an analysis of 340B solutions
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Abstract

**Purpose:** This paper will review 340B program compliance requirements, provide an overview of existing hospital data sources and compare available software solutions to provide hospitals with the basic understanding of 340B needed to accurately evaluate current and future 340B solutions.

**Summary:** Because multiple departments use data for different purposes, hospital data environments pose complex data integration challenges. But in order to maintain 340B compliance and realize maximum 340B savings, hospitals need data from multiple data sets.

Adding to the situation’s complexity, many tools now being used as 340B software were not initially designed for 340B compliance or for use as a 340B solution. Solutions not specifically designed for 340B have limitations caused by being retrofitted from their primary intended use. Furthermore, many companies that provide 340B software solutions are not solely focused on the hospital market for 340B and are not dedicating their energies to supporting the hospital market’s specific and evolving needs. Lastly, with the expansion of 340B during 2010, the industry has seen an influx of new vendors and “experts” that, intentionally or not, often spread confusion and inaccurate information.

**Conclusion:** It is imperative to understand each hospital’s unique limitations related to data and operations, as well as the limitations of those systems being considered and evaluated for use in a hospital.

Technology is absolutely essential for 340B tracking, but not all solutions deliver the same capabilities. It is imperative that hospitals define their needs and have a list of minimum and desired requirements when deciding how to participate and comply with 340B. The program’s benefit is significant to all qualified hospitals, and compliance is a must in order to protect the integrity of the program and the assistance it delivers to Safety Net providers and the communities they serve.

Older software solutions, often referred to as “split-billing” solutions, were not typically built for 340B compliance and are not capable of delivering the necessary requirements to maintain 340B program integrity. Split-billing solutions on their own cannot support a compliant 340B program or optimize desired results. Newer solutions powered by rules-based compliance engines provide a significantly-improved opportunity for regulatory compliance and compliant capture of 340B benefits.
SECTION 1: Basics of 340B

This section provides an overview of 340B essentials. Although this paper was written to be as inclusive as possible, it assumes a basic understanding of the hospital industry. Some pharmacy knowledge is preferable.

340B overview

The 340B Drug Pricing Program enables certain eligible healthcare organizations, referred to as covered entities (CEs), to receive discounts on drug prices. The program is budget-neutral for the federal government.

The program was part of government legislation designed to ease the financial burden on safety net institutions that serve a disproportionate number of patients who are unable to pay for the services they receive. The healthcare services provided by these safety net entities are of vital importance to their local communities and patients. This ambitious program has been immensely successful in helping CEs meet their safety net missions in underserved communities.

What types of facilities qualify for this benefit?

For purposes of this white paper, the focus will be on qualified hospital entities, including Disproportionate Share Hospitals (DSH), Sole Community Hospitals (SCH), Rural Referral Centers (RRC), Critical Access Hospitals (CAH), Children’s Hospitals, and Free-standing Cancer Centers.

Other entities, such as Community Health Centers (CHC) and Federally Qualified Health Centers (FQHC), also qualify for 340B. However, the software and technology needs of these environments are much different from hospitals and will not be explored in this white paper.

What is the benefit?

Reduced cost of goods (typically medications) for eligible outpatient (OP) areas of a hospital. These price reductions typically result in 25 – 50 percent savings on eligible OP pharmaceutical purchases for covered entities. (This program can also benefit the hospital’s safety net mission through contract pharmacy relationships.)

Where does the cost savings come from?

Pharmaceutical manufacturers provide price reduction savings. The government requires drug manufacturers to give 340B pricing to CEs in order for manufacturers to participate in other programs such as Medicaid drug reimbursement.
What's the catch?

In order to benefit from the program, CEs are required to follow stringent rules and regulations. Two important rules to note:

- Only drug dispensations associated with specifically-qualified outpatient clinical services are eligible 340B transactions.
- Dispensations are limited to patients for which the CE is responsible, in one or more eligible areas of that CE.

