1

Recent Developments in 340B Drug Pricing Program Compliance and Enforcement

Elizabeth S. Elson, Esq.
Anil Shankar, Esq.

October 18, 2012

FOLEY
FOLEY & LARDNER LLP

2

Speakers

Elizabeth Elson
Of Counsel
Foley & Lardner LLP
Los Angeles Office

Anil Shankar
Associate
Foley & Lardner LLP
Los Angeles Office

FOLEY
FOLEY & LARDNER LLP

Agenda

- Requirements of the 340B Program
  - Overview of 340B Business Models
  - Definition of Patient
  - Use of Contract Pharmacies
- Compliance and Enforcement
  - Impact of Health Care Reform on 340B
  - Recertification Requirements
  - Audits of Covered Entities
  - Ensuring Compliance with Program Requirements

340B Drug Pricing Program

- Federal drug pricing program
  - Operated by the Office of Pharmacy Affairs (OPA) in the Health Resources and Services Administration (HRSA)
- Drug manufacturers are required to provide significant discounts to participating Covered Entities on covered outpatient drugs
  - 340B discounts not required for drugs administered in an inpatient setting
- Intended to provide relief to facilities that provide care to the medically underserved

340B Drug Pricing Program (cont'd)

- Manufacturers that participate in Medicaid must also participate in the 340B program
- Manufacturers must provide front-end discounts on covered outpatient drugs purchased by participating, government-supported facilities (Covered Entities)
  - Ceiling price is established by statute
  - Linked to the price paid by Medicaid, which includes significant discounts
  - For brand name drugs: the lower of a) the manufacturer's "best price" or b) 15.1% off the drug's average manufacturer price (AMP)

340B Drug Pricing Program (cont'd)

- In general, drugs may be billed to payors at the retail price
- 340B does not specifically prescribe how the savings must be used or spent by the Covered Entity
  - However, recent Congressional inquiry into several hospitals' use of 340B savings
  - Congressional intent language

7

340B and Medicaid

- Covered entities may not receive a 340B discount for drugs that are subject to a Medicaid rebate
  - Providers required to inform HRSA (by providing their Medicaid billing number) at the time they enroll if they plan to purchase and dispense 340B drugs for their Medicaid patients and bill Medicaid
  - Follow procedures established by State Medicaid agencies
- A State Medicaid program may
  - Require Covered Entities to carve out Medicaid patients from 340B so the State can claim the rebate
  - Allow Covered Entities to use 340B drugs for Medicaid patients, and reduce Medicaid payment to the Covered Entity
  - Allow Covered Entities to use 340B drugs for Medicaid patients, and pay an increased dispensing fee

8

Covered Entities

- Covered Entities must fall into one of several statutory categories
- Health centers
  - Federally qualified health centers (FQHCs), including FQHC look-alikes
  - Native Hawaiian Health Centers
  - Tribal/Urban Indian Health Centers
- Ryan White HIV/AIDS Program Grantees
  - Ryan White Grantees (early intervention services for HIV disease)
  - State AIDS Drug Assistance Programs (ADAPs)

Covered Entities (cont'd)

- Specialized Clinics
  - Title X family planning clinics
  - STD clinics
  - Comprehensive Hemophilia Diagnostic Treatment Centers
  - Tuberculosis clinics
  - Black lung clinics

Covered Entities (cont'd)

- Disproportionate Share Hospitals (DSH) that:
  - Are publicly owned and operated, are formally granted governmental powers, or have a contract with State or local government to provide health care to the low-income indigent
  - Have a Medicare DSH percentage > 11.75%
  - Do not purchase covered outpatient drugs through a Group Purchasing Organization

