Opportunities and Risks of Hospital Participation in the 340B Drug Pricing Program During an Era of Increased Scrutiny and Enforcement

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Overview

- Hospital 340B compliance issues
- 340B enforcement actions against hospitals
- Anti-diversion/patient eligibility requirement
- Duplicate discount prohibition
- GPO prohibition
- 340B reimbursement threats
- Medicare Part B payment cuts
- Political climate
- 340B opportunities

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Hospital 340B Compliance Issues

- Anti-Diversion/Patient Eligibility
- Duplicate Discounts
- Group Purchasing Organization (GPO) Restriction (applicable to disproportionate share, children's and cancer hospitals)
- Maintain Auditable Records
- 340B Database Errors
- Orphan Drug Restriction (applicable to rural referral centers and sole community, critical access and cancer hospitals)

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Hospital 340B Compliance Issues (cont'd)

HRSA Sanction Authority for Diversion, Duplicate Discount and Orphan Drug Violations

- Repayment to manufacturers
- Interest on repayments for knowing and intentional violations
- Removal from 340B for violations that are systematic, egregious, knowing and intentional
- Health Resources and Services Administration (HRSA) Notice: "A finding of non-compliance in two or more audits, depending on the type of violation, may be considered systematic and egregious, as well as knowing and intentional, which may result in the covered entity being removed from the 340B Program…"

HRSA Sanction Authority for GPO and Auditable Records Violations

- Removal from 340B program
- Repayment to manufacturers

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340B Enforcement Actions Against Hospitals

- To our knowledge, no covered entity (CE) has been terminated or subject to interest payments as a result of violating above requirements
- HRSA's reliance on sub-regulatory guidance weakens its enforcement authority
  - Recent White House Executive Orders
  - *Genesis* case
- To our knowledge, no hospital has been legally compelled to make repayments by a manufacturer
  - No private right of action under *Astra USA v. Santa Clara County* case
  - No dispute resolution regulation yet

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340B Enforcement Actions Against Hospitals (cont'd)

A growing number of manufacturers are using informal means to identify and address 340B compliance issues with CEs and HRSA urges CEs to work in "good faith" with manufacturers

- CE should be cooperative
  - Failure to cooperate could lead to formal manufacturer audit and serve as "reasonable cause" that violation occurred
- CE must balance its own interests
  - Compliance with federal and state privacy laws
  - No "fishing expeditions" – need specific NDCs, time period, general explanation of why data is being requested
- Issues
  - Old data is difficult to retrieve – retrieval fees, wholesalers change, manual processes often involved, etc.
  - Evolving HRSA guidance – cannot apply current standards to past practices
  - Attorney-client privilege

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Anti-Diversion/Patient Eligibility Requirement

340B statute prohibits a CE from reselling or transferring 340B drugs to anyone other than its "patient." HRSA issued a three-part definition of "patient." 61 Fed. Reg. 55,156 (Oct. 4, 1996)

1. Record maintenance test

The covered entity maintains records of the individual's health care.

2. Professional care test

The individual must be under the care of a physician or other health care professional who is employed by, under contract with, or in a referral relationship to the covered entity such that responsibility for the individual's care remains with the covered entity.

3. Qualified health care service/range of services

The individual must receive a range of health care services that are consistent with the services for which grant funding or FQHC look-alike status has been provided to the covered entity. (This requirement is not applicable to hospitals.)

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Anti-Diversion/Patient Eligibility Requirement (cont'd)

- An individual will not be considered a patient of the covered entity if the only health care service received is the dispensing of a drug or drugs for self-administration in the home setting.
- Only provider-based hospital outpatient departments (HOPDs) may purchase, dispense or administer 340B drugs. HRSA guidance states that, '[o]utpatient facilities which are an integral component of the DSH will be included on the DSH Medicare cost report, and only those facilities will be eligible for PHS [3408] discount pricing." 59 Fed. Reg. 47,884, at 47,885. (Sept. 19, 1994).

