THE 340B PROGRAM:

What You Need To Know!

Health Care Compliance Association
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340B Program: Basic Purpose

To enable “covered entities” to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.

– Congress
340B Program: Basic Premise

The 340B Program requires drug manufacturers to give discounts on outpatient drugs to certain safety-net health care covered entities – in order to have their drugs covered by Medicaid.

- Robin Hood

340B Program: Basic Evolution

From The Pharmacy To The C-Suite:

340B Savings Now Drive Budgets and Operations!
340B Program: BIG ISSUES!

- Definition of eligible “patient.”
- Diversion of 340B drugs and tracking problems.
- Problems with State Medicaid programs.
- Contract pharmacy challenges.
- HRSA 340B audits are increasing and evolving.
- Issues relating to use of GPOs.
- Risk with relying on older 340B guidance.

- REALLY BAD IDEAS THAT SOUND REALLY GOOD!!

340B Program: Expand and Enhance

Moving the 340B Program Forward

Who is in favor?
Who is in opposition?
340B Program: ACA - Expand and Enhance

- The ACA provided for a larger and better 340B Program:
  - It expanded to more hospitals.
  - It enhanced 340B integrity provisions.
  - It questioned non-discriminatory practices.
  - It required a GAO review to address questions about the 340B Program.

GAO Concerns: HRSA Oversight

- Inadequate oversight by HRSA!
- HRSA relies on “self-policing.”
- HRSA’s compliance guidance is unclear.
- Lack of a strong audit program.
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GAO Concerns: DHS Hospitals

- No clear criteria for contracts between DSH hospitals and government agencies.
- Government official and hospital executive agree - HRSA does not review the contract.
- What value is required for compliance?

GAO Concerns: Patient Definition

- Definition of “patient” lacks clarity!
- Wide variations in the interpretation of the existing definition of “patient.”
- Health care has changed since HRSA defined “patient” in 1996.
GAO Report: Message to HRSA

- Develop adequate criteria for DSH hospitals’ government contracts.
- Finalize the definition of “patient.”
- Clarify non-discrimination guidance.
- Conduct selective 340B audits.

GAO Report: HRSA Responds

- Register all child/use/delivery sites.
- Annual recertification of CEs required.
- Random and targeted compliance audits.
- Manufacturers now more aware of audit rights.
- More guidance to CEs.
- Planned for a 340B “Mega-Rule.”
- Strategizing to reach goals of “Mega Rule.”
340B Program: Basic Obligation

Basic 340B Obligations
of a
Covered Entity

340B CE: Basic Obligations

- Register CE/sites in 340B database.
- Keep 340B database current and accurate.
- Recertify CE/sites eligibility annually.
- Prevent diversion to ineligible “patients.”
- Prevent Medicaid duplicate discounts.
- Maintain auditable records of 340B compliance.
- Self-report “material breaches” to HRSA.
- If applicable, no use of GPO for covered outpatient drugs.
340B Obligation: Eligibility

• Certain nonprofit health care organizations, within the following categories:
  ➢ Health Centers
  ➢ Hospitals
  ➢ Specialized Clinics
  ➢ Ryan White Program Grantees

• ACA increased eligible organizations.

340B Obligation: Registration

• Entering the 340B Program has its delays!
• HRSA has online registration process for entry into 340B Program and updates.
• HRSA requires hospitals to register certain off-site outpatient sites/clinics/services.
• NO NEED to register clinics within 4 walls of the registered 340B parent hospital.
• Consider Medicaid Exclusion File completion!
340B Obligation: Recertification

- On an annual basis each CE must recertify its registration information to HRSA.
- What persons are authorized to submit a recertification?
- Annual recertification form contains a broad attestation by the authorized person.

340B Obligation: Qualifying As A Patient

“To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity.”

HRSA – Eligibility and Registration Guidance
340B Obligation: Qualifying As A Patient

- CE has established a relationship with an individual, such that the CE maintains records of the individual’s health care.
- The individual receives health care services from a health care professional who is either:
  1) employed by the CE; or
  2) provides health care under contractual or other arrangements, such that responsibility for the care provided remains with the CE.

