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Proposed Omnibus 340B Guidance

Questions and Answers

I. PROGRAM ELIGIBILITY

Q: What are the proposed changes to child site criteria and/or eligibility?

A: For hospital entities, the language has changed slightly in the new regulation. Proposed guidance states that off-site outpatient facilities of a covered entity hospital may participate in 340B as child sites "if the hospital covered entity provides its most recently filed Medicare cost report demonstrating that: (1) each of the facilities or clinics is listed on a line of the cost report that is reimbursable under Medicare; and (2) *the services provided at each of the facilities or clinics have associated outpatient Medicare costs and charges*." Since child site locations are generally outpatient facilities and clinics, the impact appears to be minimal.

A: For Children's Hospitals, an outpatient facility qualifies as a child site when the hospital demonstrates that the outpatient facility: *"(1) is an integral part of the hospital, and (2) would be correctly included on a reimbursable line with associated Medicare costs and charges on a Medicare cost report, if [a cost report were] filed."* (Unchanged)

A: For Grantee child sites there are proposed changes. Traditionally, only hospital covered entities have had an expanded reach utilizing "child sites" that are able to participate in 340B. The proposed guidance states that "*a non-hospital covered entity also may include associated health care delivery sites located at a different address. These associated health care delivery sites will be listed on the public 340B database as able to purchase and use 340B drugs for their eligible patients if the nonhospital covered entity ("parent site") registers the associated sites and provides information demonstrating that each site is performing services under the main qualifying grant, contract, designation, or project*." (New)

II. DRUG ELIGIBILITY

Q: What is the proposed change to Drugs eligible for purchase (i.e. definition of covered outpatient drug)?

A: Historically, HHS identified certain parameters regarding covered outpatient drugs that excluded "bundled drugs" from 340B eligibility. According to published guidance in May 1993, "*a covered outpatient drug does not include any drug, biological product, or insulin that meets this limiting definition*". The limiting definition has previously stated that "*if a covered drug is included in the per diem rate (i.e., bundled with other payments in an all-inclusive, a per visit, or an encounter rate), it will not be included in the 340B Program. However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program*." (59 FR 25110, 25113).

Proposed guidance now states "*further, the limiting definition in section 1927(k)(3) to exclude covered outpatient drugs for purposes of the 340B Program only applies when the drug is bundled for payment under Medicaid as part of a service in the settings described in the limiting definition. In contrast, a drug provided as part of a hospital outpatient service which is billed to any other third party or directly billed to Medicaid would still qualify as a covered outpatient drug*".

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Interpretation of this section has been speculated to mean that only bundled drugs for Medicaid patients will be excluded as a 340B covered drug, while all other bundled drugs under different payers will be included as a 340B covered drug. If passed as written, this would have significant impact on GPO purchasing, software applications, and operational processes in many outpatient procedural areas.

III. PATIENT ELIGIBILITY

Q: What is different about the newly proposed patient definition?

A: The proposed patient definition is narrower than the previous definition. For example, in the newly proposed patient definition, prescriptions received from an outside referral provider would no longer be 340B eligible. Also, the newly proposed criteria specifically requires employment or contractual relationship between the provider and the entity; previous language stating "other arrangement or referral relationship with a 340B entity" has been removed. In addition, one of the biggest proposed changes is that prescriptions must be pursuant to a health care service that is classified as *outpatient*; if this change goes into effect hospital discharge prescriptions would not qualify as 340B eligible.

Q: What is the new proposed Patient definition?

A: The proposed guidance provides that an "individual will be considered a patient of a covered entity, on a prescription-by-prescription or order-by-order basis" if all of the following six conditions are met:

(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. An individual will not be considered a patient of the covered entity if the individual's health care is provided by another health care organization that has an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization's records. Access to an individual's records by a covered entity, by itself, does not make the individual a patient of that covered entity
Interpretation included: HHS interprets the statute such that a 340B eligible patient receives a health care service from the covered entity, and the covered entity is medically responsible for the care provided to the individual. An individual who sees a physician in his or her private practice which is not listed on the public 340B database or any other non-340B site of a covered entity, even as follow-up to care at a registered site, would not be eligible to receive 340B drugs for the services provided at these non-340B sites.

