340B Program Compliance: Pitfalls, Disclosures and Best Practices

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340B – Overview

340B

History/Purpose:

- **Section 340B of the Public Health Service Act (42 U.S.C. § 256b)** was implemented by Congress in 1992 of Public Law 102-585, Section 602.
- The 340B statute requires pharmaceutical manufacturers to enter into an agreement with HHS to provide discounts on **"covered outpatient drugs"** purchased by certain providers called **"covered entities"** that serve the nation's vulnerable patient populations as a condition of the manufacturer's drugs being reimbursable under Medicaid and Medicare Part B.
- Participation in the 340B program provides covered entities with access to significant pricing discounts on covered outpatient drugs.

2

340B – Polling Questions

340B

I am employed by:

- A hospital or health system
- A 340B grantee
- A consulting organization
- A law firm
- A government entity
- Other

3

340B – Polling Questions

340B

I would describe my level of knowledge of 340B as:

- Minimal (just beginning to learn about 340B)
- Average (deal with 340B matters occasionally)
- Expert (routinely advise on 340B compliance matters)

4

340B – Overview

340B

Administration of the 340B Program:

- **Federal Regulatory Agency**
  - The Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA) is responsible for administration and oversight of the 340B Program.
- **Prime Vendor Program (PVP)**
  - Contractor to OPA that provides guidance on 340B program. Current prime vendor is Apexus.

5

340B – Overview

340B

340B Program Guidance:

- 340B Program guidance is generally issued through Federal Register Notices, Policy Releases, and FAQs.
- All Program guidance is on the HRSA website: http://www.hrsa.gov/opa/programrequirements/index.html (Federal Register and Policy Notices), http://www.hrsa.gov/opa/faqs/index.html (OPA FAQs).
- HRSA proposed "Mega guidance" in August 2015 that would affect all aspects of program.

6

340B – Overview

340B

Status of 340B Regulations:

- Calculation of 340B Price and Manufacturer Civil Monetary Penalties. Final rule issued January 5, 2017 (82 Fed. Reg. 1210). Includes Penny Pricing Policy. Implementation postponed for fifth time until July1, 2019. 340B Health, AHA and others have filed lawsuit contesting delay.
- Mandatory Dispute Resolution. Proposed rule issued on August 12, 2016. (81 Fed. Reg. 53381). Withdrawn.

7

340B – Compliance Issue Overview

340B

Principal Compliance Issues for Providers:

1. **Anti-Diversion/Patient Eligibility**
2. **Duplicate Discounts**
3. **Group Purchasing Organization (GPO) Restriction (applicable to 11.75% DSH, Children's and Cancer Hospitals)**
4. Orphan Drug Restriction (applicable to RRCs, SCHs, CAHs, and Cancer Hospitals)
5. OPA Database Errors
6. Maintain Auditable Records

8

340B – Sanctions for Non-Compliance

340B

OPA Sanction Authority for Diversion and Duplicate Discount Issues:

- Repayment to manufacturers.
- Interest on repayments for knowing and intentional violations.
- Removal from 340B for violations that are systematic, egregious, knowing and intentional. 42 USC § 256b (a)(5)(c),(d)(v)(I),(II).
- HRSA Notice: "A finding of non-confidence 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 CE being removed from the 340B Program…"

9

340B – Sanctions for Non-Compliance

340B

Repayments to Manufacturers – Process and Tools:

- Develop template letter to Manufacturers stating facts;
  - Offer options: 1) credit and rebill, 2) check, 3) reverse accumulation (not favored)
- Develop spreadsheet with all identified drugs, quantities, & estimated amount to be credited (examples upon request);
- Develop spreadsheet to track all letters and refunds;
- Scan and preserve copies of emails, letters, checks and dates of activities;
- Preserve all of the above for future HRSA or Manufacturer audits.

