340B
Contract Pharmacies

A White Paper by
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340B Contract Pharmacies

Part II

Overview

This white paper is the second piece of a three-part series.

Part I is a review of the 340B program and a look at hospital use of 340B software. This first paper provides a basic background in 340B and may be helpful for some readers to review before looking at Part 2 of the series.

Part II is a look at contract pharmacy partnerships with 340B covered entities and the complexities of these relationships. This paper covers 340B software solutions for hospitals and contract pharmacies from the perspective of both stakeholders to assist the reader in understanding the financial, operational, and compliance challenges present in contract pharmacy arrangements. This white paper also reviews the technology and software available for dealing with these challenges.

Part III will be an evaluation of compliance, audit preparation, and documentation needs related to 340B. It will also review the audit process and upcoming key topics related to 340B compliance.

Abstract of Part II

Purpose: To assist both eligible hospitals and potential Community/Outpatient contract pharmacy (CP) stakeholders in understanding the opportunity related to 340B CP arrangements while discussing common regulatory hurdles, business challenges, and complexities inherent in this type of arrangement.

This white paper should enable both the hospital and contract pharmacies to evaluate their current participation and/or future participation. This paper is not intended to cover models for Federally Qualified Health Centers (FQHCs) or Community Health Centers (CHCs).

Summary: The benefits available through participation in the 340B program are intended to support and forward the Safety Net Mission of the covered entity (CE) so that it may continue to meet the needs of the community and patients it serves. By working with a CP, a hospital can generate additional 340B benefits which will offset losses incurred in other areas of their business such as Medicare, Medicaid, undocumented, underinsured, uninsured, and indigent patient care and their unreimbursed costs related to those services.

The 340B program provides a vital resource for hospitals that is intended to enable these entities to maintain, improve, and add services.

340B eligible hospitals that are not actively partnering with Community/Outpatient pharmacies are missing a significant part of the intended 340B benefits that are available to support their Safety Net Mission. Community/Outpatient pharmacies of any size that are not currently or have not in the past explored working with CEs are also missing an excellent
opportunity to better serve their community and are missing the potential for increased volume, profit, and margin.

CEs partnering with Community/Outpatient pharmacies are solely responsible for their own compliance and must understand and meet the full Patient Definition requirements in order to maintain the integrity of the 340B program.

Partial compliance is non-compliance, and each entity is responsible for auditing their program, pharmacy, and software vendor to ensure that the system is operating and executing as intended. Many new vendors, consultants, and companies have entered the 340B marketplace in the past few years and this has led to confusing and occasionally inaccurate information being given to CEs.

**Conclusion:** CP arrangements are a great opportunity for Safety Net hospitals to access 340B benefits helpful for improving, maintaining, and adding services for patients most in need and offsetting losses incurred for serving these populations. Software is absolutely necessary for a contracted relationship with a pharmacy to be compliant and successful for all parties, but not all software vendors were built for hospital compliance nor do they all have experience outside the FQHC and CHC clinic world.

It is imperative that hospitals and pharmacies understand their unique data capabilities and limitations in light of the regulatory guidelines, operational considerations, and financial investment needed in order to successfully deploy solutions that will meet audit requirements in an effective manner. Manual processes should be avoided at all costs and every hospital should insist on an automated data-driven process for compliance and reporting, especially since the hospital is the responsible party for the program’s compliance, not the pharmacy.

**When considering a CP partnership with a Community/Outpatient pharmacy, hospitals should:**

1. Define minimum requirements for their 340B software vendor.
2. Understand the full Patient Definition along with how it will be tracked and reported in the event of an audit.
3. Put a strategy in place for their program participation that is regularly reviewed and evaluated.
4. Define how these resources are benefitting their Safety Net Mission and review the impact with executive leadership on an annual basis.
About the Author

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He has combined his clinical, hospital pharmacy operations and business background in his current role as a Senior Vice President of Sales at Sentry Data Systems helping hospitals achieve 340B understanding and compliance.

Michael’s professional activities include participation in the healthcare industry as:

- 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.
SECTION 1: Contract Pharmacy Overview

This section provides the foundation looking at detail related to contract pharmacies (CPs) and 340B program management. This discussion assumes some basic knowledge in the areas of 340B, healthcare business, Community pharmacy operations, and Outpatient pharmacy activity.

What is the 340B Drug Pricing Program?

The 340B Drug Pricing Program enables certain eligible healthcare organizations called covered entities (CEs), to receive discounts on drug prices. 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 program is budget neutral for the federal government. The healthcare services provided by these Safety Net entities are of vital importance to their local communities and patients. This program has been immensely successful in helping CEs meet their Safety Net Missions in underserved communities.

Hospitals that have Outpatient pharmacies may dispense 340B medications to outpatients that meet the full 340B Patient Definition requirements. A hospital or CE has two options for achieving this opportunity: (1) an owned Outpatient pharmacy and/or (2) a contracted Community/Outpatient pharmacy.

Any eligible hospital (with or without an owned Outpatient pharmacy) can choose to contract with Community pharmacies to dispense eligible 340B prescriptions on their behalf. The result will be savings at existing Outpatient sites for medication dispensed when using an external CP.

For purposes of this paper, a contract pharmacy (CP) is defined as a Community/Outpatient pharmacy that has engaged in a business arrangement with a CE in its community to provide a Community/Outpatient pharmacy service on behalf of the hospital. In this case, the Community/Outpatient pharmacy is dispensing, billing, and collecting payments for 340B eligible medications provided to patients of the CE on behalf of the CE.

Frequently Asked Questions

What is the full Patient Definition?
The full Patient Definition is a set of requirements for illustrating that a patient who receives medication is actually a patient of the CE. Showing compliance with this full Patient Definition often requires data from disparate systems.

Can any hospital contract with a Community/Outpatient pharmacy for 340B?
No, only 340B eligible CEs approved by the Office of Pharmacy Affairs (OPA) can access 340B pricing.
Can any Community/Outpatient pharmacy do this?
Yes, any Community/Outpatient pharmacy that contracts with a CE and is approved by OPA can act as a CP.

How is a contract with a pharmacy established?
An agreement must exist between the CE and CP and be approved by OPA in order to have a CP-to-CE relationship.

What is the agreement between the hospital and the pharmacy?
The agreement between the CE and the CP is called a Pharmacy Services Agreement (PSA). This PSA defines how the arrangement will work.

Why would a hospital without an Outpatient pharmacy want to do this?
By partnering with a CP, a CE will be able to maximize its 340B benefits by extending its 340B participation to a Community/Outpatient pharmacy which will further offset losses in other service areas. This should assist the CE in being able to continue providing services and/or improving services to its community.

Can a CE have multiple contract Community/Outpatient pharmacies?
Yes, the Federal Register Notice* in March 2010 enabled CEs to contract with multiple CPs. Each location for a CP must be approved by OPA.

* Federal Register Notice of March 5, 2010 (PDF - 73 KB) (Volume 75, Number 43 pp 10272-10279)
Final Notice Regarding 340B Drug Pricing Program: Contract Pharmacy Services

Should a CE contract with an external pharmacy if it owns an Outpatient pharmacy?
A CE that owns an Outpatient pharmacy deciding whether or not to contract with a Community pharmacy has some important factors to consider. Generally, hospital-owned Outpatient pharmacies are not convenient to the public, have limited hours, and only serve a small part of a CE’s patient mix. Engaging with an external CP can expand a CE’s services into the surrounding area.