340B requirements review

One of the most confusing and misunderstood aspects of 340B compliance today is determining what is an eligible medication. It’s important to understand in detail how data correlates to an eligible dispensation based upon the Office of Pharmacy Affairs (OPA) regulations. Taking that understanding a step further, and tracking exact purchases to exact usage, is even more important.

A compliant eligible dispensation (available for 340B replenishment) must meet all of the following conditions:

1. Dispensed to an OP of the CE.
2. Dispensed/administered in an eligible OP location.
3. The NDC recorded at dispensation must (with few special exceptions) match the exact 11-digit NDC from purchase.
4. Ordered by an eligible physician or through referral by an eligible physician.
5. Provided for an eligible healthcare service, as evidenced in a patient’s health record.
6. Tracked accurately, such that all dispensation data is available for audits.
7. Dispensed to a patient for whom the CE maintains responsibility for care.
340B frequently-asked questions

What is an eligible location?
An eligible location needs to meet two expectations:

• It is within a qualifying section of the cost report that qualified the entity for 340B status.
• It is part of the hospital in which the CE is responsible for the care the patient receives.

What does it mean for a CE to be responsible for care?
An entity is “responsible for care” if it meets the definition of providing care, such as:

• Billing for a service provided under the CE.
• Recording the visit in the CE’s admission, discharge and transfer (ADT) system as with any normal patient.
• Recording details of the care provided in the CE’s health/medical record system.

Why is the 11-digit NDC match important?
Since the manufacturer provides for the cost savings, it is important to maintain NDC replenishment integrity. NDCs identify a drug, its manufacturer and the package size. If NDC integrity is not maintained, the wrong manufacturer could end up providing the discount. Exceptions to the 11-digit rule are very limited and can be replenished only in the case where only a nine-digit match is available. NDC matches of less than nine digits cannot legally be replenished.

Some things to consider
An easy way to clarify if a location is eligible is to look for “above the line” locations on the cost report that helped a CE qualify for 340B status.

A good question to ask when evaluating whether or not a CE is responsible for the patient’s care: “If there was a lawsuit related to the care, would the CE be liable for the healthcare services provided?”
Does a dispensation need to meet all the requirements to be eligible?

Yes. Simply put, partial compliance is non-compliance. Using only a physician's eligibility or a patient’s status as a justification for eligibility is a path that will lead to diversion and other compliance issues when audits take place. A patient cannot be “mostly” eligible or 75 percent eligible. The patient definition requirements should be viewed as a whole and never as separate parts.

Does the medication have to be used only for indigent patients?

No, 340B hospitals have no restrictions based on a patient’s income, assets, ability to pay or medical criteria.

Is it legal for 340B prices to generate positive revenues?

Yes, because all 340B entities are non-profit. Positive revenue generated in one service area is utilized to enhance services or to offset costs in other areas.

What if a CE does not have a retail pharmacy of its own?

Contract pharmacy relationships are allowed. A contract pharmacy relationship refers to the agreement made by a CE with a pharmacy in its community to dispense medications on the CE’s behalf for the CE’s 340B-eligible patients.

Does a CE have to choose just one retail contract pharmacy?

No, a CE can utilize multiple pharmacies to serve a CE's patient population.
SECTION 2: A look at 340B solutions

For CEs looking to participate in 340B, there are a few types of solutions available, and each option has its own strengths and weaknesses. Each 340B solution is only as strong as a CE’s understanding of the solution and its limitations. The four different solution types are:

1. Homegrown solutions
2. Manual split-billing solutions
3. Software split-billing solutions
4. Rules-based compliance engines

What is split billing?

Split billing is the process of separating the inpatient (IP) and OP hospital charges from 340B-eligible areas. Effectively, this method identifies all of a CE’s OP charge codes and uses them to identify drug replenishment opportunities at 340B pricing.