60

340B – Compliance Issues

340B

OPA Sanction Authority For GPO Violation and Failure to Maintain Auditable Records:

- Termination from program, but OPA has not terminate if covered entity is currently in compliance.
- Compliance suggestions:
  - Complete regular self audits of parent, child sites and contract pharmacies
  - Don't assume staff will comply with directions
  - Education and Validate
  - If error – correct within 30 days – Notify and follow HRSA Guidelines

61

340B – Audits

340B

Audits of Covered Entities:

- HRSA audits began in 2012. Audit reports posted:
  - 51 audits in FY 2012
  - 94 audits in FY 2013
  - 99 audits in FY 2014
  - 200 audits in FY 2015, 2016 and 2017
  - 101 audits in FY 2018 (to date)
- Manufacturers may also audit providers, but OPA must approve audit work plan based on "reasonable cause" of violation. 61 Fed. Reg. 65,406 (Dec. 12, 1996).
- **Alert:** HRSA vs Bizzell Group
  - Greater knowledge and less control over outcome!

62

340B – Definition of Patient

340B

Anti-Diversion/Patient Eligibility:

Definition of "patient" for 340B includes three criteria:

1. **Record Maintenance Test** -The covered entity **maintains records of the individual's health care**.
2. **Professional Care** -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.)

- 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.

13

340B – Eligible Facilities

340B

Anti-Diversion/Patient Eligibility: Eligible Facility

- Only provider-based outpatient departments may dispense 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).
  - **Example:** Hallway Prescriptions

14

340B – Patient Definition / Physician Administered Drugs

340B

Anti-Diversion/Patient Eligibility:

- **LOCATION, LOCATION, LOCATION**
- For drugs administered in hospital, no exception to "location rule". Drugs must be administered in outpatient area.
- In hospital areas in which outpatient may switch to inpatient (ED, observation), hospital must develop a 340B policy to determine when patient is eligible outpatient (e.g. based on dispensing of drug, administration of drug, hospital billing)
  - **Compliance Tip: 340B Policy** – Dispensing vs Administration

15

340B – Patient Definition / Self Administered Drugs

340B

Anti-Diversion/Patient Eligibility:

- **LOCATION, LOCATION, LOCATION**
- Prescriptions for retail (i.e., self-administered) drugs must be written in hospital outpatient department with some exceptions:
  - Discharge prescription.
  - Prescription written as the result of a referral. (CE medical record must include written referral and record of visit, or summary of visit, from outside clinic that wrote prescription.
  - SNFs and NFs?

16

340B – Potential Changes

340B

HRSA Proposed "Mega Guidance":

- Six part definition of patient
- Would prohibit 340B use for:
  - Discharge prescriptions
    - Could results in **readmissions** resulting in financial penalties
    - **Note:** Penalties levied against safety-net hospitals, in fiscal year 2019, will drop by apx 25% from fiscal year 2018
  - Prescriptions written outside hospital but administered in hospital
    - Infusion clinics should be on alert
  - Drugs administered to outpatients who are ultimately admitted to hospital
    - Current CMS payment rule - Outpatient diagnostic service and outpatient non-diagnostic services within 72 hours of admission are bundled with the inpatient claim

17

340B – Duplicate Discounts

340B

Duplicate Discount Prohibition:

- Drug manufacturers are required to give rebates to State Medicaid programs on drugs reimbursed under State Medicaid programs, either FFS or managed care, but are protected from giving a both a 340B discount and a Medicaid rebate on the same drug.
- Covered entities may elect to use 340B drugs for Medicaid patients ("carve-in") or may elect not to use 340B for Medicaid patients ("carve-out"). May make different election for each Medicaid billing number.
- Medicaid programs submit for rebates on carve-out 340B drugs, but forgo rebates for entities that carve-in.
- Covered entities notify OPA of their election and OPA maintains an "exclusion file" for State Medicaid to determine if an entity has carved-in. State may also require billing modifier to identify 340B drugs.

18

340B – Duplicate Discounts

340B

Duplicate Discounts – Compliance Suggestions:

- Contact your state Medicaid program now to identify person who is able to assist your entity if you need or suspect a duplicate discount matter.
- **Note:** Medicaid also is audited by OPA/HRSA - their records must also be accurate. Medicaid is motivated to help entities to ensure compliance.
- Medicaid will direct your entity to identify and correct possible errors.
- Entity will maintain documentation to prove compliance with Medicaid related to duplicate discounts.

