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340B Drug Pricing Program Omnibus Guidance: Preparing for HHS' Long-Awaited Guidance
Navigating Covered Entity Eligibility and Drug and Patient Eligibility; Preventing Duplicate Discounts in Medicaid Managed Care

TUESDAY, OCTOBER 13, 2015
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Navigating 340B Drug Pricing Program Omnibus Guidance
Determining Covered Entity Eligibility, Defining Eligible Drugs and Patients, Preventing Duplicate Discounts in Medicaid Managed Care

October 13, 2015

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Select provisions of the Proposed Guidance most relevant to covered entities

Key differences between Proposed and current guidance

Possible impacts and next steps

- Covered entity eligibility and registration
- Eligible drugs
- Eligible patients
- Medicaid and duplicate discounts
- Auditable records and audits
- Contract pharmacy arrangements
- ADAPs
- Manufacturer Requirements
- Program Integrity
Introduction to the 340B Program

- Created by federal statute in 1992 and codified at Section 340B of the Public Health Service Act (42 U.S.C. 256b)
- Establishes a ceiling price on “covered outpatient drugs”
- Discounted drugs are available to eligible “covered entities” for dispensing to eligible “patients”
- Drug manufacturers that participate in Medicaid are required to offer 340B discounted drugs to covered entities
Recognizing the need for further clarity of 340B Program requirements, HRSA proposed issuing a “mega-regulation covering a multitude of topics

- **April 2014** – HRSA submits the “mega-regulation” to OMB
- **May 2014** – An unrelated federal court decision restricts the scope of HRSA’s authority to issue notice-and-comment rules
- **November 2014** – In light of the decision, HRSA withdraws the “mega-regulation” from OMB
- **August 2015** – HRSA publishes the Proposed Omnibus Guidance

HRSA is accepting comments on the Proposed Omnibus Guidance until **October 27, 2015**
KEY TAKEAWAYS:

PART A: PROGRAM ELIGIBILITY AND REGISTRATION
Hospital Eligibility

- **Current Guidance**
  - Hospitals may be eligible to participate in the 340B Program based upon:
    - Sole government owner / operator;
    - Formal grant of governmental powers; or
    - Contract with state or local government

- **Proposed Guidance**
  - Expands upon requirement for contract with state or local government as the basis for 340B eligibility
    - Contract must “create enforceable expectations for the provision of health care services” to low-income individuals not eligible for Medicare or Medicaid
Key Takeaways: Program Eligibility and Registration

Off-Site Outpatient Facilities (Child Sites)

- **Current Guidance**
  - Facilities and clinics not located at the same “physical address” as the parent hospital covered entity
  - Each facility or clinic must be listed on a Medicare-reimbursable line of the Medicare cost report
  - Children’s hospitals not filing cost reports may attest to child site eligibility

- **Proposed Guidance**
  - To be eligible, a child site’s services provided must have associated outpatient Medicare costs and charges

- **Practical Implications**
  - Causes a delay in registering newly-opened child sites in the 340B Program, and delays access to 340B drugs for those sites
Key Takeaways: GPO Prohibition

- Disproportionate share hospitals, children’s hospitals and cancer hospitals participating in the 340B Program are prohibited by statute from purchasing covered outpatient drugs through a group purchasing arrangement (GPO)

- Current Guidance
  - Compliance with the GPO prohibition is an eligibility requirement, and hospitals must attest to compliance at registration and during recertification
  - **Exception** – Off-site outpatient facilities not participating in the 340B Program
    - Located at a different physical address
    - Not participating in the 340B Program or listed in the 340B Database
    - Separate drug purchasing accounts
    - Ensure GPO drugs are never provided to hospital outpatients or other child sites enrolled in the 340B Program
Key Takeaways: GPO Prohibition (Cont.)