The split-billing process

1. Generate a billing feed / report from the hospital IT system for eligible items.
2. Provide the report, arranged by charge code (CDM), to the split-billing consultant (for manual solutions) or split-billing vendor (for software solutions).
3. Accumulate CDM use until a CDM’s usage meets a package size and is ready for replenishment.
4. Allow the consultant or vendor to place a “split” 340B order (separate from non-340B orders) containing an NDC that is linked or similar to the CDM that was ready for replenishment on the next purchase.
340B solution type #1: home-grown

Home-grown solutions are the least popular type of 340B solutions due to the cost, required subject matter expertise and risk associated with them. In most cases, homegrown solutions developed as a work-around to compensate for limitations in other software or information systems a CE has in place. Since these solutions are developed for their unique situation, and are rarely deployed due to the cost and expertise required to deliver and maintain them, this white paper will focus on the more practical 340B solutions for hospitals.

340B solution type #2: manual split-billing solution

These solutions are usually called software solutions, but are more accurately described as some sort of manual aggregation of a few files that are sent to a consultant or other group. These solutions, like homegrown solutions, are not optimal long-term compliance solutions and have a degree of risk due to the manual interpretation of the outside parties involved. This solution is rarely deployed by entities that have a focus on compliance and program maximization. They are more often used as an add-on when a CE has an existing relationship or other partnership with a consulting firm.

Strengths – manual split-billing solution

• Can be installed quickly.
• Requires a relatively simple data set.

Weaknesses – manual split-billing solution

• Uses charge codes, not NDCs.
• Fails to provide NDC-level compliance.
• Provides limited reporting.
• Relies on third-party involvement.
• Requires ongoing manual intervention.
• Carries high total cost due to lost opportunity.
• Loses capture of eligible dispensations from mixed-use environments (ER, OR, Cath Lab) where patient was admitted.
• Involves fluctuating prices, as consulting fees may exceed software costs over the term of the contract.
340B solution type #3: split-billing software solution

During the 1990s, split-billing software was cutting edge and dominated 340B conversations. During this time, “split-billing” became a standard term for the industry when referring to 340B software. Some people still view it as a comprehensive solution that addresses all of their 340B needs.

Most split-billing solutions started as (or still are) a foundation intended for inventory management. Inventory management solutions are charge code-driven, not NDC-driven, which is a standard of pharmacy inventory management.

In inventory management, what is important is how many acetaminophen 325mg a CE has, not necessarily each different NDC of acetaminophen 325mg. It is a function of totals versus discrete manufacturers or NDCs.

Strengths – split-billing software solution

- Requires a relatively simple data set.
- Implements in a time frame of less than 60 days in most cases.
- Instills a sense of confidence because the term is well-known and widely-used in the industry.

Weaknesses – split-billing software solution

- Uses CDM data, rather than specific NDC data.
- Purchases specific NDCs without data on use of specific NDCs.
- Tracks single NDCs or is limited to a specific manufacturer at any one point in time, regardless of purchasing practices.
- Relies on the hospital to report OP CDM usage.
- Misses some mixed-use opportunity due to hospital IT billing limitations and split-billing software intended use.
- Lacks specific NDC use data for compliance reporting.
- Incurs high cost due to lost capture opportunity.
- Carries added costs due to consulting fees needed to maintain compliance.
- Does not enable incorporation of federally-mandated Policies & Procedures (P&Ps).
340B solution type #4: rules-based compliance engine

The newest and most advanced type of 340B software incorporates a rules-based compliance engine. A rules-based engine is a software program that is set up based on a specific set of rules – in this case, the CE’s P&Ps. A rules-based engine is focused on enabling an entity to automate its processes to execute the exact same way every day, regardless of who places orders.

This type of solution was built specifically for 340B compliance and enables an entity to have the maximum compliant capture of opportunity. While this type of solution was ahead of its time when it came out in the early 2000s, today it has reached a point of necessity for CEs who value compliance and want to be prepared for congressionally-mandated HRSA audits and an increasing number of manufacturers’ audits.

