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HRSA's Proposed 340B Program Guidance: What Providers Need to Know



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On Aug. 28, the Department of Health and Human Services's (HHS) Health Resources and Services Administration (HRSA) published its long-awaited, if still only proposed, 340B program guidance.[1]

Created in 1992, the 340B program requires manufacturers to make outpatient drugs available at a substantial discount to certain defined ''covered entities.''[2]

[1] 80 Fed. Reg. 52300 (Aug. 28, 2015).
[2] *Id.*

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Over the past 23 years—during which time program participation has exploded to include over 11,000 health care providers and 600 drug manufacturers[3]—the program has been intermittently regulated through the issuance of periodic notices, policy releases,[4] and FAQs[5] issued by HRSA (and its ''prime vendor,'' Apexus[6]).

The net result of this informal regulation has been growing confusion on the part of both manufacturers and covered entities as to the precise contours of many of the program's most important components. The proposed guidance addresses most, if not all, of these issues. In many cases, the proposed guidance, if adopted, would simply codify the positions most recently set forth by HRSA and Apexus in the ''authorities'' referenced above. In other cases, however—such as the proposed definition of a patient of a covered entity—the proposed guidance arguably reflects a sea change.

Set forth below is a summary and analysis of some of the most significant provisions of the proposed guidance. Comments on the proposed guidance are due by Oct. 27.[7]

Patient Eligibility

Patient Definition

The prohibition on dispensing drugs purchased under the 340B program to individuals who are not ''patients'' of the covered entity has been a continual source

[3] *Id.*
[4] *See* http://www.hrsa.gov/opa/programrequirements/policyreleases/index.html.
[5] *See* http://www.hrsa.gov/opa/faqs/index.html.
[6] *See* https://www.340bpvp.com/resource-center/faqs/.
[7] 80 Fed. Reg. at 52300.

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of confusion. HRSA published a fairly cryptic ''patient'' definition in 1996[8] and then proposed (but never adopted) a substantially revised definition in 2007.[9]

During its recent compliance audits of covered entities, HRSA ''learned more about how the definition of patient is applied in different health care settings'' and, based on this education, is now proposing a much more detailed—and, at least arguably, a much narrower—definition of ''patient'' in the proposed guidance.[10] Specifically, and with a few limited exceptions, the proposed guidance would establish the following six-part test for determining, ''on a prescription-by-prescription or order-by-order basis,'' whether an individual is a ''patient'' of a covered entity for 340B purposes:

1. ''The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database.''[11]
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.''[12] (According to HRSA, ''[s]imply 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.''[13])
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 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.''[14] (Significantly, the ''use of telemedicine, telepharmacy, remote, and other health care service arrangements . . . is permitted, as long as the practice is authorized under State or Federal law and otherwise complies with the 340B Program.''[15])
4. ''The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract.''[16]
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 cost of 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.''[17]
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 in this section is met for each 340B drug.''[18]

The fact that the investigation is on a prescription-by-prescription basis is significant. For example, the proposed guidance notes that ''[a]n individual who sees a physician in his or her private practice . . . 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.''[19] However, if ''the patient returns to the covered entity for ongoing medical care, subsequent prescriptions written by the covered entity's providers may be eligible for 340B discounts.''[20] Similarly, it appears that outpatient drugs prescribed to patients on discharge after receiving an inpatient service may not be eligible for 340B pricing. (''[A]n individual cannot be considered a patient of the entity furnishing outpatient drugs if his or her care is classified as inpatient.''[21])

Covered Entity Employees

In the preamble to the proposed guidance, HRSA emphasizes that simply because an individual is employed by a covered entity does not mean that the employee automatically qualifies as a ''patient'' of the covered entity for 340B purposes. ''The 340B Program does not serve as a general employee pharmacy benefit or self-insured pharmacy benefit . . . 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.''[22]