- **Proposed Guidance**
  - Retains current exception and formally adds additional exceptions
    - Inpatient status changed to outpatient by third party reviewer
    - Cannot access drug at 340B or WAC price
  - Violations of the GPO Prohibition
    - “Systemic” v. “Isolated” violations
    - Repayments to manufacturers – Credit / rebill process within 30 days
    - **Violations by child sites** – May remove a child site without removing the covered entity, if violations are limited to child site and child site has a separate drug purchasing account
  - Clarifies that GPO Prohibition applies to covered entity “owned or operated pharmacies”

- **Practical Implications**
  - Difficulty in identifying certain types of GPO violations
  - Lack of clarity regarding end date for repayments to manufacturers
  - Disparity between nature of non-compliance and potential repayment obligations
KEY TAKEAWAYS:

PART B: “COVERED OUTPATIENT DRUGS”
Only “covered outpatient drugs” are eligible for purchase at 340B prices – so what is a “covered outpatient drug”?

- Defined by reference to the Social Security Act § 1927(k)(2)

- Generally includes:
  - FDA-approved prescription drugs
  - Over-the-counter (OTC) drugs written on a prescription
  - Biological products that can be dispensed only by a prescription (other than vaccines)
  - FDA-approved insulin

- But, also includes a “limiting definition” at § 1927(k)(3), excluding drugs bundled for Medicaid payment
Key Takeaways: “Covered Outpatient Drugs” (cont.)

Current Guidance

– Covered entity may interpret the definition of “covered outpatient drug” so long as it is: “defensible, consistently applied in all areas of the entity, documented in policy / procedures, and auditable.” (Apexus FAQ 1355)

– Result

• Covered entities currently apply a variety of interpretations of “covered outpatient drug”
Key Takeaways: “Covered Outpatient Drugs” (cont.)

- **Proposed Guidance**
  - Explicitly applies the “limiting definition” but only to Medicaid
  - Drugs that are part of a bundled payment for Medicaid reimbursement, and are billed to and paid for by Medicaid as part of bundled payment are excluded from definition of “covered outpatient drug”

- **Practical Implications**
  - May require significant changes to existing policies / procedures
  - Determining 340B drug eligibility – may not be able to determine at the time of dispensing or billing
  - Additional implications for hospitals subject to the GPO Prohibition
KEY TAKEAWAYS:

**PART C: DEFINITION OF “PATIENT”**
Key Takeaways: Definition of “Patient”

- Drugs purchased at 340B prices may only be dispensed to eligible “patients” of the covered entity.

- **Current Definition of “Patient” (finalized in 1996)**
  - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care.
  - 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 the responsibility for the care provided remains with the covered entity.
  - The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or federally qualified health center lookalike status has been provided to the entity. *(Does not apply to hospitals)*
Key Takeaways: Definition of “Patient” (cont.)

- **Proposed Definition of “Patient”**
  1. The individual **receives a health care service at a covered entity site** that is registered for the 340B Program and listed on the public 340B Database
     - Individual that sees a physician in the physician’s private practice, which is not listed on the 340B Database, would not be eligible to receive 340B drugs – including any referral or follow up care from the covered entity
  2. The individual receives a health care service from a health care provider who (i) is **employed** by the covered entity or (ii) is an **independent contractor** of the covered entity such that the covered entity **may bill for services on behalf of the provider**
     - Privileges or credentials at a covered entity are not sufficient
     - If a patient is referred from the covered entity to an outside provider, and receives a prescription from that outside provider, the prescription would not be 340B-eligible
     - Question as to what “may bill for services on behalf of the provider” actually means
Key Takeaways: Definition of “Patient” (cont.)

- **Proposed Definition of “Patient” (cont.)**

  3. An individual receives a drug that is ordered or prescribed by the covered entity provider **as a result of the service described in 2**
      - An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug
      - Telemedicine is acceptable

  4. The individual is classified as an outpatient **when the drug is ordered or prescribed**
      - The patient’s classification status is determined by how the services for the patient are billed to the insurer
      - An individual who is self-pay, uninsured or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently
Key Takeaways:
Definition of “Patient” (cont.)