How many pharmacies should a CE contract with?
There is no magic number, and this answer will depend on what makes logistical sense and must factor in a CE’s demographics, patient population, and which pharmacies are willing to partner with a CE and its 340B software provider. Each entity should make this decision based on local demographics and patient needs.

Are a CE’s employees eligible for 340B?
Being an employee of a CE does not, in and of itself, meet the 340B Patient Definition. Only patients of a CE are eligible for 340B drugs. An employee can only be a patient by meeting the Patient Definition. Eligibility is not based on employment status in any way.
If a CE has a self-funded health plan, does that meet the Patient Definition requirement for employees because the CE pays for the care?
No, this only signifies an employer to employee relationship, not a patient to provider relationship. Being an employee of a CE does not qualify an individual’s medications for 340B pricing.

Should a CE just contract with as many pharmacies as possible?
No, there is work, resource allocation, logistics planning, feasibility analysis, and monetary cost to every pharmacy a CE contracts with for 340B participation. Low volume pharmacies are typically not going to provide benefit to a CE or the CP.

Note: A model with “aggregation” across stores may make some lower volume pharmacies appropriate in certain cases.

Can a CE make its patients go to a certain pharmacy?
No, there are state and federal laws that specifically deal with patient choice as well as disclosure. Patients must have the right to choose their pharmacy.

Note: Later, this paper will look at employee benefit plans and incentives that are commonly used to promote business at a specific Community/Outpatient pharmacy.

Is a prescription written from a pad or blank from a CE enough to determine eligibility?
No, a prescription alone does not meet Patient Definition requirements for 340B eligibility. In fact, practices like this put hospitals at significant risk if audited.

Is having a doctor’s name alone meeting the Patient Definition?
No, partial compliance is non-compliance. Using only a doctor’s name as eligibility criteria puts a hospital at significant risk in an audit.

Can a CE contract with a chain for all of its locations?
Theoretically a CE could do this, but there is no reason to. Also, OPA will have to approve each address location as a CP.

How does a pharmacy get connected with a CE?
Typically a CE approaches a CP to participate as a partner. However, CPs that want to be more proactive can check www.hrsa.gov/opa for the CE database to see if local hospitals participate in the program.
SECTION 2:
Patient Definition Criteria

This section is devoted to providing a comprehensive review of the elements that currently support Patient Definition compliance.

Understanding compliance and tracking needs related to CP services is critical to proper utilization of the 340B benefits from contracting with a pharmacy.

The Patient Definition that defines qualifying drug dispensations under 340B must be followed to maintain the integrity of the program. A thorough understanding of the criteria and how they are applied is imperative for all CEs, who are solely responsible for ensuring compliance with the Patient Definition both for hospital use of the 340B program and in any CP relationships.

The Patient Definition is clearly articulated at http://www.hrsa.gov/opa/patientdefinition.htm

Summary of the Patient Definition

An individual is a "patient" of a CE* only if:

* The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care, and the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.

* Note: This white paper relates to the hospital Patient Definition specifically.

Breaking this all down can be complicated and is probably the most misunderstood and most misrepresented piece of 340B. It is very important that CEs take ownership of understanding the definition and ensuring that their software vendors and partners are following the definitions as intended.

While FQHCs and CHCs are not covered here, it is worth noting that the identification of a patient in those environments is much more simple than in a hospital environment, where a CE can have eligible and ineligible patients, often has many physical locations, and offers a wide range of service offerings that may not all meet the “healthcare service” criteria for 340B purposes.

Patient Definition Requirements

To truly validate a CE’s compliance with the Patient Definition, it is necessary to evaluate the requirements of patient eligibility by clearly listing them and asking questions related to each:
1. **A patient must be seen in an eligible location for the Covered Entity.**
   - Is there a documented visit at the CE?
   - Is the location the patient was seen at on the hospital’s Medicare cost report?
   - Is this location “above the line” on that cost report?

2. **The CE must own the record for the care provided.**
   - Does the CE own this record or is it a doctor’s office leasing space?
   - Is the record partly owned through a joint venture?
     - If the record is partly owned, then the record likely doesn’t meet the requirement for being at an eligible location and is not a valid 340B record.

3. **The responsibility for care provided must remain with the CE.**
   - If there were a lawsuit related to the care and the drugs dispensed, would the CE be the primary liable party?
   - How long is the CE “responsible” for the care of the patient?
   - Does the “type” of care (Emergency Room or Clinic) come into consideration for the assignment of responsibility?

4. **Care must be provided by an eligible physician.**
   - Is the physician who wrote the prescription a physician that is contracted, employed, or otherwise affiliated with the CE?

5. **The care provided must be for an eligible healthcare service.**
   - Can the CE differentiate a healthcare service vs. a diagnostic-only service?

6. **The prescription must be auditable to a 340B clinical location.**

   *Note: While this requirement is not specified in the Patient Definition, it is specified in the 2010 Contract Pharmacy Guidelines. Because multiple covered entities and contract pharmacies are operating within the same catchment areas, this is a key component in CP audits.*

If all of the above criteria have been met for a relevant prescription, then the last piece needed for a valid 340B transaction through a CP is to be able to identify these criteria at the Community/Outpatient pharmacy point of service to capture the prescription.

Integrity with the Patient Definition is imperative for compliance. Any CE intentionally using 340B medication for patients that do not meet all the criteria above is at significant risk in an audit. CEs should perform regular self-audits or hire outside independent third-party auditors to maintain compliance with these requirements.
What challenges will a CE face for meeting the Patient Definition?

The IT Challenge

The information required to clearly define a patient under 340B comes from multiple hospital departments and/or systems. While electronic health records are widely used, they are not designed to bring together all this information for the purposes of 340B.

In addition to the challenge of a hospital needing to define a patient through data, the CE or hospital does not typically have access to records of a non-owned Community/Outpatient pharmacy, and the pharmacy does not have access to all the hospital records necessary to meet the above criteria. The disparate data sources, regulations, and need for reporting make this a challenging task, as the transaction takes place at the CP but the validating data is present in disparate sources throughout the CE.

The Operational Challenge

The ability to bring all this data together is a complicated task that requires careful attention to detail and a dedicated software vendor with CP experience. On top of this a CE needs to consider how its Policies & Procedures (P&Ps) are incorporated into the data to determine eligibility.

Manual processes for eligibility determination—such as barcodes, cards, pharmacist identification of a prescription pad or a doctor—will not meet reporting requirements and, if used exclusively, place the hospital at increased risk. The operational challenge is automating the review of all of a CE’s data at two separate locations (the CE and the CP) to determine eligibility based upon its policies.

The Compliance Challenge

Compliance with the Patient Definition is a must. Fully understanding how the Patient Definition correlates to CE & CP data is crucial. Being able to utilize the required P&Ps when evaluating this data for eligibility determination is the only way to ensure compliance. All hospitals should invest significant time in reviewing the Patient Definition and how their software choices are related to their ability to meet this requirement.

