The 340B Program:
Challenges and Opportunities

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Overview

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Overview and History of the 340B Program

- The 340B program is a federal drug discount program, created in 1992 by the Veteran's Health Care Act, which is codified as Section 340B of the Public Health Services Act.
- The 340B program was created after the Medicaid drug rebate program, following increases in the price of drugs.
- Pharmaceutical manufacturers that sign a Pharmaceutical Pricing Agreement with HRSA must sell their covered outpatient drugs at a discount to covered entities.
- "Covered entities" included primarily FQHCs and DSH Hospitals.
- The statute created three safeguards against abuse by covered entities, prohibiting—
  1) Diversion: The resale of drugs purchased at 340B prices by covered entities to "a person who is not a patient of the entity;"
  2) Duplicate discounts: The application of both a Medicaid rebate and a 340B discount to a drug; and
  3) Use of GPOs: The use of group purchasing organizations by certain covered entities.

ACA's Changes to the 340B Program

- The Affordable Care Act (Pub. L. 111-148, 111-152) expanded the 340B program as follows:
  - Additional covered entities:
    - Children's hospitals (if DSH > 11.75%)
    - Critical access hospitals
    - Free standing cancer hospitals (if DSH > 11.75%)
    - Rural referral centers (if DSH > 8%)
    - Sole community hospitals (if DSH > 8%)
  - Exclusion of orphan drugs from 340B pricing for some newly-covered entities:
    - "For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition."

ACA's Changes to the 340B Program

- The Affordable Care Act (Pub. L. 111-148, 111-152) expanded the 340B program as follows:
  - Additional **HRSA authority** with respect to **manufacturers** to—
    - Develop a pricing methodology for calculating ceiling prices
    - Establish procedures for refunds to covered entities
    - Provide covered entities with access to a website listing ceiling prices
    - Develop a mechanism to
      - report discounts/refunds to other purchasers, and
      - if such discounts/refunds affect ceiling price, the issuance of commensurate refunds to covered entities
    - Audit manufacturers and wholesalers
    - Impose civil monetary penalties on manufacturers that knowingly and intentionally charge a covered entity a price exceeding the ceiling price.

ACA's Changes to the 340B Program

- The Affordable Care Act (Pub. L. 111-148, 111-152) expanded the 340B program as follows:
  - Additional **HRSA authority** with respect to **covered entities** to—
    - Develop procedures to enable and require covered entities to update their information online
    - Develop a system to verify the online information regarding covered entities
    - Develop guidance regarding the options for covered entities in billing to state Medicaid agencies to avoid duplicate discounts
    - Establish an identification system for covered entities
    - Impose sanctions on covered entities that willingly and intentionally engage in drug diversion, exclude covered entities that divert drugs systematically and egregiously, and refer cases to OIG and FDA

Recent Developments - Orphan Drug Rule

- In May 2011, HRSA issued a proposed rulemaking to "implement" the ACA's orphan drug provision (76 FR 29183):
  - "For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" *shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition*."
- HRSA proposed to limit the exclusion to orphan drugs that are used for the indication for which they received an orphan designation. In purchasing the drugs, covered entities would specify the indication and receive the appropriate pricing.
- HRSA finalized the rule largely as proposed in 2013 (78 FR 44016), drawing criticism from drug manufacturers, which culminated in a lawsuit before the DC District Court.

Recent Developments - Announcement of “Mega-Rule”

- In early 2014 while the litigation with PhRMA was under way, HRSA announced that it was planning to issue a major rulemaking addressing the following topics:
  a) the definition of an eligible patient;
  b) compliance requirements for contract pharmacy arrangements;
  c) hospital eligibility criteria;
  d) and eligibility of off-site facilities.

- All of these topics have previously been addressed in HRSA’s Federal Register notices, but HRSA’s only rulemaking had been the Orphan Drug Rule.

- HRSA set June 2014 as the anticipated issuance date for the “Mega-Rule”.

Recent Developments - PhRMA v. HHS Decision

- On May 23, 2014, the DC District Court struck down HRSA's Orphan Drug Rule, concluding that the agency has **no statutory authority to promulgate legislative rules except to implement those provisions where such authority is specified**:
  1) implementation of an administrative dispute resolution mechanism for claims by manufacturers and covered entities;
  2) regulatory issuance of standards and methodology for the calculation of ceiling prices; and
  3) establishment of standards for the imposition of civil monetary penalties applicable to participating manufacturers.

- The DC District Court refused to consider the legality of the Orphan Drug Rule as an interpretive rule (as opposed to a legislative rule).

Aftermath of the PhRMA Ruling

- Following the PhRMA ruling, HRSA announced that the Orphan Drug Rule represents its interpretation of the statutory orphan drug provision, and that it will thus retain the rule as an interpretive rule.

