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340B Compliance: Overcoming Challenges With Diversion, Duplicate Discounts, and Orphan Drug Restrictions

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Today's faculty features:

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340B Compliance: Overcoming Challenges

Preparing for a 340B Audit

August 6, 2015

presented by:

Kathryn R. Watson, Esq.

of

FELDESMAN TUCKER LEIFER FIDELL LLP

Disclaimer

- Presentation is intended as general information only, not as specific legal advice
- Opinions expressed are mine
- Consult qualified legal counsel for specific advice

Agenda

1. Overview of the 340B Program
2. Overview of 340B Audit Processes
3. Key 340B Audit Findings
4. Tips for Preparing for a 340B Audit

340B Essentials

- Enacted in 1992 – Section 340B of the Public Health Service Act (42 USC Section 256b)
- Requires drug manufacturers to sell covered drugs at a substantial discount in order to have the drug covered under Medicaid
- Available only to certain types of organizations, which are called “Covered Entities” (CEs) and specified in the statute (*e.g*. Federally-qualified health centers)
- Applies only to “covered outpatient drugs”

340B Essentials

HRSA Grantees

Federally Qualified Health Centers

Native Hawaiian Health Centers

Tribal/Urban Indian Health Centers

Ryan White Programs

Title X Family Planning Clinics

STD, Black Lung, TB Clinics

Hemophilia Treatment Centers

Hospitals

Disproportionate Share Hospitals

Critical Access Hospitals

Rural Referral Centers

Sole Community Hospitals

Children's Hospitals

Free Standing Cancer Hospitals

340B Essentials

- 340B drugs may be dispensed only to a "patient" of a Covered Entity and may not be resold – *i.e*. "diversion" prohibited

- Covered Entity may not request payment under Medicaid for a 340B drug if that drug is subject to the payment of a rebate to a state Medicaid agency – *i.e*. "duplicate discounts" prohibited

340B Audits

HRSA Audits

- Targeted and random
- Initiated by engagement letter from OPA
- Introductory teleconference and request for copies of specified documents (policies, procedures, internal controls)
- Entrance conference with key management staff
- Audit performed by HRSA Regional Office auditors following Government Auditing Standards