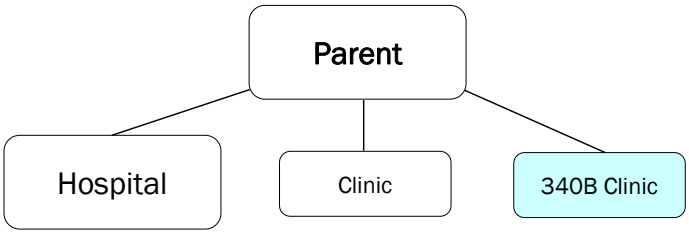
Covered Entities (cont'd)

- Other hospital Covered Entities were added by the Affordable Care Act
  - Children's hospitals with Medicare DSH > 11.75%
  - Freestanding cancer hospitals with Medicare DSH > 11.75%
  - Critical access hospitals (CAHs)
  - Rural referral centers with a Medicare DSH > 8%
  - Sole community hospitals with a Medicare DSH > 8%
- Must also be publicly operated, formally granted governmental powers, or be a non-profit with a contract to provide care to the indigent

Enrollment is Required

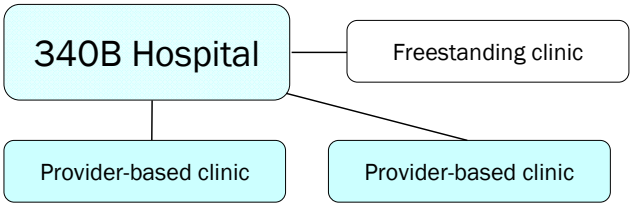
- Eligible Covered Entities must notify OPA of intent to participate in the 340B program
- Recent changes to registration of new Covered Entities or new locations
  - May only be submitted the first 15 days of the quarter (Oct. 1-15; Jan. 1-15; Apr. 1-15; July 1-15)
  - Registrations effective the start of the following quarter
- Eligible entities, locations using 340B drugs, and contract pharmacies should be registered with OPA and included on its Covered Entity database

340B Business Model Example



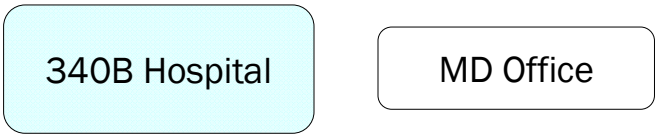
- Only the 340B Clinic is a Covered Entity
- Parent may only purchase drugs at 340B discounts for patients of the 340B Clinic, and should establish separate purchasing accounts and dispensing records

340B Business Model Example (cont'd)



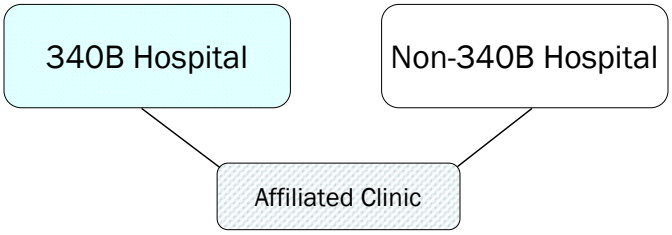
- Only clinics listed as reimbursable centers on the 340B Hospital's most recently filed cost report are deemed part of the 340B Hospital and can access 340B Drugs
- Clinics should meet the Medicare provider-based rules
- Reliance on *most recently filed* cost report may lead to delays

340B Business Model Example (cont'd)



- MDs are not Covered Entities under 340B
- If the MD office is not a reimbursable center on the 340B Hospital's cost report, it may not purchase 340B Drugs
- Individuals who are patients of the 340B Hospital may receive 340B drugs purchased by the 340B Hospital

340B Business Model Example (cont'd)



- 340B Hospital and a non-340B Hospital establish a joint venture clinic
- Affiliated Clinic may only use 340B drugs if it is on the 340B Hospital's most recently filed cost report (licensed and operated as part of 340B Hospital)

Prohibition on Resale/Diversion

- Covered Entities may not sell (or otherwise transfer) drugs purchased under the 340B program to persons who are not "patients" of the Covered Entity
  - Prohibits transfer of 340B drugs to other entities (includes separate entities and ineligible facilities within the same facility)
  - Prohibits dispensing of drugs to non-patients

