

A Primer on the 340B Drug Discount Program

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This information bulletin was developed to inform Ryan White grant recipients about the history of the federal Section 340B Drug Discount Program (the “340B Program”) and compliance concerns within the 340B Program.¹ The bulletin (1) provides an overview of the legislative history of the 340B Program, (2) identifies five 340B compliance risk areas, and (3) examines current trends within those 340B compliance risk areas.

Overview of the 340B Program

The 340B Program expands access to affordable outpatient prescription drugs in the United States.² Established by Congress in 1992, the 340B Program seeks to leverage federal dollars by requiring pharmaceutical manufacturers that enroll in Medicaid to offer their drugs to eligible safety net providers at a steep discount. Safety net providers eligible to participate in the 340B Program, including but not limited to Ryan White grant recipients, are statutorily described as “covered entities.”

Covered entities provide health care services to underserved communities or to patients with medical conditions that are unduly expensive to treat. By saving covered entities money on the cost of outpatient drugs, the 340B Program enables covered entities to allocate more resources to expanding needed health services.

According to the legislative record, the 340B Program was designed to permit covered entities “to stretch scarce Federal resources

as far as possible, reaching more eligible patients and providing more comprehensive services.”³

Compliance with the 340B Program

The 340B Program existed with little fanfare and scant government regulation until health care reform debates raised the 340B Program’s profile in 2010.⁴ In fact, the Office of Pharmacy Affairs (OPA) – the division within the Health Resources and Services Administration (HRSA) that manages the 340B Program – did not receive funding from Congress specifically appropriated for 340B Program oversight activities until 2009.⁵

In 2012, OPA audited approximately 200 covered entities. OPA is on track to audit nearly 300 covered entities in 2015. The dramatic rise in government audits – in addition to an increase in audits of covered entities by manufacturers – underscores the importance of your organization assuring compliance of its 340B operations.

To help Ryan White grantees prepare for government and manufacturer audits, this information bulletin highlights compliance risk areas and provides recommendations to mitigate associated risks.

There are changes to the 340B Program on the horizon. This summer of 2015, it is projected that OPA will release its “MegaGuidance,” which is anticipated to change contract pharmacy requirements and the definition of an “eligible patient” for

purposes of the 340B Program. This bulletin notes topic areas where the anticipated MegaGuidance may impact the analysis, but it is incumbent upon the covered entity to track any new OPA requirements.

Risk Area 1: Site Registration

As a condition of participation in the 340B Program, covered entities must register with OPA. Since the passage of the Affordable Care Act in 2010, covered entities have been required to recertify annually.⁶ OPA also requires that covered entities list every covered entity site on the OPA online database. OPA has taken the position that failure to list a site on the agency's website disqualifies the site. Accordingly, OPA auditors are paying close attention to database records.

As covered entities, Ryan White grantees should establish policies to assure that the OPA database accurately reflects all sites in the scope of their grant award. We recommend identifying a specific covered entity employee, by title, in the organization's 340B policies and procedures as charged with regularly checking the database and verifying accuracy of the records.

Risk Area 2: Duplicate Discounts

The 340B Program was established in the aftermath of the 1990 Medicaid Rebate Program, under which drug manufacturers who participate in Medicaid have to offer rebates to state Medicaid agencies for covered outpatient drugs dispensed to fee-for-service enrollees.

The 340B Program requires that covered entities comply with program guidance in avoiding duplicate discounts.⁷ If a duplicate discount occurs, the covered entity must repay the drug manufacturer.⁸

All covered entities must disclose whether they carve-in or carve-out fee-for-service Medicaid scripts from their 340B program.⁹ In other words, you must either always use discounted 340B drugs to fill covered outpatient drug prescriptions for Medicaid fee-for-service beneficiaries ("carve-in") or you must never use 340B drugs to fill such prescriptions ("carve-out"), and you are required to tell OPA which method you employ. If a covered entity decides to bill Medicaid for drugs purchased under 340B with a Medicaid provider number, then all drugs billed to that number must be purchased under the 340B Program and that Medicaid provider number must be listed on the HRSA "Medicaid Exclusion File."¹⁰

If your organization carves in, you must complete your listing in the Medicaid Exclusion File and be sure to comply with your state billing instructions to identify all 340B claims to the state.