- HRSA then acted to enforce its interpretive rule:
  - In October 2014, HRSA sent out letters to over 50 drug manufacturers, notifying them that they are out of compliance with the interpretive rule because they do not offer 340B pricing for non-orphan indications of their orphan drugs. HRSA instructed the manufacturers to notify the agency of a refund plan within 30 days.
  - In February 2015, HRSA posted the names of 13 manufacturers whose orphan drugs were not offered at 340B prices for non-orphan indications. HRSA advised states to collect full rebates on the drugs when dispensed to Medicaid patients.

Aftermath of the PhRMA Ruling

- PhRMA promptly filed another lawsuit with the DC District Court to challenge the Orphan Drug Interpretive Rule.
- **PhRMA's argument**:
  - HRSA's action is final agency action, and thus reviewable under the Administrative Procedure Act.
    - Consummation of decision-making process
    - Legal consequences, "implementation" of the statute
    - Expectation of compliance
  - The rule is inconsistent with the statutory language.
    - Statutory text does not contain a use-based restriction
    - No deference is due, because the rule conflicts with the statutory language
    - Congress intended to exclude orphan drugs from 340B, regardless of indications
- Motion for SJ filed 2/25/15.

Aftermath of the PhRMA Ruling

- **HHS's argument**:
  - No jurisdiction because the rule is not a final agency action.
    - The rule is not binding, and has no legal effect
    - The rule creates "practical" rather than legal consequences
  - HHS's interpretation is consistent with the statute and is entitled to Skidmore deference
    - HHS's interpretation is consistent with the 340B statute, and its objectives, as well as with the Orphan Drug Act, because orphan drugs receive statutory benefits under the Orphan Drug Act and the ACA only for orphan designations
    - Congress should not be presumed to have intended to force entities to pay higher prices for orphan drugs for common diseases, as it would result in the payment of higher prices up to 90% of the time

- Motion for SJ filed 1/27/15.

Future 340B Rulemaking

- HRSA retracted the anticipated “Mega-Rule,” noting that it would proceed through guidance instead, scheduled for 2015 release.

- However, HRSA has also begun the rulemaking process for other statutory provisions created by the ACA, where it has specific authority to promulgate regulation.
- In 2010, HRSA issued advance notices of proposed rulemaking (ANPR) for 2 areas in which it has authority to promulgate regulations:
  a) administrative dispute resolution (75 FR 57233); and
  b) manufacturer civil monetary penalties (75 FR 57230).

- Additionally, HRSA may begin rulemaking addressing the calculation of ceiling prices.

HRSA's 340B Audits of Covered Entities

Posted audit results, for entities that agreed to Final Reports, as of 2/27/15:

	FY 2012	FY 2013	FY 2014	FY 2015
CEs audited	51	81	42	4
No adverse findings	19 (37%)	21 (26%)	14 (33.3%)	0 (0%)
Diversion	16 (31%)	41 (51%)	17 (40%)	3 (75%)
Duplicate discount	17 (33%)	23 (28%)	8 (19%)	0
Database record	15 (29%)	38 (47%)	13 (31%)	1 (25%)
GPO	0 (0%)	1 (1%)	3 (7%)	1 (25%)

HRSA's 340B Audit Process

- 2011 GAO report recommends auditing by HRSA.
- Selective audits begin in FY 2012.
- HRSA has developed a program-specific audit process for 340B compliance.
- **Pre-Audit**
  - Covered entities selected for audit receive an engagement letter explaining what to expect and how to prepare.
  - HRSA regional auditors conduct an introductory teleconference with the entity to request and obtain specified documents, including policies, procedures, and internal controls.
  - HRSA regional auditors work with the entity to schedule an opening meeting with key covered entity management to discuss expectations for the onsite audit.

HRSA's 340B Audit Process

- **Onsite Audit**
  - review of relevant policies and procedures and how they are operationalized;
  - verification of eligibility, including GPO and outpatient clinic eligibility;
  - verification of internal controls to prevent diversion and duplicate discounts, including outpatient and inpatient definitions, HRSA Medicaid Exclusion File designations, and accuracy of covered entity's 340B database record;
  - review of 340B program compliance at the covered entity, outpatient or associated facilities, and contract pharmacies; and
  - testing of 340B drug transaction records on a sample basis.

HRSA's 340B Audit Process

Policy / Process documents

- 340B manual and other policy documents used by entity
- Contracts with contract pharmacies
- Medicare cost report
- 340B registration data
- Contracts with government entities
- Scope of services
- Referral agreements with other providers
- Wholesaler agreements

Data documents

- Claims data
- Inventory records
- Prescription data, including drug dispensed, price, prescriber, cost, payer, pharmacy, and other data
- List of eligible prescribers

HRSA's 340B Audit Process

- **Post Audit**
  - HRSA regional auditors collect the facts throughout the audit but are not authorized to summarize any findings to the entity. Any auditor statements made during the audit are not considered final and are subject to change.
  - HRSA regional auditors forward a preliminary report to OPA for review.
  - OPA reviews the preliminary report, drafts a Final Report and issues the report to the covered entity, with a request for a corrective action plan (CAP), if applicable.