Strengths – rules-based compliance engine

• Built for 340B compliance.
• Provides comprehensive reporting focused on regulatory compliance.
• Includes audit preparation capabilities.
• Maximizes compliant savings capture.
• Uses NDC data.
• Captures mixed-use setting eligibility with accuracy.
• Incorporates federally-mandated P&Ps.
• Delivers best overall ROI in most cases.
• Should adapt to changes in operations or regulations.

Weaknesses – rules-based compliance engine

• Involves an upfront investment of entity resource time compared to less sophisticated solutions.
• Mandates entity time for initial set up of compliance policies.
• Necessitates more data to facilitate true compliance.
• Requires an installation timeline that is typically longer than other 340B solutions.
• Includes initial investment that may be more than the up-front costs for split-billing software.
SECTION 3: Key compliance factors and capture maximization

This section reviews basic compliance requirements and provides background on the challenges of using hospital information systems to meet these requirements. This section also includes self-assessment questions that will help in determining a current level of compliance. Finally, this section will contrast split-billing solutions and rules-based compliance engines as they relate to each of these points.

The following key concepts will be reviewed:

1. 11-digit NDC compliance and tracking multiple NDCs
2. Policies & Procedures (P&Ps)
3. Reporting

11-digit NDC compliance and tracking multiple NDCs

Background

Following 340B guidelines requires that the drug being replenished is the same drug that was dispensed in eligible OP situations, as evidenced by an exact 11-digit NDC match. Exceptions to the 11-digit rule are very limited and can be replenished only in the case where only a nine-digit match is available. NDC matches of less than nine digits cannot be legally replenished.

IT Challenge

Today’s hospital information and billing/financial systems were not set up to bill at the exact NDC level. They were set up to bill at the drug level or charge code. Today’s pharmacy information systems do recognize multiple NDCs, but that information is transmitted to the financial system as a charge code for that item, not as an NDC.

Entities that barcode are often under the impression that the NDC is tracked throughout their information systems, but this is not the case. Typically, the NDC is only used to verify that it is representative of the entered charge code or drug, also called an alias. The charge code and primary NDC, if any, is what makes it to the billing side.
Operational Challenge

Due to drug shortages, wholesaler short supplies and manufacturer back orders, it is very common that multiple NDCs are purchased for the same item or charge code and that multiple different NDCs for the same item or charge code are in a hospital and used on any given day. Most pharmacy directors report that up to 10 percent of medications ordered seem to be short or unavailable for some reason and require a substitute NDC.

Items for Consideration

1. 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 drug item.

2. Check to see how many alias NDCs are recognized under a CDM or charge code in the pharmacy charge master or order entry system.

3. Check to see how many NDCs are in the financial billing system.

4. Check to see how many NDCs are tracked in 340B software at the same exact time and if it is possible to differentiate the usage of each of those to equal the total amounts that have been purchased.

5. Review a simple example comparison of how multiple NDCs are handled by split-billing software and a rules-based compliance engine, as shown on the next page.
## Handling multiple NDCs: the differences between split-billing solutions and rules-based engines

<table>
<thead>
<tr>
<th>Example action step</th>
<th>Split-billing response</th>
<th>Rules-based engine response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Five different NDC packages of acetaminophen 325mg are purchased. (five separate NDCs with a quantity of 1,000 each).</td>
<td>Tracks purchases of five different NDCs.</td>
<td>Tracks purchases of five different NDCs.</td>
</tr>
<tr>
<td><strong>2.</strong> Replenishment eligibility is accumulated.</td>
<td>Accumulates replenishment eligibility by the OP charge code used and does not track specific NDC use except for the NDC linked. In this case, one NDC is accumulated.</td>
<td>Accumulates and tracks replenishment eligibility based on an 11-digit NDC and the mapped OP charge code used—in this case, five different NDCs.</td>
</tr>
<tr>
<td><strong>3.</strong> 5,000 dispensations have been accrued.</td>
<td>Tracks 5,000 dispensations (based on OP charge code) of acetaminophen 325mg and bundles all of the dispensations under one bucket for replenishment.</td>
<td>Tracks eligibility for five distinct and separate NDCs, each of which has reached the full package size and can be replenished only based on the actual NDC usage.</td>
</tr>
<tr>
<td><strong>4.</strong> A replenishment order is placed.</td>
<td>Creates a 340B purchase order for acetaminophen 325mg packages totaling a quantity of 5,000, without regard to the specific NDCs used. The accumulator or bucket can apply to any similar item.</td>
<td>Creates a 340B purchase order for each of the five specific, 11-digit NDCs that have earned replenishment eligibility. This activity would be documented, illustrating 340B compliance.</td>
</tr>
</tbody>
</table>
As each NDC is purchased for the first time, it should be bought at non-340B pricing and should never use a previous NDC’s replenishment eligibility to order it at 340B pricing. The use of 340B pricing is reserved for replenishment of 340B drugs or establishing a 340B inventory that can be tracked.

