PUBLICATION

HRSA Issues Long-Awaited 340B Program Omnibus Guidance Proposal

September 2, 2015

After much anticipation, the Health Resources and Services Administration (HRSA) late last week released its 340B Drug Pricing Program Omnibus Guidance Proposal (the Proposal). HRSA indicates that its goal in issuing the Proposal is to provide clarity in the marketplace for all 340B Program stakeholders and to strengthen the agency's ability to administer the Program effectively. Although the Proposal largely reaffirms many of HRSA's existing policy interpretations, it also contains some significant changes, including proposals that are likely to limit 340B patient eligibility. For example:

- In contrast to the existing three-part test for identifying individuals who qualify as 340B patients, HRSA is now proposing a six-part test that will be applied on a "prescription-by-prescription or order-by-order basis. Although many of the core requirements in HRSA's current definition remain intact, there are several substantial policy interpretations that will limit the number of individuals who can qualify as 340B patients.
  For instance, the provision of outpatient infusion services would not qualify an individual as a 340B patient unless the infusion is prescribed in the covered entity by a health care provider who is employed or under contract with the covered entity. Additionally, the definition limits 340B patient status to those patients billed as outpatients. This calls into question the ability of covered entities to qualify discharge prescriptions for 340B, implicates reimbursement rules (e.g., the Medicare three-day payment window), and impacts the timing of drug purchasing and replenishment.
- HRSA is proposing to clarify the definition of "covered outpatient drug" to specify that the term operates in the 340B Program only to exclude drugs bundled for and receiving bundled reimbursement under Medicaid.
- HRSA articulates additional exceptions to the prohibition on obtaining covered outpatient drugs through group purchasing organizations (GPOs). For example, changes in patient status (from inpatient to outpatient) arising from payor audits would not be considered a violation of the GPO prohibition. HRSA is proposing some leniency with regard to isolated violations of the GPO prohibition. Isolated violations (as distinguished from systemic violations) of the GPO prohibition would not require termination of the covered entity from the 340B Program.
- HRSA is being more direct about the oversight and compliance obligations of contract pharmacy arrangements. For example, if the Proposal is finalized, covered entities would need to engage in quarterly reviews and have annual independent audits of each contract pharmacy location. Covered entities would also need to seek advance approval from HRSA before allowing Medicaid patients to access 340B drugs through contract pharmacy arrangements.
- HRSA is proposing that covered entities and manufacturers retain auditable 340B records for no less than five years and provides that manufacturer audits are limited to a review of records not exceeding the five-year record retention standard.
- Entities covered by the 340B program should also note that HRSA is proposing an advanced notification process for manufacturers to use before engaging a specialty pharmacy or restricted distribution network, or before limiting distribution of outpatient drugs due to potential or actual shortages.

HRSA is seeking comments regarding the Proposal on or before October 27, 2015. The agency expects to finalize the Proposal in a Final Notice to be issued at a later date.

Detailed Summary Of The Key Changes And Clarifications Offered In HRSA's Proposal

Significant "Patient" Definition Changes

The most significant policy changes in the Proposal have to do with the definition of individuals deemed eligible to receive 340B drugs (i.e., 340B patients). The 340B definition of patient has been the source of some ambiguity since HRSA defined it almost 20 years ago. Although many of the core requirements remain intact, there are several substantial policy interpretations that, as discussed below, would limit the number of individuals who qualify as 340B patients.

New Patient Definition: In contrast to the existing three-part test for identifying individuals who qualify as 340B patients, HRSA is now proposing a six-part test that will be applied on a "prescription-by-prescription or order-by-order basis."

> ***Proposed Criterion 1:*** **The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database**.

This criterion is not included in the current patient definition. However, the receipt of health care services from a 340B-covered entity has always been an implicit requirement.

> ***Proposed Criterion 2:*** **The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider.**

This criterion seeks to ensure that the health care provider who prescribes or orders a 340B drug is appropriately connected to the 340B-covered entity. Noticeably absent from the criterion is the current ambiguous reference to health care professionals who provide health care under "other arrangements (e.g., referral for consultation)." HRSA now expressly seeks to exclude patients from eligibility when they receive services from another health care organization that has an affiliation arrangement. This suggests that prescriptions issued pursuant to services requested by the covered entity (e.g., referral for consultation), or that are proximally-related to covered entity services will no longer be eligible.