The complex details of the CP arrangement become more clear when analyzed from both hospital and Community/Outpatient pharmacy points of view by taking a look at what is necessary to maintain compliance and form a successful relationship. This dual-perspective analysis will enable both parties to more fully understand each side’s needs and concerns.
SECTION 3:

Hospital Perspective

This section will review contracted Community/Outpatient pharmacy relationship benefits, challenges and critical concepts to consider from the standpoint of the Hospital.

A hospital that engages with a CP is able to extend its 340B benefits into the Community/Outpatient pharmacy space and by doing so enables itself to better serve its community and patient base. Many hospitals don’t have the space, expertise, or staff to run their own Community/Outpatient pharmacy, and often those that do are not conveniently located and have limited hours when compared to a typical community pharmacy. CPs were approved and intended to assist the CE in its ability to meet the needs of a diverse patient population.

Contracting with a pharmacy enables a hospital to expand their network of Community/Outpatient pharmacies into the community to better serve its patient population through improved access. By working with the CP, a new source of 340B benefits may also be generated to offset the CE’s losses as well as enabling the CE to continue and/or expand important programs or services for the community. The benefit is a lower cost of drugs and/or an expansion of the 340B program to the CE.

There are a few different hospital benefits derived by utilizing owned and contracted Community/Outpatient pharmacies in connection with 340B.

Hospital Benefits in CP Relationships

• Reduced readmissions can be achieved in scenarios where a patient may not be able to afford the normal Community/Outpatient pharmacy cost of a medication and the entity may choose to either provide the medication at no cost, subsidize the cost, or enable the patient to purchase the medication at its reduced cost, enabling compliance with the prescribed medication regimen that may otherwise never be taken/purchased by the patient.
• Continuity of care (which goes along with the above bullet point) may be improved, as a CP relationship can serve to provide pharmacy services to patients that have no other access to affordable medications.
• Potential 340B benefits generated on some prescriptions can offset losses incurred by providing services to some of the communities containing the most in-need patients and in some cases enable entities to either continue providing services or add new services for their community.
• Patient satisfaction can also be positively impacted if programs are established with the CP for discharge prescriptions and planning that can be convenient to patients leaving the care of the CE.

The hospital is responsible for 340B compliance and audit preparation. The data required to define eligibility starts with the CE and must be defined and linked to each Community/Outpatient pharmacy prescription.
The following is a list of critical components every CE should be familiar with in order to comply with regulations and maximize 340B benefits. This paper will evaluate each of these with a brief educational discussion related to the necessity of the component.

**Critical hospital components for 340B CP Management**

- Identifying and instituting federally required P&Ps.
- Tracking, reporting, and determining full Patient Definition compliance.
- Establishing an optimal network of Community/Outpatient pharmacies.
- Monitoring of financial transactions at the Community/Outpatient pharmacy level (the data is outside hospital systems).
- Connecting with wholesalers to order medications.
- Reporting regulatory requirements from both the Manufacturer and the Health Resources and Services Administration (HRSA).
- Automating compliance.
- Generating Safety Net benefits.

The next few items will explore factors critical to a CE’s success which warrant some additional review to avoid confusion and CE missteps.

**Identifying and instituting federally required P&Ps**

Governmental regulations require that P&Ps related to 340B are in place and followed for a CP relationship. Regardless of how a CE chooses to comply, it is expected that it has established policies, can produce these policies, and follows these policies.

**Questions to Consider - Policies & Procedures**

- Does the CE have policies in place today related to 340B?
- Can the CE audit these policies quickly and easily?
- Do these policies match a CE’s practices?
- How does a CE update its policies?
- Can the 340B software a CE is using or considering incorporate P&Ps?

**Tracking, reporting, and determining full Patient Definition compliance**

Compliance with the Patient Definition is the most difficult, most misunderstood, and most often misrepresented part of 340B today. It is 100 percent the CE’s responsibility to understand and comply with the regulatory requirements of 340B. CE-provided data must be sufficient to verify the full Patient Definition in addition to the 340B location of service for each prescription. The exception to location of service is a referral prescription; however, referral prescriptions must be auditable to the 340B location and provider making the referral.
Common mistakes CEs make with Patient Definition compliance

1. Basing 340B eligibility on a physician name and/or physician identifiers only.
   a. Physicians often write prescriptions for friends, wives, husbands, children, colleagues etc. However, if no visit occurred at the CE, this prescription is not eligible.
   b. If a CEO, CFO, Pharmacy Director, or any covered entity employee receives a prescription from a colleague physician and the clinical service is not documented in the hospital’s health record system, this does not meet Patient Definition requirements.
   c. Some 340B software systems use doctor-only eligibility checks, which lead to incorrectly qualifying eligibility for people that received prescription services only.

2. Basing compliance on employee status or on a self-funded health plan. This is not compliant and does not qualify any person as a patient. (This compliance topic will be covered more fully in Part III of this white paper series.)
   a. Paying for a person’s healthcare does not meet the responsibility for care requirement. The responsibility for care clause in the Patient Definition means “medical responsibility” only
   b. Setting up a system to call every employee annually or performing a physical exam each year does not qualify as a “healthcare service” when audited.

3. Handing out eligibility cards. Usually, nurses or discharge personnel are trained on handing these cards out.
   a. This process requires a very manual determination that can be changed based upon the reasoning of the nurse or caregiver providing the card.
   b. Cards can be handed off to different patients.
   c. This practice does not enable any tracking or recording for audit reasons, and a CE will be in a position with no data at the time of audit.

4. Using a barcode to define eligibility. A CE would either choose to have people manually place barcodes on prescriptions with the risks described above or a CE would put a barcode on every prescription, which is also risky since a prescription does not equal eligibility.
   a. This does not use Patient Definition criteria.
   b. This is not capable of producing a report showing Patient Definition data that supports eligibility.
   c. This process is likely to be over-encompassing and result in diversion.
   d. This process is best suited for CHC and FQHC clinic models as it is a useful in a situation with a closed system of physicians and patients.

Establishing an optimal network of Community/Outpatient pharmacies

Contract pharmacies are approved on a case-by-case basis by OPA. A CE will need to establish a network of pharmacies based on its specific needs and patient demographics.
Questions to Consider – Establishing a Pharmacy Network

- Can a CE get any pharmacy in its area to work with it?
- Will the Community/Outpatient pharmacies in a CE’s area work with any vendor it chooses?
  - It is inconvenient and burdensome for Community/Outpatient pharmacies to work with multiple vendors. Many Community/Outpatient pharmacies, both independent and chain, are starting to lean toward preferred software vendors or sole source vendors they will work with based on capabilities.
  - Many pharmacies today have experiences with multiple software vendors and have determined those that are capable of providing the business-related services and expertise needed to participate in 340B-related relationships.
- Is a software vendor claiming to have a pre-established or pre-approved network for CP purposes?
  - The idea of “pre-established” pharmacy network for 340B is a statement used to mislead hospitals.
  - Understand that no pharmacy is approved for a CE’s use until both parties sign a PSA and OPA has approved the arrangement.

Monitoring of financial transactions at the Community/Outpatient pharmacy level (the data is outside hospital systems)

This function should not be overlooked as it is fairly complicated and can lead to significant problems if not handled correctly up front.

