Changes to the 340B Program: What Your Practice & Hospital Need to Know

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Off-Label Use Disclosure(s)

I do not intend to discuss an off-label use of a product during this activity.

Financial Disclosure(s)

I have not had any relevant financial relations during the past 12 months to disclose.
A Golden Opportunity or The Perfect Storm?
Why the sudden and expanded interest in 340B?

• frustration that my non-340B site is paying considerably more for product
• shifts in eligibility
• astronomical rise in oncology product availability and pricing
• changing landscape of who owns who

Does a 340B hospital buying a practice or clinic automatically make them eligible for drug discounts? Not necessarily!
A significant portion of the world has price controls on pharmaceuticals. The US doesn’t, except for the military and VA & through the 340B Program.
What’s the 340B Drug Pricing Program??
An important benefit with significant responsibility!!

• Overseen by HRSA (Health Resources and Services Administration), within HHS (Department of Health and Human Services)

• Participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs

• Program’s intent is to allow safety net entities to increase patient services with savings they achieve by buying product at a lower cost

• The three components of the program include
  • Federal Team/OPA
  • Pharmacy Services Support Center (PSSC/PharmTA)
  • 340B Prime Vendor Program (PVP)
Eligible Entities

Federal Grantees

- Hemophilia Treatment Centers
- Federally Qualified Health Centers/ Look A-likes
- Ryan White Programs
- Sexually Transmitted Disease/Tuberculosis
- Title X Family Planning
- Urban/ 638 Health Center
- Native Hawaiian Health Centers

Non-grantees (tax status must be not-for-profit)

- Disproportionate Share Hospitals (DSH adjustment % > 11.75%)
- Critical Access Hospitals
- Rural Referral Centers
- Sole Community Hospitals
- Children’s Hospitals
- Free Standing Cancer Hospitals
Requirements for Manufacturers

- obligated to calculate 340B prices accurately and to communicate prices to distributors

- at a minimum, the discount is
  - 23.1% for brand name drugs (except clotting factor and drugs approved exclusively for pediatric use for which the basic rebate is 17.1% of AMP)
  - 13% for generic and over-the-counter drugs
  - additional discounts can be negotiated, some are up to 60% below retail prices & 51% less than AWP

- with adequate inventory must sell product to enrolled Covered Entities

- cannot condition sales on a Covered Entity’s promise of compliance

- right to audit a Covered Entity if reasonable evidence suggests non-compliance with prohibition against duplicate discounts or diversion
Are there other opportunities for savings?

• Yes!

• Since the 340B Program requires that the participating facility cease using GPO pricing for all products in the participating area, it allows the creation of a 340B “GPO”

• Currently this is APEXUS, chosen by HRSA
  • Negotiate sub-ceiling discounts of up to 60%
  • Provide education
  • Operate a help/call center
340B Program Oversight: Who does what?

HRSA oversees regulations & guidances, manages covered entity & manufacturer eligibility & enrollment

Manufacturers audit covered entities for suspected “diversion” or “duplicate discounts” HRSA intervenes as needed
340B oversight: not what it used to be!

Why the changes? More users = more oversight needed

March 2010: ACA expansion of 340B program & HRSA permits contracting with multiple pharmacies

What changed?

6/2011: OIG reports failure of self-policing to ensure avoidance of Medicaid duplicate discounts

9/2011: GAO says greater oversight by OPA and manufacturers needed

1/2012: annual enrollment recertification begins and first audits of 340B covered entities

5/2012: OPA approves first manufacturer audit plan

9/2012: Senator Grassley sends letters of inquiry with specific detailed data requests to facilities

2/2014: OIG issues report to HRSA requesting improvements
340B Drug Pricing Program: Important Benefit, Significant Responsibility

The 340B Program, administered by the Health Resources and Services Administration (HRSA), plays an integral role in supporting our health care safety net. These designated hospitals, clinics and other providers work with very limited resources to confront the most intractable health problems facing millions of Americans. The 340B Program helps these health care providers stretch scarce federal resources by allowing eligible entities to purchase drugs for outpatient use at a significant discount. Studies show that entities participating in the 340B Program are able to expand the type and volume of care they provide to the most vulnerable patient populations as a result of access to these lower cost medications. The number of providers participating in this program has increased in recent years. The vast majority of these providers (82 percent) dispense these discounted drugs through an in-house pharmacy; a small minority of covered entities (18 percent) contract with pharmacies to dispense these discounted drugs to eligible patients, and of those, 75 percent use fewer than five contract pharmacy arrangements.

The 340B Program provides eligible entities with an important benefit that comes with significant responsibility. To ensure that both 340B covered entities and participating manufacturers are in compliance with program requirements, HRSA has, in recent years, made a number of noteworthy investments. All entity types now are required to recertify annually, attesting to compliance with all program requirements. In addition, in Fiscal Year 2012, HRSA began conducting a systematic approach to auditing covered entities, including risk-based and
What do I need to do?

