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WHAT EVERY AMC NEEDS TO KNOW ABOUT THE 340B PROGRAM

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AHLA LEGAL ISSUES AFFECTING ACADEMIC MEDICAL CENTERS AND OTHER TEACHING INSTITUTIONS

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Agenda

- History of 340B Program
- Sources of Law
- Key 340B Concepts
- Operational Considerations
- Potential Opportunities for AMCs to Increase 340B Utilization
- Potential threats to 340B Revenue

History of 340B Program

- 340B Program was necessitated by the Medicaid Drug Rebate Program
  - Enacted in 1990
  - Formula discouraged discounted sales to safety net providers
- 340B Program enacted in 1992
- Modified by the ACA to add new “covered entities” and new penalties
- 340B proposed “Mega-Guidance” issued, then withdrawn

Sources of Applicable Law

- HRSA operates the 340B Program through the Office of Pharmacy Affairs, or “OPA”
- HRSA/OPA are required to comply with the 340B statute
- HRSA/OPA has issued 19 Federal Register Notices, 2 of which are actually regulations
- HRSA/OPA has also issued 8 “Policy Releases”
- HRSA/OPA regularly issues FAQs
- HRSA/OPA has engaged Apexus as its prime vendor and allows Apexus to decide matters of agency policy
- HRSA/OPA often sets policy through its adjustments during audit

Key 340B Concepts

- "Covered Entity"
  - Two types – PHS grantees and safety net hospitals
  - Safety net hospitals include DSH, TEFRA cancer centers, children's hospitals, RRCs, SCHs, and CAHs
- For hospitals that are seeking covered entity status, requirements vary but include:
  - Ownership, operation, or agreement with, a state or local government entity
  - Satisfaction of a DSH percentage threshold
  - Prohibition of purchasing GPO drugs for outpatient areas
  - Refraining from purchasing orphan drugs through 340B Program (n/a for DSH hospitals)
- Hospitals that fall within multiple categories can enroll in whichever one suits them best

Key 340B Concepts *(cont.)*

- "Covered Entities" *(cont.)*
  - May include "Child Sites"
    - Technically these are sites to which 340B drugs can be shipped, but HRSA now gives these sites a more expansive role
    - Separately listed in OPA covered entity database
  - HRSA requires certain cost reporting treatment for Child Sites:
    - Site must be on a reimbursable line of the cost report
    - Site must have Medicare charges associated with it

Key 340B Concepts *(cont.)*

- "Patients"
  - Furnishing drugs to *non-patients* qualifies as impermissible diversion
  - 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

Key 340B Concepts *(cont.)*

- "Patients" *(cont.)*
  - "Records" standard seems pretty lax, but:
    - Can't just be for the administration of drugs
    - HRSA has stated that it must be a medical record, and not a record relating to the CE's employer health plan
    - Many providers believe that the care rendered and the 340B drug administered or dispensed must relate to each other

Key 340B Concepts *(cont.)*

- "Patients" *(cont.)*
  - Eligible professional questions include:
    - What is the minimum nexus to the CE? HRSA says mere privileges don't count (FPP members almost certainly qualify)
    - Does the "professional" have to be a physician? HRSA's guidance is mixed
    - What does "referral for consultation" mean under HRSA's current interpretation?

Key 340B Concepts *(cont.)*

- "Covered Outpatient Drugs"
  - Drugs that are "incident to" an inpatient or outpatient hospital service, or a physician service, are not considered covered outpatient drugs for 340B purposes.
  - HRSA has claimed that an analysis needs to be undertaken for each use of a drug:
    - Is the drug covered separately in the particular setting in which it's being used?
    - Is the drug covered separately for the particular payer in this particular setting?

Key 340B Concepts *(cont.)*

- "Covered Outpatient Drugs" *(cont.)*
  - Apexus FAQ (1355) states:

  If the covered entity interprets the definition of covered outpatient drug referenced in the 340B Statute (Social Security Act 1927 (k)) and decides that drugs do not meet this definition, a GPO may be used for drugs that are not covered outpatient drugs. The decision the covered entity makes should be defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable."