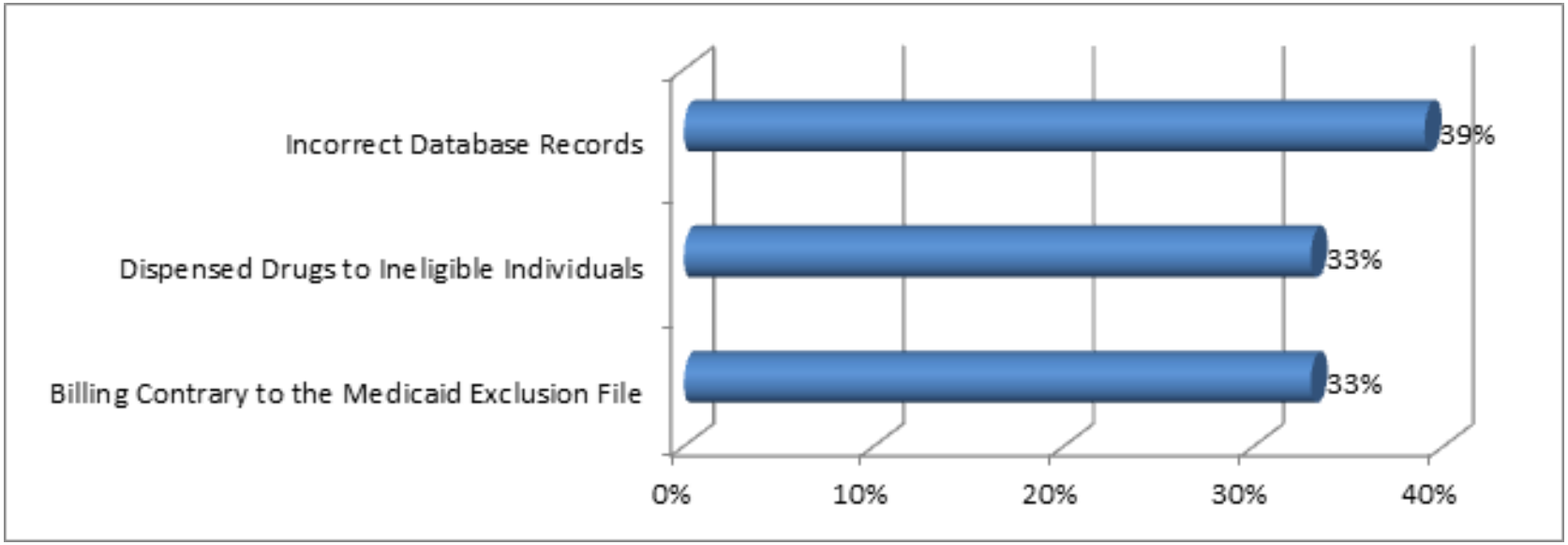
340B Audits

HRSA audit procedures include

- Review of relevant policies and procedures and their implementation
- Verification of CE eligibility & Medicaid exclusion file listing
- Verification of internal controls to prevent diversion and duplicate discounts
- Contract pharmacy compliance
- Testing 340B transaction records on sample basis
- OPA report with findings, requesting corrective action plan and public letter if adverse findings
- “notice and hearing” (42 U.S.C. Sec. 256b(a)(5)(D))

340B Audits

- FY 2012: OPA audited 51 covered entities
- 2015: OPA on track to audit ~200 covered entities



340B Audits

Manufacturer Audits

- Written notice to CE of alleged violation, based on reasonable cause
- 30 day period for “good faith” resolution
- Requires HRSA approval
- 15 days notice of audit to covered entity
- Requires independent auditor following Government Auditing Standards
- Written report (shared with OIG)
- Covered entity can challenge findings using voluntary dispute resolution procedures

Potential Sanctions

- HRSA Sanctions
  - Corrective action
  - After notice and hearing:
    - Repay amount of discount to manufacturer
    - Pay interest on discount for “knowing and intentional” diversion
    - Removal from 340B Program and disqualification for a “reasonable” period of time if violation was “systematic and egregious”
- Collateral Sanctions

Key Audit Findings

- Duplicate Discount
- Diversion
- Contract Pharmacies
- Site Registration
- Auditable Records

Duplicate Discounts

- A covered entity shall not request payment under Medicaid for prescribed drugs with respect to a drug that is purchased at 340B price “if the drug is subject to the payment of a rebate to the State”

(42 USC 256b(a)(5)(A)(i))

340B and Medicaid FFS

- Medicaid Exclusion File
- HRSA initially stated that CE's should bill Medicaid at "actual acquisition cost" plus a "reasonable" dispensing fee established by the state Medicaid agency (June, 1993)
- HRSA later instructed CEs to follow billing guidelines established by their state's Medicaid agency (March, 2000)
- ACA instructed HHS to develop more detailed guidance on methodologies and options for billing Medicaid

340B and Medicaid Managed Care

- ACA requires manufacturers to pay rebates on Medicaid MCO drugs, *except for 340B drugs*
  - No "duplicate discount" issue under 340B statute
  - Medicaid agencies can claim rebate on non-340B drugs (raises reporting issues)
- CMS Proposed Rule re: Medicaid managed care (80 Fed. Reg. 31098)

Diversion

- Patient Definition (61 *Fed. Reg*. 55156 (October 24, 1996))
  - Covered Entity has established a relationship with the individual, such that the Covered Entity maintains records of the individual's health care; and
  - 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 such *that the responsibility for the care remains with the Covered Entity* (emphasis added); and
  - 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 Covered Entity status has been provided to the entity.

340B Eligible Patients

NOTE: Appropriate scope of "patients" for 340B purposes is controversial

- HRSA proposed significant revisions to the 340B Patient Definition. (72 *Fed. Reg*. 1543 (January 12, 2007))
- New definition may be on the horizon through MegaGuidance (this fall??), which may address:
    - Specialty referrals
    - Discharge prescriptions
    - "Off-premises" services
    - Contracted providers and volunteers
    - Patient record maintenance
    - Case management

Contract Pharmacy Arrangements

- Statute does not address contract pharmacies
- Many (if not most) non-hospital CEs did not have an in-house pharmacy, limiting benefit of 340B Program
- In 1996, HRSA allowed CEs to contract with a commercial pharmacy to dispense 340B drugs to eligible patients, on limited basis (61 *Fed Reg*. 43549 (August 23, 1996))
  - One contract pharmacy per delivery site
  - No chain pharmacy arrangements
  - No contract pharmacy if CE operated an in-house pharmacy
  - More robust dispensing models allowed pursuant to an Alternative Methods Demonstration Project (AMD)