• To participate in the 340B Program, covered entities must register with HRSA

• HRSA adds covered entities to its database after receiving and approving their registration forms

• Covered entities must annually sign an agreement certifying that they meet 340B Program requirements and that their information in the database is correct

• Once approved, covered entities may purchase covered outpatient drugs under the 340B Program at or below 340B ceiling price

• 340B ceiling prices are calculated using a statutorily defined formula. Drug manufacturers participating in Medicaid must sell covered outpatient drugs to covered entities at or below the 340B ceiling price
Program Prohibitions

• Diversion
  • Drug provided to individuals who are not patients
  • Drug dispensed in an area of a larger facility that is an integral part of the eligible and participating entity (e.g. an inpatient service, a non-covered clinic)
  • Entities are encouraged to enroll all eligible outpatient or children sites

• Duplicate Discounts
  • Accessing the 340B Discount + Medicaid Rebate on same drug
  • Covered Entities must report Medicaid billing status
  • HRSA recommends that covered entities refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits
How can I determine if a patient is eligible for medications bought through the 340B program?

Use this algorithm presented in a 340B peer to peer webinar

340B Patient Eligibility: Case Studies for Hospitals webinar 10/30/13
340B Prescription Verification Algorithm

**Prescription/Drug Order**

- **Is the prescription from a 340B covered entity?**
  - **NO** → **STOP**
  - **YES**

- **Is the drug for outpatient use?**
  - **NO** → **STOP**
  - **YES**

- **Does the covered entity maintain a record of the individual’s health care?**
  - **NO** → **STOP**
  - **YES**

- **Did the individual receive health care services from the covered entity?**
  - **NO** → **STOP**
  - **YES**

**Questions to Ask Yourself**

- Does the prescription/drug order originate from a covered entity currently registered on the OPA database?
- Is the prescription from an off-site outpatient facility eligible and registered for 340B?
- Does the prescription result from a referral arrangement?
- Is the prescription for inpatient or outpatient use?
- Does the health record document the care provided, and when appropriate, the prescriptions written?
- Is the covered entity providing more health care services than the dispensing of the prescription for subsequent self-administration or administration in the home setting?
What is a Duplicate Discount?

• A Duplicate Discount occurs when both the 340B discount and a Medicaid rebate are paid on the same unit of utilization.

• Example:
  – Drug A WAC = $100
  – Drug A 340B price = $40  (60% off WAC)
  – Drug A Medicaid rebate = $55  (55% of WAC)
  – If Duplicate Discount occurs, manufacturer loses $15 per unit sold  (100 - $60 - $55 = -$15)
Self-Auditing to Avoid Duplicate Discount in the 340B Program

August 27, 2014

3 PM – 4 PM Eastern

*The 340B Peer-to-Peer Resource Network operates under a Health Resources and Services Administration contract with the American Pharmacists Association Federal Contracts and Grants. The intent of this program is for 340B Leading Practice Sites to share their operational best practices and not the official policies of the Office of Pharmacy Affairs. The mention of trade names, commercial practices, or organizations does not imply endorsement by the U.S. Government. Additionally, your practice setting may require differences to ensure 340B program integrity and meet all state or federal requirements.
Definition of a Duplicate Discount

A duplicate discount occurs when the same drug is:

- Purchased with an up-front 340B discount
- Credited with a back-end transaction Medicaid rebate

Covered entities are ultimately responsible for prevention of duplicate discount.
### Appropriate Listing in Medicaid Exclusion File

<table>
<thead>
<tr>
<th>Carve-In Status</th>
<th>Carve-Out Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>340B drugs are also provided to Medicaid patients</td>
<td>Medicaid patients are excluded and always receive non-340B drugs</td>
</tr>
<tr>
<td>- Answered “Yes” to the question “Will you bill Medicaid for drugs purchased at 340B drug price?”</td>
<td>- Answered “No” to the question “Will you bill Medicaid for drugs purchased at 340B drug price?”</td>
</tr>
<tr>
<td>- List all NPIs/Medicaid provider numbers used to bill 340B drugs</td>
<td>- Do not list any NPIs/Medicaid provider numbers</td>
</tr>
<tr>
<td>- For each registered facility</td>
<td>- For each registered facility</td>
</tr>
</tbody>
</table>

A consequence of a “carve-in” program is that covered entities must identify their “carve-in” claims to the Medicaid agency for proper adjudication of the claim.
Complexity of Duplicate Discount Prevention

**Fee for Service**
State may have specific policies such as billing at actual acquisition cost or using modifier

**Medicaid Managed Care**
Entity should reach out to the Medicaid managed care organization to verify that they are not seeking rebates and document their verification

**Physician Administered**
State may have different policies for physician administered drugs than for retail pharmacy transactions

**Medicaid Billing**

**Retail**
(In-House vs. Contract Pharmacy) Carve-out Medicaid at contract pharmacies or report to HRSA alternative arrangement that will be used to prevent duplicate discount use
Conclusion: Self-Auditing for Duplicate Discount Prevention

<table>
<thead>
<tr>
<th>Fee for Service</th>
<th>Medicaid Managed Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is your state specific 340B policy? Are you registered on OPA database, according to your billing practices?</td>
<td>Do you serve Medicaid managed care patients and are the Medicaid managed care organizations seeking rebates?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physician Administered</th>
<th>Retail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you administer 340B drugs to Medicaid patients? Is so, what is your state specific policy for 340B administered drugs?</td>
<td>Do you dispense 340B drugs from in-house pharmacy(ies)? From contract pharmacy(ies)? Do you have a mechanism in place to prevent duplicate discount?</td>
</tr>
</tbody>
</table>
Conclusion:
Self-Auditing for Duplicate Discount Prevention