Key 340B Concepts *(cont.)*

- "Covered Outpatient Drugs" *(cont.)*
  - Orphan drugs are excluded for Cancer Centers, CAHs, RRCs and SCHs.

Key 340B Concepts *(cont.)*

- "GPO Prohibition"
  - Contained within the 340B statute
  - Applies to DSH hospitals, cancer centers and children's hospitals, but not to RRCs, SCHs, or CAHs
  - Drugs for inpatient use can be purchased through a GPO
  - Applies to "ship to" pharmacies, but not contract pharmacies

Key 340B Concepts *(cont.)*

- "GPO Prohibition" *(cont.)*
  - Applies to all outpatient areas, unless a site is carved out by meeting each of the following:
    - The site is located at its own address, separate from the Parent Site
    - The site is not itself registered as a Child Site
    - The site has its own account for purchasing drugs
    - The site has records that show that its drugs are not being commingled with 340B stock

Key 340B Concepts *(cont.)*

- "Medicaid Exclusion"
  - Statute prohibits seeking 340B pricing on utilization where the State is separately seeking rebates under the Medicaid Drug Rebate Program
  - HRSA uses an "exclusion list" to allow CEs to "carve in" Medicaid
  - CMS requires States to reimburse for drugs at their "actual acquisition cost"
  - Most challenging is determining how to avoid duplicate utilization for Medicaid managed care

Key 340B Concepts *(cont.)*

- "Contract Pharmacy Arrangements"
  - CEs were originally allowed to use contract pharmacies in 1996, and HRSA expanded and formalized its policy in 2010 guidance
  - If an individual is a "patient" of the CE, then a contract pharmacy can replenish inventory for drugs dispensed to the individual using 340B purchasing, so long as it has an appropriate agreement with the CE

Key 340B Concepts *(cont.)*

- "Contract Pharmacy Arrangements" *(cont.)*
  - General requirements:
    - CE must specify in an agreement that CE bears ultimate responsibility to ensure against diversion and duplicate discounts and meet all other 340B program requirements
    - CE must assume responsibility for the pricing of the drug
    - CE must be responsible for buying the drug, even if it is shipped to the contract pharmacy (aka "bill to ship to")
    - CE must agree to provide comprehensive pharmacy services, such as dispensing, recordkeeping, and drug utilization review

Key 340B Concepts *(cont.)*

- "Contract Pharmacy Arrangements" *(cont.)*
  - General requirements *(cont.)*:
    - Patient freedom to choose pharmacy must be honored
    - Parties must comply with all applicable Federal, State, and local laws
    - Contract pharmacy must provide periodic reports to CE indicating its compliance with its agreement
    - Contract pharmacy must have tracking system to prevent and detect diversion

Key 340B Concepts *(cont.)*

- "Contract Pharmacy Arrangements" *(cont.)*
  - General requirements *(cont.)*:
    - Reconciliations of dispenses and patient lists must be made
    - Cannot use for Medicaid beneficiaries
    - Both parties must acknowledge that they are subject to audit by HRSA and manufacturers
    - An annual outside audit of compliance with the 340B requirements is expected

Key 340B Concepts *(cont.)*

- "Contract Pharmacy Arrangements" *(cont.)*
  - Operational features include:
    - Patient presents prescription to contract pharmacy
    - Software invisibly determines if the individual meets the patient criteria for the CE
    - If there is a match, then the software accrues 340B utilization for invoicing to CE
    - Claim is paid by payer just like any other claim
    - Invoicing generates two outcomes:
      - CE receives payer's reimbursement, minus an admin fee
      - CE is informed of when new 340B drug is to be ordered for pharmacy (referred to as a "virtual inventory" system)

