Summary of HRSA’s Proposed Mega-Guidance
August 31, 2015

The Health Resources and Services Administration (HRSA) proposed omnibus guidance (aka mega-guidance) for the 340B program on Aug. 28. Comments are due on or before Oct. 27.

HRSA is currently enforcing many, if not most, of the policies in the mega-guidance in existing policy notices, FAQs, or similar documents. It is currently enforcing others through their covered entity audits.

Other sections of the mega-guidance, however, appear to propose entirely new policies, which presumably would not be enforced until the mega-guidance is finalized at a later date. Our analysis is complicated by the fact that, at times, it is hard to distinguish between statements in the mega-guidance that reflect current policy and statements that reflect proposed policy that will be enforced at some future date. Also, it is also unclear whether the mega-guidance will replace existing guidance documents.

The mega-guidance is divided into eight parts, labeled A through H. We analyzed them not in alphabetical order, but rather in order of their potential impact on hospitals.

We briefly outline these eight parts below. Note: Each of these eight outlines links to a separate, comprehensive, and much longer analysis.

- Part C - Individuals Eligible to Receive 340B Drugs

Basically, under the proposed guidance, for a prescription/order to be filled with 340B priced drugs, the prescription/order must be written by a hospital provider as a result of a documented outpatient service at a 340B registered location. In many ways, this test is similar to what we are seeing enforced today in HRSA audits. But there are two key exceptions: (1) the use of 340B in connection with most services furnished outside the hospital would be explicitly prohibited; and (2) 340B could only be used for drugs that are ordered in connection with a service that is billed as outpatient.

The first limit would apply to drugs prescribed in connection with documented referrals to outside providers, follow-up care (even in affiliated clinics), and care in clinics that are not listed as reimbursable on the hospital’s Medicare cost report (e.g., clinics located in correctional facilities). It would also prohibit 340B use in connection...
with infusion drugs unless the order for infusion was written by a hospital provider as a result of a service provided at the hospital. In a recent 340B Health survey, the vast majority of respondents reported that they have already limited their 340B program so that it is only used in connection with care furnished at the hospital, with the exception of physician-administered drugs. In that case, about 37 percent of respondents reported that limiting 340B use for physician-administered drugs to situations where the order was written by a hospital provider would be highly problematic or so problematic the hospital would consider ending participation in the 340B program.

The second limit would appear to bar 340B for drugs in connection with discharge prescriptions when a patient is discharged from an inpatient setting, even though such drugs are billed on an outpatient basis. It would also appear to bar 340B use for drugs written in connection with outpatient services if the patient is admitted and the patient’s payer requires the hospital to bill for the outpatient service as part of the inpatient stay. Medicare, for example, has a rule stating that outpatient services furnished within 72 hours of an inpatient stay must be billed as part of the inpatient service. Although hospitals would not be able to use 340B for these drugs, under the proposed guidance, it is unclear if hospitals subject to the GPO exclusion would be permitted to use GPO pricing for those drugs. It would not appear to be HRSA’s intention to require WAC pricing for those purchases, but it is an area of concern.

This section of the guidance addresses several other issues, including inventory management and repayment policies. The guidance suggests that HRSA is describing its current expectations of how virtual replenishment systems should operate. In particular, the language suggests that HRSA expects hospitals to identify the exact drug administered to a 340B-eligible patient and ensure the drug ordered in a replenishment order is the same exact drug. Notably, HRSA does not refer to use of national drug codes (NDCs) to identify the exact drug.

The guidance also includes an expectation that covered entities work with manufacturers to repay them for instances of diversion within 90 days of identifying a violation. HRSA has not previously articulated this policy in writing, but the language HRSA uses suggests an expectation that entities meet this standard now. The guidance also says covered entities must notify HHS and manufacturers of diversion, which appears to differ from HRSA’s current policy that only requires entities to report “material breaches” of program requirements to HHS.

**Part B – Drugs Eligible for Purchase Under 340B**

The guidance states that it is proposing a definition of “covered outpatient drugs” that makes Medicaid drugs that are paid as part of a bundled rate ineligible for 340B pricing. Drugs that are paid separately by Medicaid would still qualify for 340B. Many state Medicaid agencies pay separately for expensive infusion drugs and bundle most other drugs in payment for other services. In addition to reducing the number of drugs for which hospitals can obtain 340B discounts, this provision would require hospitals to track drugs bundled into payments for Medicaid services to ensure that 340B is not used. It would appear that hospitals subject to the GPO exclusion would be permitted to use GPO pricing for those drugs, since GPO pricing is permitted for drugs that do not qualify under the definition of covered outpatient drugs.