19

340B – Duplicate Discounts & MCOs

340B

Duplicate Discount and Medicaid Managed Care:

- The Affordable Care Act § 2501(c) made duplicate discount prohibition applicable to Medicaid MCO drugs.
- Exclusion File does not apply to Medicaid MCO claims. HRSA Policy Release 2014 -1.
  - **Compliance Tip:** MCO's and Manufacturers are requesting information related to use of modifiers and identifying potential non-compliance with your state Medicaid rules. Be alert and know your state rules.

20

340B – State Medicaid Billing Issues

340B

State Medicaid Billing Requirements for 340B Drugs:

- States may require 340B claims to be flagged (e.g. UD modifier for physician administered drugs ;"20"; "08" and/or "05" for retail claims).
- Recent state initiatives to require covered entities to carve out to avoid disputes on duplicate discounts.
- **Compliance Tip:** Even if a State Medicaid relies on modifiers, and not the Medicaid Exclusion File, to identify covered entities that carve in or out, HRSA will issue an audit finding if the Medicaid Exclusion File listing is incomplete or inaccurate.

21

340B – Group Purchasing Organization Purchases

340B

GPO Restriction:

- Certain hospitals (acute care with DSH > 11.75%, children's and cancer) may not purchase any covered outpatient drugs through a GPO. Exception: Prime Vendor Program (Apexus).
- HRSA issued a Program Notice on 02/07/13 - "Statutory Prohibition on Group Purchasing Organization Participation." This guidance states:
  - **Violations of the GPO restriction will result in termination** from the 340B program.
  - **Provider-based departments of a hospital may elect not to participate in 340B** if they meet four requirements:
    - Are located at a different physical address than the parent;
    - 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
    - Hospital maintains 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.

22

340B – Group Purchasing Organization Purchases

340B

GPO Restriction:

- GPO restriction does not apply if the drug has not entered into an agreement to participate in the Medicaid Drug Rebate Program. CMS website has list of drugs for which manufacturer has entered into agreement. Apexus recommends verifying on OPA website and with manufacturer.
- Some manufacturers take position that GPO prohibition violation means that CE must repay all 340B discounts during period of the violation.

23

340B – Drug Shortages

340B

National Drug Shortages

- **Result in purchasing from GPO**
  - Prove the lack of availability for all WAC or 340B purchases
  - Complete HRSA Form
  - Share documentation and form with HRSA timely.
  - Retain all documentation for at least 3-years
    - HRSA audits
    - Manufacturer dispute, etc.

24

340B – Audit and Monitoring

340B

Monitoring and Auditing Summary		Area of Focus			
Activity	Frequency	Individual Facility Eligibility	Diversion Prevention	Duplicate Discount Prevention	GPO Prohibition Compliance
Review Accuracy of OPA Database Information	Quarterly	√	√	√	√
Compare Medicare Cost Report to OPA Database	Annually	√	√		
Review OPA and Apexus websites for changes in guidance	Monthly	√	√	√	√
340B Continuing Education	Ongoing	√	√	√	√
Review locations that have populated in split-billing software	Annually	√			√
Review patient status indicators stored in the split-billing software	Biannually	√			√
Communication with state Medicaid agencies	Annual			√	
Child Site Supply Purchase Review	Quarterly				√
Retail Specific Auditing and Monitoring					
Annual independent audit	Annually	√	√	√	
DEA provider list update	Monthly		√		
DEA provider list audit	Quarterly		√		
Audit of 340B scripts	Monthly	√	√	√	
Hospital Mixed Use Auditing and Monitoring					
Mixed Use (within Four Walls Auditing)	Monthly	√	√	√	√
Crosswalk Audit	Monthly		√		√
Clean 340B Inventory Monitoring					
Inventory Count	Quarterly		√		√
Diversion prevention surveillance	Monthly	√	√	√	√

