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## **340B Drug Discount Program: Expansion Issues, Diversion Concerns, and Implications for Price Reporting and Compliance**

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# Overview of the 340B Program and Key Requirements for Participants

- Created through enactment of Public Health Service Act (PHSA) section 340B in 1992.
- Administered by the Health Resources and Services Administration (HRSA)
  - Office of Pharmacy Affairs (OPA)
- Requires participating manufacturers to charge “covered entities” a reduced price for “covered outpatient drugs”.
  - Manufacturers must participate in 340B in order to have their drugs covered under Medicaid.
  - Since the program’s inception, 340B discounts have applied only to covered outpatient drugs; inpatient utilization is not eligible for 340B pricing.
  - Statutory “ceiling” price sets the maximum price a manufacturer may charge a covered entity for a covered drug, but manufacturers can offer such drugs for a lower (“sub-ceiling”) price.
- Statutory prohibitions applicable to covered entities:
  - “Duplicate discounts”: covered entities cannot request 340B prices for utilization without notifying the State Medicaid program, so as to prevent the state from seeking a rebate under the Medicaid Drug Rebate Program (MDRP).
  - “Diversion”: covered entities cannot resell or transfer a covered drug purchased using a 340B price to a person who is not a “patient” of that covered entity.
  - GPO Purchases: certain 340B hospitals cannot purchase 340B covered outpatient drugs from a group purchasing organization (GPO).
- Additional requirements for covered entities and manufacturers are discussed in OPA guidance.

# GAO Report (Sept. 23, 2011): Significant Issues Related to Program Oversight and Compliance

- Focuses more on HRSA's oversight and covered entities' compliance than on manufacturer practices.
  - But some comments do relate to manufacturer compliance.
- "HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with the program requirements."
  - "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." GAO Report at 21.
  - GAO noted that the oversight issues are compounded by continued program expansion, particularly with respect to growing numbers of disproportionate share hospital entities and contract pharmacies. GAO Report at 27–30.
- GAO made four key recommendations:
  - Conduct selective audits of 340B covered entities to deter potential diversion.
  - Issue new, more specific guidance on the definition of a 340B patient.
  - Further specify the 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require review of manufacturers' plans to restrict distribution of drugs at 340B prices.
  - Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

# Pricing Issues

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- Considerations for Price Reporting
  - Because 340B pricing is based on a manufacturer's MDRP price reporting, inaccurate MDRP price reporting can lead to inaccurate 340B pricing.
  - Providing the steeply discounted 340B price to an entity that is not, in fact, an eligible covered entity (or for utilization that is not, in fact, 340B-eligible utilization) may have best price implications.
- Covered Entity Compliance Issues May Create Issues for Manufacturers
  - Inaccuracies in HRSA's covered entity database
  - Difficulties of current manufacturer audit guidelines—which render it difficult, and in most cases impossible, to monitor, remedy, or seek enforcement related to:
    - Diversion, duplication discount issues, or GPO prohibition violations
      - GAO noted issues in all three areas.
    - Example: Santa Clara
      - 340B rules require manufacturers to continue making 340B prices available even where they have concerns about an entity's eligibility and ability to claim that pricing.
- Pricing Transparency Issues
  - Under ACA, HRSA is required to develop a system to verify 340B pricing and to post verified ceiling prices on the agency's website; implementation is pending.
  - Implications for manufacturer price reporting?
    - Risk of inconsistent regulatory guidance?

# Compliance Issues and the Orphan Drug Exclusion

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- HRSA's May 2011 proposed rule would narrow the statutory exclusion applicable to certain covered entities by excluding from 340B eligibility only the specific orphan-designated uses of orphan drugs.
  - Appears to conflict with the plain text of the statute
    - “Covered outpatient drug” for purposes of 340B “shall not include a drug designated” by the HHS Secretary under FFDCA section 526.
  - Some 340B hospitals contend that prices above the 340B price for non-orphan uses of a drug are “overcharges”.
    - Allegation made even though the rule has not been finalized; merely proposed
  - Manufacturers are between a rock and a hard place in the interim.
    - CMS' failure to support explicitly voluntary 340B pricing is inexplicable.

# Concerns About 340B Entities

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- Concern About Focus on Spread: Disturbing Anti-Kickback Implications
  - Contract pharmacy relationships, “referral” agreements, “shared savings” agreements, fee sharing with consultants, etc.
- Concerns About Clinical Pathways Being Changed to Secure Higher Spreads
  - Concerns about manipulations of admissions processes and prescription choices (including brand vs. generic switching) to maximize margins
  - Concerns about perceived misuse of outpatient observation stays: higher co-payments and absence of qualifying stays
  - Concerns about early discharges
  - Potential billing issues
- Concerns About Diversion:
  - “Patients” who are not patients
  - Inpatient diversion
  - Violations of the GPO prohibition
  - Credit/rebill requests that appear to be designed to mask diversion; etc.

# “Patient” Definition and Diversion Issues

- GAO’s focus on the currently insufficient definition of a 340B-eligible “patient” echoes a wide variety of health care stakeholders who have expressed concerns related to the 340B “patient” definition and covered entity compliance.
  - Overly broad interpretations of the regulatory 340B “patient” definition, or outright violations of existing program guidance, constitute diversion.
- Some examples of “patient” diversion issues:
  - Administrative “services” only
  - Employee-only relationships
  - Use of “contracted” providers to extend the scope of the 340B program where those “contracts” create merely superficial ties
  - Use of “referral relationships” where care is actually being transferred to a different provider
- HRSA on the record in its 2007 proposed revision of the “patient” definition (not finalized):
  - “Through covered entity networking, contracting, and other arrangements, additional questions about the definition of a 340B patient have arisen. . . . **[I]t is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion** of medications purchased under the 340B Program.” 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) (emphasis added).



