Specialty Healthcare Benefits Council
Defining Specialty Health

Proposed Rule Changes for 340B Programs: Overview and Impact

Anthony Zappa, PharmD, MBA

ABSTRACT

The 340B drug discount program provides substantial savings to certain nonprofit healthcare providers and facilities. Recent proposed changes to program rules may result in significantly lower savings and more rigorous compliance oversight requirements. Covered entities must be aware of these changes and how they will impact program results.

Am J Pharm Benefits. 2015;7(5):233-237

The 340B drug discount program was created in 1992 as a means for certain nonprofit hospitals and clinics to purchase prescription drug products at lower prices. The intent of the program was to allow these providers and facilities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] In 2013, purchases of drug products within the 340B program exceeded $7 billion.[2]

Since the initial legislation was passed, rules and regulations governing the 340B program have been revised to clarify aspects of the regulations, add facilities to the program, and increase the number of prescriptions eligible for inclusion. On August 27, 2015, the HHS and the Health Resources and Services Administration (HRSA) released a new draft guidance covering many parts of the 340B program.[3] Although some changes are simple clarifications of previous statements or guidance, others could have a material impact on savings and compliance oversight if implemented as written.

Assessment and Impact of the Proposed Rules

The following is an assessment of the proposed rules and their potential impact on covered entities. For ease of use, the comments will follow the structure used in the published proposed guidance beginning on page 52300.

1. The definitions of "contract pharmacy" and "in-house pharmacy" (page 52316) indicate that pharmacies owned by covered entities cannot be contract pharmacies. Part A, Registration (page 52318), clarifies that entity-owned pharmacies will also not be listed as a child site, but rather as an authorized ship-to location for the parent and any child sites. Many hospitals have registered their owned pharmacies either as child sites or contract pharmacies in the past, and these would now be converted to ship-to locations.
2. The description of off-site outpatient facilities (page 52317) does not include any proximity requirements.

PRACTICAL IMPLICATIONS

The 340B drug discount programs provide certain nonprofit healthcare providers with substantial cost savings that can be used to expand and enhance care programs. Recent proposed changes to 340B program rules will require covered entities to review their programs and assess the economic, operational, and regulatory impact. Specifically:

- Entities must be prepared for more intensive oversight activities, especially for contract pharmacy programs.
- Removal of certain prescriptions could result in savings decreases of 30% to 40%.

Currently, most covered entities include off-site clinics if they are within 25 to 30 miles of the parent entity. It would be good for HRSA to clarify this definition.

3. In several locations, including page 52317, the proposed guidance includes the requirement that entities cease "purchasing and using 340B drugs" when a parent or child site loses or voluntarily gives up their eligible participation. The guidance does state that entities are liable to manufacturers for repayment of discounts received when the entity was not eligible. However, there is no mention of what happens to 340B products purchased prospectively while the entity is eligible and then held in inventory for future use. Presumably, the entity would have to return the product for credit against the 340B account or reimburse manufacturers for discounts received on partial packages.

4. The opening paragraph in the section on the GPO exclusion (beginning on page 52318) specifically mentions that any pharmacy owned or operated by a covered entity subject to the group purchasing organization (GPO) exclusion is also excluded from participating in a GPO. (Note that these pharmacies would be listed as ship-to locations, not child sites or contract pharmacies.) This seems to answer "yes" to an open question with existing guidance: Are entity-owned pharmacies, registered with HRSA as ship-to locations, subject to the GPO exclusion (including retail GPOs for non-340B prescriptions or hospital GPOs for own-use prescriptions)? Depending on the pharmacy's product and patient mix—especially if dispensing for employees not eligible for 340B—this could have a significant impact on margins.

5. Item (d) (page 52319) notes that violations of the GPO exclusion are now subject to a notice and hearing process (described in Part H of the proposed guidance). If an entity is found to be in violation, it is immediately made ineligible *as of the date of the violation* [emphasis added]. Thus, entities would be required to reimburse manufacturers for all discounts received as of the date of the violation.

6. Part B (page 52319) notes that drugs billed to Medicaid as part of a bundled payment are not eligible for 340B discounts. This is currently the standard of practice, and as noted in the introductory text on page 22, drugs billed as part of bundled services to any other payer, or billed directly to Medicaid (as a separate line item), could be included in 340B programs. This clarification must be noted by covered entities to avoid the loss of potential discounts.

