The 340B Drug Pricing Program:
340B Audits and the new Mega-Guidance

New England Healthcare Internal Auditors
Fall Conference

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The 340B Program required drug manufacturers to provide outpatient drugs to eligible healthcare organizations at significantly reduced prices:

- The 340B Program provides on the deepest discount on pharmaceuticals in the country, trailing only the Department of Defense and Veterans Healthcare Administration contracts
- Up to 2,048 hospitals and health systems participated as covered entities in 2014
- 340B Entities accounted for over $7 billion in drug spend in 2013, roughly 2% of total spend across the United States

The program has come under increasing levels of scrutiny since its expansion after the Affordable Care Act (ACA) in 2010.

The Office of Inspector General (OIG) previously filed reports indicating inconsistent operational practices across covered entities and limited oversight by HRSA.

Health Resources and Services Administration (HRSA) has attempted to issue formal guidance in the past; however, the guidance left many unanswered questions and "gray" areas.

HRSA released omnibus guidance (aka Mega-Guidance) in August 2015 in an attempt to clarify existing policy and provide a framework for program audit and enforcement.

340B Program Overview

- The Veterans Health Care Act of 1992 requires pharmaceutical manufacturers whose drugs are covered by Medicaid to provide discounts on outpatient covered drugs purchased by specific public health services that serve the nation’s most vulnerable patient populations.

- Eligible entities receive discounts based on the utilization of pharmaceuticals by covered outpatients. Covered entities must enroll in the program to participate.

- The program sits under the Health Resources and Services Administration (HRSA) and administered by the Office of Pharmacy Affairs (OPA).

- The 340B Program provides the third deepest discount on pharmaceuticals in the U.S., trailing only the Department of Defense and Veterans Healthcare Administration contracts.

- A typical 340B hospital can expect to save approximately 25% to 35% off of the Group Purchasing Organization (GPO) cost for drugs used for covered outpatients.

Program Administration

- OPA is part of HRSA’s Healthcare Systems Bureau and has three primary functions:
  
  - Administer the 340B program
  - Develop innovative pharmacy delivery models and provide technical assistance
  - Act as a federal resource for pharmacy issues

- The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract with the OPA. The PVP, for which there is no cost to participate, serves its participants in three primary ways:
  
  - Negotiates sub-340B pricing on pharmaceuticals
  - Establishes distribution solutions and networks that improve access to affordable medications
  - Provides other value-added pharmacy-related products and services

- The 340B price is the ceiling price, meaning that it is the ceiling or highest price that 340B covered entities would have to pay for a drug.

Eligible Entities

Only non-profit health care organizations that have certain Federal designations or receive funding from specific Federal programs can qualify as a 340B Covered Entity.

Hospitals
- Children’s Hospitals
- Critical Access Hospitals (CAH)
- Disproportionate Share Hospital (DSH)
- Free Standing Cancer Hospitals (CAN)
- Rural Referral Centers (RRC)
- Sole Community Hospitals (SCH)

Specialized Clinics
- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

Health Centers
- Federal Qualified Health Centers (FQHC)
- FQHC Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Ryan HIV/AIDS Program Grantees
- Ryan White HIV/AIDS Program Grantees

Enrollment and Recertification Process

- Eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.

- Each covered entity is required to annually recertify their eligibility in order to continue participating in the 340B program.
  - Covered entities that do not complete the recertification may have their participation in the 340B program terminated.
  - If there is a change in a covered entity’s eligibility status, the covered entity has a responsibility to immediately notify OPA and should stop purchasing drugs through the 340B Program.

Eligible Patients

According to HRSA, an individual is not considered a patient of the covered entity if the only health care services received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

340B Patient Definition - An individual is a patient of a 340B covered entity if the following criteria is met:

- 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; and
- 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 for Federally-qualified health center or look-alike status has been provided to the entity (DSH hospitals are exempt from this requirement).


Covered Drugs

Generally, the 340B Program covers the following outpatient drugs:

- FDA-approved prescription drugs
- Over-the-counter (OTC) drugs written on a prescription
- Biological products that can be dispensed only by a prescription (other than vaccines); or
- FDA-approved insulin
- But NOT Orphan Drugs

The following drugs are not covered:

- Vaccines
- In-patient drugs

Orphan Drugs

- The Affordable Care Act contained a restriction on the use of Orphan Drugs by new covered entities (i.e., CAH, RRC, SCH, and CAN) and restricts them from purchasing orphan drugs at 340B prices.
- Drug is designated by FDA as an “orphan drug” at request of sponsor if FDA finds that the drug is being or will be investigated for a rare disease or condition.
- Orphan drug must have received FDA marketing approval to meet the definition of 340B covered outpatient drugs.
- Some of the restricted 340B entities are large orphan drug users.
- Some manufacturers waiting for Federal policy before taking action.
- Other manufacturers have indicated they will stop selling orphan drugs through 340B Program to newly-eligible entities - whether or not used for purpose related to orphan status.