Definition of Patient

- "Patient" is not defined in Section 340B
- HRSA's regulatory definition is controlling
  - Published in October 1996
  - In 2007, HRSA proposed revising the definition of patient; the proposed rule was never finalized
  - GAO and Congress have commented on the need for a new definition

19

Definition of Patient (cont'd)

- Three requirements

  (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; and

20

Definition of Patient (cont'd)

- Three requirements (cont'd)

  (3) The individual receives a health care service or range of services from the Covered Entity which is consistent with the service or range of services for which grant funding or federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

- An individual is not a "patient" of a Covered Entity if the only health care service the individual receives from the Covered Entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting

Definition of Patient (cont'd)

- Linchpin of the 340B Statute – defines what Covered Entities may do with 340B drugs
- Examples of gray areas:
  - Covered Entity patients return to the Covered Entity pharmacy for conditions treated by outside health care providers
  - Outpatient initiatives by a Covered Entity (e.g., provision of care in mobile clinics, at prisons, etc)
  - Treatment of services referred by the Covered Entity to an outside provider

Definition of Patient (cont'd)

- Risks associated with the definition of patient have increased, but new guidance not provided
- New guidance likely in the future
  - GAO has advocated a "new, more specific definition of a 340B patient"

23

Contract Pharmacies

- 340B statute is silent as to delivery methods for 340B Covered Entities to provide 340B drugs to patients
- HRSA allows Covered Entities to use an in-house pharmacy or to contract with a retail pharmacy
- Starting in 2010, HRSA allowed Covered Entities to utilize multiple contract pharmacies
- Retail pharmacy chains have begun marketing 340B services to Covered Entities, greatly expanding access to 340B drugs

24

Contract Pharmacies (cont'd)

- "Ship-To/Bill-To" arrangements
  - Covered Entity pays for drugs at 340B price under its contacts with manufacturers
  - Drugs are shipped to the contract pharmacy, which maintains inventory
- Contract pharmacy bills payors/patients on behalf of the Covered Entity
  - Fees for contract pharmacies subject to negotiation
  - Covered Entity can establish discounts for patients

25

Contract Pharmacies (cont'd)

- Contract pharmacy and Covered Entity establish a mechanism to screen individuals to determine if they qualify as a patient of the Covered Entity, and to track ordering, receipt, and dispensing of 340B drugs
  - Limited guidance on requirements
- Compliance with 340B program rules (including prohibition on diversion) is always the responsibility of the Covered Entity
- Contractual arrangements must include HRSA's required elements, and should be reviewed by counsel

26

Compliance and Enforcement

- Environment is rapidly changing
- Historically, relied on self-policing, subject to potential audits by HRSA or by manufacturers
- Health care reform, as well as inquiries by Congress and the GAO, have led HRSA to take a more active oversight role
- Expanded access, including increased use of contract pharmacies, has led to increased risks

27

Health Care Reform: New Sanction Authority for 340B Violations

- Potential Sanctions:
  - Forfeiture of 340B discounts to the manufacturer
  - Monetary penalties and applicable interest for knowing and intentional violations
  - Disqualification from the program for systematic and egregious violations
  - Possible referral to OIG or other federal agencies for further review
  - Disqualification and prohibited re-entry

28

Enhanced Oversight

- The Affordable Care Act amended the 340B statute to require HRSA to develop procedures to enable and require Covered Entities to regularly update information (at least annually)
- Goal is to ensure program integrity, compliance, transparency, and accountability by requiring Covered Entities to ensure accuracy of the information in the 340B database

29

Enhanced Oversight (cont'd)

- HRSA has emphasized the importance of maintaining current and accurate information in its database of Covered Entities
  - Used by manufacturers to screen Covered Entities
  - Publicly available (http://opanet.hrsa.gov/opa)
  - HRSA recommends listing all sites that will utilize 340B drugs
  - HRSA requires registration of all contract pharmacy arrangements

