Structuring 340B Contract Pharmacy Arrangements: Meeting Legal and Regulatory Requirements

THURSDAY, JUNE 2, 2016

1pm Eastern  |  12pm Central  |  11am Mountain  |  10am Pacific

Today’s faculty features:

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Outline

I. Structuring and implementing contract pharmacy arrangements
   A. Overview and need for services
   B. Due diligence
   C. Fee structures
   D. What operational and contractual considerations should counsel keep in mind when structuring and implementing these arrangements?
   E. What compliance challenges must be overcome when structuring a contract pharmacy arrangement?

II. 340B entity compliance issues
   A. Certifications
   B. Contractor-associated liability
   C. Covered entity requirements

III. A look ahead
   A. Enforcement and sanctions
   B. What compliance measures is HRSA likely to adopt in the final version of the proposed mega-guidance that was published last year?
Overview and Need For Services
340B Program Overview

The 340B Drug Pricing Program

requires drug manufacturers who participate in Medicaid to provide outpatient drugs to eligible healthcare organizations ("Covered Entities," or "CEs") at significantly reduced prices.
340B Program Overview

❖ CEs receive significant discounts on covered outpatient drugs
  ► Estimated average savings of 25-50%
  ► Estimated $12 billion in 340B drug purchases in 2015

❖ CEs are defined in statute and include
  ► HRSA-supported health centers,
  ► Ryan White clinics and State AIDS Drug Assistance programs,
  ► Medicare/Medicaid Disproportionate Share Hospitals,
  ► children’s hospitals, and
  ► other safety net providers.
340B Program Overview: Contract Pharmacies

- HRSA permits CEs to contract with pharmacies to provide pharmacy services on the CE’s behalf to CE patients.

- Initially, CEs were limited to one contract pharmacy relationship.

- In 2010, HRSA allowed CEs to enter into multiple contract pharmacy relationships.

- Contract pharmacies (“CPs”) are a growth area, but also one under OIG (and manufacturer) scrutiny.
Contract Pharmacy Arrangement: Example Process Flow

- **Wholesaler**
  - CE purchases 340B Drugs
  - Drugs shipped to CP

- **Covered Entity**
  - 340B eligible patient relationship
  - CP remits reimbursement less fee

- **Contract Pharmacy**
  - CP adjudicates script
  - CP dispenses; collects Patient cost-share
  - CP remits reimbursement less fee

- **Patient**
  - Payer reimburses CP

- **Payer**
  - CP adjudicates script
  - Payer reimburses CP
Need For Services

HRSA: “[T]he delivery of pharmacy services is central to the mission” of covered entities, which “rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program [emphasis supplied].”


BUT, in addition to OIG scrutiny, there is growing backlash among some 340B stakeholders to CP arrangements
Due Diligence
Contract Pharmacy Due Diligence

• Three Areas of Inquiry
  ▪ The Pharmacy
  ▪ The Vendor
  ▪ The Covered Entity
The Pharmacy

- What is the business justification for the contract pharmacy relationship?
- What is the pharmacy’s compliance record?
- Is the pharmacy a good fit for the covered entity’s culture?
- What processes does the pharmacy have in place to ensure 340B outpatient drugs are dispensed only to qualifying patients?
- How does the pharmacy store prescription records?
- Is the pharmacy equipped to connect to the covered entity through its EHR?
- What restrictions might exist on the pharmacy through managed care or vendor agreements?
The Vendor

- What is the vendor’s experience and reputation?
- Is the vendor a good cultural fit for the covered entity?
- Does the vendor offer a system that supports compliance?
  - Identifying eligible patients
  - Preventing duplicate discounts
- How does the vendor support inventory management?
- What are the vendor’s reporting capabilities?
- How is the fee structured?
- Does the covered entity control the revenue?
The Covered Entity

- Is the contract pharmacy network exclusive?
- What is the pharmacy’s role and responsibilities in audits?
- How would the arrangement affect the pharmacy’s business model?
- Will the engagement affect any wholesaler arrangements?
- Will the engagement impact any rebates?
- What miscellaneous costs might exist?
  - EHR
  - Additional oversight
- What is the covered entity’s compliance record?
- Is the covered entity a good cultural fit?
Fee Structures
Fee structures

- HRSA permits CEs and CPs wide flexibility to develop mutually acceptable fee structures

- Compensation must comply with state and federal fraud and abuse requirements
Fee structures

✧ In a typical contract pharmacy arrangement, the contract pharmacy receives a **fixed dispensing fee** for each 340B prescription dispensed.