Contract Pharmacy Arrangements

- HRSA issued revised guidance in 2010 (75 *Fed. Reg*. 10272 (March 5, 2010)
  - Allows contracting with multiple pharmacies, pharmacy chains, and/or operating an in-house pharmacy
  - Applies to all contract pharmacy arrangements
  - Replaces all prior guidance
- AMDP still available for other arrangements, *e.g*. network delivery models
- Substantial emphasis on compliance – in fact, not just on paper

Contract Pharmacy Compliance

Key compliance concerns

- Diversion
- Duplicate Discounts - CE's contract pharmacy may not dispense drugs purchased at 340B price to Medicaid FFS patients unless the contract pharmacy and the state Medicaid agency have established "an arrangement" to prevent duplicate discounts

CE cannot "outsource" its compliance responsibility

Prepare for an Audit

- Comprehensive 340B Program policies and procedures.
- Methodologies for routine self-auditing.
- Routine processes for internal corrective action.
- Verify that contract pharmacy arrangements comply with the 340B requirements and are properly listed in the OPA database.
- Meet state-specific requirements and to ensure prevention of duplicate discounts.
- Keep an eye out for changes in the law (i.e., MegaGuidance)

Some Audit Resources

- *Clarification of Manufacturer Audits of 340B Covered Entities* (Release 2011-3, November 21, 2011)
- *Manufacturer Audit Guidelines* (61 *Fed. Reg.* 65406 (December 12, 1996))
- *Clarification of HRSA Audits of 340B Covered Entities* (Release 2012-1.1, February 8, 2013)
  - www.hrsa.gov/opa/programintegrity

- 340B University: www.340bpvp.com

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340B Compliance: Overcoming Challenges with Diversion, Duplicate Discounts, and Orphan Drug Restrictions

Strafford CLE Conference
August 6, 2015

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Agenda

- Overview of 340B Covered Entity Responsibilities
- Manufacturer Audits of Covered Entities
  - Duplicate Discounts
  - Diversion and Its Various Forms
  - Orphan Drug Exclusion and Litigation
  - Additional Issues Relating to Covered Entity Compliance
- HRSA Audits of Covered Entities
- Other Manufacturer Concerns
- Pending Developments

The views expressed in this presentation are of the speaker only.

Overview of Covered Entity Responsibilities

- Covered entities participating in 340B must:
  - Prevent duplicate discounts*;
  - Not engage in diversion*;
  - Recertify eligibility every year;
  - Maintain an accurate listing in the 340B database, including registering new outpatient facilities and contract pharmacies (if applicable);
  - Not purchase covered outpatient drugs through a GPO (applicable only to certain entity types); and
  - Not purchase orphan drugs at 340B prices if the drug is used for its orphan-designated indication(s) (applicable only to certain entity types)*.
- All entities also must maintain auditable records and permit compliance audits by HRSA or, with HRSA's approval, by a manufacturer.
- According to OPA, only some of these requirements may be the subject of manufacturer audits (specifically, those marked with an asterisk (*)).
  - But, all may be the subject of government audits.
  - And, OPA investigates reports from manufacturers regarding all of these issues.

Manufacturer Audits: The Requirements

- 1996 audit guidelines for manufacturer audits (reiterated in HRSA Policy Release No. 2011-3 (Nov. 2011) on manufacturer audits):
  - Reasonable cause to believe the covered entity is in violation of the diversion and/or duplicate discount prohibitions, including, for diversion, compliance with the orphan drug exclusion final rule
    - "Reasonable cause" can include, for example, significant changes in order quantities, or failure to respond to a manufacturer's inquiries about 340B purchasing practices
  - Written notification of the suspected violation(s) provided to the covered entity and completion of a 30-day, good faith resolution period
  - Engagement of independent public accountant to perform the audit in accordance with Government Accounting Standards (GAS)
  - Submission of audit plan to OPA prior to implementation
  - Covered entity is not the subject of another audit during the same time
- OPA has accepted 8 manufacturer audit work plans as of April 2014, and is encouraging manufacturers to submit more.