Contract Pharmacies

- 340B Program allows entities to have multiple contract pharmacies for increased patient access to cost effective pharmaceuticals.
- The Covered Entity purchases the drug, but “ship to - bill to” procedure may be used.
- The Covered Entity retains legal title to all drugs purchased under 340B. The Covered Entity must pay for all 340B drugs.

Challenges with Contract Pharmacies

- Diversion tracking
- Audits and records
- Discount management and tracking
- Data exchange (PHI, remote hosting)
- Inventory management

Current 340B Program Prohibitions

- **DUPPLICATE DISCOUNT**: Covered entity is prohibited from accepting a discount for a drug that would also generate a Medicaid rebate to the State.
- **DIVERSION**: Covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.
- **GPO EXCLUSION**: DSH hospitals, children’s hospitals, and free-standing cancer hospitals may not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.
- **ORPHAN DRUGS**: Free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals may not purchase selected rare disease drugs at 340B prices.

Source: U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA).

Evolution of the 340B Program

**2010**
- 340B program was significantly expanded with the passage of the Affordable Care Act and the concurrent release of additional federal guidance.
- Additional expansion included provisions for contract pharmacy partnerships that allowed participating entities to partner with retail pharmacies to help service their patients.

**2011**
- Expansion resulted in increased scrutiny from lawmakers and drug manufacturers.

**2012**
- In response to scrutiny regarding program oversight, OPA briefed the Senate Appropriations Committee in February 2012:
  - Plans to strengthen program to ensure compliance with existing requirements
  - Timetable for issuing new regulations that address compliance concerns raised by both OIG and GAO

**2013-2014**
- Senate Appropriations Committee later reaffirms 340B’s intent in July 2013.
- Bipartisan letters of support are issued from over 100 lawmakers in August 2013.

Source:
Recent 340B Program Developments

Orphan Drug lawsuit stalls planned 340B Regulations

Drug industry lawsuit challenges legality of HRSA’s October 2013 regulation that allows certain rural and free-standing cancer hospitals to buy orphan drugs at 340B pricing when prescribed for non-orphan indications:

- **May 2014** - Federal district court ruled that HRSA lacks the authority to legislate on Orphan Drugs

Ruling seen as a victory for drug manufacturers; however it also undermined HRSA’s ability to govern 340B without further legislative action.

340B Mega-Guidance released on August 28, 2015

Topics Included:
- Program eligibility and registration
- Drugs eligible for purchase under 340B program
- Individuals eligible to receive 340B drugs
- Prevention of duplicate discounts and maintenance of auditable records
- Contract Pharmacy arrangements
- Manufacturer responsibilities
- Rebate option for AIDS drug assistance programs
- Program integrity
- Accurate 340B ceiling pricing

Recent 340B Program developments

GPO Prohibition Enforcement

- On February 7, 2013, HRSA issued a policy release to clarify its position regarding the GPO Exclusion. Compliance deadline was April 7, 2013 and extended to August 7, 2013:
  - Hospital subject to the GPO prohibition may not purchase covered outpatient drugs through a GPO for any of its covered locations.
  - Means opening wholesale acquisition cost (WAC) accounts with their drug wholesalers and overhauling their virtual drug inventory software
- Covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. May be subject to repayment to manufacturers:
  - Covered entities unable comply by the extended deadline must immediately notify HRSA, and will be terminated from the program
- Non-compliant hospitals identified by HRSA after the extension will be involuntarily terminated

OIG/GAO Reports

- Releases reports on program oversight, contract pharmacy, and 340B ceiling price transparency
- GAO Publishes report in June 2015 implicating high part B drug spend across 340B DSH Hospitals
HRSA Audits

HRSA audits

- HRSA began conducting audits in January 2012
  - 364 audits posted on public website
  - Heavy emphasis on hospitals
- HRSA removed “preliminary findings” in 2014; now issues final report only.
  - As of October 2015 XX% of HRSA audits have resulted in sanctions for covered entities to make repayments to manufacturers
- Audits include interviews, documentation reviews, process walkthroughs, and claims testing
  - Some auditors have targeted known 340B “weak spots” such as controlled substance ordering, emergency room prescriptions, and radiological items
- Audited findings are posted publicly along with a public letter to manufacturers if any repayments are owed.

HRSA audits

The table below shows the trend in audit results over time.

