CHAPTER 5

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Operations and Business Considerations in Implementing and Optimizing 340B Software:

340B Considerations in the Mixed-Use Pharmacy

Hospital covered entities (CEs) implementing 340B program software are compelled to balance operations with a focus on both compliance and drug savings. This balancing act commonly illuminates the intersection of pharmacy supply chain operations, drug charge capture, and hospital information system (HIS) data. Understanding the flow of data and the strengths and limitations of each dataset is critical to a successful and effective 340B software implementation. 340B software will, regardless of the selected vendor, heighten the requirement for accurate and comprehensive charge capture, drug formulary and chargemaster maintenance, and strategic drug purchasing. CEs must meet the challenge of supplying accurate and auditable transactional pharmacy data and must identify or hire skilled personnel to meet the complex business and compliance requirements of supply chain management in the 340B program.

Although relatively simple first-generation 340B software programs and rudimentary tracking systems (e.g., spreadsheets) were used to manage CEs' 340B programs prior to the current audit era, operational requirements, business risks, and audit preparedness demand more sophisticated 340B software functionality. This chapter highlights critical operational requirements and describes pharmacy operations and HIS requirements to support software implementation steps. It also provides a map of key personnel required to complete implementation and maintain 340B program software.

WHAT IS 340B SOFTWARE?

For the purposes of this chapter, the authors refer to 340B software (also known as *split billing* or *mixed-use* software) used in the non-retail hospital setting.

Fundamentally, mixed-use 340B software collects and collates drug charges and, based on hospital indicators, assigns drug utilization for eligible outpatients to 340B inventory replenishment. The software assigns inpatient charges to group purchasing (GPO) contracts. Replenishment purchases for 340B-ineligible outpatients (e.g., Medicaid carve-out), purchases stemming from untracked or unattributed inventory, and purchases for new inventory (e.g., new drugs or expanding inventory) are funneled to the non-contract wholesale acquisition cost (WAC) accounts.

Charge data, inpatient/outpatient indicators, and Medicaid status are provided to the software vendor through one or more data feeds. These data must be consistent with hospital clinical or

financial systems and must support a Health Resources and Services Administration (HRSA) audit or other audits months or years in the future.

A fundamental step in implementing 340B software is building a *crosswalk* that converts drug charge quantities in the hospital's HIS into National Drug Code (NDC)-specific packages to be purchased from distributors or manufacturers for replenishment. Managing inventory replenishment, based on the charge assignment referenced above, is the culmination of the 340B data feed, crosswalk, and pharmacy supply chain integration in the software. Maintaining data integrity and the crosswalk relationships comprises a significant portion of the required 340B software and program maintenance going forward. Timely, complete, and accurate maintenance of 340B software and the associated data tables, purchasing accounts, and practices is crucial to achieve the greatest 340B savings value while remaining compliant. Lax or delayed maintenance is the most common reason for compliance lapses and savings loss.

KEY POINT

A well-executed software implementation requires planning and the engagement of sufficient resources and sponsorship. Extended or delayed implementation and poorly executed plans risk lost savings and may have 340B compliance implications.

A well-executed 340B software implementation project plan with full information technology (IT) support can be completed in approximately 120 days. If implementation is prolonged for months, it may be due to lack of an executive champion, the timing and focus of competing IT projects and support, irregularities in source data, or operational changes necessary to support compliant utilization of 340B drugs. CEs should check references for specific vendors to better gauge implementation time and resource requirements with a focus on the key elements of the project outlined below. To avoid significant delays, CEs should consider the following:

- Identify an engaged executive champion, often the Authorizing Official, to secure required IT resources and priority early in the project.

- Assign a professional project manager to coordinate multiple hospital departments, consultants, the 340B software vendor, and HIS specialists. Don't rely on the software vendor install team to manage the project independently.

The software implementation team should include, at various stages, an executive champion, pharmacy leadership and operations (e.g., informatics), finance (e.g., reimbursement, patient financial services), legal and/or compliance leadership, and IT. If available, CEs should consider assigning project management resources to the 340B software implementation project. In most organizations, pharmacy or supply chain leadership will have primary responsibility for 340B program management. As such, they should be intimately involved in the 340B software implementation project.

BILLING TRANSACTION FEEDS AS A SOURCE OF 340B DATA

Constructing billing transaction feeds for the 340B software vendor is a significant risk during 340B software implementation for several reasons:

- CEs and CE team members may be new to the 340B program. Moreover, 340B management personnel may have limited or no software implementation experience.

- Software vendors are focused on technical requirements—customers may unknowingly make technical decisions with 340B compliance and/or financial implications. Simply