(2) The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider. If a patient is referred from the covered entity for care at an outside provider and receives a prescription from that provider, the drug in question would not be eligible for a 340B discount at that covered entity. "Services" is not defined.
Interpretation included: Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard. Simply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B Program purposes.

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(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 would not be considered a patient of a covered entity whose only relationship to the individual is the dispensing or infusion of a drug. The dispensing of or infusion of a drug alone, without a covered entity provider-to-patient encounter, does not qualify an individual as a patient for purposes of the 340B Program. However, if the covered entity infuses a drug and meets all other criteria as defined in this section, an individual may be classified as a patient for purposes of 340B.

(4) The individual's health care is consistent with scope of the Federal grant, project, designation, or contract (for Federal Grantees)

(5) The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient. Therefore, an individual cannot be considered a patient of the entity furnishing outpatient drugs if his or her care is classified as inpatient.

(6) The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care. An individual will be considered a patient if he or she has an established relationship such that the covered entity maintains auditable health care records that demonstrate the covered entity has a provider-to-patient relationship for the health care service that results in the order or prescription and that the covered entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to an individual.

Q: What do you foresee as is biggest impact of the newly proposed patient definition?

A: If the regulation goes through as currently written, the biggest impact to covered entities will likely be the exclusion of discharge prescriptions from 340B eligibility and the exclusion of referral providers and non-employed/non-contract providers from 340B eligibility.

Q: Has HRSA made any exceptions for eligibility of employees of the covered entity?

A: No. HRSA's position on employee 340B qualification has not changed. Proposed guidance states "that only individuals who are patients of the covered entity are eligible for drugs purchased through the 340B Program. Employees of covered entities do not become eligible to receive 340B drugs solely by being employees, but by being a patient as defined in this guidance." Covered entities that solely have financial responsibility for employees' health care, and contract with prescribing health care professionals loosely affiliated or unaffiliated with the covered entity, would not meet the level of responsibility for health care services as outlined in the guidance.

IV. GPO PROHIBITION

Q: In the proposed regulation, does the GPO Prohibition still apply to DSH, PED, and CAN?

A: Yes, eligibility criteria for a DSH, PED, and CAN still requires that these entities do not purchase covered outpatient drugs on a GPO account. The proposed guidance states: "*A GPO may only be used by one of the affected covered entities to purchase drugs dispensed to inpatients or to purchase drugs which do not meet the definition of covered outpatient drug. This prohibition extends to any pharmacy owned or operated by these covered entities, and takes effect as of the start date of enrollment in the 340B Program. The prime vendor program established pursuant to section 340B(a)(8) of the PHSA is not considered a GPO subject to this prohibition.*"

Q: What further clarification has HRSA provided regarding GPO Prohibition in the proposed guidance?

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A: The proposed guidance further clarifies specific situations which would not violate the GPO statutory prohibition. (1) GPO account may be used at an off-site outpatient facility that is not participating in the 340B Program or listed on the public 340B database as long as that facility has a purchasing account separate from that of any 340B enrolled site. The facility must ensure GPO purchased drugs are never provided to outpatients of the hospital or other child sites enrolled in the 340B Program. (2) 340B eligibility can be maintained when GPO drugs are first provided to an inpatient whose status is subsequently changed to outpatient by a third party, provided there is sufficient documentation of the patient's change of status. "Sufficient documentation" is not elaborated on. (3) An exception to the GPO prohibition will be made for hospitals that cannot access a drug at the 340B price or at wholesale acquisition cost (WAC) to prevent disruptions in patient care. The entity must document the facts surrounding the purchase and provides HHS with the name of drug in question, the manufacturer, and a brief description of the attempts to purchase the drug at the 340B price and the WAC price prior to purchasing the drug through a GPO.

Q: What is stated regarding use of previously-purchased GPO Drugs?

A: The proposed guidance states that newly enrolled covered entities subject to the GPO prohibition must stop purchasing covered outpatient drugs through a GPO before the first day the covered entity is listed on the HRSA database. However, if a covered entity has GPO-purchased drugs remaining in inventory on or after the listed 340B start date, the proposed guidance would allow the entity to use those drugs "until expended".

Q: Since GPO prohibition is an eligibility criteria, does a violation of the statue imply that the covered entity will be removed from the 340B program?