Key 340B Concepts *(cont.)*

- Sanctions
  - No FCA liability
  - If diversion is found, then expectation is that there will be a repayment to the manufacturers
  - If there has been "knowing and intentional" non-compliance, interest may be payable
  - If there is also evidence of "systematic and egregious" non-compliance, removal from the program may ensue

Operational Considerations

- Enrollment
  - 4 windows a year, to take effect prospectively at the beginning of the next calendar quarter
  - Parent Site, Child Sites, and Contract Pharmacies, must all be enrolled separately
  - Secondary campuses must have each department enroll separately
  - Revalidation occurs annually

Operational Considerations *(cont.)*

- "340B Administrator" or "Splitter Software"
  - Software that tracks utilization in outpatient areas and "mixed use" areas
  - "Accumulates" to one of 3 accounts: (a) 340B; (b) GPO; or (c) WAC
  - Connects with contract pharmacies

Operational Considerations *(cont.)*

- Self-auditing
  - Most policies provide for annual self-auditing
  - Should be able to trace back all 340B purchasing to the dispensing (or prescription for) a covered outpatient drug for a patient receiving outpatient department services
  - In its Mega-Guidance, HRSA proposed requiring disclosures to HRSA for any diversion, but HRSA points to no legal authority for such a requirement
  - Many CEs simply notify the affected manufacturers, sometimes with an offer to repay (or earn out) any potential diversion, and sometimes not

340B Opportunities for AMCs

- Centralization of pharmacy services
  - AMCs and other health systems are creating their own “contract pharmacy” that benefits all of the constituent hospitals
  - Must make sure that the pharmacy sits under the System, and not the CE, so as to make sure that it is a “contract pharmacy” and not a “ship to pharmacy”
  - Such pharmacies are not subject to the GPO prohibition
  - Can use clout to achieve ideal GPO pricing while also centralizing 340B dispensing and capturing more of the 340B retail dispensing upside
  - Sometimes involves centralization of specialty pharmaceuticals as well

340B Opportunities for AMCs *(cont.)*

- Expansion of provider-based clinics
  - HRSA's current interpretation of an eligible prescription is that it must be issued in space qualifying as a reimbursable cost center
  - AMCs and others have historically been reluctant to convert primary care physician offices into provider-based clinics because of dual coinsurance concerns
  - BiBA 2015 changes that landscape
  - Also unclear if a freestanding office could qualify as a "reimbursable cost center" even without becoming provider-based

Threats to 340B Revenue

- Now-withdrawn (kind of) Mega Guidance would have added many new requirements to the definition of "patient:"
  - The patient must be receiving care at the Parent Site or a Child Site.
  - The patient must be receiving care from an employed physician, or one who has reassigned his benefits to the covered entity.
  - The patient's prescription is the result of the service received from the eligible physician.
  - The services must be consistent with those allowed to be furnished under the PHS grant (for PHS grantees).
  - The services leading to receipt of the prescription must be outpatient services.
  - The patient records must be accessible to the covered entity.
- However, HRSA's audits sometimes treat some of these requirements as if they have been implemented.

Threats to 340B Revenue *(cont.)*

- HRSA Audits
  - HRSA's intent is to audit every CE at least once every 5 years
  - Audits follow a HRSA process
    - Transmit audit letter
    - Perform onsite and desk review
    - Issue requests for additional information with specified deadlines
    - Findings issued
    - CEs can file a "Notice of Disagreement"
    - HRSA issues final findings, which have no appeal rights associated with them
    - CE provides CAP and open letter to manufacturers

Threats to 340B Revenue *(cont.)*

- HRSA Audits *(cont.)*
  - Preparation for audit is important
  - Preparation includes:
    - Reviewing CE's 340B policy and comparing it to HRSA's guidance (including those parts of the Mega-Guidance that HRSA is still considering existing policy)
    - Asking questions of key staff regarding how they can prove compliance with all applicable requirements
    - Reviewing self-audit reports, including any audits of contract pharmacies
    - Compiling all necessary documentation, such as a the contract with the State or local governmental entity undertaking to provide care to the indigent