Questions to Consider – Monitoring Community/Outpatient pharmacy Financial Transactions

- Can a CE view data that is outside the hospital environment and aggregate this information to determine revenue to collect for both the hospital and Community/Outpatient pharmacies?
  - In order to accurately track the financials of this program, a CE will need this data.
- Can reversals and payor changes be tracked?
  - These are common in the Community/Outpatient pharmacy environment and must be tracked.
- How will the arrangement account for timeliness and accuracy?
  - This impacts cash flow for both parties.
- What reports are available from a vendor?
- Is the transaction 100 percent visible to the CE?
- Can the following factors be tracked:
  - Third-party payment
  - Co-payment
  - Cash payments
- Cost of medication to wholesaler
- Cost of transaction with software vendor
- Dispensing fees to the pharmacy
- Gross and NET to the CE

- If the CE is audited, will it have access to the final adjudicated claim at the Community/Outpatient pharmacy level?
  - This should be recorded and readily available for the CE in its deployed software system.

Connecting with wholesalers to order medications

This is very basic and it should be expected that any and all software vendors are able to facilitate this in a competent manner. However, the level of detail and control given to the CE may vary by software vendor, pharmacy, etc.

Questions to Consider – Connecting with Wholesalers

- Who at the CE will handle ordering medications and distributing them to the CP and is this automatic or manual?
- What are the details of the billing process?
  - The 340B order is coming from the CE account and being paid by the CE.
    - Can this be approved by the CE before release?
    - How does the CP get the bill to arrange payments with the CE?
  - Does the wholesaler give confidential CE cost information to the CP?
- How will replenishment be coordinated with the Community/Outpatient pharmacy eligible usage?
  - How are usage quantities tied to replenishment?
  - What if full package sizes are not met?
  - What if a drug is discontinued?
- How can both parties ensure that replenishment can happen frequently enough and in a reasonable time frame?
- How does the drug replenishment tie to the actual financial transaction?

Reporting regulatory requirements (Manufacturer and HRSA)

In the current 340B environment, the most important concern both a CE and CP should have is compliance, which necessitates the ability to record, report, and audit on the regulatory requirements of the program. This information should be accurately tracked, securely stored and reportable on a real-time basis.

Minimum tracking requirements for any 340B CP compliance software

- Full Patient Definition requirements
- Location of clinical service
- Community/Outpatient pharmacy adjudication information
- Replenishment information
- Financial exchange of funds
Automating compliance

No CE should attempt to participate in 340B without a software solution in place that is capable of meeting a minimum set of criteria defined by the CE. While this paper outlines many of the items every entity should demand of its software solution, the reality is some may interpret the regulations differently and willingly take risks associated with those interpretations. Regardless of a CE’s position, it should be able to automate the process from start to finish with reporting that meets the requirements it defines.

Generating Safety Net benefits

Setting out to establish CPs should return a new source of 340B benefits to the CE that in turn is intended to support its Safety Net Mission. It is advisable that every CE understand how the benefits afforded by the 340B program are used to extend services to its community, add new services, and maintain existing services.

It is helpful to review the impact the 340B program has on a hospital at top levels. Having an understanding of the importance of the 340B program and the necessity of compliance to that program is vital.

Key Hospital Challenges for CP Relationships

The challenge of incorporating all the necessary data components for the Patient Definition and the P&Ps onto hospital data is paramount to a successful and compliant CP program. Both hospital and pharmacy data must be used at the Community/Outpatient pharmacy point of service to determine eligibility, reorder medication and determine financial exchanges. CEs face some difficult but manageable IT, operational, and compliance challenges in handling CP relationships. Understanding its basic challenges helps a CE to evaluate other third parties it may work with as well as the software it might choose for CP purposes.

To conclude the hospital overview, it is helpful to understand the IT and Operational challenges every hospital should be aware of before embarking on a CP relationship.

The IT Challenge

- Hospital and Community/Outpatient pharmacy data are not naturally combined and always reside in disparate systems.
- Hospital Patient Definition data resides in multiple locations.
- CP data is not “owned” or seen by the hospital.
- The inclusion of P&Ps is not a standard offering of hospital IT systems.
- Requirement for consistent integration of hospital data, Community/Outpatient pharmacy data, wholesaler information, switch adjudication data, and policy requirements.

The Operational Challenge

- Not every location in every hospital is eligible.
o Each CE must evaluate its cost report against their OPA Covered Entity listing and their local outpatient credentialed physician listings.
  - It is important for a CE to differentiate between eligible and non-eligible locations.

• Using manual processes results in variability of application.
  o Manual processes assume everyone acts the same, understands the same information, gets updated at the same time, etc. It is nearly impossible to maintain consistency or compliance using manual processes.
  o Point of Community/Outpatient pharmacy service is outside the CE’s data systems and CP staff are not employees of the CE, making it difficult to educate and control processes.
  o Does the CE want to leave the compliance factor up to the Community/Outpatient pharmacist dispensing the prescription? The CE has no control over this employee, but the responsibility for maintaining compliance resides with the CE.

• Hospitals often have a number of potential discharge locations.
  o Normally there are many discharge locations, making it impossible to track each one if not doing so in an automated way.
  o An entity could either be non-compliant if aggressive in assuming eligibility for all patients at specific locations or alternatively miss benefit if using a conservative manual approach to determining patient eligibility related to locations.

• The number of people involved in discharging a patient adds to the complexity of determining eligibility.
  o People learn and understand differently.
  o Multiple people can increase the risk of different interpretations of Patient Definition and compliance.
  o A hospital may have to consider how to handle recourse with staff when there is (and there will be in a manual situation) a compliance issue.

Hospital Challenges Conclusion

Bringing both the IT and operational components together in a system that can consistently report data needed for compliance is key.

It may be impossible for a CE to find old data to support 340B related to usage at a Community/Outpatient pharmacy. The CE should have a technology system that it can audit any day at any time where both Patient Definition and dispensing information are available in record and report formats from one integrated system.

When preparing for a CP relationship, all CEs should, at a minimum, require the ability to access all 340B-related data for internal audit purposes on an as-needed basis. This should not require any third-party permission or limitation in access. With this data a CE should be able to track the components of compliance it needs.

It is important to note that the current 340B Contract Pharmacy Guidelines contain an expectation that CEs routinely audit these arrangements. Additional information is available at http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.
Section 4:  
Contracted Community/Outpatient Pharmacy Perspective

This section will review contracted Community/Outpatient pharmacy relationship benefits, challenges, and critical concepts to consider from the standpoint of the Community/Outpatient pharmacy.

Since the CP venture requires the involvement of a Community/Outpatient pharmacy it is important for the hospital to also understand some of the basic considerations that could impact the participation of a Community/Outpatient pharmacy in the program.

The reality is that in any partnership, each party must win or benefit in order for the partnership to continue to exist. A CP should anticipate seeing some key benefits as a direct result of its participation.

Potential benefits for a CP range from improved profitability through a new business offering to increased prescription volume. Having a relationship with a local hospital is often an opportunity for a pharmacy to expand its service in a community.

Community/Outpatient pharmacy benefits in CP relationships

- Improved or continued patient loyalty through the PR boost of community involvement.
- New revenue through new patients or increased prescription volume is possible if the hospital advertises the relationship, implements a collaborative discharge program, or sets up a cash plan or discount plan for individuals who otherwise may not get their medication filled or be able to afford their medication.
- Improved front-end purchase potential with good margins for the pharmacy through increased traffic or prescription volume.
- Increased profit margins on existing prescriptions that now fall under the 340B program as well as new prescriptions.
- Convenience to patients and the ability to either save first fill discharge medications from going elsewhere or bring in new customers due to improved access as a result of discharge programs.
- New prescriptions otherwise never filled generating added value for the CP through cash and discount programs.