25

340B – Compliance Risk Monitoring Processes

340B

- If evidence of diversion, duplicate discounts, group purchasing or any other 340B compliance problem is uncovered;
  - **340B Compliance Committee takes appropriate Corrective Actions**
    - 340B Program Manager
    - 340B Compliance Officer
    - Legal, internal and/or external
- Corrective Action Plans (**CAP**s) are developed, monitored and completed for the following:
  - HRSA audits
  - External reviewer: annual audits
  - Non-compliance with purchasing, eligibility, diversion, duplicate discounts, GPO prohibition, etc.
  - Proposed new regulations
  - Changes in any and all federal regulations

26

340B – Corrective Action Plans

340B

- **Corrective Acton Plans May Include:**
  - Offering refunds to manufacturers
  - Notifying manufacturers of accumulator adjustments to correct past errors
  - Communicating with state Medicaid programs about duplicate discount concerns.
  - If the relevant non-compliance is material (>5%); disclose the nature of the violation to OPA and describe the corrective action taken.

27

340B – Quarterly Monitoring Reviews

340B

August	Date	Auditor	Sample Size	Pass /Fail
Crosswalk Audit				
DEA List Audit				
DEA List Changes				
Mixed Use Audit				
Mixed Use Audit Top 3				
Retail 340B Script Audit RCH				
Retail Code Match 340B Script Audit RCH				

28

340B – Quarterly Monitoring

340B

- **In addition, the 340B Program Manager reviews daily and/or weekly all 340B purchased from all 340B sites.**
  - This review is to ensure that all 340B purchases have been made according to the HRSA regulations. (Include Provider Base Practices as well as all outpatient locations)
  - If errors are identified, the purchase will be corrected timely to ensure compliance.
  - The pharmacy purchasing staff will be educated and trained to avoid purchasing errors in the future.
  - Corrective Action Plans will be developed by the 340B Compliance Committee if a significant error occurs in one or more 340B program or continues to occur.

29

340B – Disclosures

340B

- During annual recertification, covered entities certify that they will disclose breaches of program requirements.
- HRSA has indicated that only "material" breaches should be disclosedhttp://www.hrsa.gov/opa/selfdisclosures/selfdisclosure.html.
- Apexus guidance on establishing "material" breach standard. https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf.
- Even immaterial violations trigger repayment obligation to manufacturer.

30

340B – Compliance Issues

340B

Disclosures

- CE required to disclose "material" breaches. CE P&Ps should include standard for determining "material".
- Guidance on HRSA and Apexus websites regarding disclosures (information needed, etc.)
- Even if disclosure to HRSA is not required (*i.e.* not material breach), HRSA requires repayment to manufacturers.
- HRSA expects CE and manufacturers to work out repayment issues.
- HRSA usually requests periodic updates on CE's corrective actions.

31

340B – Compliance Issues

340B

What is New?

- Medicare Part B reimbursement for 340B drugs reduced from ASP+6% to ASP-22.5% beginning January 1, 2018. Second lawsuit challenging cut. Sets dangerous precedent for other payers.
  - **Only applies to Status K drugs (Non-Pass-Through Drugs, Biologicals-Separate APC payment)**
- Congressional scrutiny continues. Bipartisan Congressional letter dated 08/27/18 to HRSA asked why HRSA had not asserted authority to issue regulations and guidance.
- Several legislative bills introduced, mainly addressing hospital transparency. Doris Matsui (D-CA) introduced SERV Communities Act → favorable to covered entities.

32

340B – Compliance Issues

340B

What Should be Done Now?

- Educate, Educate, Educate
- Review policies at least annually or when non-compliance occurs
- On-going Audit and monitoring
- Include 340B analysis in acquisition/new entity checklist
- Assure information in the 340B database is current
- Identify appropriate resources
- Review processes to determine impact of any new regulation.
- Work with 340B Health on advocacy efforts

33

340B – Program Resources

340B

- ***Health Resources and Services Administration (HRSA)- Office of Pharmacy Affairs (OPA)***
  http://www.hrsa.gov/opa/
- ***Prime Vendor Program (PVP)***
  http://www.340Bpvp.com
- ***340B Health***
  http://www.340BHealth.org

34

Questions?

340B

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35