

# Key Compliance Factors of the 340B Program



*AND THE CHALLENGES THEY POSE FOR HOSPITALS*





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**T**he 340B Drug Pricing Program offers discounts on outpatient drugs to eligible healthcare organizations, known as covered entities (CEs), to ease the financial burden on safety-net providers that serve a disproportionate number of indigent patients. Several types of health care organizations qualify for 340B, but we will address hospitals specifically.

Drug manufacturers provide price reductions — which average 25-50% off average wholesale pricing — as a condition of participating in Medicaid and Medicare. They extend the reductions through either direct purchase by covered entities, or through wholesalers or distributors that sell to the CE for dispensing to patients at their CE-owned retail pharmacies or through contract pharmacy relationships.

Covered entities are required to follow guidance and regulations from the federal government. In addition, CEs may be subject at any time to an audit by the Health Resources & Services Administration

(HRSA) to determine compliance with 340B regulations.

In this whitepaper, we'll outline the basic compliance requirements for 340B hospitals and discuss the challenges of using hospital information systems to meet these requirements.

*The key compliance factors are:*

- 11-digit National Drug Code (NDC) compliance and tracking to an eligible patient;
- Policies & procedures; and
- Reporting.

## 11-digit NDC compliance and tracking multiple NDCs

### Background

NDCs, which are used for 340B replenishment, identify a drug, its manufacturer and the package size. If an incorrect NDC is used, the wrong manufacturer could end up providing the 340B discount, or the price may not be consistent with



package size, strength or formula. Many state Medicaid programs require NDCs in reporting at the patient level, often with a modifier to indicate a 340B-eligible claim.

Under 340B guidelines, the drug being replenished must be the same eligible, outpatient drug that was dispensed to a qualified patient, as evidenced by an exact 11-digit NDC match. Exceptions to the 11-digit rule are limited exclusively to cases where only a nine-digit match is available. NDC matches of fewer than nine digits are not compliant with HRSA guidelines.

### IT challenge

Today, many hospital information and billing/financial systems bill by drug or Charge Description Master (CDM) code, not by NDC numbers. Modern pharmacy information systems recognize multiple NDCs, but they transmit the information to the financial system as a CDM code to bill correctly. While this automated crosswalk between NDCs and CDMs may seem advantageous, it creates compliance issues for the covered entity.

Even if you use bedside barcode scanning, NDCs may not be tracked throughout your information system. Typically, the NDC is used only to verify the representation of the entered charge code or drug, and it's referred to as an alias. The CDM and primary NDC (if any) are what makes it to the billing side, not the actual NDC administered to the patient.

### Operational challenge

Several factors contribute to the tracking challenges surrounding NDCs, including ongoing drug shortages, wholesaler short supplies and manufacturer backorders. This can result in hospitals receiving the same drug but with multiple NDCs, which must align to the same charge code. In fact, most pharmacy directors report that up to 10% of medications ordered are shorted or unavailable and require a substitute NDC. Hospital systems are increasingly forming collaboratives to manufacture certain drugs to overcome these drug shortages and avoid this growing problem.

### Best practices when working with multiple NDCs:

- Check wholesaler invoices for a few common items, such as acetaminophen 325mg, and validate how many different NDCs were purchased in the last 120 days for the same item.
- Check to see how many alias NDCs are recognized under a CDM or charge code in the pharmacy CDM or order entry system.
- Check to see how many NDCs are in the financial billing system.
- Check to see how many NDCs are tracked in 340B software at the same exact time, and whether it is possible to differentiate the usage of each to equal the total amounts purchased.

### Establishing and tracking eligibility

Each NDC purchased for the first time should be bought at non-340B pricing and should never use a previous NDC's replenishment eligibility to order at 340B pricing, unless a manufacturer has authorized that practice (for example, a new NDC due to formulation or packaging from the same manufacturer). The use of 340B pricing in traditional models is reserved for replenishment of 340B drugs or establishing a "virtual" 340B inventory that can be tracked to the patient level.

If a CE experiences a shortage and needs to buy a new NDC under 340B before it has eligible use, the NDC can be treated as 340B inventory. A rules-based compliance engine would consider the NDC to be 340B virtual inventory for future use since historical use of that NDC would yet to be established. The NDC's actual administration to eligible patients would then be tracked until it accrued a full unit of issuance.

The non-compliant practice of NDC bundling makes this a critical issue. Some CEs may, intentionally or unintentionally, bundle different drugs — including generic and/or brand name versions of a similar item — to accrue eligibility for one drug.





Bundling becomes an issue when it forces the wrong manufacturer to provide a savings benefit on an eligible medication. The 11-digit NDC match is necessary to avoid bundling and preserve 340B program integrity.

### Conclusion

Finding a 340B software solution with 11-digit NDC compliance and the ability to track multiple NDCs is critical to help maximize program participation and accurately document pharmacy activity. It's essential to understand the difference between tracking all NDCs and tracking a single manufacturer or using a bundling process, as this will affect both 340B compliance and benefits.

## Policies & procedures

### Background

Policies & procedures (P&Ps) are federally mandated and should reflect a CE's operations and decisions related to the 340B program. In an audit, CEs are required to present their P&Ps for review along with their data on dispensations and purchases.