This is true, moreover, even if the covered entity has sole ''financial responsibility for employees' health care, and contract[s] with prescribing health care professionals loosely affiliated or unaffiliated with the covered entity.'' In that case, HRSA posits, the ''covered entity would be acting primarily as the insurance provider for these individuals and not as the health care provider of these individuals'' and for 340B program purposes ''there is a fundamental difference between the individuals for whom the covered entity provides direct health care services and meets all criteria in this section and employees for whom a covered entity only provides insurance coverage.''[23]

Handling Diversion

An issue that frequently arises is how to address inadvertent drug diversion and similar errors; for example, a covered entity (1) dispenses a drug purchased at a non-340B price to an individual who is ''340B eligible,'' or (2) inadvertently dispenses a drug purchased at a 340B price to an individual who does not meet the program's definition of ''patient'' (*e.g.*, an inpatient).

- Under the first set of circumstances—where the economic harm of the error falls on the covered entity—HRSA notes that some covered entities

[8] 61 Fed. Reg. 55156, 55157-58 (Oct. 24, 1996).
[9] 72 Fed. Reg. 1543 (Jan. 12, 2007).
[10] 80 Fed. Reg. at 52306-07.
[11] *Id.* at 52319.
[12] *Id.*
[13] *Id.* at 52306.
[14] *Id.* at 52319.
[15] *Id.* at 52307.
[16] *Id.* at 52319.
[17] *Id.*
[18] *Id.*
[19] *Id.* at 52306.
[20] *Id.* at 52307.
[21] *Id.*
[22] *Id.*
[23] *Id.*

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''have attempted to retroactively look back over long periods of time at drug purchases not initially identified as 340B eligible'' and then (1) ''re-characterize[d] these purchases as 340B eligible'' and (2) ''purchase[d] 340B drugs on the basis of these previous transactions.'' While the proposed guidance would not prohibit this so-called ''banking'' practice, it does provide that if a covered entity ''wishes to re-characterize a previous purchase as 340B,'' it ''should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction.''[24]

- Under the second set of circumstances—where the economic harm of the error falls on the manufacturer—HRSA states that it is ''aware that manufacturers and covered entities currently work together to identify and correct errors in purchasing within 30 days of the initial purchase through a credit and rebill process'' and the agency ''encourages manufacturers and covered entities to continue this practice.'' In all events, the agency states, covered entities ''are expected to work with manufacturers regarding repayment within 90 days of identifying the violation'' and a ''manufacturer retains discretion as to whether to request repayment based on its own business considerations . . . For example, a manufacturer may prefer not to accept payments below a *de minimis* amount or to process repayments owed through a credit/rebill mechanism.''[25]

Covered Entity Eligibility

Parents and Children

Another issue that has been a source of some confusion relates to where a 340B covered entity begins and ends. In the proposed guidance, HRSA clarifies that in the case of covered entities that are hospitals, ''[a]ll off-site outpatient facilities and clinics (child sites) not located at the same physical address as the parent hospital covered entity . . . are able to purchase and use 340B drugs for eligible patients,'' provided the hospital's most recently filed Medicare cost report demonstrates to HRSA that (1) ''[e]ach 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.''[26]

Impact of Losing Eligibility Generally

HRSA also clarifies that if it loses its eligibility, a ''covered hospital entity must immediately notify HHS,'' which will then ''list that date on the public 340B database as the termination date.''[27] The proposed guidance further clarifies that ''[a]n off-site outpatient facility's eligibility to participate in the 340B Program is tied to the eligibility of the parent hospital.''[28] Thus, ''[i]f a parent hospital loses eligibility to participate in the 340B Program, all registered child sites will simultaneously lose eligibility and must immediately cease purchasing and using 340B drugs.''[29]