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Anti-Diversion/Patient Eligibility Requirement (cont'd)

- HRSA's interpretation of its patient definition guidelines has narrowed over time such that, in general, a prescription is only 340B eligible if it originates from a 340B-registered hospital site.
- This "location" test has a few execptions:
  - Discharge prescriptions
  - Prescriptions written as a result of referral from 340B entity to outside entity, but only if (1) the referral is documented in the CE's medical record and (2) the CE receives a record or summary of visit at which the prescription is written
  - Drugs administered within a 340B-registered hospital site such as infusion drugs
- "Courtesy" prescriptions are ineligible even if written within a registered hospital location

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Duplicate Discount Prohibition

- Drug manufacturers are required to give rebates to state Medicaid programs on drugs reimbursed under state Medicaid programs, either fee-for-service (FFS) or managed care, but are protected from giving both a 340B discount and a Medicaid rebate on the same drug.
- CEs must choose between using 340B drugs for Medicaid patients ("carve-in") or not using 340B ("carve-out"). They may make a different election for each Medicaid billing number.
- Medicaid programs submit for rebates on carve-out claims, but forgo rebates for carve-in claims.
- For FFS drugs, CEs notify HRSA of their election and submit their Medicaid billing numbers and NPIs for all carve-in claims. This billing information is posted on HRSA's Medicaid Exclusion File so states can exclude such claims from their rebate requests.

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Duplicate Discount Prohibition (cont'd)

- States often require CEs and their pharmacies (in-house and contract) to apply claims modifiers when billing 340B drugs
- Typical 340B modifier include:
  - UD modifier for physician administered drugs
  - "20"; "08" and/or "05" for retail drugs
- Centers for Medicare and Medicaid Services (CMS) requires Medicaid managed care organizations (MCOs) to identify 340B claims using these modifiers so that the claims can be excluded from the states' rebate requests
- Many states and their MCOs are not using these claims identification standards to prevent duplicate discounts.

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Duplicate Discount Prohibition (cont'd)

States and CEs sometimes disagree over how duplicate discounts should be avoided for drugs billed to Medicaid MCOs. Examples of problematic state MCO duplicate discount policies:

1. States shifting repayment obligation for MCO-related duplicate discounts to CEs
2. Mandatory (and default) carve-out policies for all Medicaid
3. Use of Medicaid Exclusion File for MCO drugs
4. States interpreting contract pharmacy carve-out language in their State Plan Amendments (SPAs) as applying to MCO drugs
5. States carving out drug benefit from MCOs and administering on FFS basis

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GPO Prohibition

- DSH, children's and cancer hospitals are prohibited by the 340B statute from purchasing covered outpatient drugs through a GPO or other group purchasing arrangement.
- For hospitals that use replenishment-based virtual inventory systems, initial purchases of an NDC must be on a non-340B, non-GPO account, typically at wholesale acquisition cost (WAC), and replenishment under the hospital's 340B and GPO accounts must be for the same NDC (including package size) as for the drugs dispensed or administered. See HRSA Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization Participation (Feb. 7, 2013)
- Repayment methodology for GPO prohibition violations is unclear – refund the 340B discounts or repurchase the non-compliant GPO purchases at WAC?

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GPO Prohibition (cont'd)

- HOPDs may "opt out" of the 340B program in order to access and use GPO drugs if they meet four requirements:
  - Are located at a different physical address than the hospital's parent site;
  - Are not registered on the OPA 340B database as participating in the 340B program;
  - Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
  - Maintain records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database.

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340B Reimbursement Threats

- A growing number of pharmacy benefit managers (PBMs) and other third party payers are
  - Offering CEs and their in-house or contract pharmacies lower reimbursement rates than those offered to non-340B entities;
  - Establishing 340B-specific barriers to participating in payer's pharmacy network; and/or
  - Excluding CE pharmacies from pharmacy network entirely
- Two steps in addressing discriminatory reimbursement
  1. Analyze whether discriminatory terms in payer's contract is applicable
  2. Engage in advocacy to block or rescind implementation of discriminatory terms

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340B Reimbursement Threats (cont'd)

- A growing number of states have passed laws prohibiting PBMs and other payers from reimbursing 340B providers and their pharmacies less than is paid to non-340B entities
- Example language
  - West Virginia SB 489: "A pharmacy benefit manager, or any other third party, that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. §256b **shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities**, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program…"
- Dispensing Fees Provision
  - Rhode Island H 5094: "Rhode Island department of health shall use the same dispensing fee in its reimbursement formula for 340B prescription drugs as the department uses to pay for non-340B prescription drugs under the Medicaid program."