If a CE experiences a shortage and needs to buy a new NDC under 340B before it has eligible use, the NDC should be treated as 340B inventory. A rules-based compliance engine would consider it 340B virtual inventory for future use, since there would be no historical use of that NDC before. The NDC’s use would then be tracked until it had accrued eligibility.

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

An example would be generic drugs, where multiple manufacturers commonly make equivalent drugs, but in different package sizes. Each of these variations would have its own 11-digit NDC. A CE would be bundling if they used a variety of NDCs, from multiple manufacturers, to earn replenishment eligibility for one specific 11-digit NDC.

The issue with bundling is that it may force one manufacturer to give a savings benefit when the original eligibility came from another manufacturer’s medication. This practice is effectively non-compliant and necessitates the 11-digit NDC match to avoid it and preserve 340B program integrity.

**Conclusion**

Finding a solution with 11-digit NDC compliance and the ability to track multiple NDCs isn’t just a luxury option or a bonus feature—it’s a vital, necessary component of any compliant 340B software that will maximize program participation and accurately document pharmacy activity. It’s key to understand the difference between tracking all NDCs, versus just tracking one manufacturer or using a bundling process, as this will impact both 340B compliance and benefits.
Policies & Procedures

Background

Policies & Procedures (P&Ps) are federally mandated. If audited, a CE will be asked to present its P&Ps for review with its data related to 340B. A CE’s P&Ps should follow its actual operations and decisions related to the program.

IT Challenge

Today’s hospital information systems do not have the ability to do what is necessary for 340B, resulting in the need for a third-party solution.

Operational Challenge

One challenge is tracking and the other is ordering. Since people take vacations and multiple people often perform similar tasks, it is very difficult to ensure 100 percent compliance with a CE’s P&Ps related to 340B since they are so complex and rely on information outside of the pharmacy system itself in order to determine eligibility.

Items for Consideration

1. Are P&Ps for 340B in place today?
2. If P&Ps are in place, is there a way to audit or track that they are enforced?
3. Does the current system allow for P&Ps to be electronically enforced or is enforcement dependent upon the person placing the order that day?

Conclusion

It is optimal to find a solution that incorporates P&Ps into the system. This approach 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 by an entity, as well as the potential penalties that could result from an audit, are too great to risk manual variation based on human error and employees’ differing levels of understanding or knowledge related to the 340B program.
Reporting

Background

Reporting is especially important since 340B requires data from multiple hospital IT systems. Reporting enables a CE to track and understand its data environment, communicate success to executives, find areas for improvement or added savings, perform regular internal audits, and provide information for external auditors. Auditors evaluating covered entities based on congressional scrutiny have been asking for very detailed data sets related to 340B compliance.

The ability to respond to an audit appropriately is entirely dependent on the type of 340B software in place. Each audit situation differs based on the source of the audit, but it is likely that an audited CE will be requested to show that 340B purchases match actual dispensations, down to 11-digit NDC detail.

IT Challenge

Information that enables compliance comes from multiple sources, both internal and external to the hospital. An internal example could be drug charges or admission, discharge, and transfer data (ADT) while an external example would be wholesaler purchases and pricing files.