✧ Many contract pharmacy arrangements also use what is known as a “**replenishment model**”
  - CP uses its own inventory initially
  - Accumulator software is used after the fact to tally the eligible 340B patients from records of prior prescriptions
  - CE then replenishes the inventory, in an amount equaling the actual prior usage by such eligible patients, with covered drugs purchased at the discounted 340B price from manufacturers.
## Typical Financial Arrangement – “Pass-Through Model”

<table>
<thead>
<tr>
<th>Transaction</th>
<th>Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP buys initial inventory</td>
<td>$100</td>
</tr>
<tr>
<td>CP bills payer</td>
<td>$120</td>
</tr>
<tr>
<td>CP collects co-pay</td>
<td>$20</td>
</tr>
<tr>
<td>CP collects reimbursement</td>
<td>$100</td>
</tr>
<tr>
<td>CP transfers total reimbursement to CE</td>
<td>$120</td>
</tr>
<tr>
<td>CE pays CP fixed dispensing fee for the 340B prescription (if not already netted out of reimbursement transferred to CE)</td>
<td>$20</td>
</tr>
<tr>
<td>CE pays for replenishment inventory</td>
<td>$60</td>
</tr>
<tr>
<td>Gross Margin to CP (dispensing fee)</td>
<td>$20</td>
</tr>
<tr>
<td>Gross Margin to CE (reimbursement – COGs – dispensing fee)</td>
<td>$40</td>
</tr>
</tbody>
</table>
Other Fee structures

- Tiered Dispensing Fees
- Percentage of Collections Fees
- “Reference Pricing” Model
Operational and Contractual Considerations
Operational Considerations

• The Compliance Challenge
  • Applying the covered entity’s policies and procedures to the contract pharmacy
    • Patient definition
    • GPO prohibition
  • Ensuring adequate oversight of the day-to-day contract pharmacy operations
    • Contract pharmacy registration
  • Conducting internal and external audits
  • Understanding financial expectations
    • Third party payors
    • Financial assistance
    • Dispensing fees
Operational Considerations

• The IT Challenge
  • Incorporating all necessary data components to identify eligible patients
    • Minimizing/eliminating manual processes
  • Understanding inventory management protocols
    • Replenishment
    • True Ups
    • Formulary
  • Making appropriate payments
Operational Considerations

- **The People Challenge**
  - Developing policies and procedures that allow covered entity and pharmacy employees to work as a team
    - Identifying key contacts
    - Understanding when and how audits will be conducted
    - Discussing implementation or operational issues
    - Developing a mechanism to resolve disputes
Contractual Considerations

- **Vendor Agreement**
  - **Fee Structure**
    - Flat fee per claim?
    - Stop loss function?
    - Fees on claim reversals?
    - Application of other federal and state laws
- **Non-Exclusivity**
- **Replenishment**
  - HRSA encourages covered entities and manufacturers to use credit/rebill process for errors made within 30 days.
  - Avoid prolonged look-back periods where an attempt is made to reclassify drugs as 340B eligible.
  - Covered entities are responsible for requesting 340B pricing at the time of original purchase.
- **Reports**
  - Access to all data?
Contractual Considerations

• Contract Pharmacy Agreement
  • HRSA Essential Covered Entity Compliance Elements
• Operational Needs
  • The Compliance Challenge
  • The IT Challenge
  • The People Challenge
• Term and Termination
• Compliance with Laws
• Exclusivity v. Non-Exclusive
Contracting Compliance Challenges
Contracting Compliance Challenges: HRSA’s 12 Essential Compliance Elements

- Ship to, Bill to
- 340B Pricing Restriction
- Tracking System
- Subject to Audits
- Comprehensive Pharmacy Services
- Compliance with law
- Patient Eligibility Verification
- Maintain Auditable Records
- Patient Choice
- Contract Pharmacy Reporting
- Duplicate Discounts Prohibited
- Provision of Agreement to OPA
- Maintain Auditable Records
Typical Roles – Allocation of Functions Among Different Parties Underscores Need for Compliance Coordination