Also different is the requirement that the covered entity bill or have the ability to bill for services on behalf of the provider. This qualification seems to be defining the type of practitioner who will qualify as a "health care provider" for purposes of this criterion. Specifically, HRSA appears to be limiting its view of "health care provider" to those practitioners who bill payors for their professional services (e.g., MDs, physician assistants, nurse practitioners, etc.), as opposed to clinical staff (e.g., nurses) who do not.

> ***Proposed Criterion 3:*** **An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in criterion 2 above. 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.**

In this criterion, HRSA ties 340B prescriptions to the service furnished at the covered entity. It further provides that certain types of services, on their own, are not sufficient to qualify an individual as a 340B patient. HRSA has always maintained that 340B patient status is not satisfied if the only health care service furnished to an individual is the dispensing of a drug. Now, however, another type of service – infusion – will not be sufficient

unless the infusion is prescribed in the covered entity by an employed or contracted health care provider. If the Proposal is finalized, registered outpatients of a covered entity would not qualify as 340B patients if their infusion services are furnished based on a prescription for infusion that is written by a private practitioner. The clarification will be controversial and could result in a significant contraction of 340B spending on infusion drugs.

> ***Proposed Criterion 4:*** **The individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract.**

This criterion applies to federal grantees and is generally consistent with the current requirements. HRSA is now clarifying that the requirement also applies to hospitals that participate solely on the basis of a federal grant, project or contract.

> ***Proposed Criterion 5:*** **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 (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured or whose 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.**

Proposed criterion 5 is new, confusing and potentially limiting. It would require that an individual be classified as an outpatient *when the drug is ordered or prescribed* and *based on how the services are billed to payors.* An individual's patient status classification may change from the time a drug is ordered or prescribed to the time the services are billed. Notwithstanding this issue, the proposed guidance along with preamble discussion reflect HRSA's intention to assess 340B patient status based on how the services are billed to payors.

If finalized, the Proposal would likely delay when hospitals are able to identify 340B patients within their drug purchasing and replenishment systems. Further, tying 340B eligibility to billing potentially implicates other reimbursement rules, such as the Medicare three-day payment window rule. That rule requires Prospective Payment System hospitals to bundle the technical component of all outpatient diagnostic services and related therapeutic services with the claim for an inpatient stay when services are furnished to a Medicare beneficiary in the three days preceding an inpatient admission. Under this Proposal, hospital patients who receive drugs in outpatient departments and are later admitted to inpatient status may no longer qualify as 340B patients. The Proposal would also limit the ability to qualify discharge prescriptions for 340B purchasing.

> ***Proposed Criterion 6:*** **The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition is met for each 340B drug.**

This criterion is generally consistent with HRSA's interpretation of the current records requirement that "the covered entity has a relationship with the individual, such that the covered entity maintains records of the individual's health care." The criterion suggests that *access* rather than direct *maintenance* of auditable records will be sufficient.

Exceptions: HRSA proposes two exceptions to the definition of "patient." First, the agency reaffirms its long-standing interpretation that individuals enrolled in a Ryan White HIV/AIDS Drug Assistance Program will be considered a "patient" of the covered entity for purposes of the 340B Program. It also provides that a covered

entity may temporarily follow alternative patient eligibility criteria, with approval by HRSA, when normal health care operations are disrupted due to a public health emergency.

Covered Outpatient Drug Definition Clarified

HRSA is proposing to clarify the term "covered outpatient drug." That term, which takes its definition from the Medicaid Drug Rebate Program statute, is defined to exclude drugs that are bundled for reimbursement purposes (i.e., "provided as part of, or as incident to and in the same setting") with various categories of services, including outpatient hospital services. This "limiting definition" has been the source of controversy, with some 340B stakeholders asserting that 340B pricing does not apply to drugs that are subject to bundled payment by any payor. HRSA now clarifies that the limiting definition operates in the 340B Program only to exclude drugs bundled for and receiving bundled reimbursement under Medicaid. Thus, drugs provided as part of a hospital outpatient service which are paid for on a bundled basis by Medicaid do not qualify as a covered outpatient drug and cannot be accumulated for 340B purchasing. However, drugs provided as part of hospital outpatient services that are billed (1) to any other payor, or (2) directly to Medicaid would still qualify for 340B purchasing as a covered outpatient drug.