Operational Challenge

Reporting for 340B could be as simple as identifying which medications are ready for 340B purchase, but ideally, is sophisticated enough to point out potential areas of concern or opportunity related to compliance and savings.

Items for Consideration

1. What type of reports are available today? At a minimum, a CE should have:
   a. GPO, 340B, & Wholesale Acquisition Cost (WAC) purchase reports.
   b. IP & OP utilization reports.
   c. A report of savings based on each distinct NDC.
   d. A report of potential savings.
   e. A list of items ready to be replenished.
2. It is an added benefit if these reports exist:
   a. Comparison of purchases vs. utilizations for all IP/OP medications.
   b. Audit reports demonstrating compliance with patient definitions.
   c. Alerts when new CDMs are added or new NDCs are purchased.
   d. Notifications by NDC when penny buy opportunities exist.
   e. Specific audit functionality by NDC, time frame, patient, etc.

Reporting can impact both savings maximization and compliance with 340B regulations. It may be helpful to take a deeper look and review a few examples to better demonstrate the need for robust and comprehensive reporting from any technology solution.

Example #1

Proactive reports can assist in savings maximization

Penny buys are drugs that sometimes become available for literally pennies. These savings opportunities can come and go with no notice. The ability to know what is available at this price is crucial to a CE’s full and maximized 340B participation, yet no hospital system or inventory management system has the ability to proactively tell a CE if these prices are available.

Entity Challenge

The difficulty for a CE is determining when these penny buy items are available. A typical hospital pharmacy buyer has tens of thousands of contracted items to sift through. If they’ve ever seen a penny buy, it’s usually a result of stumbling across one by accident.

Items for Consideration

1. Does a CE have a history of purchasing penny buys?
2. Can the CE’s current or future software proactively alert them when penny buys are available?
3. If the CE procures these for an area such as oncology prior to use, how are those items tracked?

A solution that can proactively alert an entity when penny buys are available can lead to added savings for a CE. Having the ability to know they exist and respond appropriately is key to maximized participation.

Example #2

Tracking drug detail for purchases and utilizations improves troubleshooting

**Purchases vs. Utilizations** may seem like an odd 340B reporting requirement, but it is probably one of the most important components of 340B compliance and maximization.

Access to accurate, updated details on purchases and utilizations is a vital piece of 340B program participation.

Entity Challenge

The hospital environment’s tracking of purchases (by pharmacy buyers) and utilizations or dispensations does not allow for much direct comparison, unless an outside software solution is able to aggregate the disparate sources of information and match them up.

Having access to real time purchase and utilization comparison is vitally important. If pharmacy staff are able to quickly determine that they purchased 500 units of an NDC but only 100 have been charged, this alerts them to a potential compliance issue or opportunity for added savings. Knowing a specific place to look for information enables further research on that specific item and aids in determining the issue, whether it is building inventory on the shelf, missed charges in a hospital location, a wrong multiplier in the charge master, pilferage, or something else.

Why does this matter for 340B? If an NDC is not being replenished because of error or theft, this is a lost opportunity. This example of reporting is a simple yet very effective tool to maximize savings and compliance.
an analysis of 340B solutions

Items for Consideration

1. Does the 340B solution offer clear comparisons of purchases to utilizations for individual NDCs?

2. How much time does pharmacy staff have to dedicate to troubleshooting and locating potentially missing inventory?

3. Can data be accessed tying a purchased NDC to a dispensation?

After practicing compliance and compiling the right data for it, reporting purchases and utilizations may be the next most important factor a CE has to maintain both compliance and savings maximization. If the correct reporting and detail of data does not exist, a CE will be significantly hindered in an audit situation and will likely achieve less savings overall.

Conclusion

Reporting enables a CE to conduct regular self-audits, and, in the event of an audit, provide the appropriate information auditors would require to determine compliance with 340B regulations. Effective reporting is also key to keeping executives informed regarding the CE’s day-to-day operations and performance.
SECTION 4: What is an ideal 340B solution?