Manufacturer Audits: Duplicate Discounts Issues

- A covered entity may not request Medicaid payment for a drug that is subject to the payment of a Medicaid rebate.
  - See 42 U.S.C. § 256b(a)(5)(A) ("duplicate discount prohibition").
- Covered entities that bill Medicaid must determine whether they will use 340B drugs for Medicaid patients ("carve in") or whether they will use only non-340B drugs for Medicaid patients ("carve out").
  - If a covered entity chooses to "carve in," it must so notify HRSA and must ensure that it maintains an accurate listing in the Medicaid Exclusion File.
  - Confusion abounds here: OIG audit underscores that.
- Added complexities with 340B exclusion for now-required (per ACA) rebates on Medicaid managed care utilization
  - Most states have not yet issued guidance on this subject.

Manufacturer Audits: Duplicate Discounts Issues (cont'd)

- Mounting evidence that duplicate discounts are happening with disturbing frequency:
  - OIG Report (June 2011)
  - OIG Contract Pharmacy Report (2014)
  - Data analysis and audits conducted by manufacturers
  - HRSA audit results summaries of FYs 2012, 2013, and 2014 government audits, posted as of 7/15/2015, show 70 audited covered entities—approximately a quarter of the 281 total entities audited by HRSA—were found to have violated the duplicate discount prohibition.
    - Violations include:
      - The entity having billed Medicaid contrary to information contained in the Medicaid Exclusion File
      - Medicaid claims being incorrectly coded when provided to the state
    - Corrective action plans are still pending for many 2012 – 2014 HRSA audits, and HRSA undertook dozens more covered entity audits in 2015.

Manufacturer Audits: Diversion Issues

- Covered entities "shall not resell or otherwise transfer" any 340B drug "to a person who is not a patient of the entity."
  - See 42 U.S.C. § 256b(a)(5)(B) (prohibition on diversion).
- Examples of diversion:
  - 340B-priced drugs dispensed to ineligible patients
  - Misuses and abuses of HRSA's existing "patient" definition guidance (e.g., employees)
  - Outpatient entities inappropriately listed as participants in the program
  - Contract pharmacies using 340B product for their own account
    - OIG Contract Pharmacy Report (2014)
  - Inpatient/outpatient diversion

Manufacturer Audits: Diversion Issues (cont'd)

- The scope of what is and is not "diversion" under 340B hinges significantly on how the term "patient" is defined.
- Under current program guidance, a person is a "patient" of the covered entity for 340B eligibility purposes if:
  - The covered entity has established a relationship with the person such that the covered entity **maintains records** of the person's healthcare;
  - The person receives health care services from a provider employed by, **or under a contractual or other relationship with**, the covered entity such that **responsibility for the care provided remains with the covered entity**; and
  - The person receives a service or range of services consistent with the service or range of services for which grant funding or Federally center look-alike status has been provided to the entity. (This requirement does not apply to disproportionate share hospitals.)
- This current definition (issued in 1996), is outdated, insufficiently specific, and prone to manipulation, as HRSA itself recognized in its 2007 attempt to revise it.
  - "Direct care" standard should be reflected in the guidance.
- HRSA/OPA is working on a revised definition of a "patient" for 340B purposes, which the Agency plans to include in an omnibus 340B proposed guidance anticipated for release in 2015.

Manufacturer Audits: Orphan Drug Exclusion and Litigation

- Manufacturers may audit affected covered entities' compliance with the orphan drug exclusion if the manufacturer's audit request is approved by the government and "directly pertains to the covered entity's compliance with" the statutory orphan drug exclusion.
- HRSA finalized its proposed "indication-specific" interpretation of the statutory 340B orphan exclusion (42 U.S.C. § 256b(e)) in July 2013.
  - HRSA's 340B Orphan Drug Exclusion Final Rule was the first-ever formal regulation for 340B (creating a new Part 10 in 42 C.F.R.).
  - Some stakeholders strongly opposed the rule as contrary to the plain language of the statute and administratively unworkable.
  - The D.C. District Court invalidated HRSA's 340B Orphan Drug Exclusion Final Rule on May 23, 2014, holding that the Agency lacked the statutory authority to promulgate it.

