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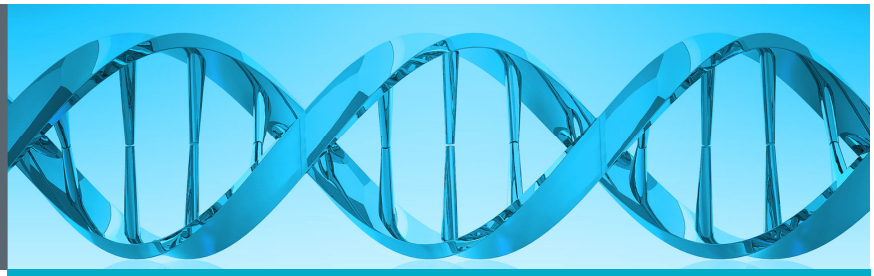
Health Care



September 2015

Summary of Key 340B Omnibus Guidance Proposals

In this Issue:

Part A - 340B Program Eligibility and Registration

Hospital Eligibility

- No change to disproportionate share percentage requirements and thresholds as this would likely require a statutory change
- HRSA will continue to use a hospital's most recently *filed* Medicare cost report to assess eligibility; HRSA restated its longstanding position that if a hospital files a cost report that does not meet the applicable disproportionate share percentage, it will be terminated from the 340B Program immediately upon filing the cost report.
- HRSA is seeking comments on how hospital offsite locations demonstrate eligibility for 340B and what data points HRSA should use to verify eligibility. HRSA previously considered relying on provider-based designations and CMS-855A practice location data.

Group Purchasing Organization ("GPO") prohibition

- Applies to DSH, children's and freestanding cancer hospitals
- HRSA identified a number of exceptions to the GPO prohibition, some of which are simply restatements of existing exceptions:
  - A GPO account may be used at a child offsite outpatient location if the location is not registered in the 340B Database, and it uses has a separate (from the main hospital) GPO account to purchase drugs.
  - *No violation of the GPO prohibition if 340B drugs are provided to an inpatient whose status is subsequently changed to outpatient by a*

third party, such as a payor or Medicare Recovery Audit Contractor. This is a decent win for hospital Covered Entities that often see retroactive reclassifications that impact 340B eligibility.

- Polsinelli has seen this issue numbers of times during audits.

- No violation if a 340B price or wholesale acquisition cost ("WAC") price is unavailable and advises HRSA of the same.

- HRSA proposes to allow newly qualified Covered Entities to use their remaining GPO inventory purchased prior to the 340B start date on outpatients without violating the GPO prohibition.

- Covered Entities and manufacturers permitted to use a credit/rebill process for erroneous GPO purchases if done within thirty (30) days of discovery.

- HRSA is proposing a notice and hearing process relative to findings of non-compliance with the GPO prohibition.

Part B – Drugs Eligible for Purchase Under 340B

Bundled Drugs and the Application of the Limiting Definition

- HRSA applies Section 1927(k)(2) of the Social Security Act (including the limiting definition) to determine if a drug is a "covered outpatient drug" and therefore subject to 340B. If a drug is considered a covered outpatient drug, the manufacturer has to offer the drug to Covered Entities at the 340B price and Covered Entities subject to the GPO prohibition cannot use GPO-priced drugs for covered outpatient drugs.

- Historically, many providers considered medical gas and IV solutions to fall outside of the covered outpatient drug definition due to the fact that the items are typically bundled in with all hospital services and are not separately reimbursable by payors. As a result, many Covered Entities subject to the GPO prohibition took the position that the bundled payment resulted in the gases and solutions falling under the limiting definition, therefore they were not covered outpatient drugs. These Covered Entities would then use GPO-pricing for such items.

- HRSA clarified its interpretation of the limiting definition to state that it only applies to drugs paid under a bundled payment by Medicaid, not other payors. The consequence would be that even if other payors do not separately pay for these items, HRSA believes the items are still covered outpatient drugs. As a result, manufacturers have to extend the 340B discount, and Covered Entities subject to the GPO prohibition will have to find a compliant way to order these bulk items at 340B (for outpatients) and GPO (for inpatients).

  - This will present added complexities to virtual inventory systems and staff.

Part C - Individuals Eligible to Receive 340B Drugs

Changes to the Patient Definition

- *Patients receive care at Covered Entity or Covered Entity child sites registered for the 340B program and listed on the database*. HRSA also indicated that follow-up care outside of the Covered Entity will no longer qualify prescriptions for 340B. Historically, HRSA had a limited exception that would permit Covered Entity to dispense 340B drugs as a result of follow-up care – the proposed Guidance effectively eliminates that exception.

