

Patient Protection and Affordable Care Act Expands Preferential 340B Drug Pricing To New Entities

C. Frederick Geilfuss, II and Maureen Kwiecinski, Foley & Lardner LLP

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (as amended PPACA), extended the benefits of preferential drug pricing under the 340B Drug Discount Program (the 340B Program) to newly eligible covered entities. This expansion allows newly eligible covered entities – namely, certain critical access hospitals, rural referral centers, sole community hospitals, free standing cancer hospitals and children's hospitals – to receive a financial benefit in terms of access to reduced price pharmaceuticals.

The Section 340B Drug Pricing Program

The 340B Program is a federally-mandated drug pricing program that requires pharmaceutical manufacturers participating in the Medicaid program to provide up-front discounts on covered outpatient drugs purchased by certain entities. The 340B Program was intended to stretch limited federal resources available for patient treatment by mandating that pharmaceutical manufacturers provide significant discounts to certain specified safety-net covered entities. The 340B Program was established under two federal statutes: Section 340B of the Public Health Services Act (PHSA) (created under the Veterans Health Care Act of 1992)¹ and Section 1927(a) of the Social Security Act (SSA).²

The Office of Pharmacy Affairs (OPA), which is part of the federal Health Resources and Services Administration (HRSA), administers the 340B Program and is supported by its HRSA-funded contractor, The Pharmacy Services Support Center (PSSC). The PSSC provides guidance and technical assistance to all 340B covered entities.

Under the 340B Program, eligible covered entities, which voluntarily agree to participate, receive significant pricing discounts for covered outpatient drugs dispensed to their patients. The 340B Program sets a ceiling or maximum price that pharmaceutical manufacturers may charge covered entities for such covered drugs. Covered entities may negotiate prices below this ceiling price.³ OPA does not regulate the use of the savings enjoyed by 340B Program participants. Thus, covered

© 2010 Bloomberg Finance L.P. All rights reserved. Originally published by Bloomberg Finance L.P. in the Vol. 3, No. 8 edition of the Bloomberg Law Reports—Health Law. Reprinted with permission. Bloomberg Law Reports® is a registered trademark and service mark of Bloomberg Finance L.P.

The discussions set forth in this report are for informational purposes only. They do not take into account the qualifications, exceptions and other considerations that may be relevant to particular situations. These discussions should not be construed as legal advice, which has to be addressed to particular facts and circumstances involved in any given situation. Any tax information contained in this report is not intended to be used, and cannot be used, for purposes of avoiding penalties imposed under the United States Internal Revenue Code. The opinions expressed are those of the author. Bloomberg Finance L.P. and its affiliated entities do not take responsibility for the content contained in this report and do not make any representation or warranty as to its completeness or accuracy.

entities may utilize the savings to expand access to available services or for other purposes.

Surveys indicate a high rate of satisfaction among 340B participants and many report significant savings from participation in the 340B Program. A survey of participating covered entities conducted for the HRSA, found that in 2003 and 2004 over half of the participating covered entities reported dollar savings of more than 30 percent on drug costs compared to what their costs would have been without the 340B Program discount.⁴ Other reports indicate an average savings for an entity of \$19,688 per month and more than 96 percent satisfaction with the cost savings of those who participate.⁵

Eligible Covered Entities

The preferential pricing of the 340B Program is available only to non-profit private or government-owned entities that meet certain requirements (covered entities). Prior to PPACA, eligible covered entities included, among others, certain federally qualified health centers, Ryan White/HIV Clinics, black lung clinics, family planning clinics, State-operated AIDS drug purchasing assistance programs, comprehensive hemophilia diagnostic treatment centers, Native Hawaiian Health Centers, urban Indian organizations, disproportionate share hospitals (DSH) (with a DSH adjustment percentage greater than 11.75 percent), and children's hospitals.

PPACA expands the entities eligible to participate in the 340B Program, assuming other statutory requirements are met, to include certain children's hospitals,⁶ free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

The table below outlines the requirements that must be met in order for a newly eligible entity to be considered a covered entity under the 340B Program.