**Part D – Prevention of Duplicate Discounts and Maintenance of Auditable Records**

The proposed guidance suggests that covered entities have an obligation under current federal law to prevent duplicate discounts for Medicaid managed care claims (MCO). No federal agency has previously articulated this position, which is contrary to the position of the 340B Coalition. However, HRSA would maintain the current policy of permitting covered entities to make different carve-in or carve-out decisions for fee for service (FFS) and MCO, including different decisions between Medicaid MCO plans.
HRSA proposes that covered entities inform HRSA of its carve-in and carve-out decisions with respect to Medicaid MCOs, possibly through a yet-to-be developed exclusion file or other mechanism that would make the covered entities’ choices available to the public. HRSA also proposes that covered entities have a mechanism for identifying Medicaid MCO claims, though it does not prescribe any specific mechanism.

The proposed guidance makes a number of proposals with respect to how to prevent duplicate discounts relating to contract pharmacy. For example, the guidance proposes that in order to use 340B drugs in a contract pharmacy, the covered entity, contract pharmacy, and state Medicaid agency have an HRSA-approved written agreement describing how duplicate discounts will be prevented. Under current policy, which applies only to FFS Medicaid, covered entities are required to have an “arrangement” with the state Medicaid program that is reported to HRSA, so these provisions in the proposed guidance represent an increased area of oversight by HRSA.

HRSA proposes that covered entities maintain auditable records for five years from the date a drug was ordered or prescribed. If a covered entity terminates itself, a child site, or a contract pharmacy from the 340B program, the entity must maintain relevant auditable records for five years from the termination date. HRSA proposes to use discretion and not remove a covered entity from the 340B program for a non-systematic failure to comply with the auditable records requirement. For example, the agency would not terminate a covered entity that can generally produce 340B records for patient eligibility but cannot produce records for a particular patient who received a 340B drug. However, consistent with what we are seeing in HRSA audits, the agency said it will remove an entity for a systematic failure to meet the auditable records requirement. A covered entity removed from the program could re-enroll after demonstrating to HRSA that it can comply with all program requirements, including the obligation to maintain auditable records.

**Part E – Contract Pharmacy Arrangements**

It appears that the proposed guidance is intended to replace HRSA’s 2010 contract pharmacy guidance. But because this intent is not explicitly stated, it is not absolutely clear. If replacement is, in fact, intended, it would mean that only those portions of the 2010 guidance that are reaffirmed in the proposed guidance would remain in effect. Under the proposed guidance, covered entities would retain their ability to contract with multiple pharmacies. The proposed guidance does not impose new limits on the number of pharmacies or the geographic distance pharmacies may be from the hospital. The guidance proposes several technical changes to the rules around registering contract pharmacies. It also adds new requirements regarding covered entity oversight of contract pharmacies and enhances HRSA’s role in such oversight. In addition to the current expectation that covered entities perform an annual audit of their contract pharmacies, the guidance proposes that covered entities conduct quarterly reviews of each contract pharmacy location and disclose any noncompliance found during the audits and reviews to HRSA. The proposed guidance appears to require that any instance of noncompliance be disclosed, no matter how minor. There is no materiality standard mentioned in this section. Notably, many of the detailed provisions in the 2010 guidance, such as the contractual provisions, are not referenced in this proposed guidance.

**Part H – Program Integrity**

**Covered Entity Audits and Corrective Action Plans**

Most of the policies described in this section of the proposed guidance reflect HRSA’s current policies regarding how it conducts audits. HRSA notifies a covered entity of its intent to audit; the audit can be in-person or solely by reviewing documentation; covered entities have one opportunity to challenge any findings made pursuant to the audit (in writing, there is no opportunity to request an oral hearing); and may need to submit corrective action plans (CAPs) for findings the entity does not successfully challenge. Also consistent with current enforcement policy that we have seen in audits, the proposed guidance states that HRSA may not
remove a covered entity from the 340B program based on a finding of noncompliance so long as the entity can demonstrate it is currently compliant.

The proposed guidance appears to offer flexibility on the time frame for submitting CAPs. Currently, covered entities have 60 days to submit a CAP, but the proposed guidance states that HRSA will work with covered entities on the time frame for submitting the CAP, depending on the scope of the findings. It also states that HRSA may verify a covered entity’s compliance with its CAP at any time and that the CAP should be considered to be and maintained as auditable records.

**Manufacturer Audits of a Covered Entity**

The standards described in the proposed guidance generally mirror HRSA’s existing standards as reflected in the 1996 manufacturer audit guidelines.

**HHS Audit of Manufacturer and its Contractors**

The proposed guidance for the first time proposes standards for auditing manufacturers, which mirror the standards used for covered entities in many ways.