- *Physicians or other eligible prescribers who treat eligible patients must be employed by or contracted with Covered Entity such that Covered Entity may bill on their behalf*. HRSA made it very clear that medical staff privileges are not enough. The billing standard noted above presumably means Covered Entity must have a sufficient contractual arrangement with the prescriber that would allow Covered Entity to bill the prescriber's *professional fees* provided to Covered Entity's patients. Under various payor programs, this would require a personal services arrangement. This is a significant deviation from the existing patient definition and could considerably limit the scope of the 340B program. For example, orders or referrals to Covered Entity from independent community physicians for items such as chemotherapy and infusion would not result in 340B eligibility for the drugs administered at Covered Entity. This may have a significant impact on rural areas where access to care is an issue. Providers will have to examine their physician contracts and patient flow (e.g., are patients seen by a Covered Entity oncologist prior to the infusion) to determine if adjustments need to be made.

- *Patients receive drugs that are ordered or prescribed by the Covered Entity provider as a result of the service described in bullet point 2 above*. HRSA is effectively tying the Covered Entity visit to the Covered Entity provider who prescribes the drug in order to qualify. It seems that this element may not be necessary, but we believe it exemplifies HRSA's intent to require the drug be ordered / prescribed and administered / dispensed as a result of a Covered Entity visit so as to avoid any doubt as to the scope of the program. HRSA's commentary indicates that this may include care via telemedicine.

- *Drug is ordered or prescribed pursuant to a health care service that is classified as outpatient*. Although it's still unclear, we believe this eliminates the ability to fill discharge prescriptions using 340B drugs in the contract pharmacy setting if the prescription is written while the patient is an inpatient. This proposed change could potentially reduce the number of 340B-eligible prescriptions.

- *The individual's patient records are accessible to the Covered Entity and demonstrate that Covered Entity is responsible for care*. HRSA's commentary indicates that the medical record must demonstrate a provider-to-patient relationship. Again, this reinforces HRSA's apparent desire to require a tighter bond between Covered Entity, its providers and patients.

- *Patient care fits within the scope of the 340B provider's grant, designation or contract.*

Covered Entity Employee Eligibility

- HRSA reiterated its position that the 340B Program does not serve as a general employee pharmacy benefit.

- Employees must meet above patient definition on a prescription-by-prescription basis to qualify for 340B.

Drug Replenishment Models

- HRSA's commentary recognizes replenishment models exist and can be effective.

- HRSA encourages Covered Entities and manufacturers to use credit/rebill process for errors made within 30 days.

- HRSA's commentary indicates that Covered Entities should avoid prolonged look-back periods where they try to reclassify drugs as 340B-eligible. Covered Entities are responsible for requesting 340B pricing at the time of the *original purchase*.

Repayment

- Covered Entities are expected to work with manufacturers regarding repayment within ninety (90) days of identifying a violation.

- HRSA's commentary suggests that they are going to continue defer to manufacturers and Covered Entities regarding voluntary repayments. For example, HRSA indicated that manufacturers retain discretion to request a repayment or to decide to forgive the issue of non-compliance if the repayment would be below a *de minimis* threshold established by the manufacturer.

Part D – Covered Entity Requirements

Prohibition of Duplicate Discounts

- *Fee-for-Service (FFS).* HRSA intends to maintain the Medicaid Exclusion File procedure whereby a Covered Entity will be listed on the 340B database if it notifies HRSA at the time of registration whether it will purchase and dispense 340B drugs to its Medicaid FFS patients (carve-in) and bill the State, or whether it will purchase drugs for these patients through other mechanisms (carve -out).

- *Medicaid Managed Care (MCO*). Cover Entities may make site by site determinations for carve-in or carve-out status for its MCO patients. However, the Covered Entity must provide to HRSA (HRSA proposed via the Medicaid Exclusion File) identifying information of the Covered Entity site, the associated MCO, and the decision to carve-in or carve-out. The HRSA guidance also encourages covered entities, States, and Medicaid MCOs to work together to establish a process to identify 340B claims (e.g., use of certain modifiers and codes on claims).

- *Contract Pharmacy.* HRSA will presume contract pharmacies listed on the database will not dispense 340B drugs to Medicaid FFS or MCO patients. If a Covered Entity desires otherwise, the Covered Entity will need to provide HRSA a copy of the written agreement with the contract pharmacy and State Medicaid agency/MCO describing the system to prevent duplicate discounts. HRSA must approve of the arrangement.

    - This would likely require revisions to many existing contract pharmacy arrangements that currently carve-in Medicaid MCO patients.

Maintenance of Auditable Records

- HRSA has proposed a record retention standard for all 340B Program records for a period of no less than five years. This would apply to all child sites and contract pharmacies, and in the case of termination, the requirement extends five years post termination.

Part E – Contract Pharmacy Arrangements

Registration

- HRSA clarifies that registration of a contract pharmacy on the 340B database will only be accepted from the Covered Entity.

    - We believe this will change workflows relative to many retail chains that have historically completed these registrations.

Compliance with Statutory Requirements

- To assist with contract pharmacy compliance, HRSA proposes clarification to its audit expectations and will offer standards for audit and quarterly reviews of contract pharmacy operations to ensure that

compliance efforts result in the early identification of problems, implementation of corrections, and the prevention of future compliance issues.