Medicaid Exclusion File

- Is covered entity status consistent with Medicaid billing practices for each facility / pharmacy?
- **340B drugs are provided to Medicaid patients**: did entity respond “YES” on Medicaid Exclusion File indicating a **carve-in status**?
- Are all Medicaid/NPI numbers used for billing Medicaid listed? Are all numbers listed accurate?
- **340B drugs NOT administered/dispensed to Medicaid patients**: did entity respond “NO” on Medicaid Exclusion File indicating a **carve-out status**?
- There should not be any Medicaid/NPI numbers listed

Policy & Procedures

- Specific to prevention of duplicate discount
- Is the entity Medicaid Exclusion File status defined (carve-in or carve-out) and indicated for each facility / pharmacy registered?
- Are state Medicaid 340B requirements included (if applicable)?
- Are the mechanisms used to prevent duplicate discount described?
- Are the monitoring activities to verify duplicate discount prevention, indicated?

Monitoring

- Is the Medicaid Exclusion File status consistent with billing practices?
- Are the Medicaid/NPI numbers accurate and up-to-date on OPA database if carving-in?
- Carve-out: Medicaid claims do NOT include 340B dispensations
- Carve-in: all 340B billing transactions appropriately identified; non-340B transactions are not flagged as 340B
- Contract pharmacy transactions are reviewed for Medicaid exclusion unless arrangement with state Medicaid and OPA
Prohibition of duplicate discounts: How does it work?

• Subjecting drug manufacturers to duplicate discounts on 340B-purchased drugs is prohibited by law

• Duplicate discounts occur when a drug manufacturer pays a State Medicaid agency a rebate under the Medicaid drug rebate program on a drug sold at the already-discounted 340B price

• Risk of duplicate discounts applies to both MCO Medicaid and traditional fee-for-service Medicaid (FFS Medicaid)

• Covered entities choose whether to dispense 340B-purchased drugs to Medicaid beneficiaries & indicate their choice in HRSA’s covered entity database

• State Medicaid agencies use this information to identify Medicaid payments for 340B-purchased drugs and exclude those drugs from rebate requests to drug manufacturers
Manufacturer Expectations when Issues are Detected

• If an issue is detected, Manufacturer first engages Covered Entity in informal dispute resolution.
  • Manufacturer may send a letter or request in-person meeting
  • Manufacturer seeking data/policies to address issue(s)

• Return/refund of the 340B discount is the expected remedy when duplicate discounts or diversion are determined
  • Covered entity may need to disclose on next annual enrollment recertification

• Unresolved informal disputes with Covered Entities may form the basis for a manufacturer audit
What Parts of the 340B Program Need Clarification?

• contract pharmacy arrangements
  • create complications in preventing diversion
  • since covered entities address these complications in different ways, they produce “inconsistency” as to which prescriptions are eligible for the program.
  • create complications in preventing duplicate discounts
  • May not offer the 340B price to uninsured patients
“No one knows how many retail, third-party-paid prescriptions are being resubmitted for 340B rebates. But by building mega-networks that extend far beyond their community, hospitals have the opportunity to profit on an increasing share of prescriptions paid by Medicaid, Part D plans and commercial payers. It raises serious questions about the economic motivations for this explosive network growth.”

Today's Datapoint
AIS August 5, 2014

• 290 ... health care providers (which is 1.2% of all 340B covered entities) account for nearly half of the drug discount program’s **35,000 contract pharmacy** arrangements, according to an analysis of Health Resources and Services Administration data conducted by Pembroke Consulting, Inc.
Could the 340B Program expand in scope?

Only through changes in

- Eligibility criteria
- Patient definition
340B Drug Pricing Program: Change & Evolution

- **1992**: Veterans Healthcare Act
  - Section 340B

- **1996**: Contract Pharmacies Added

- **2005**: Marketing Campaign to Increase Awareness & Enrollment

- **2009**: Children’s Hospitals Added

- **2010**: Patient Protection and Affordable Care Act
  - Multiple Contract Pharmacies & 5 New Entity Types

©Genentech USA, Inc., 2012
Growth of 340B Covered Entities

Projected Growth of Section 340B Covered Entities
Source: HRSA Office of Pharmacy Affairs Quarterly Data – 340B Drug Pricing Program Activity

©Genentech USA, Inc., 2012
### 10 States With The Highest Uninsured Rates Post-ACA