7. Part C (beginning on page 52319) contains several changes to the patient definition. HHS is now using a 6-part test to determine if patients and prescriptions are eligible for inclusion in a 340B program. At least 2 of these criteria are significant for both hospitals and nonhospital entities.

   a. *Individuals must receive care from a covered entity site registered for the 340B program*. This is unchanged from current guidance.

   b. *Individuals must receive care from a healthcare provider employed by the entity, or who is an independent contractor of the entity. The entity must bill for services given by these providers*. This is a significant change. Entities can no longer include prescriptions written by outside referral providers. The impact to large, multi-clinic systems will likely be small; however, the impact to smaller hospitals without specialty clinics, as well as primary care-based community health centers and Federally-Qualified Health Centers, will be large. This is especially true as it relates to specialty drug prescriptions, which carry substantial 340B discounts that average $1500 or more (upwards of $5000 to $10,000 for hepatitis C and oncology).

   Part C, subpart (1) of the introductory text (page 52306), specifically mentions that prescriptions resulting from telemedicine services can be included in 340B programs, as long as the practice is authorized under state and federal law. Also, surprisingly, Part C, subpart (3) (page 52307), specifically mentions medication therapy management (MTM) as an eligible service. Because eligibility only requires a service by a "healthcare provider" (which is not defined in the document), it could be that a prescription resulting from a pharmacist-provided MTM service, either allowed by state law or under

a collaborative practice agreement with a physician, may qualify for 340B discounts. This could be a substantial boon to systems offering MTM programs, including those offering such a service to employees or select clinic patients.

c. *Individuals will not be considered eligible if the only service received was infusion or dispensing of a drug.* The existing guidance excludes patients who only use the entity for receiving prescriptions without a related medical service. However, it does not exclude patients only using an entity-based infusion center, as may be the case when a community-based oncologist refers a patient to a hospital-based infusion center for chemotherapy, for example. To qualify under the proposed guidance, patients receiving infusions would also need to receive some medical service from an employed or contracted provider within a registered entity clinic. (Arguably, patients receiving some form of medical evaluation from an employed infusion nurse, prior to the start of their infusion, could be made to qualify if all other criteria are met.)

d. *Individuals must receive care that is consistent with the covered entity's scope of grant, project, or contract.* This is consistent with current guidance and practice.

e. *Individuals must be classified as "outpatient" when the drug is ordered or prescribed.* Status is determined by how services are billed to an insurer, or how the entity's policies and procedures would treat patients who are uninsured, cash-pay, or receiving charity care. This is significant, especially for hospitals that have active discharge prescription programs (also called "meds-to-beds" programs). The proposed guidance would remove these prescriptions from 340B programs entirely, as the patient status is tied to the prescribing event and not dispensing or delivery. Based on personal experience with hospital-based programs, excluding discharge prescriptions could mean a loss of 20% to 30% of savings for large hospitals with associated clinic systems, and 75% to 80% of savings for hospitals without specialty clinics.

f. *Individuals must have a provider-to-patient relationship that can be demonstrated through auditable healthcare records and where the entity maintains responsibility for that care. The auditable records also need to establish that all criteria for patient inclusion have been met.* This is similar to existing guidance, but seems to imply that the entity maintains responsibility for more than just the service it provided.

Impact. Excluding referral prescriptions is likely to be small overall, simply because most covered entities do not currently have electronic medical record systems that capture referrals in a manner necessary to establish 340B eligibility (ie, there may be a record of the referral, but no record that the referral occurred or that a prescription was generated from it). In contrast, exclusion of discharge prescriptions could be materially significant to many hospital-based 340B programs. Many hospitals and health systems are establishing ambulatory pharmacy and meds-to-beds programs specifically to capture the 340B savings available from these prescriptions. Loss of 340B savings on these prescriptions significantly lowers the gross margin available (from 40%-50% to 10%-15%), leading many pharmacies to operate at break-even or worse.

If an entity's program performance was heavily influenced by discharge prescriptions, it may choose to voluntarily cease to participate because the available savings no longer outweigh the compliance requirements. Subsequently, by stopping the 340B program, the hospital may be able to start purchasing under GPO contracts that provide similar savings.

8. Part C, subpart (c) (page 52319), includes a statement that entities using inventory replenishment models may only order 340B drugs based on actual prior usage for eligible patients. This means that entities would not be able to take advantage of "penny buys" and proactively purchase products at 340B prices to dispense at a later date.