GPO Prohibition: Exceptions, Isolated Errors and 30-Day Grace Period to Correct Errors

Disproportionate Share Hospitals (DSH), and children's and freestanding cancer hospitals are prohibited, as a statutory condition of participation in the 340B Program, from obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. HRSA has taken the position that violations of the GPO prohibition will result in removal from the 340B Program after a notice and hearing process. HRSA is now interpreting the statute to allow for several exceptions to the GPO prohibition.

Exceptions: The first exception is not new and re-affirms HRSA'sPolicy Release 2013-1 in which the agency described outpatient clinic sites and areas of covered entity hospitals where the GPO prohibition applies. As in the Policy Release, the Proposal provides that a covered entity may use a GPO to obtain covered outpatient drugs for an off-site outpatient clinic if the clinic is located at a separate physical address from the 340B-covered entity, is not participating in the 340B Program, or listed on the 340B database, and purchases drugs through a separate account from the 340B-covered entity.

HRSA is now expressly articulating additional exceptions to the GPO prohibition. Specifically, covered entities will not be considered in violation of the statutory GPO prohibition when:

- A GPO-purchased drug is provided to an inpatient, who, upon subsequent review (e.g., insurer, Medicare Recovery Audit Contractor or hospital review), results in a designation of the patient as an outpatient for payment purposes; and
- A hospital can only access a covered outpatient drug through a GPO account because the drug is not available at the 340B or wholesale acquisition cost (WAC) price. In this circumstance, the covered entity would need to document the circumstances surrounding the use of GPO pricing and provide HRSA with the name of the drug in question, the manufacturer and a brief description of the attempts to purchase the drug at 340B price and the WAC price prior to purchasing the drug at GPO pricing.

Isolated Violations: Isolated violations of the GPO prohibition would not require expulsion from the 340B Program. Though "isolated violation" is not defined, if a covered entity can demonstrate that the purchase of covered outpatient drugs at GPO pricing is an isolated error, HRSA may allow the covered entity to continue to participate in the 340B Program under a corrective action plan.

30-Day Grace Period for GPO Purchasing Errors: HRSA signals in preamble discussion that GPO purchasing errors identified and corrected through credit and rebill processes within 30 days of the initial purchase will not result in a finding that the GPO prohibition has been violated.

Diversion: 30-Day Grace Period to Correct Errors and 90-Day Repayment Period

Consistent with the 340B statute, if 340B drugs are found to have been diverted to an individual who is not a 340B patient, the covered entity is responsible for offering repayment of the 340B discount to all affected manufacturers. In preamble discussion of purchasing processes and repayment obligations, HRSA "encourages" manufacturers and covered entities to continue working together to identify and correct errors in 340B purchasing within 30 days of the initial purchase through a credit and rebill process. Also in preamble discussion, HRSA sets forth its expectation that covered entities work with manufacturers to repay any 340B discounts within 90 days from when the covered entity identifies that 340B drugs have been diverted (e.g., used on non-340B patients), and to notify HRSA of corrective actions regarding diversion, including any manufacturer agreements on repayment. Although the apparent 30-day grace period and 90-day repayment period are not expressly stated as part of the Proposed guidance, the preamble discussion suggests that errors caught and corrected within 30-days of the initial purchase will not be viewed as diversion for which repayment and corrective action, including notification to HRSA, will be expected.