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- Common audit findings include:
  - Diversion issues
  - Duplicate discounts
  - Lack of oversight at contract pharmacies

Source: [http://www.hrsa.gov/opa/program/integrity/index.html](http://www.hrsa.gov/opa/program/integrity/index.html)
Omnibus Guidance Release
Areas receiving clarification in 340B Omnibus Guidance

Part A: Program eligibility and registration

Part B: Drugs eligible for purchase under 340B program

Part C: Individuals eligible to receive 340B drugs

Part D: Prevention of duplicate discounts and maintenance of auditable records

Part E: Contract pharmacy arrangements

Part F: Manufacturer responsibilities

Part G: Rebate option for AIDS drug assistance programs

Part H: Program integrity

Omnibus Guidance Release
Changes to entity, drug, and patient eligibility

Part A – Eligible Covered Entities

Hospitals are 340B program eligible if the state/local government is the sole operating authority of the hospital or if a contract exists between private non-profit hospitals and state/local government to provide care to low-income individuals creating “enforceable expectations,” including the provision of “direct medical care.”

Other Requirements:
1. Offsite facilities or clinics must have “associated outpatient Medicare costs and charges”
2. Hospital clinics be listed on a reimbursable line of a filed Medicare cost report
3. Covered entities must self-disclose any 340B program violation

Part B – Drugs Eligible for Purchase

The omnibus guidance proposes a definition of “covered outpatient drugs” that makes Medicaid drugs paid as part of a bundled rate ineligible for 340B pricing. This provision would require hospitals to track drugs bundled into payments for Medicaid services.

Hospitals subject to the GPO exclusion would be permitted to use GPO pricing for those drugs if:
1. They are the only available source of a drug and the drug was needed to prevent disruptions in care
2. A patient's status is changed from inpatient to outpatient, GPO pricing is permitted during the inpatient period

Part C – Patient Eligibility

340B pricing will be prohibited in connection with services provided outside the covered entity, excluding drugs prescribed through referrals to outside providers, follow-up care, and care in clinics that are not listed as reimbursable on the hospital's Medicare cost report, including cancer infusion centers

HRSA requires that a prescription be written by a hospital as a result of a documented outpatient service at a 340B registered location, barring eligibility for:
1. Drugs prescribed when a patient is discharged from an inpatient setting, although such drugs are billed as outpatient
2. Drugs prescribed through outpatient services, yet the patient is admitted and the patient’s payer requires the hospital to bill for the outpatient service as part of inpatient stay
Omnibus Guidance Release
Changes to entity requirements, pharmacy arrangements, and manufacturer responsibilities

**Part D – Covered Entity Requirements**
The omnibus guidance focuses on two items for covered entity responsibilities:
- Prohibition of duplicate discounts
- Maintenance of auditable records

HRSA is proposing that covered entities must retain 340B program records for a period of not less than five years. Failure to maintain auditable records is grounds for losing eligibility to participate in the program.

**Part E – Contract Pharm. Arrangements**
There is new guidance proposed by HRSA related to registration:
- The covered entity is the only party that may submit contract pharmacy registration.
- A covered entity may request additional contract pharmacy locations under a public health emergency declared by the Secretary for the geographic areas and time period specified in the declaration.

HRSA expects the covered entity to perform monitoring, at least quarterly, to reconcile 340B prescribing records with 340B dispensing records.

**Part F – Manufacturer Responsibilities**
Although much of the omnibus guidance was seemingly directed at hospitals, it includes provisions for manufacturers related to pricing agreements, recertification, auditing, and repayments, including:
- The “must offer” provision from the Affordable Care Act
- Manufacturers maintain auditable records for at least five years
- Manufacturer must issue refunds or credits to covered entities within 90 days after a determination by the manufacturer or federal government that an overcharge has occurred
- A manufacturer recertification process by annually reviewing and updating their information

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Omnibus Guidance Release
Changes to rebate options and program integrity

**Part G – Rebate for AIDS Drug Assistance Programs**
A State AIDS Drug Assistance Program eligible to participate in the 340B program may register for and participate in the 340B program through this option.

The omnibus guidance provides information regarding:
- Procedures for the AIDS Drug Assistance Program rebate option
- Qualified payment
- Multiple 340B discounts and rebates
- Audits
- Manufacturer rebates

**Part H – Program Integrity**
The new guidance is generally consistent with information communicated in the past. The new guidance continues the current policy of allowing hospitals a single, 30-day opportunity to respond to allegations and challenge audit findings through written submissions.