9. Part D of the proposed guidance (beginning on page 52319) deals with prevention of duplicate discounts, specifically to prescriptions covered by Medicaid. Of note, subpart (c) (page 52320) specifically states that contract pharmacies "will not dispense 340B drugs for Medicaid FFS [fee-for-service] and MCO [managed care organization] patients," unless otherwise noted on the public 340B database published by HHS. This restriction, and the mention of Medicaid MCOs, is new. It stems from the extension of Medicaid rebates to Medicaid MCO plans in the Affordable Care Act, which require Medicaid MCO plans to report drug usage to state Medicaid agencies so these programs can claim rebates from manufacturers.

Currently, nearly all contract pharmacy programs exclude FFS Medicaid prescriptions because of the clear risk of duplicate discounts. However, these

programs have historically included Medicaid MCO prescriptions, unless specifically excluded by state Medicaid programs, as in Arizona, Minnesota and Massachusetts. To prevent duplicate discounts, pharmacies are supposed to identify and flag Medicaid MCO prescriptions when submitting claims for payment, using claim fields established by the National Council on Prescription Drug Programs (NCPDP). This is rarely done in practice. Removing the Medicaid MCO plans entirely will allow 340B program administrators to exclude the claims during their qualification processes and remove the onus from contract pharmacies or covered entities.

Entities may choose to include Medicaid MCO claims in their contract pharmacy programs, but only if they sign a contract with the pharmacies that clearly describe a system for avoiding duplicate discounts. These contracts must be approved by HHS before they can proceed. Because of this requirement and the challenges presented by the NCPDP-defined identification process, most covered entities will likely not pursue this option.

Impact. According to data collected by the Kaiser Family Foundation, Medicaid covers 16% of all insured people in the United States (range = 9%-24%).[4] In 2011, most states with Medicaid MCO plans had over 80% of all Medicaid participants in these plans,[5] meaning the removal of Medicaid MCO prescriptions would exclude about 13% of all insured patients, if all 340B contract pharmacy programs follow the proposed guidance.

Note, however, that the vast majority of prescriptions received by people covered by Medicaid are generics, which are often excluded from 340B programs because of zero to minimal levels of savings. It is possible that the actual number of excluded prescriptions will be much smaller than expected for this reason.

10. Program compliance is a key part of 340B administration. HRSA has stated several times that large contract pharmacy networks are a compliance risk. They considered such networks in its selection of programs to be audited.

    Part E of the proposed guidance, specifically subpart (b)(3) (page 52321), introduces a new oversight requirement for contract pharmacy programs. In addition to an annual independent audit of each contract pharmacy location, covered entities are also expected to perform a quarterly review of the pharmacies' performance and compliance with program rules. The proposed guidance did not state what a quarterly review should include or if it needs to be performed by an independent auditor or review organization.

    Clearly, this will present administrative and financial burdens to all entities—especially those with large contract pharmacy networks (ie, more than 10-20 locations). It could result in a contraction of the larger networks, placing emphasis on pharmacies that have large volumes of prescriptions generated by covered entity providers. It may also result in new products and services from 340B administrators (that have access to broad claims databases) and auditing firms.

    Also, while not specifically in the proposed guidance, page 52311 of the introductory comments recommends that covered entities should compare 340B prescribing records with contract pharmacies' 340B dispensing records, at least quarterly, to ensure that neither diversion nor duplicate discounts have occurred. This will be extremely onerous for many entities, especially those with limited e-prescribing systems or volumes.

11. Most 340B contract pharmacy programs use a retrospective replenishment model for drug purchases. Pharmacies dispense from their standard, commercial inventory and receive replacement inventory from the covered entity after the prescription has been qualified as eligible for inclusion in the 340B program. Essentially, the pharmacy lends product to the covered entity, which then buys a replacement drug at 340B pricing and sends it to the pharmacy. This process is facilitated by a "bill-to/ship-to" process whereby the entity is billed for the drug but the order is shipped directly to the pharmacy.

    Recently, some entities found that certain manufacturers are limiting access to 340B discounts by establishing limited-distribution or specialty distribution networks that require dispensing pharmacies—who also normally buy the drugs—to be certified or approved by the manufacturer. At least 1 manufacturer has prevented covered entities from accessing discounts by stating that it cannot sell these products to the covered entity because it is not an approved buyer, even if the dispensing contract pharmacy was approved to dispense them. In other words, the manufacturer will not establish a bill-to/ship-to arrangement if the bill-to entity is not an approved purchaser. Discounts on these products can be thousands of dollars, meaning that many entities are losing out on substantial savings.

