The 340B Program: Challenges and Opportunities

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Overview

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- Aftermath of the PhRMA Ruling
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Overview and History of the 340B Program

- The 340B program is a federal drug discount program, enacted in 1992 as part of the Veteran's Health Care Act, which is codified as Section 340B of the Public Health Services Act.
- Congress created the 340B program to address the increase in drug prices that followed the enactment of the Medicaid drug rebate program.
- Pharmaceutical manufacturers that sign a Pharmaceutical Pricing Agreement with HRSA must sell their covered outpatient drugs at a discount to covered entities.
- "Covered entities" initially 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; and
  d) 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 APA.
    - 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 is at odds 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 Affordable Care Act 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, planned 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.

Future 340B Rulemaking

Issues to be covered by the rulemaking governing administrative dispute resolution (75 FR 57233):

- Administrative procedures
- Existing models
- Threshold requirements
- Hearings
- Decision-making official or body
- Appeals procedures
- Deadlines
- Discovery procedures
- Manufacturer audits (must be conducted prior to filing a claim)
- Consolidation of manufacturer claims
- Covered entity consolidation of claims
- Claims by organizations representing covered entities
- Interpretation of dispute resolutions with other provision in the ACA

Future 340B Rulemaking

- The statute permits drug manufacturers to audit covered entities (§ 340B(a)(5)(C)), however the procedure has been rarely used.

- HRSA established the following standards and requirements for audits of covered entities by manufacturers (61 FR 65406 (1996)):
  - Manufacturer must show "reasonable cause" that an entity is engaging in duplicate discounts or diversion;
  - An entity may only be audited by HRSA or a single manufacturer at a time;
  - HRSA must approve the manufacturer's audit plan, which should include objectives, staff, assessment procedures, and confidentiality safeguards;
  - Limited to a period of one year;
  - Manufacturer must first notify entity in writing, and then spend at least 30 days in good faith attempt to resolve the matter;
  - HRSA may "take over" the audit;
  - Covered entity has at least 15 days to prepare; and
  - Suggested audit steps.

Future 340B Rulemaking

Issues to be covered by the rulemaking governing civil monetary penalties for manufacturers (75 FR 57230):

- Existing models
- Threshold determination
- Administrative process elements
- Hearing
- Appeals process
- Definitions (“instance” / “knowing and intentional”)
- Penalty computation
  - HRSA proposed the following factors: (i) Previous record of overcharging; (ii) timeliness of response; (iii) cooperation and good faith; (iv) number of covered entities impacted by the overcharges; (v) impact on patient access; (vi) economic loss to covered entities; (vi) economic gain to the manufacturer; and (vii) relative economic impact on manufacturer as to sufficiency to deter.
- Payment of penalty
- Integration of civil monetary penalties with other provisions of the ACA

340B and Proposed Medicaid AMP Rule

- Because the 340B program and the Medicaid prescription drug rebate statute are inextricably linked, a change to the Medicaid policies will invariably affect the 340B program.
- The ACA changes to the Medicaid rebate program (increase in rebates; changed definition of AMP; rebates for line extensions) will also affect the 340B program.
- CMS proposed its Medicaid rebate rule in February, 2012. The agency has still not finalized the rule.
- Although the CMS regulatory agenda lists the schedule for the rule as Spring, 2015, we do not believe that the final rule will be released in that time frame.
- Until it is released, manufacturers should use their best efforts to comply with the provisions of the statute. CMS will generally permit a regulated party's reasonable attempts to comply as constituting compliance.

Results of HRSA's 340B Audits of Covered Entities

Posted audit results, 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 Audits: Corrective Actions

- When a HRSA audit uncovers violations, the agency requests that the covered entity submit a corrective action plan (CAP) within 30 days.
- Common language:
  - "Through the audit process [entity] was found to have… [list of violations]…
    [Entity] has identified all affected manufacturers and has contacted each to notify them of these violations to begin a dialogue on a method of repayment to affected manufacturers."
- Provides a contact in the covered entity for communication regarding violations.

Questions?

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