Part F – Manufacturer Responsibilities

Pharmaceutical Pricing Agreement (PPA) – Termination

- A manufacturer that terminates a PPA should maintain auditable 340B Program records for five years after the termination pertaining to compliance with 340B Program requirements.
- Refunds and credits specified may still be imposed on a terminated manufacturer for 340B drugs sold above the ceiling price during the time that the manufacturer had a PPA in effect.

Obligation to Offer 340B Prices to Covered Entities

- To reduce the potential for disputes and ensure that limited distribution plans are transparent to all stakeholders, HRSA is proposing that a manufacturer provide notification in writing of any limited distribution plan prior to implementation that includes specific product information, explanations, assurances, allocation plan details and dates for implementation and notification.
- Manufacturers may not condition 340B pricing on assurance of compliance. They must always offer the 340B price even if the manufacture has concerns about a Covered Entity's compliance.

Procedures for Issuance of Refunds and Credits

- If a manufacturer charges a covered entity more than the 340B ceiling price, HRSA states that the manufacturer must refund or credit that covered entity an amount equal to the price difference between the sale price and the correct 340B price for that drug, multiplied by the units purchased. This refund or credit is expected to occur within 90 days of the determination by the manufacturer or HRSA that an overcharge occurred.
- HRSA explains that if a Covered Entity fails to act to accept a direct repayment (e.g., cash a check) within 90 days of a manufacturer's refund and the repayment amount is undisputed by the Covered Entity, the Covered Entity has waived its right to repayment.
    - We recommend Covered Entities advocate for similar waiver language regarding payments to manufacturers by Covered Entities.

Manufacturer Recertification

- To ensure that all stakeholders have the most up-to-date information, HRSA is proposing a manufacturer annual recertification process whereby the update changes to their 340B database information as changes occur.

Part G - Rebate Option for AIDS Drug Assistance Programs (ADAPs)

- Because ADAPs may pay their patients' insurance amounts rather than use their money to purchase drugs directly, there have been circumstances where ADAPs may, for example, pay a patient's copayment to purchase a covered outpatient drugs and seek a full rebate from manufacturers. As ADAPs may profit off of this 'partial payment for a full rebate practice, HRSA proposes a mechanism to limit this occurrence.

- HRSA proposes that ADAPs accessing 340B prices on covered outpatient drugs either through a direct purchase option (i.e., at the 340B ceiling price), a rebate after the purchase, or a combination of both mechanisms (''hybrid'') perform the following actions to ensure manufacturer support for the ADAPs' rebate requests:
    - Inform HRSA during the registration process whether it will participate using direct purchase, a rebate option, or both;
    - Make a "qualified payment;" and
    - Submit claims-level data to the manufacturer to support each qualified payment to receive a rebate from that manufacturer.
- HRSA proposes that a "qualified payment" for a covered outpatient drug includes (i) the ADAPs' direct purchase at a price greater than the 340B ceiling price or (ii) the ADAPs' payment of the health insurance premiums that cover the covered outpatient drug purchases at issue and payment of a copayment, coinsurance, or deductible for the covered outpatient drug.
- HRSA will provide subsequent guidance regarding the data to be provided in support of rebate requests.

Part H – Program Integrity

HRSA Audit of a Covered Entity

- HHS is proposing a notice and hearing process under which a covered entity has the opportunity to respond to adverse audit findings and other instances of noncompliance or to respond to the proposed loss of 340B Program eligibility. The notice and hearing will be conducted based on the written submissions of the involved parties. [Note: Doesn't appear much different than current process ...]. Corrective action plans may be submitted by the Covered Entity to address findings of non-compliance.

Manufacturer Audit of a Covered Entity

- HRSA proposed a standard defining the "reasonable cause" a manufacturer must demonstrate to HRSA prior to its audit of a Covered Entity that the Covered Entity has diverted drugs or violated the duplicate discount prohibition. Examples of reasonable cause include, but are not limited to: (1) significant changes in quantities of specific drugs ordered by a Covered Entity without adequate explanation by the covered entity; (2) significant deviations from national averages of inpatient or outpatient use of certain drugs without adequate explanation by the Covered Entity; and (3) evidence of duplicate discounts provided by manufacturers or State Medicaid agencies. Non-response may also be constructed as reasonable cause.

HHS Audit of a Manufacturer and its Contractors

- HRSA proposed standards for audits of a manufacturer or wholesaler that manufactures, processes, or distributes covered outpatient drugs in the 340B Program. This audit may include either an on-site review, an off-site review of documentation requested by HRSA, or both.
- HRSA proposed a notice and hearing process regarding non-compliant audit findings (similar to the Covered Entity audit process). Manufacturers or wholesalers can submit responses to HRSA within designated timeframes to address the findings. HRSA may request corrective action, as needed. HRSA will notify CMS and other government agencies of the findings or actions as appropriate.

- HRSA explained that manufacturers can submit a corrective action plan to correct noncompliance. HRSA will determine when the audit is closed and may verify the manufacturer's compliance with the HRSA approved corrective action plan at any time.

For More Information

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[1] *U.S. News & World Report, November 2014*
[2] *Modern Healthcare, June 2015*
[3] *Chambers USA: America's Leading Lawyers for Business, May 2015*

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