Key Community/Outpatient pharmacy operational foundation

Most Community/Outpatient pharmacies are service-based businesses where customer loyalty is extremely important. Therefore, it is typically not acceptable to put additional burden on the front line pharmacist that might result in delayed processing time, patient confusion, or any potential negative customer satisfaction situation.
While the needs and priorities of a given CP may vary between independent pharmacies, regional chain pharmacies, or national chain pharmacies, in today’s technological environment there is absolutely no reason for a CP to need to determine eligibility, run manual reports to send to the software vendor, or have negative service impact from CP program participation.

The following is a list of key components every Community/Outpatient pharmacy should consider before entering a CP relationship. It is recommended that CEs understand the needs of their business partners to ensure successful relationships. This paper will evaluate each of these with a brief educational discussion related to the necessity of the component.

## Critical Components for 340B CP Management

- Automated system that reduces manual intervention.
- Seamless dispensing process.
- Preparation for cash flow impact.
- Inventory level management.
- Detailed and timely reporting.
- Understanding a CP's cost of goods.
- Evaluation of switch fee changes.
- Potential added volume and new patients.

### Automated system that reduces manual intervention

Manual intervention by front line pharmacists and technicians is an extremely risky option for both the CE and CP. It is unrealistic to expect the pharmacist dispensing the medication to determine eligibility. The requirements of Patient Definition are complex and difficult if not impossible to determine manually. Any manual processes will directly result in dissatisfied patients, longer processing times, possible patient confusion about what the program is, and a significant compliance risk.

### Questions to Consider – Automated Systems vs. Manual Intervention

- Does the CP want the Community/Outpatient pharmacist put in the position of identifying eligibility based on a manual process such as a specific prescription pad, physician, or manual card system?
- Does the CE want a person who does not work for it determining compliance on its behalf?
- If manual reports or data downloads are required, does this requirement fit into the CP’s workflow and does it really make sense to use this manual process today when it can be fully automated?

### Seamless dispensing process

The dispensing process is typically visible to a CP’s customers through wait times, copays and a myriad of other factors.
It can lead to confusion and dissatisfied Community/Outpatient pharmacy customers if participation in 340B leads to a negative change in the pharmacy patients’ experience with problems such as process delays, copay changes, or wait times, Community/Outpatient pharmacists should not put themselves in a position to explain what 340B is or why one prescription may qualify and the next does not. It is complicated and eligibility determinations may not always be readily apparent. Further, what if a prescription is reversed later or disqualified from 340B for some reason after a pharmacist had explained it as eligible to a customer?

Preparation for cash flow impact

Cash Flow is important to every business, and it is how a CP pays its staff, replenishes its inventory, and keeps its lights on and doors open. Consideration should be given to how the 340B process impacts a CP’s cash flow.

In a normal Community/Outpatient pharmacy workflow without 340B, the pharmacy would dispense a drug, collect payments, and replenish medication from those revenues. There is a change in CP relationships, since the Community/Outpatient pharmacy under 340B typically collects funds from patients on behalf of the CE for those same prescriptions and sends those funds to the CE, who replenishes eligible drugs for the pharmacy.

Questions to Consider – Cash Flow Impact

• When does the pharmacy send the collected revenue to the CE?
• How long on average does it take a CP to collect third-party payments?
• When does the CE replenish the medication to the pharmacy?
• Does the CP keep the dispensing fee agreed upon or send all payments through and need to collect the dispensing fee after?
• Are cash and third-party transactions handled any differently?
• What is the timing between the CP sending cash and receiving drug replenishment?

Inventory level management

Inventory management is a key priority for all Community/Outpatient pharmacies. Poor inventory management can directly impact cash flow and even patient satisfaction if medication is not available when needed. It will be very important for both parties to understand how Community/Outpatient pharmacy inventory replenishment works and how that fits into a CP’s current processes. Since it is typical that items are replenished upon use of a full bottle size, the CP will need to understand how it floats and receives inventory to account for its internal operations.

Questions to Consider – Inventory Level Management

• What is the CP’s replenishment schedule from the CE?
• How does the CP’s receipt of medication coincide with it sending collections to the CE?
• How does the CP know what is coming to it under 340B?
• What if a drug is back ordered?
• Does the CP use the same wholesaler as they will for 340B drugs?
• If the CP changes bottle sizes (50s v. 500s), does the cost difference make sense to have more frequent replenishments?

Detailed and timely reporting

Reporting must be accurate and easily accessible for accounting and operational purposes. Reports should, as an absolute minimum, be up to date every day based on the prior day’s activity.

**Questions to Consider – Reporting**

• What prescriptions were 340B?
• How does 340B impact a CP’s internal accounting?
• What revenue should be sent to the CE and what detail backs that up?
• How does a CP evaluate the impact of 340B on its current business?
• How are a CP’s receivables coordinated with payments to the CE?
• Are cash and/or third-party handled differently?

Understanding a CP’s cost of goods

The cost of goods (COG) for the Community/Outpatient pharmacy should be a consideration in a CP relationship. Depending on the volume of medication that will fall under 340B, it could possibly impact the Community/Outpatient pharmacy’s COG. This happens because the 340B replenishment account is solely the hospital’s account. Only a CE can have a 340B account, and if current volume at the Community/Outpatient pharmacy is now 340B, that will be replenished by the CE going forward under their 340B account and reduce the current purchase volume of the pharmacy, thereby impacting their COG. The total volume may be the same, but the 340B account is not with the CP.

**Questions to Consider – Cost of Goods**

• Is a CP’s COG based on volume?
• Does the CP get rebates today that may be impacted?
• If the Community/Outpatient pharmacy and hospital use different wholesalers, is it possible to negotiate a way to keep the CP’s COG the same for bringing a new client (the CE) on board?
• Can the Community/Outpatient pharmacy switch to the hospital wholesaler (assuming the wholesalers are not the same already) and get a better COG?

Evaluation of switch fee changes

Switching fee impacts are likely, and must be considered in a CP relationship dispensing fee model. Since all decent third-party 340B compliance software solutions get automated information on dispensed medication, they will require data from a CP’s switch. As a CP is billed per transaction, it is likely that its switching fees will increase under these agreements. When considering its dispensing fee, a CP will want to include this increased cost of doing business in its model.
Understanding a CP’s Personal Investment

An independent pharmacy is in a very competitive market today. Since these are typically sole proprietors it is important for the CE to understand that these transactions and the financials involved are coming out of the independent owner’s pocket while the hospital staff member is not putting their personal accounts at risk. This can be very personal for the CP. Giving this consideration and understanding concerns and needs will be important to a long-term, mutually successful relationship.

The other option, which is a bit more complicated, is for the CP to pass the cost increase off to the CE. This option, however, requires a CP to bill the CE and be able to provide detailed back up for the cost. Of important note here, any vendor not getting automated switch data is likely dependent on very manual processes and will require the pharmacy to run, download, and send reports in some other fashion. This manual-based setup is neither optimal or necessary if the CE has contracted with an automated 340B compliance solution.