An ideal 340B software solution will demonstrate the characteristics described for each of the key components just reviewed and will offer added features that assist in a CE’s understanding and maximization of its program. For a further breakdown of 340B solutions, compare rules-based engines to split-billing software in the areas of compliance, capture of savings, and workflow—all key considerations for a CE’s overall 340B success.

Compliance

With the increased focus on compliance and new congressionally-mandated audits already taking place, it is imperative that 340B software is able to incorporate policies for compliance.

As indicated before, split-billing software was designed from inventory management systems and was developed at a time when audits were not a concern for CEs. Split-billing was not designed to incorporate an entity’s P&Ps, a core element for ensuring compliance.

Because a rules-based engine is built around and executes on rules, it should provide 100 percent compliance with P&Ps and enable a CE to meet all 340B requirements in an automated fashion—especially since the rules are part of the system and are not manual or people-dependent. If audited, any entity using a rules-based compliance engine will have documented P&Ps that the technology is acting on as directed. This rules-based foundation provides a consistent and replicable approach to compliance and audit reporting.

Split-billing software is able to handle simple operations, such as splitting OP and IP charges (CDMs). While this is simple, it may not be adequate for your entity given the recent changes to the 340B landscape.

Rules-based engines should be able to accommodate changes that would result from either regulatory updates or operational changes such as switching from billing on the dispensation to billing on the administration.

The compliance software needs to provide audit reporting in detail.

Split-billing software, being CDM-driven, will typically track only a single NDC. With some more advanced split-billing systems, the software may allow tracking of multiple NDCs if they are from the same manufacturer. Although some will claim it’s possible to track multiple NDCs using different CDMs, often referred to as a 1-to-1 relationship, this approach is unrealistic and will not be compliant for any hospital to consider for a number of pharmacy operational reasons. This core issue results in a compliance risk for the CE.

A rules-based engine that includes audit preparation tools should instill confidence in a hospital’s overall program.
participation and compliance. Ideally, the software will feature integrated tools that were designed specifically for auditing purposes and were built with a hospital pharmacy operation in mind. This allows for detailed reporting for compliance, down to the exact NDC level.

Capture of savings

Most hospitals with a split-billing solution take one of two different approaches to capturing eligibility in mixed-use areas. Some assume it is impossible to accurately capture this area, so they exclude the area from their 340B program altogether. The other approach is to consider the entire mixed-use area as eligible, on the assumption that 340B opportunities may have been missed in other areas, and everything will even out in the end—in other words, knowingly use 340B medications for admitted ER patients, a direct violation of 340B regulations. By taking this approach, the CE assumes they are getting their entire capture with split-billing, when in reality, they might be earning unjustified eligibility from IPs in a mixed-use area, or they could be missing legitimate eligibility from OPs in a mixed-use area.

One weakness of split-billing systems in the mixed-use area relates to the way hospital billing systems will change a patient’s status. Based on the 72-hour rule for billing, patients who are admitted have their records changed to reflect IP status once admitted. This means that any record up to 72 hours prior to their admission that was an OP record is now an IP record in the hospital information system. This does not mean they were not an OP, as this is purely for billing purposes, but it creates issues for tracking.

Since most split-billing systems take batch records, the replenishment eligibility accrued by any OP dispensations that occurred in the 72 hours prior to a patient’s conversion to IP status is lost. For example, if an OP receives a dispensation at 11:45 p.m., is admitted at 11:55 p.m., and the split billing system receives a batch report at 11:59 p.m., those OP dispensations will be lost because the system reflects only the IP status. Even if the patient’s status is pulled from an automated dispensing cabinet, that status will still reflect the
status as IP, the most recent update when the report was run for OP billing.

In contrast, a rules-based engine considers only primary sources of disparate data to get the true status and eligibility information. A good rules-based engine will receive a real-time ADT feed directly from the hospital’s information system to indicate an accurate IP/OP status. In order to be effective, the 340B solution will also need to catalog the chronological order of messages and retain all pieces of data. This way, the system can match dispensation or administration data to an exact point in time that clearly defines what the patient’s IP/OP status was and shows whether the dispensation was pre- or post-admission.