Conversely, ''[a] child site may lose eligibility separately from the parent covered entity in certain circumstances.''[30] For example, ''[a]n off-site hospital outpatient facility registered as a child site will lose 340B Program eligibility'' if the parent covered entity's Medicare cost report ''demonstrates the facility is no longer reimbursable or services provided at the facility no longer have associated outpatient costs and charges under Medicare.''[31]

Where a covered entity has been terminated from the 340B program, HRSA proposes that the provider will be able to re-enroll in the program ''during the next regular enrollment period after it has satisfactorily demonstrated to HHS that it will comply with all statutory requirements moving forward and has completed, or is in the process of offering repayment to affected manufacturers as necessary.''[32]

GPO Prohibition

Where 340B program eligibility turns on compliance with the so-called group purchasing organization (GPO) prohibition, the proposed guidance appears to adopt a two-pronged approach:

- If the violation is an ''isolated error'' (and not a ''systematic violation'')—terms that are not defined in the proposed guidance — the covered entity will not be removed from the program but will be required to submit a corrective action plan (CAP).[33]

- If the violation is not isolated, then (subject to certain narrow exceptions) the covered entity[34] (or child site, if the violation is isolated to a child site) would be (1) ''deemed ineligible for the 340B Program as of the date of the violation, (2) ''immediately removed'' from the program, and (3) ''required to offer repayment to affected manufacturers for any 340B drug purchase made after the first date of violation of the GPO prohibition.''[35]

Notwithstanding the above, in the preamble to the proposed guidance, HRSA also states that it is ''aware that manufacturers and covered entities may currently work together to identify and correct errors in GPO purchasing within 30 days of the initial purchase through a credit and rebill process as a standard business practice.'' The agency further states that it ''encourages manufacturers and covered entities to continue this practice.''[36] This raises several questions, most notably perhaps the following: if an error is identified and corrected within 30 days, does that render moot the two-pronged approach described above? For example, if the error at issue was isolated, does the manufacturer-covered entity cooperation render moot the need for a CAP in order to remain in the program?

[24] *Id.* at 52308.
[25] *Id.*
[26] *Id.* at 52302.
[27] *Id.*
[28] *Id.* at 52303.
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.* at 52304.
[33] *Id.* at 52305.
[34] As noted in the previous section, if a covered entity loses its eligibility, all registered child sites would lose their eligibility as well. *Id.* at 52303.
[35] *Id.* at 52305.
[36] *Id.*

Duplicate Discounts

Background

Yet another area that has been a source of some confusion over the years relates to the confluence of two government discount programs: the 340B program and the Medicaid drug rebate program (MDRP). The 340B program requires manufacturers to sell drugs dispensed to 340B-eligible patients at a substantial discount. The MDRP requires manufacturers to pay a rebate to the Medicaid program for each unit of their drugs that is dispensed to a Medicaid beneficiary. In the absence of some relief, then, where a covered entity dispensed a 340B drug to a Medicaid beneficiary, the manufacturer would be subject to two mandated price reductions on the same unit of the same drug: the (upfront) 340B discount and the (back-end) MDRP rebate.[37]

Recognizing this, Congress required HHS to implement a system to avoid such ''duplicate discounts.'' This system generally works as follows:

- If a covered entity wishes to dispense 340B drugs to Medicaid patients—a ''carve-in'' entity for 340B program purposes—then the entity must notify HHS of this fact and provide its NPI and/or Medicaid billing numbers to the agency. These numbers then get included in HRSA's 340B program ''Exclusion File.''[38] (By way of example, if Covered Entity X is ''carve-in'' and has included its NPI and/or Medicaid billing number in the Exclusion File, state Medicaid agencies will not seek MDRP rebates from manufacturers of drugs dispensed by the covered entity to Medicaid beneficiaries, because the manufacturers already will have sold those drugs to Covered Entity X at the discounted 340B price.)
- If a covered entity does *not* wish to dispense 340B drugs to Medicaid patients—a ''carve-out'' entity for 340B program purposes—then, once again, the entity must notify HRSA of this fact. The covered entity's NPI and Medicaid billing numbers will *not* be included in Exclusion File.[39] (Again, by way of example, if Covered Entity Y is ''carve-out'' and neither its NPI nor Medicaid billing number has been included in the Exclusion Database, state Medicaid agencies will seek MDRP rebates from manufacturers on drugs dispensed by the covered entity to Medicaid beneficiaries, because the manufacturers will *not* have sold those drugs to Covered Entity Y at the discounted 340B price.)