<table>
<thead>
<tr>
<th>Role</th>
<th>Covered Entity</th>
<th>Contract Pharmacy</th>
<th>Admin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine Patient Eligibility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispense Drug and Provide Patient Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Track Replenishment and Prepare Order for Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order Replenishment Drug from Wholesaler</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bill Payer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receive Reimbursement and Collect Copay</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Contracting Compliance Challenges – Focus Areas

- Prevention of Diversion
- Duplicate Discounts, including Managed Medicaid
Contracting Compliance Challenges – Focus Areas

❖ Title to the 340B drugs must remain with CE “at all times”

❖ Mechanics of billing payers
  ► Replenishment Model
  ► Physical Inventory Model

❖ Overpayments by payers
Contracting Compliance Challenges – Focus Areas

- DSCSA (track and trace)

- Compliance with state and federal fraud and abuse laws
Contracting Compliance Challenges

- Covered Entities are ultimately responsible for 340B Program compliance, but Contract Pharmacies are indispensable partners in ensuring compliance.
Certifications
Certifications

[Image of the Opanet.hrsa.gov page]

Program Manager/Authorizing Official

Name: KIM BRYANT
Title: CEO
Phone: 256-218-3789 Ext:
Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Authorized Signature

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. Failure to recertify may be grounds for removal from the 340B Program.

The undersigned further acknowledges the 340B covered entity’s responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:
(1) all information listed on the 340B Program database for the covered entity is complete, accurate, and correct;
(2) the covered entity meets 340B Program eligibility requirements;
(3) the covered entity will comply with all requirements of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act);
(4) the covered entity maintains auditable records pertaining to compliance with the requirements described in paragraph (3) above, pursuant to section 340B(a)(5)(C) of the Public Health Service Act;
(5) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;
(6) the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing; and
(7) the covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to removal from the list of eligible 340B entities.

[Attest and Recertify button]
Certifications

- All information listed on the 340B Program database for the covered entity is complete, accurate and correct.
- The covered entity meets 340B Program eligibility requirements.
- The covered entity will comply with all requirements of the 340B Program, e.g.:
  - Diversion
  - Duplicate discounts
  - GPO prohibition, if applicable
- The covered entity maintains auditable records pertaining to compliance with 340B Program requirements.
- *Contract pharmacy arrangements will be performed in accordance with OPA requirements and guidelines.*
Certifications

• Covered entity will contact OPA as soon as possible if a breach occurs or change in 340B Program eligibility.
• Covered entity may be liable to manufacturers for repayment and could be terminated from participating in the 340B Program.
Contract Pharmacy Registration

- Enrolling in the 340B Program is a multi-step process that varies based on entity type
  - Must meet all eligibility criteria prior to registering with OPA
  - Must register the calendar quarter prior to participating in the 340B Program
  - Poor planning regarding eligibility and prospective registration requirements often result in improper or denied applications and the loss of significant savings / revenue
Contract Pharmacy Registration

- Covered entities must register contract pharmacies prior to use. A new contract pharmacy can only be registered during quarterly periods:

<table>
<thead>
<tr>
<th>Registration Periods</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 1 – 15</td>
<td>April 1</td>
</tr>
<tr>
<td>April 1 – 15</td>
<td>July 1</td>
</tr>
<tr>
<td>July 1 – 15</td>
<td>October 1</td>
</tr>
<tr>
<td>October 1 – 15</td>
<td>January 1</td>
</tr>
</tbody>
</table>
Contractor-Associated Liability
Contractor Liability?

- Compliance with 340B program rules is the sole responsibility of the CE.
- A CP generally does not have direct exposure for program violations.
- Therefore, CEs seek recourse against CPs and TPAs via contract provisions:
  - Indemnification/consequential damages
  - Insurance?
Covered Entity Requirements
Covered Entity Requirements

- Eligibility
- Diversion
- GPO Prohibition*
- Duplicate Discount Prohibition
- Orphan Drug Rule**
- Contract Pharmacy Arrangements
- OPA Database Registration

*DSHs, children’s and cancer hospital only
**SCHs, RRCs, CAHs and cancer hospitals only
Eligibility

• Hospitals
  • Certain Disproportionate Share Hospitals
  • Critical Access Hospitals
  • Rural Referral Centers
  • Sole Community Hospitals
  • Children’s Hospitals
  • Free Standing Cancer Hospitals

