

Take Control of Your 340B Savings and Compliance

What hospitals can expect from evolving software solutions

By William Sander

Most 340B hospitals rely on software to help track 340B eligibility, inventory, and replenishment and to maintain the detailed audit trail HRSA requires. However, there are fundamental differences in the types of software solutions available to address 340B compliance.

The reason for software: balancing 340B cost savings with compliance requirements

In the hospital pharmacy, drugs are purchased and dispensed by their 11-digit National Drug Code (NDC), which denotes a specific manufacturer, drug and package size - but they're billed by the charge description master, or CDM, stored in the hospital information system (HIS). The CDM refers generically to a prescribed dose that could be filled by multiple NDCs in the pharmacy. For example, a CDM representing one azithromycin pill might be filled with a brand-name drug by one manufacturer, or by a generic drug from another.

The 340B program requires the 11-digit NDC, so 340B hospitals need software to perform two tasks central to 340B compliance: 1) correlate each patient utilization event to a specific, 11-digit NDC and 2) tie each NDC to the specific purchase order and account type at which it was purchased: wholesale acquisition cost (WAC),

group purchasing organization rates (GPO), or the 340B discounted price.

The WAC account is the most expensive contract on which to purchase drugs, and our analyses indicate that it generally accounts for only about 10 to 15% of a hospital's total drug spending. GPO drug rates, which result from any negotiated prices available to multiple healthcare entities, can represent prices up to 30% lower than WAC. However, certain 340B hospital types are prohibited from using drugs purchased through a GPO account for outpatients covered by 340B. 340B prices reflect discounts of up to 50% off WAC prices, making this the most affordable drug pricing for hospitals - but 340B pricing is only available on drugs dispensed to eligible outpatients with qualifying patient events that meet all 340B requirements. (Data derived from Prices for Brand-Name Drugs Under Selected Federal Programs. Congressional Budget Office, June 2005.)

Adding to the complexity of the 340B program is the fact that pre-purchased 340B inventories for subsequent 340B eligible dispensation are impossible to manage in most hospital settings. Instead, software is used to enable a replenishment system where drugs are dispensed from neutral inventory and then replenished

with 340B drugs when accumulated eligible dispensations reach a replenishment threshold. Stated simply, whether fully automated, partially automated or manual, 340B compliance software must accumulate dispensations of each NDC into future orders eligible for 340B pricing.

While a hospital's drug spending is highly variable, depending on the hospital's mix of inpatient and outpatient encounters, the goal is to capture all eligible 340B dispensations while maintaining compliance with program guidelines. Today's software solutions must assist covered entities in meeting both of these objectives.

Three generations of software represent varying methodologies

Software for 340B program management should help hospitals navigate the complexities of the 340B program by tracking the 340B drugs that are dispensed and eligible for replenishment at the 340B price. However, not all solutions are alike. The differences are related to how the software tracks each NDC, accounts for 340B eligibility and manages replenishment. Early solutions were designed primarily to identify eligible outpatient drug dispensations from the hospital pharmacy, and the term "split-billing" was coined to describe how these solu-

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tions differentiated eligible outpatient dispensations from ineligible inpatient drug dispensations. However, as compliance requirements have become more demanding, as the role of contract pharmacies has grown and as drug costs have continued to soar, the simple “split-billing” approach is no longer adequate. Hospital pharmacies require more robust functionality and more evolved solutions that dynamically reflect changing purchasing and utilization patterns in the pharmacy.

First generation software

First generation 340B solutions follow the “split-billing” model. This type of solution typically gets the NDC from the hospital’s information system when the drug is dispensed. It is unable to tie back to the purchase of the NDC or to the inventory level in the hospital’s pharmacy. It allows only a single, static NDC to be tied to each CDM for 340B eligibility and replenishment. This limitation creates a significant risk of missed 340B eligibility and increased WAC spending. In addition, if outpatient dispensations are misqualified as GPO, a hospital’s 340B eligibility can be terminated.

Second generation software

Second generation solutions are an evolution of the “split-billing” model. These solutions attempt to accommodate changing purchasing patterns by linking the most recently-purchased NDC to each CDM using a many-to-many mapping structure. However, these solutions are limited in the way they accumulate 340B eligibility by 11-digit NDC for replenishment.

Let’s look at an example where two equivalent drugs with different NDCs are used interchangeably. If the hospital pharmacy purchased a 1,000-count bottle of NDC A yesterday, and a 100-count bottle of NDC B today, the hospital may not have accrued enough 340B-eligible dispensations to total NDC A’s full

1,000-pill package size. Regardless, the software will switch tracking to the most recently-purchased NDC - the 100-count package.

When the hospital reorders the 1,000-count bottle, it will need to be ordered at WAC pricing because the software has not tracked enough dispensations to replenish a full package size, and the software does not track the purchased quantity. In addition, the hospital has a potential compliance issue, because the remainder of the 1,000-count bottle will eventually be dispensed-but it’s not being tracked. In addition, the 100-count NDC will be over-accumulated. As you consider the compounding of injectable medications, the situation can become even more complicated.

Third generation software

The most contemporary 340B software is a total pharmacy procurement and utilization management system, which allows the most flexibility in mapping and accumulating many NDCs to many CDMs. In addition, this method directly ties replenished NDCs to the wholesaler invoice and patient utilization event as required during a HRSA audit, and it’s the only type of 340B solution that accurately accounts for the quantity of each NDC placed into inventory. The end result is that all eligible 340B dispensations are captured, tracked and allocated so that you can replenish more of your stock at 340B pricing - rather than having to replenish at WAC because you aren’t able to account for some of your dispensations.

Is your solution doing everything it could for you?

It’s important to know what you’re getting from your software solution and to understand the underlying methodology on which you are basing your 340B program compliance. First and second generation “split-billing” solutions may have you replenishing 20% or more of your

drug purchases at WAC prices because you can’t accurately track all of your 340B-eligible dispensations - or because some of your purchased NDCs are not accounted for at all.

Here are five important questions to ask yourself:

- What’s your current WAC spend? Does it represent more than 10 to 15% of your overall drug spend?
- Does your software account for the quantity of each NDC purchased as it allocates utilization to 340B, GPO and WAC?
- Do you feel confident that you can produce an audit trail to track each dose from patient to replenishment at the exact 11-digit NDC level?
- How does your 340B solution map NDCs to CDMs and track for 340B eligibility and replenishment? Are you limited to only one NDC (or only one-at-a-time) per CDM?
- Can your solution be configured to reflect your hospital’s 340B policies and procedures?

If you aren’t satisfied with the answers, it may be time to evaluate other solutions.

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