Note that some states require covered entities to select one option or the other.

Fee for Service v. Managed Care

In the proposed guidance, HRSA states that a covered entity must be either carve-in or carve-out with respect to its Medicaid fee-for-service (FFS) patients. However, a covered entity ''may make a different determination regarding carve-in or carve-out status for MCO [Medicaid managed care organization] patients'' by ''covered entity site and by MCO,'' as long as the covered entity provides HRSA with the ''identifying information of the covered entity site, the associated MCO, and the decision to carve-in or carve-out.''[40] That information will then ''be made available on a 340B Medicaid Exclusion [F]ile.''

HRSA cautions, however, that ''[w]hile the proposed use of a 340B Medicaid Exclusion File would identify the covered entity billing practices used for MCO patients, HHS encourages covered entities, States, and Medicaid MCOs to work together to establish a process to identify 340B claims.''[41] For example, covered entities ''should have mechanisms in place to be able to identify MCO patients.''

Contract Pharmacies

The government has a longstanding concern about the risk of double discounting in the contract pharmacy setting. ''Due to these heightened risks of duplicate discounts,'' the proposed guidance provides 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.''[42]

If a covered entity wishes to dispense 340B drugs to its Medicaid FFS or MCO patients through a contract pharmacy, the covered entity will have to ''provide HHS a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts.''[43] Once approved, ''HHS will list on the public 340B database a contract pharmacy as dispensing 340B drugs for Medicaid FFS and/or MCO patients.''[44]

Contract Pharmacy Arrangements

In addition to addressing contract pharmacies in the context of the duplicate discount issue, the proposed guidance also addressed contract pharmacy arrangements more generally. According to HRSA , through its audits of covered entity/contract pharmacy arrangements, the agency ''has observed that not all covered entities have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements.''[45] To address this issue, the proposed guidance provides that (1) each covered entity is ''expected to conduct quarterly reviews and annual independent audits of each contract pharmacy location,'' and (2) ''[a]ny 340B Program violation detected through quarterly reviews or annual audits of a contract pharmacy should be disclosed to HHS.''[46]

[37] *Id.* at 52308.
[38] *Id.*
[39] *Id.*
[40] *Id.* at 52309.
[41] *Id.* at 52309.
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.* at 52311.
[46] *Id.* at 52321.

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Program Integrity

HRSA Audits of Covered Entities

For several years, HRSA has been conducting audits of covered entities.[47] In the proposed guidance, the agency proposes the adoption of a ''notice and hearing'' process pursuant to which a covered entity will have ''the opportunity to respond to adverse audit findings and other instances of noncompliance or to respond to the proposed loss of 340B Program eligibility.''[48] This process would be ''conducted based on the written submissions of the involved parties.''[49] More specifically:

- HRSA would ''initiate the notice and hearing process by providing written notice to a covered entity of a proposed finding of noncompliance with specific 340B Program requirements.''[50]
- The covered entity would then have 30 days to respond ''in writing to each issue of noncompliance, providing details and documentation where appropriate.''[51]
- After reviewing ''all documents and information submitted by the covered entity,'' HRSA will issue ''a final written notice with its final determination regarding noncompliance.''[52]
- If HRSA's final determination of noncompliance ''includes a finding that the covered entity is no longer eligible for the 340B Program,'' the covered entity will be ''removed from the 340B Program'' and the entity will be ''responsible for repayment to affected manufacturers for 340B drug purchases made after the date the entity first violated a statutory requirement.''[53]
- If the agency's final determination of noncompliance does not relate to program eligibility, ''the covered entity may have to submit a [CAP].''[54] If the CAP ''addresses all findings of noncompliance, HRSA may determine that the covered entity can continue to participate in the 340B Program.''