Potential added volume and new patients

Prescription volume and new patients can drive any Community/Outpatient pharmacy’s success. It is not guaranteed under the 340B program that a CP will get any additional volume just by participating. There are some specific steps a CE and CP can take to be strategic in attempts to capture higher volumes under this program.

A patient’s choice regarding which Community/Outpatient pharmacy to utilize can never be removed, but marketing based on value and convenience of services can be used to capture additional patient volume.

Suggestions for adding volume and new patients through a CP arrangement

- Consider a cash program for indigent patients, as this may allow some patients the opportunity to get prescriptions that they could not otherwise afford.
- Look into marketing the CP partnership that is intended to improve access and services for the Safety Net population of that community.
- Research setting up discharge prescription services for patient convenience.
- Evaluate having the CP be a preferred pharmacy for a CE employee plan.

Note: Employees do not qualify for 340B by being an employee of the CE, but they do represent a potential for prescription volume improvements that may or may not fall under this program.

Recommendations for Community/Outpatient pharmacies evaluating CP arrangements

Here are some simple but key recommendations for potential contract pharmacies to consider. While this list is not comprehensive, it will give CPs a good foundation for getting started and even evaluating their current participation if they are already a CP.

- Consider any manual processes that impact a CP’s workflow.
  - CP’s should never need to download and send reports.
  - A CP’s front line pharmacist should not need to identify 340B eligibility.
- Utilize a CP’s current wholesaler.
  - Use this to negotiate no impact to a CP’s COG.
  - A new relationship with the CE by a wholesaler is desirable.
- Incorporate 340B ordering with regular ordering transactions.
  - Know what is coming and consider that in a CP’s order placement.
Consider package sizes, as it may benefit a CP to utilize a smaller package size to get more frequent replenishments (replenishment is typically done once a full bottle size is used at 340B).

- Consider inventory swell on the start up. Sometimes a CP will be asked to “go back” a few weeks. This could mean a large first order.

- Ideally, work with as few vendors as possible.
  - Using multiple vendors creates added work and complexity.
  - Multiple vendors can lead to duplicate payments on a single receipt by the pharmacy resulting in a financial loss if not closely tracked.

- Avoid getting mixed up with a non-compliant CE.
  - While the CE is solely responsible for compliance, is the marketing perception or risk worth working with a hospital who is either intentionally non-compliant or uses a vendor that is unable to provide for compliance?

- Work with the CE to determine how to potentially generate new volume.
  - Cash programs for indigent.
  - Preferred pharmacy under the employee benefit program.
  - Discharge prescriptions.
  - Coordination with case management discharges.

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**Caution for Pharmacies Contracting with Multiple CEs**

Be careful when partnering with multiple CEs. Depending on the software vendor capability, it is possible for two different CEs to claim the same prescription qualifies.

*Note: This situation is most likely to occur when a vendor with limited compliance capabilities working on behalf of a CE is only matching partial eligibility identifiers such as the doctor, benefit card or prescription pad and not the full Patient Definition.*

In this case a CP could pay out twice on the same prescription even though it will only get paid once. Very few software vendors have capabilities to accurately and completely define a patient. Only work with one software vendor in these cases where they can differentiate between the CEs or decide to only work with one of the CEs.

While compliance is the entity’s full responsibility, if a Community/Outpatient pharmacy knowingly engages with multiple CEs and has duplication errors, it should be able to identify this type of diversion and prevent it by working with the CEs involved. This type of issue will reflect poorly upon the Community/Outpatient pharmacy and may result in a requirement that the pharmacy make restitution to the CE as part of the diversion settlement.
Section 5:
Financial Flow and Dispensing Fees

This section is intended to assist both the CE and CP in understanding the business considerations behind how to develop and/or evaluate dispensing fees for CP services.

CP Cash Flow

The fee a CP receives for processing prescriptions on behalf of the CE is called a dispensing fee.

This dispensing fee in the 340B case is much different than the typical dispensing fee a pharmacy receives in its normal course of business.

A dispensing fee for a CP is the gross revenue it will retain in the case of a 340B prescription, and is important to carefully consider what a dispensing fee should be on the CP end and if the dispensing fee requested is reasonable on the CE end. Dispensing fees can vary widely based on a number of factors, including product mix, type of services provided, and geographic location.

Items to evaluate for determining an appropriate CP dispensing fee

- Typical profitability on the mix of drugs being considered.
  - This should be considered since the expectation for the CP is that, on average, they will do a little better on these prescriptions than they did before. When evaluating current profitability, consider the mix or type of drugs, brand v. generic, and rebates. It’s also helpful to remove non-qualifying payers such as Medicaid from evaluations.
  - Brand and Generic volumes must be considered in relation to the dispensing fee. Based on the mix and current profitability, consider how a flat dispensing fee or a separate brand and generic fee might impact a CP’s business.
  - Brand-only or “best of” scenarios will have higher dispensing fees than doing both brand and generics will, which results in taking both the winners and the losers.
• Any additional switching fees should be included in the dispensing fee consideration. A CP should check with its switch to determine the impact it might see.

• Inventory swell is possible, especially in earlier phases as a CP starts to understand the operational processes a bit better. What, if any, is the financial impact of this swell?

• Cash flow impact may be positive or negative depending on how third-party collection, payment to the CE, and replenishment back to the CP line up. A CP should evaluate and understand how these processes might impact its cash flow.

• Drug purchase volume impact is likely. If a CP’s COG is based on tiers, it is key to understand this and proactively look for options to minimize or remove this impact and consider unavoidable costs in its dispensing fee.

• Added prescription volume or new patients may positively impact a CP’s business. Consideration should be given to programs that may result in new volume.

• Additional work required by the CP if the CE software solution is not optimal, requires manual uploads, downloads, or other work and/or lacks experience with Community/Outpatient pharmacies. This may be a reason not to contract or to consider the impact in a CP’s dispensing fee.

• Current prescription volume is potentially impacted by the program. A CP may view the impact differently if 5 percent versus 50 percent of its prescriptions would fall under this program. The CP should attempt to gain a sense of what the change might look like (the reality is a CP will not be able to know exactly what the change will be, but it should be able to know a ball park estimate).

What is a typical dispensing fee?

There is no correct answer, as it will end up being a function of many factors and is ultimately a business decision.

Using “best of pricing” or “brand only” models will lead to a higher dispensing than a model including all brand and generics.

It is important to find an agreed-upon dispensing fee to foster a successful relationship between the CP and CE, but, in the end, the return doesn’t change much based on the dispensing fee model, and the complications of administering and tracking the program are increased based on the complexity of the dispensing fee model.
Section 6: Types of Vendors

This section is focused on the various 340B software vendors available for hospitals and Community/Outpatient pharmacies considering a CP relationship.

Alongside the rapid growth of the 340B industry and increased compliance mandates has come an onslaught of new types of vendors and consultants related to 340B. Some are specialized companies while others have just added a 340B service onto a current platform that does something unrelated to CE and CPs in the realm of prescription processing.

The challenge here is that software built around FQHCs and CHCs (clinics) is unprepared for the rigors of hospital CE and CP program management, as the former are completely different types of entities and organizations when compared to hospitals.

When communicating with consultants, it is vital to evaluate the person’s experience with hospitals and CPs specifically and ask for credentials related to 340B. CEs need to ensure the consultants they work with have both knowledge and insight into managing programs for their type of organization. Optimally, it would be a consultant who has experience as a hospital leader having participated in 340B for years and made decisions related to 340B management and maximization.