Some key program integrity requirements in the new guidance are:
- New 90-day window from identification of 340B drug diversion for covered entities to work with manufacturers regarding repayment
- No definition of “materiality” for instances of non-compliance or any clarification of self-disclosure process for non-compliance identified by covered entities
- New requirement to maintain auditable records for at least 5 years

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"Patient" Definition

340B “Patient” Definition
Current definition

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

2. 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;

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 FQHC look-alike status has been provided to the entity [Hospitals are exempt]; and

4. An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
340B “Patient” Definition

Proposed definition

1. The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B Program database;
   - No longer support for referral arrangements for follow up/specialty care outside the covered entity

2. The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider;
   - Privileges/Credentials not enough
   - New requirement that covered entity must be able to bill for professional services

3. The individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2).
   - The individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;
     - Necessary relationship between 340B drug ordered and type of service received
     - Exclusion of infusion drugs

4. The individual receives a health care service that is consistent with the covered entity’s scope of grant, project or contract;
   - Covered entity hospitals exempt
   - Generally consistent with current definition

5. The individual is classified as an outpatient when the drug is ordered or prescribed, as determined by status when billed to payor;
   - Elimination of ability to purchase 340B drugs for discharged inpatients; reduction of contract pharmacy purchases
   - Administratively burdensome/challenging

6. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for that care is with the covered entity, and that each element of this patient definition is met for each 340B drug
   - Generally consistent with current definition
Duplicate Discounts

Prohibition of duplicate discounts

HRSA reiterates that contract pharmacies will not dispense 340B drugs to Medicaid Fee-For-Service (FFS) or Managed Care Organization (MCO) patients (i.e., will be "carve-out"), unless the covered entity obtains Department of Health and Human Services (HHS) approval on a written agreement that describes a system to prevent duplicate discounts.

The guidance adds further complexity in an attempt to prevent Medicaid duplicate discounts. The guidance allows CEs to choose a different carve-in/carve-out election for MCO vs. FFS as well as different elections by covered entity site and by MCO. It also doesn’t explicitly require the carve-in/carve-out elections to be made available publicly through the 340B Medicaid Exclusion File.

HRSA does not propose new mechanisms beyond the existing Medicaid Exclusion File.
**Duplicate Discounts**

**Graphical Illustration**

1. **Step 1**: Manufacturer sells drug at 340B discount
2. **Step 2**: 340B drug is dispensed to Medicaid patient
3. **Step 3**: Covered entity bills Medicaid for 340B drug
4. **Step 4**: State submits rebate request
5. **Step 5**: Manufacturer pays rebate on 340B drug

STEPS 1 AND 5 = DUPLICATE DISCOUNT

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**Contract Pharmacy Arrangements**
Contract Pharmacy Arrangements

Registration and compliance with statutory requirements

New guidance is proposed by HRSA related to registration:

- The covered entity is the only party that may submit contract pharmacy registration.

- A covered entity may request additional contract pharmacy locations under a public health emergency declared by the Secretary for the geographic areas and time period specified in the declaration.

New guidance is proposed by HRSA related to compliance with statutory requirements:

- HRSA expects the covered entity to perform monitoring, at least quarterly, to reconcile 340B prescribing records with 340B dispensing records.

- HRSA continues to recommend covered entities use independent auditors to perform annual audits of their contract pharmacies

HRSA & Manufacturer Audits
HRSA and Manufacturer Audits of Covered Entities

Proposed guidance

- Proposed guidance is to continue current policy of allowing hospital a single, 30-day opportunity to respond to each allegation of non-compliance and may challenge audit findings through written submission only.
- Proposed guidance establishes “notice and hearing process” for responding to HRSA audit findings but no actual “hearing”.
- HRSA states that a covered entity’s refusal to respond to manufacturer questions may be “reasonable cause” for manufacturer audit.

Operational and Financial Takeaways
Operational and Financial Takeaways
Considerations for 340B hospitals

- **Financial impact**: Infusion centers and contract pharmacy are typically large drivers of program savings and are areas most affected within the proposed guidance.

- **Audit and monitoring**: Proposed guidelines included detailed expectations for audit and monitoring activities. Most entities perform routine auditing and monitoring, but many lack a formal, structured, and integrated plan.

- **Technology**: Certain configurations may already be possible within existing information technology infrastructure (i.e. accumulating/replenishing based on final billed status), while others may require additional investment of time and resources (i.e. excluding “bundled” drugs for Medicaid patients).

- **Resources**: Will changes require an additional investment in full-time 340B resources?

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Operational and Financial Takeaways
Considerations for 340B hospitals

- Final Guidance could be issued as early as **Q1 2016**

- Perform a **risk assessment** to analyze the effects of proposed guidance in its current form:
  - Financial – analyze how program savings/return on investment is affected
  - Operational – assess additional resource requirements and procedural changes
  - Regulatory – look at at-risk areas based on current standards and findings from recent HRSA audits

- Propose **internal controls** to address risk areas

- Assess the possibility of **immediate corrective action** versus waiting until the guidance is released in final form:
  - Audit and monitoring practices
  - Error reporting procedures
  - Develop a repository for program documentation
  - Software and data infrastructure modifications
Additional Questions?

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