30

Recertification

- In Spring 2012, HRSA began requiring Covered Entities to:
  - Update information in HRSA's Covered Entity database
  - Recertify compliance with 340B program rules
- Ryan White programs, STD/TB, family planning clinics and hospitals were completed in 2012; FQHCs anticipated in January 2013

Recertification Requirements

- During recertification, the Covered Entity will attest to the following:
  1. All information listed on the 340B program database for that Covered Entity is complete, accurate, and correct;
  2. the Covered Entity has continuously met all 340B program eligibility requirements;

Recertification Requirements (cont'd)

3. the Covered Entity is complying with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
4. the Covered Entity maintains auditable records demonstrating compliance with the requirements described in paragraph (3) above;
5. the Covered Entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described in (3) above;

Recertification Requirements (cont'd)

6. if the Covered Entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the Covered Entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the Covered Entity has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);

Recertification Requirements (cont'd)

7. the Covered Entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material breach by the Covered Entity of any of the foregoing; and
8. if the entity does not notify OPA in a timely fashion, the entity acknowledges that it may be required to remit payment back to manufacturers which would represent the difference between the 340B discounted price and the drug's non-340B purchase price.

HRSA Audits of Covered Entities

- All Covered Entity types may be audited
- In FY 2012, HRSA began conducting both random and targeted audits of Covered Entities
  - Random audits focus on program types with "higher risk," due to volume of purchases, complexity of program administration, or use of contract pharmacies
  - Targeted audits may be triggered by whistleblowers, manufacturers, or self-reporting

HRSA Audits of Covered Entities (cont'd)

- Focus areas of HRSA audits:
  - Verification of eligibility
  - Review of policies and procedures and how they are operationalized
  - Review of internal controls to prevent diversion and duplicate discounts
  - Review of contract pharmacy compliance
  - Test of 340B drug transaction records on sample basis

37

A-133 Audits and Site Visits

- A-133 audits required for non-federal entities expending $500,000 or more of federal awards in a year
- A-133 compliance supplement now includes 340B program compliance questions
- Grantee site visits will include 340B program compliance questions beginning in FY 2013

38

Manufacturer Audits of Covered Entities

- Manufacturers are also authorized to audit 340B Covered Entities regarding compliance with drug diversion and duplicate discount requirements
- Manufacturers must submit an audit work plan to OPA prior to conducting audits

39

Ways to Ensure Compliance/Prepare for Recertifications and Audits

- 340B Covered Entities should have a 340B compliance plan in place
  - Ensure all employees involved in the program are trained and understand the compliance plan
  - Review program's compliance prior to recertification
- Covered entities (and any contract pharmacy) must maintain accurate records documenting compliance with 340B program requirements
  - Records are subject to audit by a OPA or by a manufacturer
  - Procedures and systems controls designed to ensure compliance with rules regarding diversion and duplicate discounts should be developed and regularly reviewed/updated
  - Covered entities should have a complete "audit trail" from purchase to pick-up by the patient

40

Ways to Ensure Compliance/Prepare for Recertifications and Audits (cont'd)

- Pay special attention to "mixed-use" settings where inpatients and outpatients receive drugs (e.g., ER or oncology clinic) and to the relationships and drug distribution within a health care system in which some entities are 340B Covered Entities and some are not
- Covered entities should establish procedures to periodically audit their own records and the records of contract pharmacies
- Make sure to keep information on the OPA Covered Entity database current

Questions?

FOLEY
FOLEY & LARDNER LLP

Presented by

Elizabeth S. Elson, Esq.
Foley & Lardner LLP
555 S. Flower Street, Ste. 3500
Los Angeles, California 90071
Tel: (213) 972-4500
Fax: (213) 486-0065
email: eelson@foley.com

Anil Shankar, Esq.
Foley & Lardner LLP
555 S. Flower Street, Ste. 3500
Los Angeles, California 90071
Tel: (213) 972-4500
Fax: (213) 486-0065
email: ashankar@foley.com