All newly eligible entities must be:				
1. Owned or operated by a unit of State or local government, <u>or</u>				
2. Is a public or private non-profit corporation formally granted governmental powers by a unit of State or local government, <u>or</u>				
3. Is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under Medicare or Medicaid.				
Children's Hospitals	Free-Standing Cancer Hospitals	Critical Access Hospitals	Rural Referral Centers	Sole Community Hospitals
A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the SSA	— —	A critical access hospital as determined under section 1820(c) of	A rural referral center as defined by section 1886(d)(5)(C)(i) of the SSA	A sole community hospital as defined by section 1886(d)(5)(C)(iii) of the SSA

		the SSA		
PPS-excluded	PPS-excluded	-- --	-- --	-- --
DSH > 11.75%*	DSH > 11.75%*	-- --	DSH ≥ 8.0%*	DSH ≥ 8.0%*
Does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.	Does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.	-- --	-- --	-- --

* for the most recent cost reporting period

Covered Drugs

A covered entity is entitled to the 340B discount on certain "covered outpatient drugs" including prescription drugs, and over-the-counter drugs, if an individual with prescriptive authority writes a prescription for the drug. Vaccines and drugs given to the patient in inpatient care settings are excluded from the 340B Program. Notably, certain 340B-eligible hospitals, including disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals, may not obtain 340B Program discounts on covered outpatient drugs purchased through a group purchasing organization or other group purchasing arrangement.⁷ However, newly eligible critical access hospitals, rural referral centers, and sole community hospitals are not subject to this group purchasing limitation.⁸

It is also important to note that for newly eligible entities under PPACA, the term "covered outpatient drug" does not include "orphan drugs." Orphan drugs are drugs specifically designated as such by the Food and Drug Administration (FDA). Such drugs have been developed specifically to treat a rare medical condition (one which afflicts a US population of less than 200,000 people drugs or for which there is no reasonable expectation that the cost of developing a drug available for such condition will be recovered from sales). Orphan drug designation qualifies the sponsor of the drug for certain tax credits and marketing incentives under the Orphan Drug Act. A list of FDA-designated orphan drug is available through the FDA's website.⁹

An earlier version of PPACA, as initially passed by the Senate, expanded the 340B Program to include drugs provided by covered entities in the inpatient setting, however, this proposed expansion was rejected through the Health Care and Education Reconciliation Act that amended the Senate bill. A similar, but more limited expansion is currently pending. The American Workers, State, and Business Relief Act of 2010 (H.R.4213) would extend 340B Program discounts to inpatient drugs utilized by patients who are uninsured or who do not have insurance that provides prescription drug coverage.¹⁰

340B Program Enrollment and Retroactive Benefits

An eligible covered entity must notify the OPA of its desire to participate in the 340B Program. Each entity must submit information in a manner specified for it.¹¹ New covered entities may become eligible at the start of a calendar quarter (January 1, April 1, July 1 or October 1); however, in order to allow time for verification and processing of registration information, applicants must submit required information at least one month before the quarter during which the covered entity wishes to commence participation.

Once the OPA successfully and processes the registration information, the covered entity is eligible to purchase pharmaceuticals at the 340B Program price. Each covered entity then determines how it will order and receive the discounted drugs. A covered entity may do so by contacting drug manufacturers directly, working with a wholesaler, or participating in the Prime Vendor Program (described below).

The effective date of the expansion of the 340B Program to newly eligible covered entities is January 1, 2010, a date that occurs prior to the ability of newly eligible covered entities to successfully enroll in the 340B Program and even prior to enactment of PPACA. As such, there is potential for such newly eligible covered entities to obtain the benefits of the 340B Program retroactively. However, there is no clear guidance as to what an entity needs to do to obtain the discounts retroactively to the January 1, 2010 effective date.

While there is no established method for applying for retroactive benefits, in the past OPA provided guidance on how to apply for retroactive benefits, and it may well do so again. A newly eligible entity desiring retroactive benefits may want to notify OPA of its interest and take steps now that would be consistent with the requirements for participation, such as sending a notice to drug manufacturers of its decision to participate, maintaining records showing that the benefits are sought only for the covered entity's patients, and ensuring that no Medicaid rebates were generated from the sale of drugs for which a discount is sought.

Prime Vendor Program

The PHSA mandated the development of the Prime Vendor Program (PVP) to assist covered entities in obtaining the pricing discounts. The PVP is a voluntary program for Section 340B Program participants and is intended to benefit covered entities by having a vendor available to negotiate sub-340B pricing on pharmaceuticals. The Prime Vendor also serves to establish distribution solutions and networks that improve access to affordable medications and provide other value-added products and services. Currently, HRSA contracts with Apexus to manage the PVP. Once eligible to purchase drugs through the 340B Program a covered entity may submit a separate participation agreement to Apexus to utilize the prime vendor's services. The PVP is funded through fees charged to pharmaceutical distributors and suppliers, therefore, covered entities may participate in the PVP without charge.