### IT challenge

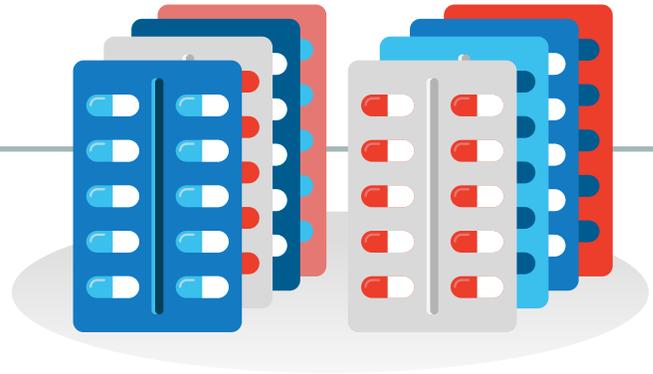
Today's hospital information systems cannot adequately incorporate P&Ps for 340B in all settings, highlighting the need for a third-party software solution focused on current law, rules and guidance. The complexity and regulatory compliance required to effectively run a 340B program requires dedicated product solutions built to address the unique challenges and intricacies of 340B.

### Operational challenges

Two common operational challenges with enforcing policies and procedures are eligible patients and ordering. It can be difficult to be 100% compliant with complex 340B P&Ps, especially at small organizations where employees often perform multiple roles outside of the 340B program. They must rely on information from multiple systems and departments to determine eligibility and remain compliant.

## What is bundling?

**Bundling** is the practice of aggregating the usage of different NDCs when the software system cannot track multiple NDCs under a single charge code or CDM.



### Conclusion

By incorporating P&Ps into the overall workflow, the ideal 340B solution ensures that, no matter who is executing a CE's 340B program, decisions are made automatically, in the same way, every day. The value of 340B savings received, and the potential penalties resulting from an audit, are too great to risk variation stemming from human error and employees' differing levels of 340B program knowledge.

## Key questions to ask:

- Are P&Ps for 340B in place today?
- If so, can you audit or track whether they are enforced?
- Does the current system electronically enforce P&Ps, or is enforcement dependent upon manual entry by the person placing the order that day?



## Reporting

Reporting is especially important for compliance because 340B requires data from multiple IT systems within a hospital. Reporting helps a CE track and understand its data environment, demonstrate success to executives, find areas for improvement or added savings, perform regular internal audits, and provide information for external auditors. It's important to note that, because of increased congressional oversight, auditors request very detailed data sets to assess 340B compliance.

The ability to respond to an audit depends entirely on the type of 340B software in place. Each audit situation differs based on the source of the audit, and it's likely that a CE will need to show that 340B purchases match actual dispensations, down to 11-digit NDC detail.

### IT challenge

Information supporting 340B compliance comes from multiple sources, both internal to the hospital, such as drug charges or admission, discharge and transfer (ADT) data, and external, such as wholesaler purchases, retail pharmacy dispensations, insurance reimbursement and pricing files. It can be difficult to maintain these disparate information sources as a single dataset.

### Operational challenge

Reporting for 340B can be as simple as identifying which medications are ready for 340B purchase. Ideally, it's sophisticated enough to highlight potential areas of concern or opportunities related to compliance and savings.

### Conclusion

Reporting enables a CE to conduct regular self-audits and, in the event of an audit, provide the appropriate information auditors require for determining compliance. Effective reporting is also key to keeping executives

## Key questions to ask:

- *What type of reports are available today? At a minimum, a CE should have:*
  - *GPO, 340B and Wholesale Acquisition Cost (WAC) purchase reports;*
  - *Inpatient & outpatient utilization reports*
  - *A report of savings based on each distinct NDC*
  - *A report of potential savings; and*
  - *A list of items ready to be replenished.*
- *It's an added benefit if the CE also has reports on:*
  - *Comparison of purchases vs. utilization for all IP/OP medications;*
  - *Audit reports demonstrating compliance with patient definitions;*
  - *Impact reports by manufacturer or pharmacy benefit manager;*
  - *Alerts when new CDMs are added or new NDCs are purchased;*
  - *Notifications by NDC when quarterly penny buy opportunities exist; and*
  - *Specific audit functionality by NDC, time frame, patient, location, etc.*

informed regarding day-to-day 340B operations and business performance.

Ultimately, compliance is one of the key attributes of a successful 340B program that hospitals must consider, along with the business aspects of optimizing benefits and streamlining workflows, when evaluating 340B management solutions. Ideally, a CE should consider software that incorporates the organization's compliance policies, includes audit preparation tools and instills confidence in the program staff. Hospital leadership will have confidence that they are not only compliant, but they have a healthy business with improved financial performance.

*Opinions expressed in this publication do not necessarily reflect official policy of THT.*

Sentry Data Systems, a trusted leader in 340B management and compliance, has been helping healthcare organizations establish strong 340B programs and reach more underserved patients since 2003. From innovative technology to expert knowledge and support, they are passionate about helping their customers optimize 340B benefit with powerful solutions that deliver the precision, compliance, insights and savings needed to run a successful program.



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