Review of current vendor type models

The following is a description of different vendor types and an overview of their strengths and weaknesses.

Depending on the type of entity, its willingness to take on risk, and desire to use automation, it may have many choices or very few.

**Clinic Model Programs** are the most common and many of these vendors are attempting to cross over into the hospital marketplace. Typically they utilize very manual processes and rely on either the physician’s name and/or prescription pad identification for eligibility determination.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
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</table>
| • Fast implementation  
  • Should be very low cost or nothing up front | • Manual processes for Community/Outpatient pharmacy and hospital  
  • Unable to track full patient definition with hospital data  
  • Audit will be a challenge in that a failure to provide information is a 340B compliance failure  
  • Lost capture or opportunity  
  • Many pharmacies are not willing to participate in manual programs |
**Manual Prescription-Based Programs** are almost identical to clinic programs and depend on the prescription pad alone as the identifying factor of compliance.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weakness</th>
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<tbody>
<tr>
<td>• Limited or no implementation needed</td>
<td>• No compliance factors are reviewed or reportable</td>
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<tr>
<td>• No up front cost to implement</td>
<td>• High risk for CE</td>
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<tr>
<td></td>
<td>• Partial compliance is non-compliance</td>
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<tr>
<td></td>
<td>• Lost capture or opportunity</td>
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<td></td>
<td>• Many pharmacies are not willing to participate in manual programs</td>
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**Prescription-Based Programs with Barcode Verification** are just a small step ahead of the prescription pad alone vendors. The only factor used by these vendors to identify eligibility is the barcode. It is likely a CE using this vendor type will have a person manually placing these barcodes on prescriptions or it will print all prescriptions with this barcode. Either mode does not use the Patient Definition to qualify the dispensation, although it is the CE’s responsibility to verify this. This method might work for clinics, but is not optimal for a hospital arrangement where compliance is desired.

<table>
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<th>Strengths</th>
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<tbody>
<tr>
<td>• Limited or no implementation needed</td>
<td>• No compliance factors are reviewed when qualifying prescription</td>
</tr>
<tr>
<td>• No up front cost to implement</td>
<td>• Patient Definition compliance reporting is not available with prescription information since only the barcode is identified as eligible</td>
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<td></td>
<td>• High risk for CE and additional risk for pharmacy</td>
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<td></td>
<td>• Lost capture or opportunity depending on set up</td>
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<td></td>
<td>• Many pharmacies are not willing to participate in manual programs</td>
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**PBM- and Employee-Based Programs** are typically promoted by PBMs as a “value service add.” These offerings are very broad in the marketplace and since this is a side offering for many vendors, these programs typically lack focus and understanding of the marketplace, regulations, and customer needs.

<table>
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<tr>
<th>Strength</th>
<th>Weakness</th>
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<tr>
<td>• Connected to prescriptions processed</td>
<td>• Limited data connections to hospital</td>
</tr>
<tr>
<td>• Usually no cost or low cost</td>
<td>• Limited (or no) hospital data experience</td>
</tr>
<tr>
<td>• Plan design typically incentivizes employees to opt for clinical services that qualify them as 340B patients and encourages them to utilize the chosen pharmacy partners</td>
<td>• Partial Patient Definition compliance is non-compliance</td>
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<tr>
<td></td>
<td>• Missed capture potential</td>
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<td></td>
<td>• Need for real-time claims from pharmacy</td>
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<td></td>
<td>• Plan designed for employee to be patient may not pass an audit because of a failure to implement a fully compliant program</td>
</tr>
<tr>
<td></td>
<td>• Focus is not on patients where the real opportunity lies</td>
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</table>
Community/Outpatient Pharmacy-Based Programs are uncommon, but when in use they rely on the Community/Outpatient pharmacy partner to deploy a mechanism of defining eligibility based upon some factor. Typically this is a very manual and person-dependent set up, with little to no actual Patient Definition compliance data available in an audit. The covered entity cannot delegate or contract its responsibility for 340B compliance.

<table>
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<th>Strengths</th>
<th>Weakness</th>
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<tbody>
<tr>
<td>• No to little implementation process and time</td>
<td>• Limited (or no) data connections to hospital</td>
</tr>
<tr>
<td>• Usually no cost or low cost</td>
<td>• Limited (or no) hospital data experience</td>
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Rules-Based Compliance Solutions are the newest solutions available and were built from the ground up for 340B compliance. These solutions connect directly to hospital and Community/Outpatient pharmacy information systems to get all necessary components of Patient Definition. Decisions on eligibility are solely based on available data and federally required policies and procedures of the entity.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weakness</th>
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<tbody>
<tr>
<td>• Compliance-focused, hospital data drives eligibility decision</td>
<td>• Set up time to get all necessary data from hospital systems</td>
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<tr>
<td>• Built for hospitals specifically</td>
<td>• Up front costs are sometimes higher than other vendor types</td>
</tr>
<tr>
<td>• Ability to record and report all necessary HRSA audit information</td>
<td>• Audit capability</td>
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<tr>
<td>• Audit capability</td>
<td>• Benefit capture</td>
</tr>
<tr>
<td>• Willingness of contract pharmacies to participate</td>
<td>• Willingness of contract pharmacies to participate</td>
</tr>
<tr>
<td>• Overall compliant benefit to cost is typically higher than other vendor types</td>
<td>• Involves a fox-watching-the-henhouse scenario</td>
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Evaluating Software Options

There are many choices for a CE’s consideration related to 340B CP software. It can be very confusing to differentiate solutions and determine what option will work best for a CE’s specific needs.

It is likely that a CE already has a sense of what matters and how it would like to comply with the 340B program. Below is a list of suggested items to consider as a CE’s minimum requirements when contracting with a 340B software solution related to CPs with hospitals. These items will directly impact a CE’s regulatory, financial, and operational success.
Questions to Consider – Evaluating 340B Software Vendors for CP Management

Compliance
- How does the vendor capture each of the Patient Definition components as defined by HRSA to determine eligibility of each prescription at 340B?
- Does the vendor capture the 340B clinical location source of prescription?
- Does the vendor qualify and capture referral prescriptions?
- Is each 340B purchase reportable with the Patient Definition information to validate or perform self-audits?

Capture
- Will any Community/Outpatient pharmacy work with a CE’s chosen vendor / solution?
- Are the Community/Outpatient pharmacies a CE needs currently live with the vendor?
- Can the software incorporate cash plans for indigent patients?

Workflow
- Who places orders on a CE’s 340B account?
- How does the Community/Outpatient pharmacy know what to send the hospital?
- How does a CE perform self-audits related to Patient Definition compliance?
- How does a CE meet HRSA audit requirements when it is time?
- What is the frequency and detail of financial transactions?

Experience
- How many hospitals and CEs is the vendor live with?
- How many CPs are live with hospitals through the vendor?
- How many active multiple CP relationships with hospitals exist for the vendor?
- How long has the vendor been doing multiple CPs with hospitals?
- How many audits (manufacturer or HRSA) has the vendor been through with clients?