Manufacturer Audits of Covered Entities

By statute, a drug manufacturer participating in the 340B program also is authorized to audit a covered entity's compliance with the statutory prohibitions against duplicate discounts and diversion (but not program eligibility).[55] HRSA proposes a ''reasonable cause'' standard, pursuant to which a manufacturer, prior to initiating an audit, would have to document ''to HHS'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'' the diversion or duplicate discount prohibitions.[56] According to the agency, ''reasonable cause'' would include, by way of example only:

- ''[s]ignificant changes in quantities of specific drugs ordered by a covered entity without adequate explanation by the covered entity,''
- ''significant deviations from national averages of inpatient or outpatient use of certain drugs without adequate explanation by the covered entity,''
- ''evidence of duplicate discounts provided by manufacturers or State Medicaid agencies,'' and
- at least under some circumstances, a ''covered entity's refusal to respond to manufacturer questions related to 340B drug diversion and duplicate discounts.''[57]

Under the proposed guidance, a manufacturer would be required to ''submit an audit work plan for HHS approval'' prior to conducting an audit.[58] HRSA would then ''review the reasonable cause documentation and the scope of the audit work plan'' and ''may limit the scope of the audit to ensure that the audit is conducted with the least possible disruption to the covered entity.''

If approved, the audit would have to (1) be undertaken by an independent certified public accountant, (2) be performed ''in accordance with Government Auditing Standards,'' (3) protect the confidentiality of patient information, (4) cover a period of no more than one year, and (5) be paid for by the manufacturer.[59] Following completion of the audit, the auditors would be required to prepare a final audit report and submit it to HRSA.[60]

HRSA Audit of Manufacturers

Finally, by statute, HRSA is authorized to audit a manufacturer or wholesaler to ensure 340B program compliance.[61] The proposed guidance provides that these audits ''may include either an on-site review, an off-site review of documentation requested by HHS, or both.''[62] Following the audit, ''if HHS determines that a manufacturer has violated the 340B Program, the manufacturer will be provided opportunity for notice and hearing.''[63] Specifically, HRSA will ''send the manufacturer written notification of any audit findings and will notify the manufacturer of the deadline to respond with its agreement or disagreement with each proposed finding.''[64] If a manufacturer disagrees with a HRSA finding, the agency will ''review any documentation submitted'' by the manufacturer, make a final determination, advise the manufacturer, and ''request corrective action, as needed.''

Conclusion

Through the proposed guidance, HRSA has attempted to provide greater clarity with respect to many of the 340B program's key components. While much of the proposed guidance is consistent with previous infor-

[47] *See* ''Program Integrity & 340B Program Audits,'' HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA), http://www.hrsa.gov/opa/programintegrity/.
[48] 80 Fed. Reg. at 52322.
[49] *Id.* at 52314.
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.* at 52315.
[54] *Id.*
[55] 42 U.S.C. § 256b(a)(5)(C).
[56] 80 Fed. Reg. at 52315.
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] 42 U.S.C. § 256b(d)(1)(B)(v).
[62] 80 Fed. Reg. at 52315.
[63] *Id.*
[64] *Id.*

mal guidance from HRSA, some provisions—most notably the proposed definition of a patient—represent a significant departure, with potentially quite significant ramifications for 340B covered entities. Further, in a few places—such as the discussion relating to compliance with the GPO prohibition—the proposed guidance introduces new ambiguities and raises additional questions. Given the significance of the 340B program and the breadth of the proposed guidance, providers would be well advised to assess how the proposed guidance could affect their operations and consider submitting comments on the proposed guidance to HHS.

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