



Special Bulletin

Thursday, August 27, 2015

HRSA ISSUES PROPOSED “MEGA GUIDANCE” ON 340B PROGRAM

The Health Resources and Services Administration (HRSA) released today its long-awaited [proposed 340B Drug Pricing Program “Mega Guidance”](#) in the form of a notice with a 60-day comment period. The notice includes the following key areas on which HRSA is either providing further clarification or seeking modifications: hospital eligibility; Group Purchasing Organization (GPO) prohibition; patient definition; duplicate discounts; contract pharmacy; and hospital audits. The guidance also proposes enhanced program integrity requirements for pharmaceutical manufacturers participating in the 340B program.

The AHA is reviewing the guidance and will seek feedback from our 340B member hospitals. We want to make certain that the new requirements do not over-burden hospitals and strike a balance between hospitals and pharmaceutical companies for ensuring program integrity.

Comments on the proposed “Mega Guidance” are due Oct. 26. Watch for additional information about upcoming member calls and an AHA Regulatory Advisory with more details.

HIGHLIGHTS OF THE PROPOSED “MEGA GUIDANCE”

Hospital Eligibility Criteria: There are currently six 340B qualifying categories for hospitals; free standing cancer hospitals; children’s hospitals; critical access hospitals; sole community hospitals; rural referral centers; and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations. HRSA proposes to expand its public database that lists all 340B hospitals to include each hospital’s qualifying category. In addition, it would list Medicare DSH hospitals by their ownership type: state or locally owned; public or non-profit with formally granted government powers by a unit of state or local government (i.e., hospital district); and private non-profit with a state or local government contract to serve low-income individuals. The guidance proposes a change with regard to private non-profit 340B hospitals that have contracts with state or local government by stating that the contracts “...should create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care.”

Eligibility of Off-site Outpatient Facilities and Clinics (“Child Sites”): The proposed guidance reiterates current HRSA policy that, to qualify for the 340B program, hospital outpatient facilities must be listed on the parent hospital’s Medicare cost report and the services provided at these outpatient facilities must have associated Medicare outpatient costs and charges. In addition, the guidance would allow HRSA to review other hospital documentation to verify that the outpatient facility qualifies as a “340B child site” such as a hospital’s trial balance report. The guidance also proposes to list hospital off-site outpatient facilities in the public 340B data base. HRSA notes it is seeking comment on alternative measures to demonstrate eligibility of outpatient facilities such as using provider-based standards or Medicare’s enrollment process for institutional providers.

340B DSH Hospitals’ Group Purchasing Prohibition: DSH, children’s and freestanding cancer 340B hospitals are statutorily prohibited from using GPOs to purchase outpatient drugs. The proposed guidance clarifies three exceptions to the GPO prohibition:

1. Hospital off-site outpatient facilities not registered in the 340B program;
2. Inpatients reclassified as outpatients by a third-party insurer, Medicare Recovery Audit Contractor or hospital review, as long as the patients’ status is documented; and
3. Situations where patient care would be disrupted if the hospital could not access a drug at 340B prices or wholesale acquisition cost.

The guidance states that, if a DSH hospital uses a drug inventory replenishment model for drug purchases, the only instance when it would not violate the GPO prohibition would be when it orders 340B drugs based on actual 340b eligible patient use. In addition, the guidance clarifies that new 340B DSH hospitals must stop purchasing outpatient drugs through their GPO on the first day the hospital is listed in the public database, but the hospital can use previously purchased GPO outpatient drugs until expended. The guidance also would extend a notice and hearing process to DSH hospitals found to be in violation of the GPO prohibition to allow the entity an opportunity to respond to any adverse audit finding.

Patient Definition: The guidance proposes the following conditions to determine an eligible 340B patient:

1. The individual receives health care services at a hospital or outpatient facility that is registered and listed in the 340B public database.
2. The individual receives care from a provider that is either employed by or is an independent contractor for the hospital such that the hospital may bill for services on behalf of the provider.