<table>
<thead>
<tr>
<th>State</th>
<th>Pre-ACA uninsured rate:</th>
<th>Post-ACA projected uninsured rate:</th>
<th>Difference before and after:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Texas</td>
<td>26.8%</td>
<td>24.81%</td>
<td><strong>-1.99%</strong></td>
</tr>
<tr>
<td><strong>2</strong> Mississippi</td>
<td>18.11%</td>
<td>21.46%</td>
<td><strong>3.34%</strong></td>
</tr>
<tr>
<td><strong>3</strong> Louisiana</td>
<td>22.41%</td>
<td>20.91%</td>
<td><strong>-1.50%</strong></td>
</tr>
<tr>
<td><strong>4</strong> Florida</td>
<td>24.73%</td>
<td>19.61%</td>
<td><strong>-5.12%</strong></td>
</tr>
<tr>
<td><strong>5</strong> New Mexico</td>
<td>24.29%</td>
<td>19.59%</td>
<td><strong>-4.69%</strong></td>
</tr>
<tr>
<td><strong>6</strong> Nevada</td>
<td>26.52%</td>
<td>19.58%</td>
<td><strong>-6.94%</strong></td>
</tr>
<tr>
<td><strong>7</strong> Alaska</td>
<td>20.48%</td>
<td>18.96%</td>
<td><strong>-1.52%</strong></td>
</tr>
<tr>
<td><strong>8</strong> Oklahoma</td>
<td>19.76%</td>
<td>18.33%</td>
<td><strong>-1.43%</strong></td>
</tr>
<tr>
<td><strong>9</strong> Wyoming</td>
<td>18.92%</td>
<td>18.29%</td>
<td><strong>-0.63%</strong></td>
</tr>
<tr>
<td><strong>10</strong> Georgia</td>
<td>21.66%</td>
<td>18.16%</td>
<td><strong>-3.50%</strong></td>
</tr>
</tbody>
</table>
HHS To Hold Off On 340B Regulation, Propose Guidance Next Year

• 11/14: Health and Human Services has “scrapped plans to issue sweeping regulations clarifying the federal 340B drug discount program” following a Federal ruling against the agency that struck down a regulation that “required drugmakers to offer reduced prices for orphan drugs if they were used for non-orphan conditions or diseases.”

• In a statement, HHS’ Health Resources and Services Administration “said that, rather than issue the omnibus regulation initially drafted, the agency will instead propose guidance next year that will address” the “key policy issues raised by various stakeholders committed to the integrity of the 340B program.”

• Separately, the agency plans to “issue proposed rules related to civil monetary penalties for manufacturers, how the ceiling prices of 340B drugs are calculated and dispute resolution.”
Proposed 340B 'mega-reg' has been withdrawn from consideration by OMB

- A proposed “mega-reg” that would have addressed certain inconsistencies in the 340B Drug Pricing Program has been withdrawn from consideration by the Office of Management and Budget (OMB).

- HHS’s Health Resources and Services Administration (HRSA) submitted the proposed rule for OMB review in April, but it was withdrawn on Nov. 13, according to Reginfo.gov.

- Industry insiders had predicted that the rule would not be released in its entirety due to ongoing litigation around HRSA’s “interpretative” version of a separate 340B rule on orphan drugs (DBN 11/7/14, p. 7).

- The mega-reg was supposed to address
  - the definition of an eligible 340B patient,
  - hospital eligibility criteria
  - eligibility of off-site facilities
  - compliance requirements for contract pharmacy arrangements, which have rapidly expanded in recent years and could lead to duplicate manufacturer discounts being paid on the same prescriptions to commercial payers and 340B entities (DBN 7/25/14, p. 1).
Proposed 340B 'mega-reg' has been withdrawn from consideration by OMB

- According to HRSA’s website, (www.hrsa.gov) the agency now plans
  - to issue a proposed guidance for notice and comment in 2015 “that will address key policy issues raised by various stakeholders committed to the integrity of the 340B program.”
  - Additionally, HRSA on Dec. 17 will host a webinar on the 340B patient definition and referral relationships.
An individual is a “patient” of a covered entity if:

1. The covered entity has established a relationship with the individual, such that the covered entity *maintains records of the health care*; and

2. The individual receives health care services from a health care Provider who is either employed by the covered entity or health care under contractual or *other arrangements (e.g. referral for consultation)* such that *responsibility for the care provided remains with the covered entity*; and

3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. (Disproportionate share hospitals are exempt from this Requirement.)

Could the 340B Program shrink? Absolutely!!

With changes in

- Eligibility criteria
- Patient definition
- Distribution models chosen by manufacturers
  - Open vs closed vs specialty pharmacy
- Language on orphan drugs or their off label use
  - Carefully follow the number of new agents coming to market with this designation & the FDA’s stance
Hospitals Upset By Increase In Cancer Medication Prices

- **TIME** (10/28) reports that some US “hospitals are seriously ticked off at Genentech...for implementing a stealth price hike for three critical cancer” medication. Last month, the company “told hospitals and oncology clinics that as of October 1, they can only buy Avastin [bevacizumab], Herceptin [trastuzumab] and Rituxan [rituximab]...through specialty distributors instead of general line wholesalers they’ve been using for years.” The change “means hospitals will lose out on standard industry discounts—which Genentech and its distributors will then pocket.”
FY 2015 Appropriations “CROMNIBUS” and the 340B DRUG PROGRAM

- The fight between PhRMA and healthcare providers over the 340B drug program continues to influence Congressional action
- In response to PhRMA’s allegations that HRSA is unable to demonstrate that the 340B program benefits the most vulnerable patients, the appropriators made several 340B related requests
  - HJES directs HRSA to provide the Committees with a briefing, by March 3, 2015, on its progress implementing FY 2014 requirements to make 340B ceiling prices available to covered entities through a secure website
  - HRSA is directed to work with covered entities to better understand the way 340B discounted sales directly support patient benefits in an effort to examine its ability to ensure patients have access to 340B savings for outpatient drugs
Rumbles in the 340B Program

• Only some 340B-covered entities work to serve large numbers of uninsured & medically underserved patients,

• National data show that many 340B hospitals aren't quite so charitable

• Possible that ¼ of all DSH hospitals benefiting from 340B are providing charity care at only a rate of 1% or less of their total patient costs.
Any top-grossing nonprofit hospitals (reported to CMS) 340B? Some!