- **Proposed Definition of Patient (cont.)**

5. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records
   - Records demonstrate that the covered entity has a provider-to-patient relationship and the responsibility for care is with the covered entity

6. For grantees, the individual receives a health care service that is consistent with the covered entity’s scope of grant, project or contract
   - Applies to each child site of the covered entity
Key Takeaways: Definition of “Patient” (cont.)

- **Key Differences**
  - Tightens the nexus between the care provided at the covered entity and the prescription written
  - Limits the practitioners who may write 340B-eligible prescriptions
  - Ties eligibility of a prescription to a service for which the covered entity could bill the patient or a third party payor as a “covered outpatient service”

- **Practical Implications**
  - Visits at private physician offices are not eligible (even if such visits are for follow-up care)
    - Provider must be employed by, or an independent contractor of, covered entity. Proposed guidance removes the “other arrangement” language
  - Inpatient v. outpatient status determinations render the use of physical inventories impractical
  - Infusion services prescriptions written by a community provider not employed by or under contract with the covered entity are ineligible
    - The 340B infusion drug must be written as a result of a covered entity provider-to-patient encounter
    - 340B Program is not a general employee pharmacy benefit – an employee of a covered entity is not eligible based solely on his or her status as an employee or as an enrollee in a covered entity’s insurance plan
Key Takeaways: Definition of “Patient” (cont.)

- **Diversion**
  - Dispensing drugs to individuals that are not eligible “patients” of the covered entity (or “diversion”) is considered a violation of 340B Program requirements
  - Covered entities are expected to work with manufacturers to make repayments within 90 days of identifying diversion
    - HRSA continues to defer to manufacturers and covered entities with respect to specific repayment terms
  - Covered entity must notify HRSA and each affected manufacturer of instances of diversion
  - Covered entity is responsible for reporting to HRSA a summary of its corrective action taken
  - **Replenishment Models** – An acceptable model, but proposed guidance warns that accumulation into a 340B account for ineligible patients, even without purchase, is considered diversion
    - Covered entities and manufacturers are encouraged to identify and correct errors in purchasing through credit and rebill process within 30 days of initial purchase
KEY TAKEAWAYS:

**PART D: COVERED ENTITY REQUIREMENTS (DUPLICATE DISCOUNTS AND AUDITABLE RECORDS)**
Medicaid Managed Care

- **Duplicate Discounts** – Manufacturers are not required to provide a 340B discount AND a Medicaid rebate on the same drug
  - Since the ACA – rebate requirement applies to Medicaid managed care organizations. However, MCOs are not eligible for rebates on drugs also eligible for 340B discounts

- **Current Guidance**
  - Covered entities may “carve-in” or “carve-out” 340B drugs from Medicaid billing – choice is illustrated on the Medicaid Exclusion File
  - Covered entities must report Medicaid billing numbers and NPIs

- **Proposed Guidance**
  - Covered entities may make different “carve-in / carve-out” decisions for Medicaid managed care and Medicaid fee for service, and may also differentiate by site
  - Covered entities must provide information to HRSA for inclusion on Medicaid Exclusion File

- HHS seeks comments on who might use the information and in what format
Key Takeaways: Covered Entity Requirements

Auditable Records

- **Current Guidance**
  - Failure to maintain auditable records is grounds for termination from the 340B Program

- **Proposed Guidance**
  - Proposes a five year record retention period – but on audit HRSA could review records back further than five years
  - If “non-systemic” records issue, the covered entity may be subject to repayment but not removal
  - Notice and hearing process prior to removal from the 340B Program
KEY TAKEAWAYS:

**PART E: CONTRACT PHARMACY ARRANGEMENTS**
Key Takeaways: Contract Pharmacy Arrangements

- Covered entities may contract with pharmacies to dispense 340B drugs to eligible patients of the covered entity.

Current Guidance
- Covered entity remains responsible for the contract pharmacy’s compliance with 340B Program requirements.
- Contract pharmacies may not dispense 340B drugs to Medicaid patients unless HHS has approved a system to prevent duplicate discounts.
- Covered entity is expected to conduct audits of the contract pharmacy arrangement.