• Federal Grantees
  • Comprehensive Hemophilia Treatment Centers
  • Federally Qualified Health Centers
  • Urban/638 Health Center
  • Ryan White Programs
  • Sexually Transmitted Disease/Tuberculosis
  • Title X Family Planning
## Hospital Eligibility

<table>
<thead>
<tr>
<th>Covered Entity</th>
<th>Non-profit / govt contract</th>
<th>DSH%</th>
<th>GPO Exclusion</th>
<th>Orphan Drug Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Access Hospital</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Rural Referral Center</td>
<td>Yes</td>
<td>≥ 8%</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Sole Community Hospital</td>
<td>Yes</td>
<td>≥ 8%</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Free-Standing Cancer Hospitals</td>
<td>Yes</td>
<td>&gt;11.75%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Children’s Hospitals</td>
<td>Yes</td>
<td>&gt;11.75%</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>DSH Hospital</td>
<td>Yes</td>
<td>&gt;11.75%</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Diversion

• Diversion is strictly prohibited!
  • 340B drugs can only be provided to **eligible outpatients**
  • Cannot re-sell, give, or otherwise transfer 340B drugs to any other **entity** or **individual**
  • Cannot loan or borrow 340B drugs to/from another entity
• Must maintain an audit trail for every dispensation
GPO Prohibition

- DSHs, children’s hospitals and freestanding cancer hospitals may not “obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement”
  - February 7, 2013 HRSA Policy Release

- Sanctions for violating GPO prohibition can include, but are not limited to the following:
  - Removal from the program
  - Corrective action plans
  - Repayments to wholesalers/manufacturers

- Examples of when the GPO prohibition applies:
  - 340B outpatients
  - Outpatients that do not meet 340B patient definition
  - Drugs that are not available at 340B pricing (must notify OPA)
  - Carved-out Medicaid patients
GPO Prohibition

• GPOs come in many shapes and sizes
• GPO accounts may include:
  • Traditional GPO accounts (Cardinal, McKesson, AmerisourceBergen, etc.)
  • Generic source accounts
  • Other collectively negotiated drug purchasing accounts (e.g. multi-covered entity health system)
Duplicate Discounts

• Manufacturers only required to provide 340B discount OR Medicaid (MCD) Drug Rebate Program rebate, not both
  • Statute places onus on covered entity and state to ensure no duplicate discounts are obtained
  • Must properly register with OPA/MCD Exclusion File
    • **Carve-in** = 340B drugs to MCD patients; state will *not* seek rebates; on exclusion file
    • **Carve-out** = non-340B drugs to MCD patients; state *should* seek rebates; *not* on exclusion file
  • Contract pharmacies must carve-out unless a limited exception is met
Orphan Drug Exclusion

• An orphan drug is a drug designated by the FDA to treat a specific rare disease or condition
• Orphan drugs cannot be purchased at 340B rates if the covered entity is a rural referral center, sole community hospital, critical access hospital or free-standing cancer hospital.
• Manufacturers are not required to provide these covered entities orphan drugs under the 340B Program.
  • A manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals
Contract Pharmacy Arrangements

- Examples of published OPA findings include:
  - Covered entity was using a pharmacy with which it had a written contract in place, but the pharmacy was not listed on the 340B database
  - Covered entity registered contract pharmacies on the 340B database without having written contracts in place
  - Patients were ineligible for 340B
Enforcement and Sanctions
Enforcement and Sanctions - HRSA

/>. CEs are subject to audit by HRSA for compliance with 340B Program requirements, including CP requirements.

/>. HRSA regularly sanctions CEs for failing to comply with CP registration and oversight requirements.

/>. Sanctions include: manufacturer repayment; CE or CP termination from the 340B program; corrective action plan
Enforcement and Sanctions - Manufacturers

- CEs are also subject to audit by manufacturers for violation of diversion or duplicate discount prohibitions.

- At least 45 days prior to conducting an audit, manufacturers must submit audit work plans to HRSA for review.

- Manufacturer audits must be performed by an independent auditor at the manufacturer’s expense.

- CEs must respond to audit findings within 30 days.