In contrast to Medicaid fee-for-service, it was not until 2010 that states could claim rebates on drugs dispensed through managed care organizations (MCOs). In expanding drug rebates to Medicaid MCOs, Congress expressly exempted 340B drugs, resulting in the states and MCOs needing to identify which MCO drugs are 340B and which are not.¹¹

As summarized by the Department of Health & Human Services Office of Inspector General, “Drug purchases by MCOs that qualify for discounted 340B rates are not subject to the Medicaid rebate because this would result in duplicate discounts from manufacturers.”¹² With regard to Medicaid MCOs, the role of covered entities in avoiding duplicate discounts is unclear. On June 1, 2015, the Centers for Medicare and Medicaid Services published a proposed regulation that clarified that it is the responsibility of the managed care entity (not the covered entity) to identify those prescriptions that were purchased under 340B in order to avoid duplicate discounts.¹³ Nevertheless, at a minimum, covered entities should disclose to Medicaid MCOs if they are using 340B drugs.

Additionally, there is a risk of double dipping in 340B between State AIDS Drug Assistance Programs (ADAPs) and other covered entities. While this risk is not technically a “duplicate discount” under the statute, it is a logistical concern as manufacturers need not provide two discounts/rebates on the same script. If your organization has patients who are enrolled in ADAP, it is unclear which covered entity should claim the 340B benefit for 340B drugs dispensed to that individual. Unlike other covered entities, ADAPs may claim the 340B benefit based on simply dispensing the drugs to enrolled patients and are not required to otherwise render health care services to the patient as Ryan White grantees are.¹⁴ To further complicate matters, ADAPs are the only covered entity able to obtain the 340B benefit either as a discount (which is credited at the time of purchase) or rebate (after the purchase credit).

In July 2014, the National Alliance of State and Territorial AIDS Directors (NASTAD) issued guidance on how to assign a 340B claim between an ADAP and other covered entity who shared a patient based on the facts pertaining to the individual patient.¹⁵ This guidance was designed to help an ADAP and grantee clearly avoid a claim for the same 340B drug.¹⁶ We recommend reviewing the NASTAD guidance and, if applicable, engaging with your state ADAP to negotiate a sensible and fair policy that will clearly identify when your organization should use 340B drugs for shared patients.

Risk Area 3: Diversion

The 340B statute forbids the diversion of discounted drugs away from eligible patients. In other words, 340B drugs may not be resold or dispensed to individuals who are not “patients” of a covered entity.¹⁷ Risk of diversion is perceived to grow as an entity’s 340B operations grow, especially through multiple contract pharmacy sites as the government questions the ability of the covered entity to properly oversee all dispensing transactions. Accordingly, an abrupt rise in 340B scripts and/or rise in the number of contract pharmacy sites may trigger an OPA audit. Regardless of an entity’s 340B operations growth or pending audits, the covered entity is responsible for preventing diversion. This may be achieved through clear oversight, appropriate policies and procedures, adequate tracking systems, and reasonable audit rights of covered entities over contract pharmacies.

To avoid diversion, it is crucial to understand how “patient” is defined for purposes of the 340B Program. Currently, a patient of a Ryan White grantee may be considered an eligible 340B patient if: (1) the grantee has an established relationship with that individual, evidenced by maintenance of his/her health care records; (2) the health care services provided are rendered by a professional employed by or under “other arrangement” with the grantee; and (3) the health care services provided are within the scope of the Ryan White grant.¹⁸

If your organization chooses to honor prescriptions written by health care professionals it does not employ, we recommend your providers clearly document referrals and follow-up care, in addition to entering in to organizational affiliations with outside practitioners through memorandums of understanding (MOUs). Such MOUs should identify each party’s responsibilities for documenting care, tracking referrals, noting treatment in medical records, and complying with privacy and confidentiality laws.

It is important to note that – through the MegaGuidance – OPA is likely to redefine “patient” for purposes of 340B. Covered entities must watch for the release of any such guidance and understand the implications on their current 340B policies and procedures.