Reports
- Can the vendor report:
  - By CP and total CE relationships with various pharmacies in aggregate?
  - NDCs dispensed and replenished?
  - Slow Movers (items not dispensed for a period of time)?
  - Wholesaler Invoices?
- Does the vendor provide a Financial Dashboard containing:
  - Gross collections?
  - Wholesaler costs?
  - Vendor fees?
  - NET Safety Net Benefit to CE?
- Can the vendor generate an Audit Report including:
  - Data by purchased item linked to Patient Definition?
  - Data by time frame linking all dispensing and Patient Definition information?
  - Data by claim from 340B hospital to dispensation to purchase?
Section 7: Current Regulatory Topics

This section touches on some of the regulatory and legislative issues surrounding 340B CP relationships.

As of the writing of this white paper, there are a few key items under scrutiny and legislative discussion related to the utilization of contract pharmacies.

Below is a description of those items for consideration, and it should be noted that the environment and expectations around each of these items might potentially change in the near future.

Multiple CPs

Multiple contracted Community/Outpatient pharmacies are appropriate and approved for use under 340B, but their use is under scrutiny. During the 2012 annual 340B meeting in Washington, D.C., there was a good deal of conversation around some instances of CEs with 200-300 Community/Outpatient pharmacies in CP arrangements. The question being asked was: “Is this appropriate or is it an overuse of the intended opportunity?”

Discussions about the CP topic included questions about whether or not there might be a potential future limit to the number of CPs a CE may have or if the likelihood of a 340B audit might be higher for a CE with more CPs in place.

Approval by HRSA for CPs

As of October 1, 2012, HRSA has new processes and timeline requirements related to the approval of contracted Community/Outpatient pharmacies. While historically these were approved daily, they are now going to be submitted with deadlines and approved quarterly as such:

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<td>1/1 to 1/15</td>
<td>4/1</td>
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<tr>
<td>4/1 to 4/15</td>
<td>7/1</td>
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<tr>
<td>7/1 to 7/15</td>
<td>10/1</td>
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Applications that miss the 15-day window each quarter must be resubmitted in the following quarter in order to be processed by OPA.
Entities and contract pharmacies now need to plan ahead and prepare to meet HRSA deadlines. A good software vendor should be prepared and able to assist a CE in planning if engaged 60-90 days in advance of these deadlines.

**Percentage Dispensing Fees**

Percentage Dispensing Fees are sometimes deployed by CPs. Based on current regulations there is nothing preventing this practice, however, there is a growing concern that this is taking away revenue from the CE. The primary question is, “Does the dispensing fee percentage need to be open-ended, and is there a point at which the profit is good enough for the CP?”

While HRSA and OPA do not advocate this practice and some speak out against it, there is no current regulation preventing it. This is currently a business decision guided by negotiation between the CP and CE.

**Medicaid Managed Care Organizations (MMCOs)**

Medicaid Managed Care Organizations (MMCOs) historically have not maintained the risk on the drug benefit and thus were not “carved out” or considered to have a need to meet the requirement of passing through actual acquisition costs. However, there seems to be a trend in a few states where this component is being negotiated into contracts with Managed Care Organizations. In some cases it may not be possible to tell the difference between the MMCO and normal third-party plan. This short-sighted lack of a requirement for a separate BIN/PCN for these plans is negatively impacting the benefit obtainable to CEs in most cases.

**Pharmacy Benefits Managers (PBM)s**

PBM$s have surged into the 340B arena in the past few years. PBM$s range in type from value-added services for current and prospective clients to a company with a goal of increasing their profits on the backs of 340B entities.

**Guidance on PBM$s**

Some PBM$s have (intentionally or not) placed themselves in the middle of hospitals’ prescription drug plans and are taking some of the benefit intended for the CE in many cases. It’s important to be aware of some key topics related to PBM$s.

- Community/Outpatient pharmacy claims submission that requires acknowledgement of 340B use.
  - There are two sides to this, and it is possible that PBM$s have an agreement with manufactures not to get both a rebate and a 340B discount on a claim.
  - The other side of this is that some PBM$s are looking to change reimbursement levels when 340B is used in order to keep more profit.
• There is a push to require pharmacies to record prescriptions in the national submission format referred to as NCPDP. There are some issues currently being discussed about this topic, such as:
  o When a medication is dispensed, its 340B status is not accessible – that only occurs when the medication is actually purchased.
    ▪ How will the NCPDP format on all these prescriptions get updated after the fact once a product is ordered under 340B?
  o What happens when a product never meets a bottle size and is reversed under 340B and no longer is a 340B prescription?
  o What happens if a product is discontinued before it is replenished?
  o What is the intention of PBM's related to 340B?
    ▪ They should not be profiting from 340B claims, as the intended use is for the CE.
  o All CEs should keep an eye on this discussion, voice their opinion and protect the integrity of the program. Currently there is a plan for Q4 changes to use this NCPDP 340B identifier.
Section 8: Establishing a Best Case CP Program

Establishment of a 340B relationship with a contracted Community/Outpatient pharmacy can represent a significant opportunity for CEs to offset losses incurred from serving patient populations unable to pay for care and further can present an opportunity for continuation or expansion of services to the communities they serve.

However, embarking on this track requires diligence and careful thought to ensure participation is compliant with full Patient Definition requirements.

It is imperative that hospitals and contract pharmacies consider the complexity involved with the regulatory, operational, and financial challenges that will be presented in these relationships.

The CP arena of the 340B industry has grown significantly since the expansion to allow CEs to work with multiple contract pharmacies in 2010. This expansion has drawn scrutiny around the compliance capabilities of CEs. It is imperative that all CEs do everything possible to ensure compliance in audit situations in order to preserve this very important benefit for their communities.

CP arrangements should only be contemplated with use of an established third-party compliance software vendor that has the proven ability to meet the demands of both hospital and Community/Outpatient pharmacy needs.

Comprehensive minimum requirements should be established by both the hospital and pharmacy when evaluating software and/or 340B participation. It is often hard to avoid the urge for a “quick implementation” option to start achieving the benefit, but this approach is a recipe for disaster. Taking the time to get the correct data, incorporate federally required P&Ps and choose a software that potential Community/Outpatient pharmacy partners are comfortable with will pay off in future success and audit preparedness.

Regular compliance, operational, and financial audits should be performed by all CEs. Hospitals should consider a process for regular audits of their program participation and report at least annually to their executive committee. Part of this regular review should also include discussion and strategy related to how this benefit is enabling continued or improved care to the most in-need patient populations.

Summary

Contracted Community/Outpatient pharmacy relationships can be beneficial for all parties, but it is imperative that each party have a clear understanding of the limitations and inherent challenges presented by any third-party software being considered.

Understanding what HRSA audit requirements are and establishing minimum reporting requirements to meet an audit inquiry are both vitally important. Audit preparedness is a necessity, especially with the current environment of high scrutiny. In other words, compliance is a requirement for participation.
About Sentry

Located in Deerfield Beach, FL, Sentry Data Systems, Inc. is a healthcare intelligence company offering technology solutions that address a wide variety of workflow, compliance, technical, and financial challenges. Sentry’s products serve more than 1,000 Covered Entities and Community/Outpatient pharmacies across the country and have saved clients millions of dollars on over 40 million patients to date. Sentry processes millions of eligibility, financial, clinical, and pharmacy transactions per day.

For additional information on Sentry’s industry-leading technology solutions, go to www.SentryDS.com.