**Workflow**

Workflow is another major consideration when evaluating 340B programs. The price of the software is directly related to the amount of work and manual intervention required after installation.

A rules-based engine may require some initial oversight and preparation, but the benefits from these early efforts will reduce ongoing workflow concerns, and the proactive alerts and reporting will save many hours down the road.

Using a rules-based engine often requires staff education on 340B rules and regulations, but this training is needed anyway, both for accuracy of mapping and to ensure that the 340B program managed by informed, committed staff.
SECTION 5: Final thoughts on choosing a 340B hospital software solution

While each CE may have its own unique operations, processes, and needs, there is one key element going forward: compliance. With HRSA/OPA audits mandated by congress already taking place, the vital importance of program integrity is apparent. Compliance is no longer an optional or luxury feature offered by rules-based engines. It is a critical component of any successful and audit-ready participation in the 340B program.

Whether a CE has a current system in place or is new to 340B and looking at options, it is important to understand the systems available and the limitations they bring when determining how to comply with 340B regulations and participate in the program.

Any solution is viable if you are willing to accept its shortcomings, and there's no one-size-fits-all solution, as each CE has unique needs and issues to address. Evaluating the true cost of a 340B solution should consider fixed cost, lost savings, compliance and risk. In other words, the return on investment is more than just what was paid up front; it is a function of the whole picture.

Analyzing a 340B solution requires acknowledging that unplanned costs may result based on the limitations of a given solution. These unexpected costs could occur and might not be seen in up-front fees:

- Lost or missed savings capture
- Cost of consultants
- Payback or fines resulting from negative audit findings
- Labor cost of locating information or generating reports manually because of poor data
- Workflow impact of managing the solution on a daily basis, such as additional steps required to place an order

Obviously, the initial cost of a 340B solution is not the only factor that affects the overall value it brings. What about compliance, risk and other hard-to-gauge costs? They matter, too.

While split-billing is a popular solution and has become a common term in 340B, this type of solution will not meet a CE’s complete needs for 340B compliance. However, if split-billing’s limitations are understood, it is possible that these solutions may work for a hospital if the entity using it invests in additional staff, pays for regular consulting services and maintains a variety of internal databases. However, when considering the alternative rules-based compliance engines available today, it would be difficult to justify the time, resources, extra cost or lost opportunities associated with a split-billing solution.
In the current healthcare data environment, rules-based compliance engines are the best choice to deliver compliance with a CE's policies, maximization of their compliant capture, comprehensive pharmacy visibility, full audit preparation and a reduction of the entity’s risk and liability related to 340B.
About the author

Michael J. Sovie Pharm.D., MBA, is a pharmacist and former Hospital Director of Pharmacy. Michael’s background and experience includes: pharmacy management and operations, installation of bedside barcoding, administration billing, electronic medication administration records, and CPOE as a hospital pharmacy leader.

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- Adjunct instructor at Wilkes University School of Pharmacy.
- Member of various hospital pharmacy associations and participant on pharmacy association boards.
- Past regional president for a chapter of the Florida Society of Health-system Pharmacists (FSHP).
- Presenter on various pharmacy topics at national meetings such as the American Society of Health System Pharmacists (ASHP) and other healthcare conferences across the country.

About Sentry Data Systems, Inc.

Located in Deerfield Beach, Fla., Sentry Data Systems, Inc. provides technology solutions that help hospitals address their three biggest challenges: reducing costs, managing compliance and producing better outcomes. More than 2,000 hospitals, integrated delivery networks (IDNs) and pharmacies across the country rely on Sentry’s integrated platform for their analytics, procurement, drug utilization and compliance solutions. Since 2003, Sentry’s solutions have processed millions of daily eligibility, financial, clinical, and pharmacy transactions, saving clients millions of dollars on more than 45 million patients.

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