HRSA's 340B Audit Process

- In its Final Report, HRSA may request that the CE submit a CAP:
  - If the CE disagrees with the Final Report, it must notify HRSA in writing within 30 calendar days with supporting documentation. OPA reviews the response and may reissue the Final Report with changes.
  - If the CE agrees with the Final Report, it must submit a CAP to HRSA within 60 calendar days for HRSA's approval.
  - Once an audit report is finalized by OPA, the findings and associated corrective actions will be summarized on the OPA public website.
  - Once HRSA reviews and approves a CAP, the CE must provide HRSA a public letter that outlines the findings, states that repayment may be necessary, and provides a contact person. This letter is posted on the HRSA website in the audit findings table. HRSA closes out the audit once the CE attests that all repayment is resolved (and that the CAP has been fully implemented).
  - Covered entities whose findings involve repayment will be subject to audit in a year.

HRSA 340B Audit Final Report

Program Integrity: FY13 Audit Results

Updated 2/25/2015. The results chart includes audits where the entity has agreed to the HRSA Final Report. Remaining audits are still under review. Information on Corrective Action Plans and Sanctions will be updated once approved by HRSA. HRSA recommends manufacturers do not contact audited entities regarding sanctions until a corrective action plan has been approved by HRSA and posted on this website.

No.	Entity	340B ID	State	OPA Findings	Sanction	Corrective Action with Audit Closure Date
1	Alder Health Services, Inc.	RWII17101	PA	No adverse findings.	None.	N/A
2	Allegan General Hospital	CAH231328-00	MI	1.Incorrect 340B database record - Registered contract pharmacies without written contract in place; 2.Diversion – 340B drug dispensed to inpatient; 340B drug dispensed at contract pharmacy, not supported by a medical record.	Repayment to manufacturers.	Public letter to manufacturers - (PDF - 33 KB)
3	Aspirus Medford Hospital and Clinics, Inc. (formerly Memorial Health Center)	CAH521324-00	WI	1.Incorrect 340B database record - Offsite outpatient facilities were not listed on the 340B database; 2.Diversion – 340B drugs dispensed to inpatients; 340B drugs dispensed for prescriptions written by ineligible providers.	Repayment to manufacturers.	Pending.
4	Athens Regional Medical Center	DSH110074	GA	1.Diversion – 340B drugs dispensed for prescriptions originating from ineligible sites and written by ineligible providers; 340B drugs were not properly accumulated; 2.Duplicate Discounts – Medicaid billing numbers were incorrect on the Medicaid Exclusion File.	Repayment to manufacturers.	Pending.

Preparing for an Audit

- Specific steps vary for entities, based on entity type and overall organization. No statutory/regulatory details.
- Preparing for an audit:
  - Internal audits: Review materials on 340B PVP's website, including templates for documents and suggested procedures.
- Monitoring ongoing compliance:
  - Steps:
    - Define the compliance goal, in detail.
    - Establish policies to achieve the compliance goal.
    - Ensure policies are operationalized.
    - Ensure operationalization of policies results in compliance goal.
    - Document the process throughout.
  - If a violation of the 340B program requirements is uncovered, a CE must disclose the violation to HRSA.

Preparing for an Audit

- **Avoiding diversion**
  - Review contracts with contract pharmacies
  - Review referral agreements and patterns
  - Review patient record systems
  - Monitor drug purchases and use in mixed use areas and ineligible sites
  - Monitor indications for which orphan drugs are dispensed
  - Monitor inventory movement
  - Monitor practices at contract pharmacies
- Definition of a patient (61 FR 55157-55158 (1992)):
  1) CE established a relationship with the individual, such that CE maintains records of the individual's health care; and
  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), such that responsibility for the care provided remains with the CE; and
  3) The individual receives a health care service…which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided…

Preparing for an Audit

- **Avoiding duplicate discounts:**
  - Review state Medicaid requirements and guidelines
  - Review reporting of drug dispensing to Medicaid patients, including managed care
  - Request confirmation of procedure compliance from state Medicaid
- 2 compliance options for Medicaid billing
  - Carve in: Bill Medicaid at acquisition cost plus dispensing fee, and the state does not request a rebate.
  - Carve out: Do not dispense 340B drugs to Medicaid patients, and allow the state to collect rebates.

Preparing for an Audit

- **Verifying 340B eligibility**
  - Review registration information in the database
- **Avoiding GPO services**
  - Use a separate GPO to purchase drugs that are not “covered outpatient drugs”
  - Monitor wholesaler purchases
  - Review wholesaler contracts
- **Generally**
  - Regularly update policies
  - Regularly monitor practices
  - Annual external audits help fill overlooked gaps

Questions?

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