- UPMC Presbyterian, including Shadyside + Montefiore, $12.21 billion
- The Cleveland Clinic, Ohio, $11.63 billion
- Cedars-Sinai Medical Center, Los Angeles, $10.59 billion
- Florida Hospital Orlando (including Altamonte, Apopka, Celebration Health, East Orlando Kissimmee and Winter Park Memorial Hospital), $10.17 billion
- Stanford (California) Hospital, $9.41 billion
- New York-Presbyterian Hospital, NYC (including Morgan Stanley Children's Hospital, NY-Presbyterian Hospital/Columbia University Medical Center and NY-Presbyterian Hospital/Payne Whitney Westchester), $8.91 billion
- Yale-New Haven (Connecticut) Hospital (including Yale-New Haven Psychiatric Hospital), $8.15 billion
- Hospital of the University of Pennsylvania in Philadelphia (including Penn Institute for Rehabilitation Medicine), $7.97 billion
- Montefiore Hospital-Moses Campus, Bronx, NY (including Children's Hospital at Montefiore, Montefiore Medical Center-Weiler Division Hospital, Montefiore Medical Center-North Division Hospital and Montefiore Westchester Square Campus), $7.68 billion
- UCSF Medical Center at Parnassus (including Mount Zion), $7.67 billion
340B program entices hospitals to snap up oncology practices


• Hospitals have been accused of using 340B discounts to line their pockets with profits

• But facilities are also apparently using the money for another purpose: to acquire community oncology practices, OncLive reported

• # of acquired oncology practices increased considerably between 2009 and 2012, trend likely continued unabated last year, according to OncLive, citing a recent report from Berkeley Research Group
Physician practices are currently in demand by hospitals, which see such deals as a good way to control costs while guaranteeing medical staff stability.

However, 340B adds another reason for hospitals to focus on oncology practices—it provides a huge edge in a facet of healthcare delivery where drugs are often the largest expense.

"That cost structure disparity creates an incentive for 340B hospitals to acquire oncologists, whether practices or individual physicians, and as 340B hospitals' relative market share grows, it puts additional pressure on those community oncologists who have remained independent," Aaron Vandervelde, author of the report, told OncLive.
Services Performed in Off - campus Provider - Based Departments

• CMS will collect data on services furnished in off-campus provider-based departments by requiring hospitals to report a modifier for those services furnished in an off-campus provider-based department of the hospital and by requiring physicians and other billing practitioners to report these services using a new place of service code on professional claims.

• Data collection will be voluntary for hospitals in 2015 and required beginning on January 1, 2016.

• The new place of service codes will be used for professional claims as soon as it is available, but not before January 1, 2016.
R umbles in the 340B Program

• 340B safety net hospitals have an additional financial burden of serving a higher % of Medicaid + low-income, Medicare patients

• This commitment’s a requirement for 340B participation

• 340B drug discounts
  • Help make oncology care sustainable within safety net hospitals with no tax liability
  • Don’t raise the cost of care but help to offset rising care + drug costs, expand community services and ensure the organization’s financial stability
  • Are exactly what the name implies: discounted pricing on eligible drugs with a cost that’s measured in slightly diminished profits for Big Pharma
Rumbles in the 340B Program

- The 340B program, intended to provide low-cost drugs for poor patients, has been under fire both from Congress and the press over the past 18 months.

- Fueled in part by concerns of critics that some safety net providers may not be using the program as intended (http://www.gao.gov/products/GAO-11-836).

- At issue?
  - The practice of some hospitals to use their 340B discount to purchase drugs in bulk, resell them to insured patients and pocket the difference.
Rumbles in the 340B Program

• The Pharmaceutical Research and Manufacturers of America, the drug industry's lobbying group, sued HHS last year, and a federal judge ruled against HHS in May 2014

• The administration, however, took the position that the outcome allowed it to reissue the same policy in a different form
Drug discount program needs help, researchers say

• Regulators need to provide a clearer direction for the 22-year-old federal program that provides drug discounts to safety net hospitals, researchers argued in a new paper.

• The RAND Corp. said the so-called 340B program faces uncertainty when it comes to eligibility and transparency that pose challenges to healthcare providers and drug companies.

• "Policymakers need a clear, objective description of the 340B program and challenges it faces on the road ahead," Andrew Mulcahy, the report’s lead author
Rand 8.2014 cont’d

• "There are increasingly divergent views on the program’s purpose and the role it should play in supporting safety net providers."

• The study comes as HRSA develops additional regulations to shape the 340B program.

• The agency issued a rule last month allowing hospitals to continue to use the program to purchase "orphan drugs" more cheaply.

• RAND said regulators must consider how best to determine eligibility for the program, and how to address record-keeping challenges that resulted from the "orphan drug" rule.