A: Not necessarily. The proposed guideline actually describes a more individualized approach to violations of the GPO statute. If the covered entity were to demonstrate the GPO violation was an isolated incident and the covered entity is currently in compliance, the covered entity will be permitted to remain in the 340B Program upon submission of a corrective action plan. If, after notice and hearing, the covered entity's GPO violation was determined not to be isolated, the covered entity would be deemed ineligible for the 340B Program as of the date of the violation and immediately removed. A covered entity removed from the 340B Program would be required to offer repayment to affected manufacturers for any 340B drug purchase made after the first date of violation of the GPO prohibition.

A: The proposed guidance also indicates that if a child site is found to be in violation of the GPO prohibition, the parent site may be able to remain in the 340B program if the parent site can demonstrate that the violation was isolated to only the child site and that the parent site did not commit a violation. However, GPO participation cannot be limited to a child site if the parent site also purchases drugs on the same account as the child site.

V. DUPLICATE DISCOUNT

Q: Are there proposed changes to Medicaid requirements and the Medicaid Exclusion File in regard to Duplicate Discounts?

A: HHS has acknowledged in this guidance that prevention of duplicate discount applies to both Medicaid fee-for-service and Medicaid managed care, a stance many entities have already taken and currently practice. There is a potential for change, however, in the way covered entities

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handle Medicaid and Managed Medicaid patients with regard to the Medicaid Exclusion File. The proposed guidance would allow covered entities to designate "carve-in" or "carve out" status for both fee-for-service Medicaid patients and MCO patients with significantly greater flexibility. The proposed regulation would permit a CE to "*make a different determination regarding carve-in or carve-out status for MCO patients than it does for FFS patients*," but also to "*make different decisions by covered entity site and by MCO*." HRSA does not indicate or address whether it will be feasible for entities to process and/or operationalize the proposed changes, but proposes to use the Medicaid Exclusion File as a tool to list entity Medicaid elections.

VI. AUDITABLE RECORDS

Q: What does the proposed guidance say about auditable records?

A: Section 340B(a)(5)(C) of the PHSA requires a covered entity to permit the Secretary and certain manufacturers to audit covered entity records that pertain to the entity's compliance with 340B Program requirements. Failure to maintain the records necessary to permit such auditing is failure to meet the requirements of section 340B(a)(5) of the PHSA. The proposed guideline states: "a *covered entity's failure to maintain auditable records is grounds for losing eligibility to participate in the 340B Program*."

There are many areas of the proposed guidance that discuss maintenance of auditable records. Key areas include:

(1) Patient Eligibility (Criteria 6): "An individual will be considered a patient if he or she has an established relationship such that the covered entity maintains auditable health care records that demonstrate the covered entity has a provider-to-patient relationship for the health care service that results in the order or prescription and that the covered entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to an individual".

(2) Changes in Patient Status: "The covered entity should maintain auditable records documenting any changes in patient status due to insurer determinations".

(3) Compliance: "covered entities must maintain records that demonstrate that all of the criteria above were met for every prescription or order resulting in a 340B drug being dispensed or accumulated through a replenishment model".

(4) Inventory/Procurement/Replenishment Models: "Each 340B drug order placed should be supported by auditable records demonstrating prior receipt of that drug by a 340B-eligible patient".

(5) Inventory Discrepancies: "Policies and procedures regarding 340B drug inventory discrepancies, and how the covered entity will reconcile any discrepancy in 340B drugs, can assist in meeting this standard. Without this information documented in auditable records, a covered entity would not be able to demonstrate that drug inventory discrepancies have not resulted in diversion".

(6) Contract Pharmacy: "Under the 340B Program, 340B drugs may not be diverted to non-patients, duplicate discounts must be prevented, and a covered entity must have auditable records pertaining to its compliance with these requirements."

(7) Repayment: "A covered entity must notify HHS and each affected manufacturer of diversion and is expected to document notification attempts in auditable records."

(8) Emergency Provisions: "A covered entity is expected to maintain auditable records pertaining to the effective dates and alternate methods to be used during the secretarial declared public health emergency".

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Q: What is the proposed recommendation for retention of records?

A. HHS is proposing a record retention standard for all 340B Program records for a period of not less than 5 years. This standard would also apply to records pertaining to all child sites and contract pharmacies.

Q: What is HHS proposing as a consequence for covered entities that do not maintain auditable records?