3. The individual receives a drug that is ordered or prescribed by the hospital's provider as a result of care provided by that provider.
4. The individual's health care is consistent with the scope of the federal grant, project or contract.
5. The individual is prescribed a drug resulting from classified outpatient health care services.
6. The individual's patient records are accessible and the hospital can demonstrate it is responsible for the patient's care.

The guidance would clarify that employees of 340B hospitals are not eligible for the 340B drug discount if they do not receive health care services from the hospital and otherwise do not fall within the 340B patient definition. It also proposes that public health emergencies declared by the Secretary of Health and Human Services (HHS) may necessitate flexibility in the definition of eligible patient. Finally, the guidance reiterates that the use of drug inventory replenishment models requires that the hospital can produce auditable records that demonstrate receipt of the drug by a 340B patient.

Duplicate Discounts: Duplicate discounts occur when a manufacturer provides a 340B drug dispensed to a Medicaid patient for which the state Medicaid program will seek a rebate on that same drug. The Medicaid Exclusion File posted on the 340B database and maintained by HRSA is intended to be used by hospitals, state Medicaid programs and manufacturers to determine whether a hospital purchases 340B drugs for its Medicaid fee-for-service patients. The guidance proposes to list in HRSA's 340B database whether hospitals purchase 340B drugs for their Medicaid patients or use non-340B drugs for their Medicaid patients. Those hospitals that choose to use 340B drugs for their Medicaid patients will have their Medicaid billing number and their National Provider Identifier (NPI) listed on the HRSA 340b Exclusion File. For Medicaid managed care patients, hospitals can decide if they will provide 340B drugs to their Medicaid managed care patients and can choose to be listed on the HRSA Exclusion File. HRSA is asking for comments on this provision.

Contract Pharmacy: Current rules allow 340B hospitals to contract with one or more licensed pharmacy to dispense 340B drugs to eligible 340B patients. Hospitals can contract with a pharmacy or pharmacy corporation for itself and all its "child sites" (outpatient facilities). The guidance clarifies that hospitals would be required to ensure that their contract pharmacy arrangement is not in violation of the federal anti-kickback statute. HRSA proposes that contract pharmacy arrangements for a hospital would be listed on the 340B public database once a written contract exists between the hospital and the pharmacy and that written contracts would be required to include all locations of a single pharmacy company the hospital plans to use. The guidance further stipulates that written contracts would be available to HRSA upon request. Additionally the guidance proposes that only the hospital could register the contract pharmacy and that groups or networks of hospitals could not register or contract for pharmacy services on behalf of their individual hospital members. Hospitals, according to the proposed

guidance, would be responsible for ensuring that the contract pharmacy is in compliance with the 340B program rules and must conduct audits and quarterly reviews.

Hospital Records, Audits, Notice and Hearings: The guidance proposes to require that hospitals maintain five years of auditable records. In recognition of the burden and disruptive nature of audits, HRSA proposes to only conduct one 340B program audit at a time at any given hospital. Hospitals also would have a formal opportunity to respond to adverse findings through a notice and hearings process. Hospitals found to be out of compliance would be given an opportunity to submit a corrective action plan subject to review and approval by HRSA. The federal statute allows pharmaceutical manufacturers to audit hospitals, and the proposed guidance stipulates that drug manufacturers would have to document probable cause for an audit. Manufacturers also must be required to follow Government Auditing Standards.

Pharmaceutical Manufacturer Program Integrity Requirements: The guidance proposes a new pharmaceutical manufacturer recertification process similar to the recertification process required for hospitals and health clinics. Specifically, manufacturers would be required to attest that they are compliant with 340B program pricing requirements. HRSA would list all certified manufactures on its public 340B database. The guidance also would propose standards for audits of pharmaceutical manufacturers and wholesalers and notes failure to comply could result in further investigations by HHS or the Department of Justice.

NEXT STEPS

The proposed “Mega Guidance” notice will be published in the *Federal Register* on August 28. Comments on the proposed rule are due Oct. 26. Further details will be provided in an upcoming AHA Regulatory Advisory and additional information about upcoming member calls to discuss the proposed guidance is forthcoming.

For more information, contact AHA’s Molly Collins Offner at mcollins@aha.org.