• http://www.news-line.com/?s340382

•
Interpretive Rule

http://tinyurl.com/lfqugdh

• HHS interprets section 340B(e) of the Public Health Service Act as excluding drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

• Section 340B(e) does not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated under section 526 of the FFDCA.
Will The Majority Of Future Drugs Meet Orphan Drug Criteria?

• Orphan Drug Market Access: Payer Insights on the Present and Future is a report that examines the regulation, pricing, reimbursement, players and stakeholder/payer interests that are shaping the current and future direction of the orphan drug sector.

• This report offers insights from US and European healthcare payers and includes illustrative case studies that highlight key aspects of the orphan drug market.
340B and Orphan drugs

- Hospitals will continue to use 340B to purchase so-called "orphan drugs" at a deep discount even if they’re not being used for their specific purpose.
- DHHS in tandem with HRSA, issued an interpretive rule.
  - Orphan drugs are available through the 340B program to free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals.
  - Clarifies that "HHS interprets section 340B(e) of the Public Health Service Act as excluding drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated,“
  - Issued to provide marketplace clarity and to protect the financial incentives available to manufacture orphan drugs, which can be be hugely expensive given the narrow band of patients for which they're intended.
Orphan Drugs & 340B: In or Out? Depends on which side you’re on

<table>
<thead>
<tr>
<th>HRSA Position</th>
<th>Pharma Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACA includes some 340B provisions &amp; clarifications, HRSA implements them</td>
<td>Pharma disagrees</td>
</tr>
<tr>
<td>HRSA defines orphan drug inclusion</td>
<td>Pharma disagrees, sues HRSA</td>
</tr>
<tr>
<td>HRSA reissues interpretive ruling</td>
<td>Pharma disagrees, sues HRSA again Oct 9</td>
</tr>
<tr>
<td>HRSA asks 50 drug manufacturers to refund 340B overcharges Oct 2014</td>
<td>Pharma digs in heels</td>
</tr>
</tbody>
</table>
FDA Clears 41 New Drugs in 2014; Approval Rate Hits 18-Year High

• FDA in 2014 approved 41 new medicines, the highest number of U.S. drug approvals since 1996
• The increase in drug approvals was primarily driven by cancer drugs and treatments for rare diseases, which accounted for nearly 40% of FDA's approvals last year. Reuters 1/1/2015.
FDA grants orphan drug status to Glassia for GVHD, a liquid alpha-1 proteinase inhibitor for the treatment of patients with graft-versus-host disease following allogeneic stem cell transplant

Orphan Drug Status to CPI-613

Orphan Drug Status Given to Lymphoseek for New Indication for Head and Neck Cancers, and RX-3117 for Pancreatic Cancer

Orphan Drug Designation to Aldxorubicin for Glioblastoma, Small Cell Lung Cancer, & Ovarian Cancer

FDA Orphan Drug Designation to Drugs for Glioblastoma & DBCL

Orphan Drug Status to Selinexor for DLBCL

FDA Grants Orphan Drug Status to ADXS-cHER2 for Osteosarcoma

Orphan Drug Status for Alvocidib

FDA Approval for CLL Drug, Orphan Drug Status for AML Therapy

FDA Grants AML Drug Pracinostat Orphan Drug Status
Orphan Drug Status to CPI-613

Orphan drug status to JCAR015 for ALL treatment for patients who have not received prior treatment

Orphan drug designation to BGB324 for the treatment of patients with acute myeloid leukemia (AML)

Orphan Drug Status Given to Lymphoseek for New Indication for Head and Neck Cancers, and RX-3117 for Pancreatic Cancer

Orphan Drug Designation to Aldoxorubicin for Glioblastoma, Small Cell Lung Cancer, & Ovarian Cancer

FDA Orphan Drug Designation to Drugs for Glioblastoma & DBCL

Orphan Drug Status to Selinexor for DLBCL

FDA Grants Orphan Drug Status to ADXS-cHER2 for Osteosarcoma

Orphan Drug Status for Alvocidib

FDA Approval for CLL Drug, Orphan Drug Status for AML Therapy

FDA Grants AML Drug Pracinostat Orphan Drug Status

FDA grants orphan drug status to MM-141 an investigational tetravalent bispecific antibody for pancreatic cancer
FDA approved the antihemophilic factor (recombinant), porcine sequence, Obizur (Baxter) for the treatment of bleeding episodes in adults with acquired hemophilia A with priority review and orphan drug status.

FDA approved Blincyto (blinatumomab) to treat patients with Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL), an uncommon form of ALL and granted breakthrough therapy designation, priority review and orphan product designation.

FDA approved a new use for Jakafi (ruxolitinib)—for the treatment of patients with the chronic bone marrow disease polycythemia vera. The new use for Jakafi is intended to treat patients who have inadequate response to or cannot tolerate hydroxyurea, another drug prescribed to treat polycythemia vera. Jakafi also received orphan product designation because it is intended to treat a rare disease.

FDA granted Fast Track designation to necuparanib (formerly M402) as a first-line therapy for use in combination with Abraxane (paclitaxel) and gemcitabine for the treatment patients with metastatic pancreatic cancer. Necuparanib received orphan drug designation for the treatment of patients with pancreatic cancer earlier this year.

FDA grants orphan drug, rare pediatric disease status to entrectinib for neuroblastoma.
A Golden Opportunity or The Perfect Storm?
Are you in a position to take advantage of a golden opportunity?