Risk Area 4: Contract Pharmacies

Beginning in 2010, OPA authorized the use of chain pharmacies and contract pharmacy networks, under contract with covered entities, in dispensing 340B drugs to eligible patients.¹⁹

Under these arrangements, covered entities are responsible for purchasing 340B drugs, while a wholesaler may ship directly to the outside pharmacy. If your organization decides to contract with outside pharmacies under the 340B Program, you must enter into a written agreement with the pharmacy. The contract pharmacy contract should specifically address how the parties will avoid duplicate discounts and diversion, as well as protect patient freedom of choice. Contract pharmacies may not use 340B drugs to dispense prescriptions paid for by the state Medicaid fee-for-service program unless there is an established arrangement with the state Medicaid agency that will prevent duplicate discounts and/or rebates. The pharmacy services contract must include the addresses of every pharmacy location, which in turn must be accurately listed in the OPA database.²⁰

As noted above, covered entities remain liable for any noncompliance with the 340B requirements. Accordingly, your organization should be sure to specify its rights to review pharmacy records and audit the pharmacy’s operations.

Moreover, be sure to exercise your due diligence prior to entering any such agreements. 340B pharmacies and administrators should be able and willing to demonstrate their tracking systems and reporting processes prior to your organization hiring them as vendors. Your organization should use prudent procurement processes when deciding whether and how to grow its 340B Program.

The growth in contract pharmacy arrangements has led to a growth in third party administrators (TPAs). These TPAs purport to assume the duties of the covered entities in running their 340B programs, but covered entities may not outsource their legal responsibility for 340B compliance. Accordingly, when TPAs make mistakes, the covered entity is on the hook with OPA. It is crucial to exercise due diligence if you seek to hire a TPA. We recommend consulting with qualified legal counsel prior to entering into any TPA contracts.

Risk Area 5: Written Policies and Procedures

OPA requires that covered entities have written 340B policies and procedures.²¹ The federal prime vendor for the 340B Program, Apexus, offers free online

template policies tailored to the various covered entity types. We recommend every organization tailor the policies and procedures to reflect their actual practices and consult qualified legal counsel to review those documents to ensure compliance with the law.

Conclusion

Ryan White grant recipients may be able to realize significant benefits under the 340B Program. The 340B Program, however, is under great scrutiny, with allegations that the Program is misused. Additionally, the anticipated OPA MegaGuidance, and possible Congressional action, is likely to increase compliance requirements. One of the best mechanisms for safeguarding this vital safety net program is to review and be in compliance with the applicable requirements.

Selected Resources Cited

HRSA. 340B Drug Pricing Program

<http://www.hrsa.gov/opa/index.html>

HRSA. Medicaid Exclusion/Duplicate Discount Prohibition

<http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html>

HRSA. Contract Pharmacy Oversight

<http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html>

NASTAD. Best Practices for Shared ADAP and 340B Drug Pricing Program Clients (July 2014)

<http://nastad.org/docs/ADAP-340B-Best-Practice-July-2014.pdf>

U.S. DHHS Office of Inspector General. States Collection of Rebates Paid through Medicaid Managed Care Organizations, f.25 (Sept. 2012)

<http://oig.hhs.gov/oei/reports/oei-03-11-00480.pdf>

340B Prime Vendor Program (Apexus)

<https://www.340bpvp.com/controller.html>

¹Prepared by Feldesman Tucker Leifer Fidell LLP for the HIV Medicine Association. This information bulletin does not constitute a legal opinion and is offered for educational purposes only. We recommend consulting qualified legal counsel to review specific policies and contracts for your organization. For more information about the 340B Program, please contact: Andrea Weddle (aweddle@idsociety.org) / Kathryn Watson (kwatson@ftlf.com).

²Section 340B is a section within the Public Health Service Act. It is codified at 42 U.S.C. § 256b.

³See H.R. Rep. No. 102-384(II), at 12 (1992). 340B savings are considered “program income” because they are generated as a result of an organization’s status as an eligible covered entity. See 2 C.F.R. § 200.80. Accordingly, these funds should be used subject to the applicable grant rules.

⁴In 2010, the Affordable Care Act (ACA) added 340B Program requirements and opportunities. See, e.g., ACA, §§ 7101, *et seq.*

⁵See Omnibus Appropriations Act of 2009, Pub. L. No. 111-008; see also William von Oehsen, *et al.*, *The 340B Drug Discount Program: A New Era of Enforcement and Oversight*, *Journal of Health & Life Sciences Law*, vol. 5, no. 3 (June 2012) 86.