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340B Obligation: Qualifying As A Patient

- **LIMITED EXTRA REQUIREMENT**: individual receives a health care service(s) from a CE which is consistent with the service(s) for which it received grant funding or Federally-qualified health center look-alike status.
- HRSA specifically exempts DSH hospitals from this requirement.
- Other providers will also be exempt considering their funding and entity status.
340B Obligation: No Duplicate Discount

- A “duplicate discount” arises when a drug manufacturer provides rebates to State Medicaid agencies and discounts to CEs for the same drugs.
- All CEs must have mechanisms in place to prevent “duplicate discounts.”
- Use of Medicaid Exclusion File.

340B Obligation: Limit GPO Use

- 340B statute prohibits some CEs from participating in GPOs for outpatient drugs.
  - The prohibition applies to all DHS, children’s, and freestanding cancer hospitals.
  - The prohibition does not apply to critical access, rural referral center, or sole community hospitals.
340B Obligation: Limit GPO Use

- DSH hospitals can use GPOs to purchase drugs that do not meet the definition of covered outpatient drugs.
- If a 340B CE is unable to purchase a 340B covered drug, contact the manufacturer, and then HRSA.
- Punishment for violating the GPO prohibition can be harsh – removal from the 340B Program for a period of time.

340B: Maintain Auditable Records

- The 340B Program requires that all CEs maintain auditable records.
- This requirement is certainly meant to increase compliance by CEs and to provide a clear picture of 340B activities for HRSA auditors.
- CEs can also benefit from good documentation.
340B: Contract Pharmacies

- A “contract pharmacy” arrangement is one in which a CE contracts with a pharmacy to provide 340B drugs to “patients” of the CE.
- This arrangement allows a CE to expand its pharmacy services for its “patients.”
- A “contract pharmacy” can operate with physically separate inventories or virtual inventories.

340B: Contract Pharmacies

- About 22% of CEs have contract pharmacies.
- The number has jumped – was 10% in 2010.
- The number of pharmacies has grown 770%.
- The total number of contract pharmacy arrangements has grown by 1,245% since 2010.
- The majority of contract pharmacies are large retail and supermarket chains.
340B: Contract Pharmacies

- A “contract pharmacy” must operate within the rules of the 340B Program.
- CEs must appropriately oversee “contract pharmacy” arrangements to prevent drug diversion and duplicate discounts.
- A CE should establish and implement a comprehensive compliance program for “contract pharmacy” arrangements.

340B Program: Self-Disclosures

- Duty of a CE to disclose “material breach” of 340B requirements – as soon as reasonably possible.
- The annual recertification form contains an attestation of this duty.
- What is a “material breach?”
- HRSA working on self-disclosure protocol, but recommends that CEs design a process of their own in the interim.
340B: Potential Sanctions

- Repayment obligations to manufacturers.
- Additional sanctions can include:
  - Paying interest on discount for “knowing and intentional” diversion.
  - Removal from the 340B Program for “systematic and egregious” actions, for a reasonable amount of time.
  - Other potential legal issues.

340B: Where Are We Now?

- The 340B Program continues to balloon.
- Some believe it is out of control because of “self policing.”
- Great uncertainty regarding the “rules.”
- Increase in resources for education and compliance efforts.
- **340B is driving business decisions.**
340B: Where Are We Going?

- Growth because of ACA, Medicaid expansion and proliferation of contract pharmacies.
- Increased audits by HRSA and manufacturers.
- Guidance from HRSA to create more clarity in rules of 340B Program.
- More pressure from pharmaceutical industry.
- **EVERYONE** wanting part of the 340B savings!

Pay Attention To Your 340B Program

- Look closely at your 340B Program – **you are responsible not your consultant**.
- Review HRSA/Prime Vendor websites for guidance.
- Create written, compliant policies which are understandable and auditable.
- Implement an ongoing program for training personnel who have a role in ensuring compliance with the 340B Program.
- Audit your 340B Program on an annual basis.
- Take care in resolving compliance issues.
Questions?

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