**Part A – Program Eligibility and Registration**

This section largely tracks HRSA’s current policy, with some exceptions. The proposed guidance states that HRSA will list a hospital as publicly owned or operated if the state or local government is the sole operating authority of the hospital. If a hospital is not operated under this type of arrangement, but wants to register as a publicly owned or operated hospital, then Internal Revenue Service (IRS) filings or other documentation from federal entities must recognize the hospital as wholly owned by a state or local government.

The proposed guidance states that the contract between private non-profit hospitals and the state or local government to provide care to low-income individuals should create “enforceable expectations” for that care, including the provision of “direct medical care.” Current policy requires that there be a “valid” contract between the hospital and the state or local government. Presumably a “valid” contract is also enforceable, so it is unclear whether this “enforceable expectations” language creates a new requirement. The language around direct medical care is also new, as the current policy refers to the provision of health care services.

The proposed guidance states that offsite facilities or clinics must have “associated outpatient Medicare costs and charges” in order to be eligible to register for the 340B program. If clinics are required to treat Medicare patients, then certain clinics will not be able to use 340B, such as free clinics or worker’s compensation clinics. 340B Health has received inconsistent reports that HRSA is already enforcing this standard.

The proposed guidance retains HRSA’s current policy that requires hospital clinics to be listed on a reimbursable line of a filed Medicare cost report prior to being eligible to register for the 340B program. However, the agency makes clear that it is seeking comments on alternatives to this test.

The proposed guidance appears to require covered entities to self-disclose any 340B program violation as opposed to the “material breach” standard that is stated in the recertification certification statement.

The guidance also describes three exceptions to the GPO prohibition. One exception mirrors an exception recognized under current policy for offsite clinics. It is unclear whether the other two exceptions reflect HRSA’s current enforcement policy or if they are new exceptions. One exception would permit use of GPO priced drugs if that was the only available source of a drug and the drug was needed to prevent disruptions in care. The second exception makes clear that if a payer changes a
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patient’s status from inpatient to outpatient, use of GPO drugs during the period that the hospital considered the patient to be an inpatient would not threaten a hospital’s 340B eligibility.

Part F – Manufacturer Responsibilities

The proposed guidance makes clear that, by entering a pharmaceutical pricing agreement (PPA), manufacturers are agreeing to comply with not only current program requirements, but also with statutory and regulatory changes that occur after the PPA is signed. This would include the “must offer” provision, which the Affordable Care Act (ACA) added to the 340B statute in 2010 and requires a manufacturer to offer a covered entity a covered outpatient drug at or below the 340B ceiling price if such drug is made available to any other purchaser at any price.

The guidance also proposes a new requirement for manufacturers’ retention of records, as they would be expected to maintain auditable records for at least five years. Similarly, those manufacturers who terminate their PPAs would also be expected to maintain auditable records for five years after termination.

HRSA proposes new procedures for a manufacturer to issue refunds and credits to covered entities for 340B overcharges. Under the proposed guidance, a manufacturer would have to issue refunds or credits to covered entities within 90 days after a determination by the manufacturer or federal government that an overcharge has occurred. This repayment obligation would apply to errors, intentional overcharges, and routine retroactive pricing adjustments. Unlike past HRSA guidance, there is no indication that covered entities would be required to request repayment. A manufacturer would have to calculate the refund by NDC and would be prohibited from using any other methodology to determine the refund amount (e.g., aggregating or netting purchases, de minimis amounts). If the amount of a repayment is not disputed, the covered entity would have 90 days to accept or execute the repayment. If the entity does not accept the repayment within 90 days, the covered entity will have waived its right to that repayment.

The proposed guidance calls for a new manufacturer recertification process. However, it is unclear from the proposed guidance whether this will be a requirement for manufacturers, as the preamble only states that HRSA will list manufacturers as participating if they annually review and update their information. The proposed guidance does not address instances where a manufacturer fails to recertify and only states that participating manufacturers should review and update their information on an annual basis.

Part G – Rebate Option for AIDS Drug Assistance Programs

Under the guidance, AIDS Drug Assistance Programs (ADAPs), which are the only type of covered entity that can elect to receive 340B pricing as an after-purchase rebate instead of as an upfront discount on a drug’s purchase price, may not request a 340B rebate on a drug purchased at a 340B price by another covered entity. Although not addressed in the proposed guidance, the preamble adds that all covered entities, not just ADAPs, must ensure that manufacturers are not subjected to multiple 340B discounts on the same drug.

Neither the preamble nor guidance addresses whether an ADAP can prevent double 340B discounts by mandating that other covered entities carve out ADAP clients.

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Please look for additional notifications from 340B Health, as we will be actively seeking your comments on how you believe this proposed guidance will impact your operations and use of the 340B program. In the meantime, we have set up a form on our website for you to submit your initial questions or comments on the mega-guidance. Please contact Charlie Hayes at 202-552-2288 or charlie.hayes@340BHealth.org to schedule a technical assistance call with a member of the 340B Health staff.