⁶42 U.S.C. § 256b(a)(7)(E).

⁷42 U.S.C. § 256b(a)(5)(A)(i).

⁸See 42 U.S.C. § 256b(a)(5)(D).

⁹Typically, the trade-off for a state allowing a 340B covered entity to dispense 340B drugs to Medicaid beneficiaries (and thereby foregoing the applicable rebate) is that the state will only reimburse the covered entity for its 340B acquisition cost plus a modest dispensing fee. We note, however, that some states have adopted a fee-for-service reimbursement mechanism that encourages 340B covered entities to dispense 340B drugs to Medicaid beneficiaries (often through enhanced dispensing fees and the like) because the 340B discount often is greater than the amount that the state could claim as rebate and the discount can be obtained at the point of sale as opposed to having to submit a rebate claim to a manufacturer.

¹⁰See 58 Fed. Reg. 34058 (June 23, 1993) (establishing the Medicaid Exclusion File); see also HRSA OPA Website, *Medicaid Exclusion / Duplicate Discount Prohibition*, available at: <http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html>.

¹¹42 U.S.C. § 1396r-8(j)(1).

¹²U.S. DHHS Office of Inspector General, *States Collection of Rebates Paid through Medicaid Managed Care Organizations*, f.25 (Sept. 2012), available at: <http://oig.hhs.gov/oei/reports/oei-03-11-00480.pdf>.

¹³Medicaid and CHIP Managed Care Rule, 80 Fed. Reg. 31098, 31257 (proposed June 1, 2015) (to be codified at 42 C.F.R. § 438.3 (s)).

¹⁴See 61 Fed. Reg. 55158 (Oct. 24, 1996) (“An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the [Public Health Service] Act will be considered a ‘patient’ of the covered entity for purposes of this definition if so registered as eligible by the State program.”).

¹⁵The NASTAD guidance is:

- (1) For clients for whom ADAP is paying 100% of the client’s drug costs (i.e., clients who have no public or private insurance), the ADAP should be the entity that receives the 340B Drug Pricing Program rebate/discount. If the other entity is paying for 100% of the client’s drug costs, then the other entity should receive the 340B Drug Pricing Program discount and ADAP should not receive a rebate. The rebate/discount must not be duplicated by the two entities;
- (2) For clients who are covered by private insurance, ADAPs should establish a policy and process that clarifies whether ADAP or the 340B entity that shares the patient is entitled to the rebate/discount. The policy could state that the entity paying for the insurance premium and/or the co-payment on the drugs should receive the 340B Drug Pricing Program rebate/discount;
- (3) If ADAP is paying for a prescription and entitled to receive the rebate and the non-ADAP covered entity that fills the prescription maintains multiple inventories (i.e., 340B and retail), the entity should not use 340B inventory to fill the prescription paid for by ADAP. If the non-ADAP covered entity has only 340B inventory, then ADAP cannot file for a rebate; both entities cannot file for a rebate on the same drug transaction. The rebate/discount must not be duplicated by the two entities; and
- (4) For clients who are uninsured receiving a prescription through a 340B entity pharmacy with only 340B inventory, the 340B rebate/discount cannot be duplicated, and ADAP must not file for a rebate. However since ADAP is paying 100% of the prescription costs, ADAP should establish a reimbursement rate to the 340B entity that reflects the loss of the rebates to ADAP.

Nat’l Alliance for State & Territorial AIDS Directors, “Best Practices for Shared ADAP and 340B Drug Pricing Program Clients,” (June 2014), available at: <http://nastad.org/docs/ADAP-340B-Best-Practice-July-2014.pdf>.

¹⁶See *id.*

¹⁷42 U.S.C. § 256b(a)(5)(B) (“With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.”).

¹⁸See 61 Fed. Reg. 55156-55158 (Oct. 24, 1996).

¹⁹See 75 Fed. Reg. 10272 (March 5, 2010) (authorizing the use of contract pharmacy networks and suggesting specific contract provisions).

²⁰See OPA, *Website: Contract Pharmacy Oversight*, available at: <http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html>.

²¹See *id.*