- The C-Suite understands the program
- IT systems are robust
- IT can support program integrity while maximizing inventory practices in a mixed-use setting
- IT can support purchasing optimization for maximizing medication access
- IT can support verifying Patient Eligibility
- Medicaid billing is sophisticated enough to revenue and avoid duplicate discounts
- There’s a sound plan for In-house Pharmacy Implementation
- Systems to prevent diversion are in place
- Pharmacy and leadership understand the audit process and are prepared

Maintaining integrity is what it’s all about
Are you Caught in the Perfect Storm?

- Facility is hemorrhaging $
- C Suite is desperate for revenue
- C Suite is mandating cost cuts
- Physician practices being bought
- 340B is perceived as that golden solution to cutting drug spend
- But….Pharmacy’s infrastructure and IT support are shaky, as is IT in many other areas

How do you respond to this?
Audits

- 2012: HRSA began auditing 340B-enrolled covered entities for compliance and identified several common areas of noncompliance.

- 5.9.14: HRSA published 340B best practices (based on the findings of its audits) that hospitals should become familiar with.
Best Practices

• Development and documentation of comprehensive 340B policies and procedures
• Development of concrete methodologies for routine self-monitoring
• Routine processes for internal corrective action
• Verification that contract pharmacy arrangements comply with 340B requirements and are properly listed in the Office of Pharmacy Affairs (OPA) database
• Strong partnerships with state Medicaid agencies to meet state specific requirements and to ensure prevention of duplicate discounts
Prevalence of insured patients, Medicaid & the Indigent Population all are driving 340B eligibility...

It’s a roller coaster ride!!

Healthcare reform continues to provide coverage to larger population segments & will tip the balance in one direction or the other!!
References
ASHP Connect Website Post 11.28.2013

• Posted by Christopher A. Hatwig MS, RPh, FASHP, President Apexus/340B Prime Vendor, Irving, Texas 972-910-6646

• with the increased scrutiny of the 340B program, along with Gov't and manufacturer audits, I would highly recommend having an internal pharmacy team member committed to management of 340B pharmacy operations to support ongoing compliance

• best time to request a dedicated resource and appropriate software to support managing the program is when the organizations is considering joining the program

• program savings should easily justify additional resources to manage it appropriately

• risk of not doing so, is just too great
Post continued…..

• I would also advise forming a interdisciplinary committee lead by pharmacy to include finance, compliance and legal departments
• can be helpful to pharmacy when conflicts may arise between expectations and obligations of Finance and Pharmacy
• You can find all the tools and resources (draft P&Ps, etc) needed to support operating a compliant program under the 340B University tab of our website at www.340bpvp.com
• The national call center is also available to address any specific questions at 888-340-BPVP
340B Drug Pricing Program: Important Benefit, Significant Responsibility

Office of Pharmacy Affairs Update

The 340B Program, administered by the Health Resources and Services Administration (HRSA), plays an integral role in supporting our health care safety net. These designated hospitals, clinics and other providers work with very limited resources to confront the most intractable health problems facing millions of Americans. The 340B Program helps these health care providers stretch scarce federal resources by allowing eligible entities to purchase drugs for outpatient use at a significant discount. Studies show that entities participating in the 340B Program are able to expand the type and volume of care they provide to the most vulnerable patient populations as a result of access to these lower cost medications. The number of providers participating in this program has increased in recent years. The vast majority of these providers (82 percent) dispense these discounted drugs through an in-house pharmacy; a small minority of covered entities (18 percent) contract with pharmacies to dispense these discounted drugs to eligible patients, and of those, 75 percent use fewer than five contract pharmacy arrangements.

The 340B Program provides eligible entities with an important benefit that comes with significant responsibility. To ensure that both 340B covered entities and participating pharmacies have a clear understanding of the rules and obligations that are associated with the program, HRSA shares program updates and new policies on a regular basis.
Peer-to-Peer Program Webinars

Upcoming Webinars

- **From Paper to Reality: Operationalizing 340B Policies and Procedures** April 09, 2014 2:00PM to 3:00PM (ET)
- **Drug Procurement Strategies in a 340B Practice Environment** April 23, 2014 2:00PM to 3:00PM (ET)
- **Developing and Maintaining Auditable Records in the Context of 340B Statute, Policy and Guidance** May 14, 2014 2:00PM to 3:00PM (ET)
- **Successful Strategies for Monitoring the Performance of Data Intermediary Vendors in a 340B Practice** May 28, 2014 2:00PM to 3:00PM (ET)

On Demand Webinars

Biweekly 340B Peer-to-Peer webinars are the primary channel for leading practice sites to communicate their experiences with stakeholders.

