharmacy) has been administered to FQHC-eligible patients. Although it would stand to reason that all floor stock in an FQHC would be eligible for 340B discounts when administered as part of an FQHC visit, the Health Resources and Services Administration Office of Pharmacy Affairs (HRSA OPA), which oversees 340B Program compliance, has recently required FQHCs to be able to tie specific drug purchases and administrations/dispensations to specific episodes of care as documented in the patients' medical records. Of course, this is more complicated and important in the setting where an FQHC is co-located with non-FQHC operations.

As a result, covered entities must establish a system to keep track of their inventories of 340B drugs and refrain from dispensing 340B drugs to ineligible patients. The practice of stocking drugs away from a central pharmacy is not itself a violation of 340B Program guidance, but a decentralized system may make it difficult for an FQHC to keep track of 340B inventory. This is especially true where the FQHC maintains a separate physical inventory of 340B drugs, because clinical employees must understand the distinction between 340B and non-340B inventories and have appropriate guidance in determining which to use. This process may be made easier through the use of a virtual inventory system, where the FQHC dispenses drugs from a central stock, then determines whether to replenish the stock under the 340B Program based on the characteristics of the dispensing event, such as the identity of the patient, the eligibility of the drug for inclusion in the 340B Program, and whether the 340B price is the best price available to the FQHC. However, although a software-based virtual inventory may make it easier to track floor stock, inventory control is still crucial, because a virtual inventory system relies on accurate data to identify the patient who receives a drug.

Contract pharmacy and referral partner relationships

FQHC compliance professionals should also be aware of issues that can arise in relationships with affiliated pharmacies. In many cases, an FQHC will wish to dispense its own 340B covered drugs through a separately licensed pharmacy owned by another entity, including both pharmacies located within the four walls of the FQHC and for-profit retail pharmacies located outside of the FQHC. HRSA permits this practice, provided that the relationship between the covered entity and the contract pharmacy is appropriately documented, and the covered entity records the relationship in the HRSA 340B database.

It is common for a retail pharmacy to have a 340B contract pharmacy relationship with a number of 340B covered entities. When this happens, it is often the case that a single patient will qualify as a patient of more than one 340B covered entity, so it can be unclear which entity's virtual stock is used to supply the patient with their prescription.

Additionally, as described in further detail below, FQHCs are required to provide a pre-defined slate of primary services to their patients. An FQHC can meet this obligation by providing care through employed providers, through providers under contract with the FQHC, or through formal referral arrangements. A patient who receives care from an FQHC-employed provider as part of an eligible on-site visit will typically be an eligible patient of the FQHC.[4] However, when the provider is employed by a different 340B covered entity, the FQHC must consider the relationships between itself, the provider, and the patient to determine whether it may dispense drugs to the patient from its 340B inventory through a contract pharmacy arrangement. It is possible that the patient will be an eligible patient with respect to both the FQHC and the other provider. Additionally, complications can arise when the patient decides to fill their prescriptions with a pharmacy that has a contract pharmacy relationship with both the FQHC and the contracted provider's employer.

Steps for compliance professionals

Compliance professionals can help their FQHCs by including a review of floor stock practices and contract pharmacy relationships in their work plans. With respect to tracking of 340B-purchased drugs, activities could include a review of applicable policies, audits of records, and conversationswith staff to determine if drugs that are stocked away from the central pharmacy can be attributed to 340B eligible patients. Additionally, if the FQHC keeps separate physical inventories of 340B and non-340B drugs, the compliance professional should consider reviewing the guidelines that are used by staff responsible for choosing which inventory to use when a drug is dispensed. Spot checks may also be conducted to determine if the FQHC is able to determine the source of particular drugs. For FQHCs that maintain virtual 340B inventories, compliance professionals can audit clinicians' records to ensure that patients who received floor stock drugs can be reliably identified.

With respect to contract pharmacy relationships, compliance professionals should consider reviewing the licensure status of pharmacies operating within the FQHC. If the pharmacy is owned by a different entity or is separately licensed and maintains a retail pharmacy permit, the compliance professional can review the FQHC's enrollment records in the HRSA 340B database[5] to determine if the pharmacy is appropriately listed as a contract pharmacy and also that a compliant 340B contract pharmacy agreement is in place.[6]

Compliance officers should consider reviewing the agreements between the FQHC and its contract pharmacies and ensuring that contract pharmacies are complying with recordkeeping, diversion, and other operational requirements. If the FQHC has contract pharmacy relationships with retail pharmacies, it is often the case that a pharmacy will also be a contract pharmacy for other 340B covered entities. In this case, the compliance professional should consider reviewing both the contract pharmacy agreement and the referral agreement to determine if 340B patient attribution is addressed in a way that can be (and actually is) implemented by each entity's workforce.

Notably, when patient attribution is appropriately addressed in a contract pharmacy's agreements with 340B covered entities, each covered entity may see decreased 340B Program volume, because each dispensed prescription will count only one time for a single provider. However, 340B Program compliance is crucial to continued eligibility to participate in the program. 340B covered entities are ultimately responsible for compliance with HRSA guidelines, so it is incumbent upon them to ensure that contract pharmacies and other affiliates are abiding by 340B Program requirements.