Proposed Guidance
- Covered entity must conduct quarterly reviews and annual audits of each contract pharmacy location.
  - Records of these reviews and audits are considered “auditable records”.
  - Covered entities must disclose to HRSA any 340B Program violations identified in reviews and audits.
KEY TAKEAWAYS:

**PART F: MANUFACTURER RESPONSIBILITIES**
Key Takeaways: Manufacturer Responsibilities

- Proposed guidance is generally consistent with current policies

Key Provisions

- Obligation to offer 340B prices to covered entities
  - Only HRSA may make eligibility determinations

- Limited distribution models
  - Must be non-discriminatory
  - Must be submitted to HRSA prior to implementation
  - Does not appear that limited distribution models are subject to HRSA approval prior to implementation
  - May be published on the HRSA website
KEY TAKEAWAYS:

PART G: AIDS DRUG ASSISTANCE PROGRAMS
Key Takeaways:
AIDS Drug Assistance Programs (ADAPs)

- State AIDS Drug Assistance Programs (ADAPs) may be eligible to participate in the 340B Program
  - **Current Guidance**
    - ADAPs may participate through a “direct purchase” option whereby the ADAP purchases covered outpatient drugs at 340B prices
  - **Proposed Guidance**
    - ADAPs may participate in the 340B Program through a “rebate” or “hybrid” option
      - and, if choosing to do so, must register as such in 340B Database
      - Choosing rebate option, ADAPs will receive rebates from manufacturers for covered outpatient drugs in an amount equal to the rebate described in Social Security Act 1927(c) multiplied by the units of drug included in the rebate claim
    - If choosing the rebate option, ADAPs must:
      - Make a qualified payment for an eligible patient and
      - Submit claims-level data to manufacturers to demonstrate qualified payment
KEY TAKEAWAYS:

**PART H: PROGRAM INTEGRITY**
Key Takeaways: Program Integrity

- **Audits of Covered Entities**
  - Covered entities are subject to audits by both HRSA and drug manufacturers
    - **HRSA audits**
      - Failure to provide records to HRSA may result in penalties, including termination from 340B Program
    - **Manufacturer audits**
      - Manufacturer audits are limited to compliance with duplicate discount and diversion requirements
      - Manufacturer audits are limited to one year
      - **Proposed Guidance**: Manufacturer can refer issues related to eligibility requirement (e.g., GPO prohibition) to HRSA for review
Key Takeaways: Program Integrity

- **Notice and hearing process**
  - 340B statute requires notice and hearing prior to imposing penalties for diversion or duplicate discounts discovered on audit.
  - **Current Guidance**
    - After an audit finding, HRSA receives written submissions from covered entities
    - HRSA will issue a final written notice with a final determination and, if applicable, a termination date
    - Covered entity may submit a corrective action plan (CAP)
  - **Proposed Guidance**
    - Notice and hearing process is based on written submissions of the covered entity and “involved parties”
    - Notice and hearing process will be offered to covered entities arising from diversion and duplicate discounts, as well as other instance of non-compliance and as a result of the proposed loss of 340B eligibility
    - Covered entities will be liable for repayment to affected manufacturers for purchases after the date of loss of eligibility or the date of the first violation of a statutory requirement.
Action Steps

- Review current policies and procedures
  - Patient definition
  - Definition of “covered outpatient drug”
  - Maintenance of auditable records
- Review actual implementation of policies and procedures
- Review contract pharmacy arrangements and audit processes
- Identify hospital eligibility category


**REMINDER:** Comments are due October 27, 2015

- Online at: *Federal eRulemaking Portal:*  
  [http://www.regulations.gov](http://www.regulations.gov)

- Via email: 340BGuidelines@hrsa.gov
  - Include “RIN 0906-AB08” in the subject line of the message

- By regular mail to:
  - Captain Krista Pedley  
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