Peer-to-Peer webinars are held on the second and the fourth Wednesday each month unless otherwise specified.
Solutions for 340B Entities

- **CONTRACTING**
  - 340B Prime Vendor Program
  - [www.340bPVP.com](http://www.340bPVP.com)

- **EDUCATION**
  - 340B University & 340B OnDemand

- **ASSISTANCE**
  - Apexus Answers Call Center
  - (888) 340-BPVP
  - ApexusAnswers@[340bPVP.com](mailto:ApexusAnswers@340bPVP.com)
340 B Guidance from Apexus

- Apexus operates a national call center, Apexus Answers, that provides free assistance from experts in the 340B Program
- Information from APEXUS aligns with HRSA
Navigating 340B and the Prime Vendor Program is a tutorial designed to provide accelerated learning about the program and insight on the 340B drug pricing program and its Prime Vendor Program, PVP. The tutorial includes 9 sections and covers important topics, including: The intent of the 340B program, who is eligible to participate, how pricing is determined, the 3 pronged resource triangle available to participants, benefits of participating in the Prime Vendor Program, how to sign-up for PVP and how the program works. Anyone who completes ‘Navigating 340B’ and successfully completes a short quiz will become ‘340B and Prime Vendor certified’ and will receive a certificate at the end.

Navigating 340B and the Prime Vendor Program was created by Apexus, a not-for-profit entity who manages the Prime Vendor Program. For more information on Apexus or the 340B Prime Vendor Program, please visit: www.340Bpvp.com
You Are Invited To Attend 340B University

Apexus offers 340B University, an in-depth educational program designed to meet the practical needs of the 340B PVP participants and other program stakeholders. Topics covered in the training include statutory ceiling price calculations, fundamentals in implementing a compliant pharmacy program and hands on training with tools and resources available to assist with program integrity.

We will feature a broad range of educational sessions, including content regarding:

- 340B Basics - Introduction to the 340B Drug Pricing Program
- Program Integrity & Audits
- Implementation/Policy - Contract Pharmacy Implementation & Mixed-Use Setting Compliance
- Pricing - Calculation and Integrity Considerations
- 340B & Medicaid: Overview on Billing & Duplicate Discount Policies

Take advantage of the opportunity for hands-on, practical advice to help with 340B program implementation. Specially designed breakout sessions have been designed to help you enhance program integrity by learning from industry leaders and networking with peers!
Objectives
After completing this program, participants should be able to:
• Describe the history, intent and statutory principals of the 340B program.
• Outline the process for addressing 340B policy and the maintenance of integrity of the 340B Program participation.
• Describe the role of the manufacturer, wholesaler, prime vendor and entity in 340B pricing integrity.
• List methods to optimize the value of the 340B PVP's products, services and tools.
• Identify the roles and responsibilities of 340B implementation and monitoring that may be managed by a pharmacy technician.
340B University meets these objectives in 1 full day or 2 half-day, intensive learning experience that mixes traditional lecture and interactive/practical application learning formats. CE for pharmacists and pharmacy technicians is available.
Target Audience
This program is targeted to pharmacists practicing in 340B-covered entities and their contracted pharmacies as well as all other 340B stakeholders, including vendors, manufacturers, consultants and pharmacy technicians with a basic understanding of pharmacy purchasing practices.
Welcome to SNHPA’s Legislative Resource Center

SNHPA’s legislative team would like to welcome you to our Grassroots Advocacy page. Not only can you access your members of Congress with a few clicks of the mouse, but you can also find information on legislation that is important to your hospital and the 340B program.

Our Government Relations team thanks you for your advocacy and reminds you that we are happy to set up a meeting with your member of Congress if you are visiting Washington!

Thank You For Your Help With 340B Congressional Letters

Thanks to all the SNHPA members who have talked with their Members of Congress about signing the pro-340B letters that were circulated by Sens. John Thune (R-S.D.) and Tammy Baldwin (D-Wis.) and Reps. Shelley Moore Capito (R-W. Va.) and Kathy Castor (D-Fla.).

As a result of your efforts, and in the face of an intense lobbying effort by PhRMA and BIO opposing the letters, more than 80 Members of Congress signed the House letter, and almost 30 U.S. Senators signed the Senate letter.

The Senate letter can be found here and the House letter can be found here.

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www.snhpa.org/340b-resources/compliance-resources/
New Analysis Shows Many 340B Hospitals Provide Minimal Charity Care; Small Percentage of 340B Hospitals Provide More
Coalition Calls for Congress to Reconsider Eligibility Criteria

WASHINGTON, D.C. (March 25, 2014) - A new analysis released today by the Alliance for Integrity and Reform of 340B (AIR 340B) indicates that a substantial portion of hospitals enrolled in the 340B program provide only a minimal amount of charity care; as such, they may not be fulfilling Congress’ expectations.

The study, compiled from newly available public data analyzed by Avalere Health, noted that the 340B benchmark amount calculated by Congress to help hospitals provide charity care is

http://340breform.org/userfiles/Final%20AIR%20340B%20Charity%20Care%20Paper.pdf
ACCC’s Position Paper
340B Drug Discount Program 10.2013

• 340B Program Allows Providers to Offer More Services to the Uninsured, Underinsured, and Medicaid Patient Populations

• Clearer Regulations Must Be Promulgated to Ensure the Long-Term Viability of the 340B Program

• Providers have expressed frustration that lack of clarity in the rules and regulations has made the program unnecessarily difficult from an implementation and compliance standpoint.

• Pharmaceutical industry participants have expressed concerns about the scope of the program expanding beyond its original intent.

• ACCC supports HRSA reviewing the definitions currently in place throughout the 340B Program and making alterations, where the agency sees fit, in order to set the program on the course for long-term viability. This includes the definitions of “patient,” “outpatient department,” and “covered entity.”