A. In accordance with the statute, a covered entity's failure to provide required records is grounds for termination from the 340B Program.

A. HHS proposes to use discretion for those entities whose failure to retain records is non-systematic. For example, if a covered entity can generally produce 340B records for patient eligibility, but cannot produce a record for a particular patient who received a 340B drug, the drug purchase would be presumed to be in violation of section 340B(a)(5)(B) of the PHSA (diversion) and the entity may be liable for repayment to the manufacturer; however, the covered entity would not be removed from the 340B Program.

A. If failure to produce records is found to be a systematic failure, it could result in a determination of ineligibility and the covered entity may be liable for repayment to manufacturers for periods of ineligibility. Prior to removal, a covered entity would be entitled to notice and hearing pursuant to this guidance regarding removal from the 340B Program for failure to meet a statutory 340B Program eligibility requirement. A covered entity removed for systematic failure to maintain records would be able to re-enroll in the 340B Program during the next regular registration period after the covered entity has demonstrated to HHS its ability to comply with all 340B Program requirements, including the requirement to maintain auditable records.

VII. INVENTORY/DRUG PROCUREMENT

Q: Does HRSA address replenishment models and the use of software "accumulators" in the proposed guideline?

A: Yes, HRSA acknowledges the use of a replenishment model and software accumulators within the guideline. HRSA states that use of replenishment models to manage drug inventory, including 340B drugs is "*permissible if the covered entity remains in compliance with all 340B requirements*." An important addition to this section includes language relating to inappropriate accumulations, stating: "*If the covered entity improperly accumulates or tallies 340B drug inventory, even if it is prior to placing an order, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of section 340B(a)(5)(B) of the PHSA"*. Again, there is no further comment about the operational impact or speculated method of enforcing this particular point.

Q: What does HRSA recommend with regard to inventory discrepancies?

A: HRSA expects that covered entities will carry out regular reviews of 340B drug inventory to ensure that any inventory discrepancy is accounted for and properly documented to demonstrate that 340B drugs are not diverted. Further, HRSA states that a covered entity should follow standard business procedures to return unused or expired 340B drugs and appropriately account for waste of 340B drugs (e.g., discards after expiration dates). *"Policies and procedures regarding 340B drug inventory discrepancies, and how the covered entity will reconcile any discrepancy in 340B drugs, can assist in meeting this standard. Without this information documented in auditable records, a*

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covered entity would not be able to demonstrate that drug inventory discrepancies have not resulted in diversion."

Q: Does the Omnibus proposal address the practice of "banking"?

A: Importantly, HRSA notes that "*covered entities are responsible for requesting 340B pricing at the time of the original purchase*," and appears to discourage the practice of "banking". Banking is an attempted to retroactively look back over long periods of time at drug purchases not initially identified as 340B eligible and attempt to retroactively re-characterize the purchases. Although HRSA appears to discourage "banking", it does not prohibit it altogether, emphasis is placed in communication with the manufacturer, transparency, and audit trail.

VIII. PROGRAM INTEGRITY: COMPLIANCE, AUDIT AND CORRECTIVE ACTION PLANS

Q: Does the 340B Omnibus Proposal suggest how covered entities should handle manufacturer repayment?

A: HRSA does not state an exact or preferred method of manufacturer repayment. Newly proposed guidance states that covered entities are expected to work with manufacturers regarding repayment within 90 days of identifying the violation. In addition, the guidance specifically states "*A covered entity must notify HHS and each affected manufacturer of diversion and is expected to document notification attempts in auditable records".*

Q: Are there new processes proposed regarding HRSA audits and audit provisions?

A: Several sections of the guidance proposes a new auditing standards for a "notice and hearing process" to allow covered entities an opportunity to challenge adverse audit findings and instances of noncompliance or to respond to the proposed loss of 340B Program. Under this process, HHS would notify a covered entity of a proposed adverse finding, and the entity would have 30 days to respond in writing to each issue of noncompliance, providing details and documentation where appropriate.

A: HHS may audit the parent covered entity site, any child site, and any pharmacy under contract with that covered entity. Additionally, HHS may audit other 340B identification numbers associated with the parent or child site. An HHS audit may include either an on-site review, an off-site review of documentation requested by HHS, or both.

IX. CONTRACT PHARMACY

Q: Does HHS propose limiting the number of contracts pharmacies an entity can contract with?