# Covered Entity Concerns: A Few Thoughts on Product Availability and Shortages

- Allegations of manufacturers not making enough product available to 340B entities at 340B prices
  - GAO stated that “36 of the 61 stakeholders we interviewed did not report any effect on covered entities’ or non-340B providers’ access to drugs related to manufacturers’ distribution of drugs at 340B prices. . . . The remaining 25 stakeholders [that GAO interviewed] . . . reported that manufacturers’ distribution of drugs at 340B prices affected providers’ access to drugs primarily in two situations. The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply of which is inherently limited; and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities.” GAO Report at 18–19.
  - Interestingly, the GAO report’s comments regarding 340B product availability focus on IVIG—but the current shortages issues, as widely reported by the media, center on generics and oncology products.
    - IVIG does not appear to be a significant issue now.
- This is a very complex issue—far more complex than many stakeholders, lawmakers, and policymakers may realize.
  - Supply challenges are real, difficult to address, and often impossible to address quickly.
  - 340B entity activity has substantially contributed to the shortage problems.



# Supply Challenges

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- Host of difficult issues
  - Manufacturing issues
  - Production capacity limitations
  - Raw material shortages
  - Regulatory barriers
    - Changes in manufacturing outputs and processes require FDA approval.
    - For drugs containing any amount of a controlled substance (e.g., ADHD drugs), DEA approval may be required, too.
  - Unpredictable demand shifts
    - Including “secondary shortage” issues (increased demand for other products in response to another product shortage)
- The new facility paradigm and its challenges

# 340B Entity Activity Has Substantially Contributed to the Shortage Problems

- Chasing the spread is a mistake; it increases the likelihood of shortages; it raises disturbing AKS compliance issues; results in harmful cost-shifting; and adversely affects patients, both in terms of access and financially.
  - Masks true increases in demand and, therefore, slows manufacturers' recognition of a need to take steps to increase production capacity
  - Distorts purchase histories that are used in base periods to determine allocations
  - Concentrates demand on a subset of products and manufacturers
    - Makes more of the market dependent on one or a few manufacturers
      - Greater risk to everyone when manufacturing issues arise
      - Disincentivizes the other manufacturers from investing in increasing capacity
- GPO violations give 340B entities “two bites at the apple”
  - Not fair to non-340B customers and their patients
- Inpatient diversion
  - Reduces product available through GPOs in shortages and means that 340B covered entities have not built an accurate purchase history with the GPOs

# 340B Entity Activity Has Substantially Contributed to the Shortage Problems

- History of trying to capitalize inappropriately on spreads during shortage situations
  - Massive orders — puts patients at risk and undermines the credibility of the program
    - GAO was asked to study “Whether mandatory sales of certain products by the 340B program could hinder patients access to those therapies through any provider.” PPACA, Section 7103(b)(2).
    - GAO report noted that, when there was a significant drop in the 340B price of a drug, some covered entities hoarded or stockpiled the drug, which resulted in shortages for other providers, including other covered entities. GAO Report at 21.
  - ASHP “Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems” specifically recommend that entities “[r]efrain from stockpiling”:
    - Can create “artificial shortages”. See ASHP, Summit Summary Report on Drug Shortages (Nov. 2010), App. E; see also HDMA Drug Availability Task Force, Ensuring Product Availability – A Recommended Voluntary Industry Guideline (2003) (identifying and discussing “Excessive Inventory Buying” as a key factor and cause in product availability issues).

# A Related Issue: Implementation and Implications of the New Statutory “Must Offer” Language

- Manufacturers do not, in my experience, have any problem with the notion that their distribution systems should be non-discriminatory, as current program guidance requires.
- But patient advocacy organizations and manufacturers have expressed concern about the potential for the new “must offer” language to be misinterpreted, as some 340B stakeholders are advocating, to create a “preference” for 340B entities over other providers and their patients.
- Creating a “340B preference” could lead to dangerous adverse effects for many patients.
  - A 340B preference could lead to situations where some products, particularly those with limited supply, become unavailable to patients of non-340B providers.
  - A concern is that a 340B preference, particularly for 340B hospitals, would force patients to shift their site of care from their provider of choice (e.g., a physician office) to a hospital—or to forego the treatment best suited for their needs.
  - There are very real patient risks associated with changing sites of service.
- For manufacturers, this is what is at issue in the implementation of “must offer”.
  - Notably, this new language makes no reference to an obligation to “sell”.
- Legislative history confirms and reinforces the meaning of “must offer” as a codification of HRSA’s existing nondiscrimination guidance—and nothing more.

# On the Horizon for 340B Compliance

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- In response to GAO's recommendations, HRSA said it will:
  - Continue to work with the manufacturers to identify potential diversion by covered entities and to develop audit plans where evidence suggests potential diversion may be occurring
  - Develop and implement comprehensive educational and communication plans related to (1) covered entity diversion, (2) 340B non-discrimination and drug distribution requirements for manufacturers, and (3) hospital eligibility criteria
  - Continue to work with manufacturers to provide clearer guidance on working with HRSA to develop specific allocation plans where needed, and continue to work with DOJ when fair, voluntary allocation plans are not developed
  - Review the draft of the proposed patient definition guidelines in view of ACA changes and develop revised guidelines for publication
  - Further publicize existing criteria for hospital participation in 340B
  - Initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011
- Other pending oversight responsibilities for the agency:
  - Rulemaking to implement formal alternative dispute resolution, civil monetary penalties, and pricing transparency requirements; further action on orphan drug exclusion proposal
  - Status uncertain given funding and resources issues