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340B Reimbursement Threats (cont'd)

State	Text	Status
Minnesota SF 278	A [PBM] … must not reimburse an entity or a pharmacy under contract with such an entity participating in the federal 340B Drug Pricing Program differently than other similarly situated pharmacies	Law - August 1, 2019
Montana SB 335 [FQHCs only]	A patient eligible to receive drugs under an agreement covered by 42 U.S.C. 256b may not be discriminated against through conditions imposed on a federally certified health entity or its contract pharmacy through which the patient is eligible to receive drugs.	Law - May 1, 2019
Oregon HB 2185	A [PBM] … may not reimburse a 340B pharmacy differently than any other network pharmacy based on its status as a 340B pharmacy	Law - July 16, 2019
South Dakota HB 1137	No [PBM] may discriminate against a pharmacy participating in a health plan as an entity authorized to participate under section 340B of the Public Health Service Act	Law - March 7, 2019
West Virginia SB 489	A [PBM]… that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. §256b shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities	Law - April 16, 2019

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Medicare Part B Payment Cuts

- Effective January 1, 2018, CMS began reimbursing for certain Medicare Part B drugs (SI "K") purchased with 340B discounts at ASP-22.5%. 82 Fed. Reg. 52,356 (Nov. 13, 2017)
- Effective January 1, 2019, CMS extended ASP - 22.5% reimbursement to new off-campus clinics subject to "site neutral" payments under section 603 of the Bipartisan Budget Act of 2015
- Part B cuts do not apply to cancer, children's, or rural sole community hospitals
- The hospital community has successfully challenged the Part B cuts in court but the government's appeal is still pending in DC Court of Appeals
- Meanwhile, CMS's proposed 2020 outpatient prospective payment system (OPPS) rule still includes the Part B cuts. 84 Fed. Reg. 40,482 (Aug. 14, 2019).

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Political Climate

- PhRMA spent a record $27.5 million on lobbying in 2018
- PhRMA and BIO have targeted 340B program for reform
- Multiple Congressional hearings and bills introduced on 340B
- Conversation has shifted to controlling high drug prices which has alleviated some of the political pressure on 340B
- Proposed rebate programs for Medicare Parts B and D would exacerbate duplicate discount problem

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340B Opportunities

- Contract pharmacies, especially for specialty drugs
- Establishing an in-house specialty pharmacy
- Hospital-based "centers of excellence" for employees and family members – both within health system and outside employers
- Medication therapy management
- Reorganize freestanding clinics into provider-based HOPDs
  - Consider both Medicare and 340B consequences of reorganizing your health system

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Medicare and 340B Consequences of Hospital Organizational Changes

Scenario	Medicare Impact	340B Impact
On-campus clinic moves off-campus	Reduced reimbursement: full OPPS to site neutral	Site remains 340B eligible before and after with no gap
Excepted off-campus clinic moves to another off-campus location	Reduced reimbursement: full OPPS to site neutral	Site remains 340B eligible before and after with no gap
Non-excepted off-campus clinic moves to another off-campus location	No change: site neutral reimbursement before and after	Site remains 340B eligible before and after with no gap
Excepted off-campus clinic moves on-campus	No change: full OPPS reimbursement before and after	Site remains 340B eligible before and after with no gap
Non-excepted off-campus clinic moves on-campus	Increased reimbursement: site neutral to full OPPS	Site remains 340B eligible before and after with no gap
On-campus clinic adds an off-campus location	On-campus site: full OPPS reimbursement Off-campus site: site neutral reimbursement	Increased 340B savings but entry of new site is delayed until cost report is filed reflecting costs and charges of new location (8-20 months)
Off-campus non-340B facility acquired or reorganized into provider-based HOPD	Increased reimbursement, but at site neutral rate	Increased 340B savings but entry of new site is delayed until cost report is filed reflecting costs and charges of new location (8-20 months)

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Questions?

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