Manufacturer Audits: Orphan Drug Exclusion and Litigation (cont'd)

- According to the D.C. District Court's decision invalidating the HRSA Orphan Drug Exclusion Final Rule, the 340B statute "specifically authorized rulemaking in three places"—and none of those specific rulemaking authorizations permits the 340B Orphan Drug Exclusion Final Rule that the Agency finalized.
- HRSA re-issued its same, indication-specific interpretation of the orphan drug exclusion in a subsequent "Interpretive Rule" released in summer 2014.
  - PhRMA filed a second lawsuit to challenge the "interpretive rule".
  - Litigation remains ongoing as of 7/20/2015.
- Following the district court's narrow interpretation of its rulemaking authority, HRSA withdrew the "mega-rule" it planned to release in 2014.
  - HRSA expects to issue a "mega-guidance" sometime this year, addressing similar topics.
  - HRSA has indicated a number of areas it intends to address in the "mega-guidance".

Additional Issues Relating to Covered Entity Compliance

- Certifying Eligibility & Maintaining an Accurate Database Listing
  - Covered entities must certify their 340B eligibility each year.
  - Annual recertification for all entity types is a relatively recent requirement.
- The recertification process, among other elements:
  - Involves the review and updating of a covered entity's listing in the 340B covered entity database;
  - Includes an obligation to register new outpatient facilities and contract pharmacies, and to update the Medicaid Exclusion File; and
  - Requires the entity to make several attestations, including that the entity will contact OPA as soon as reasonably possible if a "material breach" of the entity's compliance obligations is discovered.
- Entities must keep their 340B database entries accurate and current, including the entity's approach to compliance with the orphan drug exclusion, for those entity types subject to it.

Additional Issues Relating to Covered Entity Compliance (cont'd)

- Complying with the GPO Prohibition
  - Certain covered entities (disproportionate share hospitals, free standing cancer hospitals, and children's hospitals) may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."
    - See 42 U.S.C. § 256b(a)(4)(L)(iii)–(M) (commonly called the "GPO prohibition").
  - The GPO prohibition has been part of the 340B statute since the program's inception, but began to receive increased attention in 2013 due to a HRSA Policy Release issued February 7, 2013.
    - A number of manufacturers have long been concerned about the frequency and often unabashed nature of GPO prohibition violations by some 340B hospitals.
    - HRSA's FY 2012 Audits found that 42% of all audited hospitals subject to this statutory requirement were in violation the GPO prohibition.
  - OPA's practice on GPO issues in connection with manufacturer audits.

HRSA Audits of 340B Covered Entities

- First undertaken in FY 2012, following the GAO report's recommendation, and additional pressure from certain lawmakers
- FY 2012 Audits
  - 51 total audits conducted: 45 risk-based and 6 targeted
  - Covered more than 450 sub-sites and contract pharmacies
  - HRSA has posted results "summaries" for 51 audits as of 1/8/2014
  - Several show significant findings, including (but not limited to):
    - 16 entities diverted 340B product
    - 18 entities violated the duplicate discount prohibition
    - 7 of these entities violated both the diversion and duplicate discount prohibitions
    - 15 entities had incorrect 340B database records

HRSA Audits of 340B Covered Entities (cont'd)

- FY 2013 Audits
  - 92 total audits conducted
  - Particularly relevant findings, including (but not limited to):
    - 50 entities diverted 340B product
    - 23 entities violated the duplicate discount prohibition
    - 10 of these entities violated both the diversion and duplicate discount prohibitions
- FY 2014 Audits
  - 93 audits conducted
  - Particularly relevant findings, including (but not limited to):
    - 51 entities diverted 340B product
    - 21 entities violated the duplicate discount prohibition
    - 11 of these entities violated both the diversion and duplicate discount prohibitions
- FY 2015 Audits
  - 45 audits underway as of July 2015

Other Manufacturer Concerns

- Program expansion
- Spread thinking and activity; examination of financial incentives
- Hoarding activity or outsized orders
- Co-payment waivers without financial need
- Higher co-payments to beneficiaries
- Beneficiaries lacking “qualifying stays”
- Medicaid Drug Rebate Program proposed rule
  - Implications for Best Price exclusion if finalized
  - Fundamental Catch-22 for manufacturers; harmful to providers

Pending Developments

- 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMPs) Proposed Rule
  - Released on June 16, 2015
  - Some key issues covered in HRSA's proposed rule:
    - Definition of "covered outpatient drug"
    - Grounds for imposing CMPs on manufacturers
    - Penny pricing
    - New drug "price estimation"
- Pending Administrative Dispute Resolution Proposed Rule
- Pending 340B "Omnibus" Guidelines
  - "Patient" definition will be addressed, according to OPA
  - Other issues?

Questions?

Thank You!

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