Duplicate Discounts: Medicaid Exclusion Status for Medicaid MCO Patients

Under the 340B Program, manufacturers are prohibited from providing both a discounted 340B price and a Medicaid drug rebate for the same drug. To help ensure that manufacturers are not subject to duplicate discounts, HRSA requires covered entities to accurately report how they bill Medicaid drugs on the Medicaid Exclusion File. Currently, covered entities either include Medicaid Fee-For-Service (FFS) patients in their 340B Programs (carve-in) or exclude them (carve-out). In its Proposal, HRSA now offers guidance with regard to Medicaid Managed Care Organization (MCO) patients. HRSA would provide covered entities with discretion on whether to carve-in or carve-out the use of 340B drugs for Medicaid MCO patients. Covered entities could make differing decisions as to covered entity site and MCO, so long as the distinction is made available to HRSA. Covered entity's decisions in this regard would be made public through the 340B database and the covered entity would need to have mechanisms in place to identify Medicaid MCO patients.

Contract Pharmacy Clarifications

Contract Pharmacy Oversight: HRSA proposes to strengthen its current recommendation that covered entities conduct audits of contract pharmacy compliance. Although existing guidance reflects HRSA's expectation that covered entities fulfill their compliance obligations through the use of independent audits of contract pharmacy compliance, HRSA expressly left the method of compliance to the judgment of the covered entity. It did "not specify the precise method, personnel or items for ensuring sufficient information is obtained by the covered entity." HRSA is now being more direct. If the Proposal is finalized, covered entities would need to engage in quarterly reviews and have annual independent audits of each contract pharmacy location. The results of these reviews would need to be maintained as auditable records and violations detected through these reviews would need to be disclosed to HRSA.

Registration: HRSA proposes that covered entities are the only parties that may submit a contract pharmacy registration, certify a contract pharmacy, make changes to the contract pharmacy arrangement listed on the 340B database, and verify that all public and non-public information in the 340B database regarding its contract pharmacies is accurate. In the preamble, HRSA instructs that groups or networks of covered entities may not register or contract for pharmacy services on behalf of their individual covered entity members. This indicates that each individual covered entity would need to have a written agreement with a single contract

pharmacy company that identifies all contract pharmacy locations to be used by the covered entity and all child sites that plan to use the contract pharmacy.

Termination Authority: HRSA re-affirms its longstanding guidance that the covered entity remains responsible for contract pharmacy compliance with 340B requirements. However, HRSA now proposes that it may directly remove a contract pharmacy upon finding that the contract pharmacy is not complying with 340B requirements.

Approval Required for Medicaid FFS or MCO Patients: HRSA proposes that Medicaid FFS and MCO patients will be excluded from contract pharmacy arrangements unless the covered entity first seeks approval from HRSA. If approved, HRSA will list the contract pharmacy as able to dispense 340B drugs to Medicaid FFS and/or MCO patients.

New Five-Year Record Retention Requirement and Look-Back Period

Under the Proposal, covered entities and manufacturers must retain auditable 340B records for no less than five years. The scope of any manufacturer audits would be limited to a review of auditable records not exceeding the five-year record retention standard. Notably, the Proposal does not expressly include a scope of audit period for HRSA audits.

HRSA and Manufacturer Audits

The Proposal outlines HRSA's audit process for covered entities and manufacturers, and sets forth standards for manufacturer audits of covered entities. Key proposals and clarifications include:

- Only one 340B Program audit of a covered entity will be conducted at any given time, including a 340B Program audit by a manufacturer. As part of that audit, HRSA instructs that it may audit the parent covered entity site, any child site and any pharmacy under contract with the covered entity. Preamble discussions clarify that HRSA may separately audit another covered entity associated with the parent or child site. Thus, a health system with multiple covered entities may experience more than one HRSA audit at a time.
- Notice and hearing for noncompliance will be conducted based on the written submissions of the parties. The processes identified in the Proposal are consistent with current practice and the 340B Audit Process Program Update (July 2014). HRSA does not provide any process for continuing a dispute after issuance of the final determination. There is no process identified for independent and impartial assessment of contested audit findings.
- Manufacturer audits of covered entities must be based on "reasonable cause." The manufacturer would need to justify to HRSA's satisfaction that "a reasonable person could conclude, based on reliable evidence, that a covered entity, its child sites, or contract pharmacies may have violated either" the prohibition on diversion or duplicate discounts. Examples of reasonable cause may include (1) significant unexplained changes in quantities of specific drugs ordered by a 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.