    Part F of the proposed guidance (page 52321) states that "a manufacturer subject to a PPA [pharmaceutical pricing agreement] must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed on the public 340B database." It further states, in subpart (b), that "a manufacturer is required to offer 340B drugs to each covered entity if it is available to any other purchaser at any price." To clarify the use of limited distribution networks, the proposed

guidance includes new requirements for manufacturers. When implementing such a network, drug companies must notify HHS of its plans, an explanation for why it is needed, an assurance that it will treat 340B and non-340B purchasers equally, and specific details of its allocation process.

Based on these requirements, it is not clear if the exclusionary tactics taken in the past will be allowed to continue or if they will be stopped. Comments from covered entities may want to include requests to clarify specific situations.

Items Not Included

There are several items not included in the proposed guidance that were expected by many stakeholders:

1. There are no restrictions or limitations on the composition or size of contract pharmacy networks. Most people involved in 340B expected HRSA to limit the number of contract pharmacies allowed in networks (perhaps up to 30-40), the geographic spread allowed within the network (eg, 10 miles from the parent or child entity, whichever was party to the contract pharmacy agreements), or some combination of the 2. This would have significantly reduced networks for many disproportionate share hospitals, and would have almost entirely removed mail order and mail-based specialty pharmacies from 340B programs. The fact this change did not occur is a substantial benefit for covered entities.

   However, keep in mind that covered entities will be expected to review each contract pharmacy's performance every quarter, and will independently audit each pharmacy's performance annually. While the guidance does not state what a "review" or an "audit" entails, the tacit expectation is that covered entities will be spending considerable time and money to ensure compliance by each and every contract pharmacy. This could cause entities to scale back their networks and include only those pharmacies that represent material volume to the program. It could also change the way chain pharmacies work with covered entities—no longer will every location in a metropolitan service area be included just because they may receive a prescription from an entity-associated provider.

2. Entity eligibility appears to be unchanged. Since nearly all of the requirements are in statute, they cannot be changed by interpretive rules.

3. The new criteria for patient eligibility did not include any income requirement (ie, no requirement that the patient be indigent or low-income). The 340B programs may continue to include all patients and prescriptions, regardless of insurance or income status (except the noted change to Managed Medicaid plans and contract pharmacies).

4. There are no requirements for covered entities to report the savings received or how they were used. This was unexpected, as the growth and usage of 340B-related savings have been the concern of many stakeholders since contract pharmacy networks were expanded in 2010. Most 340B administrators and consultants will continue to strongly encourage covered entities to account for all savings received and be able to report in detail on how those monies were used within their hospitals, clinics, or systems.

SUMMARY

There are several material changes to the 340B program in this proposed guidance. The most material changes are removal of discharge prescriptions, removal of referral providers, removal of Medicaid MCO prescriptions in contract pharmacy programs, and the quarterly contract pharmacy reviews. Together, these could remove upwards of 30% to 40% of currently included prescriptions and significantly increase administrative oversight. These changes may cause some entities with small programs to voluntarily stop their programs and move back to using GPO pricing.

HRSA is accepting comments on the proposed guidance until October 27, 2015. There is no guarantee that the proposed language will be modified, or even published and implemented. Because of the time required for review and publication, implementation of any change is not expected until at least the first quarter of 2016.

Author Affiliations: Visante Inc, St. Paul, MN.

Funding Source: None.

Author Disclosures: Dr Zappa is an employee of Visante Inc, which provides advisory services to 340B-eligible covered entities.

Authorship Information: Concept and design; analysis and interpretation of data; drafting of the manuscript.

Send correspondence to: Anthony Zappa, PharmD, MBA, Visante Inc, 101 E Fifth St, Ste 2220, St. Paul, MN 55101. E-mail: tzappa@visanteinc.com.

REFERENCES

1. 340B drug pricing program. Health Resources and Services Administration website. http://www.hrsa.gov/opa/. Accessed September 11, 2015.

2. 340B is taking over the hospital market—with a 25% share. Drug Channels website. http://www.drugchannels.net/2014/02/exclusive-340b-is-taking-over-hospital.html. Published February 25, 2014. Accessed September 11, 2015.

3. 340B drug pricing program omnibus guidance. *Fed Reg.* 2015; 80(167):52300-52324.

4. Health insurance coverage of the total population. Kaiser Family Foundation website. http://kff.org/other/state-indicator/total-population/. Accessed September 11, 2015.

5. Total Medicaid managed care enrollment. Kaiser Family Foundation website. http://kff.org/medicaid/state-indicator/total-medicaid-mc-enrollment/. Accessed September 11, 2015. ajpb