A: No. There is nothing in the proposed guidance that limits or changes contract pharmacy agreements. In general, the Proposed Guidance emphasizes a CE's compliance obligations.

Q: What is HRSA recommending for compliance measures related to Contract Pharmacy?

A: HHS is proposing standards for audit and quarterly reviews. HRSA remains consistent with recommendations regarding an annual audit of each contract pharmacy location and further states: "*Conducting these audits using an independent auditor will ensure the pharmacy is following all 340B Program requirements*". In addition, as a separate compliance mechanism, the covered entity should compare its 340B prescribing records with the contract pharmacy's 340B

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dispensing records at least quarterly to ensure that neither diversion nor duplicate discounts have occurred.

Q: What is proposed regarding contract pharmacies and Duplicate Discount?

A: Due to these heightened risks of duplicate discounts at contract pharmacies, HRSA has added that "*when a contract pharmacy is listed on the public 340B database it will be presumed that the contract pharmacy will not dispense 340B drugs to Medicaid FFS or MCO patients*." If a covered entity wishes to purchase 340B drugs for its Medicaid FFS or MCO patients utilizing a contract pharmacy, the covered entity must "*provide HHS a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts*". If approved, the arrangement will be indicated on the OPA website.

X. ADAPs

Q: What are the proposed changes to the AIDS Drug Assistance Programs?

A: There has been criticism of the way in which ADAPs are able to take advantage of the 340B program by seeking full rebates on drugs that were only partially reimbursed by the ADAP. The Proposed Guidance takes steps to curb this practice. ADAPs would be permitted to seek rebates only when the ADAP makes a "qualified payment" for a drug product. A qualified payment of covered outpatient drugs would occur in two circumstances. First, the ADAP purchase of a covered outpatient drug at a price greater the 340B ceiling price constitutes a qualified payment. Second, the ADAP purchase of the ADAP client's insurance, in addition to the ADAP payment of the copayment, coinsurance, or deductible, constitutes a qualified payment for a covered outpatient drug. In addition, HRSA is proposing to require ADAPs to submit claims-level data to a manufacturer in support of each qualified payment to receive a rebate from that manufacturer.

XI. SPECIALTY PHARMACY

Q: Does the Omnibus 340B Proposal address specialty drugs that are only available via limited distribution?

A: Yes, there is a section of the proposed regulation that requires a drug manufacturer notify HRSA of specialty drug distribution prior to their implementing any type of limited distribution arrangement (drug shortage or specialty drug items). HRSA explains that manufacturers "may develop a limited distribution plan" in such cases, but "*the plan will be reviewed by HHS to ensure that the manufacturer is treating 340B covered entities the same as all non-340B providers*." HRSA may publish the plan on the 340B website. The plan must include information supporting the non-discriminatory nature of the limited distribution, including *"an explanation of the product's limited supply or special distribution requirements and the rationale for restricted distribution among all purchasers*" and "*an assurance that manufacturers will impose these restrictions equally on both 340B covered entities and non-340B purchasers*."

XII. MANUFACTURER STANDARDS

Q: What is required of a manufacturer if the manufacturer overcharges a covered entity?

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A: The manufacturer must refund or credit the covered entity for the difference in price. According to HRSA, the refund or credit should occur within 90 days of the determination that the overcharge occurred, and must be calculated by NDC, with no offsets permitted, and no exception for *de minimis* amounts. Under the proposed guidance, any restatement that results in a lower ceiling price than originally calculated would automatically trigger a required manufacturer refund to each applicable covered entity (potentially thousands), regardless of the amount, and regardless of whether the entity requests the refund.

A: Pursuant to section 340B(d)(1)(B)(ii) of the PHSA, a manufacturer must submit to HHS, along with the price recalculation information, an explanation of why the overcharge occurred, how the refund will be calculated, and to whom refunds or credits will be issued.

A: HRSA's proposed preclusion against "netting purchases" would mean that if a restatement results in a 340B ceiling price higher than originally calculated, the manufacturer would be unable to recover the undercharge via offset.

Q: What is proposed regarding manufacturer recertification?

A: HHS is proposing a manufacturer recertification process. Under this proposed guidance, HHS will list manufacturers as participating in the 340B Program if they annually review and update 340B database information.