- Unlike HRSA audits, results of manufacturer audits are not publically available.
Enforcement and Sanctions - Manufacturers

- Manufacturer Audit Guidelines:
  - Number of Audits – may only conduct audits when “reasonable cause” to believe a CE has violated 340B program requirements (examples of “reasonable cause” included in 2015 proposed mega-guidance)
  - Scope of Audits – audit work plan must be approved by HRSA. Limited to the manufacturer's drugs (not CE’s entire 340B operations)
  - Duration of Audits – audit duration of no more than 1 year; performed with the minimum time and intrusion necessary
Enforcement and Sanctions - Manufacturers

- **Post-Audit Procedures**
  - Manufacturer submits copy of final audit to CE, and CE has 30 days to respond with a corrective action proposal or grounds for disagreement.
  
    - Manufacturer submits copies of final audit report & CE response to HRSA

- **Potential sanctions (HRSA determines penalty):** manufacturer repayment; termination of participation in 340B Program; corrective action plan
Enforcement and Sanctions

- HRSA conducted 198 audits of CEs in FY 2015.

  - HRSA identified non-compliance with 340B Program requirements in more than 77% of audited CEs.
Examples of HRSA Sanctions

Decatur Memorial Hospital (FY 2016)

- Audit Findings:
  - Insufficient contract pharmacy oversight
  - Diversion
  - Duplicate Discounts

- Sanction Imposed:
  - Termination of CPs from 340B Programs
  - Manufacturer Repayments
Examples of HRSA Sanctions

- **Elica Health Centers** (FY 2016)
  - Audit Findings:
    - Insufficient contract pharmacy oversight
    - Incorrect 340B database records
  - Sanction Imposed:
    - Termination of CPs from 340B Programs
Examples of HRSA Sanctions

- North Shore Medical Center (FY 2016)
  - Audit Findings:
    - Diversion
      - 340B drugs dispensed at contract pharmacies for prescriptions written at ineligible sites.
  - Sanction Imposed:
    - Manufacturer Repayments
Examples of HRSA Sanctions

⚽ St. Joseph’s Medical Center (FY 2016)

► Audit Findings:
  - Incorrect 340B database records
    - Registered pharmacies without a written agreement in place

► Sanction Imposed:
  - Termination of CPs from 340B Programs
Omnibus Guidance
## Road to the Omnibus Guidance

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Congress expanded the 340B Program as part of the Affordable Care Act</td>
</tr>
<tr>
<td>September 2011</td>
<td>GAO issues report to Congress on 340B Program</td>
</tr>
<tr>
<td>2012</td>
<td>HRSA begins auditing covered entities for program compliance</td>
</tr>
<tr>
<td>July 2013</td>
<td>HRSA issues orphan drug regulation</td>
</tr>
<tr>
<td>September 2013</td>
<td>PhRMA initiates orphan drug litigation</td>
</tr>
<tr>
<td>April 2014</td>
<td>HRSA submits “Mega-Reg” to OMB</td>
</tr>
<tr>
<td>May 2015</td>
<td>U.S. District Court invalidates the orphan drug regulation</td>
</tr>
</tbody>
</table>
Omnibus Guidance Overview

- Part A – 340B Program Eligibility and Registration
- Part B – Drugs Eligible for Purchase under 340B
- Part C – Individuals Eligible to Receive 340B Drugs
- Part D – Covered Entity Requirements
- Part E – Contract Pharmacy Arrangements
- Part F – Manufacturer Responsibilities
- Part G – Rebate Option for AIDS Drug Assistance Programs
- Part H – Program Integrity
Omnibus Guidance

• The draft omnibus guidance contained little that directly affected contract pharmacy arrangements.
  • HRSA did not limit the number of contract pharmacies.
  • HRSA did require covered entities to register contract pharmacies.

• The draft omnibus guidance did contain many provisions that will impact contract pharmacies:
  • Revised definition for patient
  • Disproportionate share hospital eligibility
  • Medicaid MCO carve out for contract pharmacy arrangements
  • Record keeping requirements
Future of the Omnibus Guidance

- HRSA’s decision to delay finalizing the Omnibus Guidance may reflect a desire to have Congress make statutory changes to the 340B Program.
  - 21st Century Cares Act as example
- However, HRSA auditors are already examining covered entity compliance relating to key provisions of the Omnibus Guidance, i.e. discharge prescriptions.
- If finalized, the Omnibus Guidance will likely not make dramatic changes to contract pharmacy arrangements.
Questions?

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Claire F. Miley, cmiley@bassberry.com