Manufacturer Obligations Defined

The Proposal addresses various obligations of manufacturers participating in the 340B Program, including, among others, the following:

Effective Dates for 340B Pricing: HRSA reiterates that manufacturers are obligated to offer covered outpatient drugs to covered entities at the 340B discounted rate as of the date the drugs are first included in the Medicaid Rebate Program. For manufacturers voluntarily entering into Pharmaceutical Pricing Agreements (PPAs) for participation in the 340B Program, the effective date by which 340B pricing must be offered is the date the PPA is signed by both parties (i.e., manufacturer and HRSA). Finally, manufacturers with existing PPAs that have new drugs approved, the effective date for 340B pricing for the new drug is the date the drug is first available for sale.

Advanced Notification for Limited Distribution (Specialty) Networks: HRSA proposes an advanced notification process for manufacturer use of specialty pharmacy or restricted distribution networks, or before limiting distribution due to potential or actual shortages. HRSA expects manufacturers' limited distribution plan notifications to include:

- An explanation of the product's limited supply or special distribution requirements and the rationale for restricted distribution among all purchasers;
- An assurance that the manufacturer will impose the restrictions equally on both 340B-covered entity and non-340B purchasers;
- Specific details of the drug distribution plan, including a mechanism that allocates sales to both covered entities and non-340B purchasers with no previous purchase history of the restricted drug;
- The dates the alternative distribution will begin and conclude; and
- A plan for notification of wholesalers and 340B-covered entities of the restricted plan.

Refunds and Credits for Overcharges: Manufacturer refunds or credits for overcharges would need to be made within 90 days of the determination by the manufacturer or HRSA that an overcharge has occurred. HRSA will require the manufacturer to submit the 340B ceiling price recalculation, an explanation for why the overcharge occurred, how refunds will be calculated and to which covered entities refunds or credits will be issued. Unless the refund amount is disputed, a covered entity's failure to take action on a manufacturer repayment within 90 days of receipt will result in the waiver by the covered entity of the right to the repayment.

Annual Recertification Process for Manufacturers: HRSA proposes that manufacturers "should" review and update 340B database information on an annual basis. HRSA does not address what, if any, consequences would apply for a manufacturer's failure to comply with the proposed recertification process.

Rebate Options for ADAPs

HRSA is proposing to continue its longstanding policy of allowing state AIDS Drug Assistance Programs (ADAPs) to access 340B prices on covered outpatient drugs either through a direct purchase option, a rebate after purchase or a combination of both mechanisms (i.e., a hybrid option). HRSA proposes to require ADAPs that seek to participate in the 340B Program via the rebate option or the hybrid option to:

- Be registered under the rebate or hybrid option and listed on the 340B database;
- Make qualified payments for eligible patients; and
- Submit claims-level data to manufacturers documenting that qualified payments were made in support of each request for a rebate.

Under the Proposal, "qualified payment" is defined to mean:

- A direct purchase by an ADAP of a covered outpatient drug at a price greater than the 340B ceiling price; or

- A payment by an ADAP of the health insurance premiums that cover the covered outpatient drug purchase at issue and payment of a copayment, coinsurance or deductible for the covered outpatient drug.

Payment by an ADAP of only the copayment, coinsurance or deductible, in the absence of also paying for the health insurance premium, would not constitute a "purchase" of the covered outpatient drug. However, in recognition of unique challenges with identifying the types of payments that will qualify as a drug purchase by an ADAP, HRSA is both seeking specific comments on this proposal and further proposes to delay the effective date for the definition of "qualified payment" for 12 months after the publication of the final guidance.

HRSA also affirms its ability to audit ADAPs, confirms manufacturer's obligations to provide rebates under the 340B statute, and proposes a methodology for determining the correct rebate amount in cases where the ADAP has paid the health insurance premium and the copayment, coinsurance or deductible. With regard to the latter, HRSA clarifies that the amount of the rebate is equal to the rebate amount paid under the Medicaid drug rebate amount multiplied by the units of drug included in the rebate claim. Manufacturers will be expected to maintain auditable records to determine the correct rebate amount.