Other 340B Program Requirements

A key limitation for covered entities that participate in the 340B Program is that 340B drug discounts are only available to the "patients" of the covered entity. A covered entity may not seek 340B discount pricing on drugs provided to an individual who is not considered a "patient" of the covered entity. An individual is a patient of the covered entity, eligible for the benefits of 340B Program benefits, only if:¹²

- the covered entity has established a relationship with the individual such that the covered entity maintains records of the individual's health care;
- the individuals receive health care services from a professional employed by or contracted with the covered entity;
- the individual receives a health service from the covered entity which is consistent with the grant funding provided to the covered entity.

An individual is not a patient of the covered entity if the only service the covered entity provides is the dispensing of a drug or drugs for self-administration or administration at home.¹³ A covered entity that requests 340B Program pricing for a drug provided to an individual who does not meet the definition of patient described above is considered to have violated the prohibition on diversion and is subject to significant penalties (which were expanded under PPACA).

In addition to the prohibition on diversion, covered entities must report 340B Program discounts to the state Medicaid program. Under the Omnibus Reconciliation Act of 1990, the Medicaid Drug Rebate Program was created.¹⁴ It requires drug manufacturers to have a national rebate agreement with the Secretary of HHS to receive federal funding for outpatient drugs dispensed to Medicaid patients. A drug purchased under the 340B Program may not be subject to both a 340B Program upfront discount and a Medicaid rebate.¹⁵ Covered entities may not bill Medicaid more than the acquisition cost (plus a dispensing fee) for covered outpatient drugs purchased with 340B Program discounts. Covered entities must be careful to ensure that they notify the Medicaid program if they obtain the 340B Program discounts so as to avoid duplicate discounts. A covered entity may elect instead not to take the 340B Program discount for Medicaid patients and have Medicaid patients treated as they are generally for rebate purposes.

Contracts with Retail Pharmacies

A covered entity may distribute 340B Program drugs through an outpatient or other pharmacy that it operates, and/or by contracting with one or more external retail pharmacies. HRSA guidelines allow a covered entity to use a "ship to – bill to" process whereby the covered entity purchases the drugs and has the manufacturer or wholesaler ship them to an external contracted pharmacy, which then provides all pharmacy services related to the dispensing of the 340B Program drugs. Generally, the contractor must provide the covered entity with financial statements, a detailed status report of collections, and a summary of receiving and dispensing records. The contract pharmacy must also work with the covered entity to establish and maintain a tracking system to prevent diversion.

Prior to April 5, 2010, covered entities were limited to one pharmacy per site and covered entities could either operate an in-house pharmacy or contract with only one external pharmacy.¹⁶ Covered entities seeking to use other types of pharmacy arrangements, or to implement both of the allowable methods of providing pharmacy services, were required to apply to OPA for an Alternative Method Demonstration Project (AMDP). Based on guidance adopted by OPA which became effective April 5, 2010, covered entities may now enter contracts with more than one external pharmacy to obtain the benefits of the 340B Program.¹⁷

A covered entity's agreement with a contract pharmacy must meet certain requirements and the effective date of such agreement may not precede the date an entity was listed as a covered entity. HRSA has provided essential covered entity compliance elements and suggested contract provisions. In addition, the covered entity must submit to OPA a contract pharmacy registration form signed by authorized individuals of the covered entity and the contract pharmacy. Contracts with external pharmacies should be carefully drafted to ensure that only patients of the covered entity receive the 340B Program pricing and that adequate record-keeping is maintained to establish such fact. Furthermore, the OPA cautions covered entities to seek legal counsel in order to avoid potential violation of the federal Anti-Kickback statute and regulations in their relationship with contracted pharmacies.

Heightened Enforcement

PPACA directs the Secretary of HHS to address concerns related to 340B Program compliance by both manufacturers and covered entities. With respect to manufacturers, the Secretary must develop new systems for enforcing compliance with 340B Program requirements. This requirement no doubt addresses findings from an Office of Inspector General report that found a number of overcharges by manufacturers to 340B covered entities and the OIG recommendation for enhanced oversight.¹⁸ The new law requires the Secretary of HHS to:¹⁹

- Develop a system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities.
- Establish procedures for manufacturers to issue refunds to covered entities in the event of an overcharge.
- Develop a system to provide online access to applicable ceiling prices for covered drugs.
- Develop a mechanism by which rebates and other discounts provided by manufacturers to other purchasers are reported to the Secretary, and appropriate credits and refunds are issued to covered entities if necessary.
- Perform selective auditing of manufacturers and wholesalers to ensure the integrity of the 340B Program.
- Impose civil monetary penalties against manufacturers that knowingly and intentionally overcharge covered entities (not to exceed \$5,000 for each instance of overcharging a covered entity that may have occurred).

PPACA also includes strengthens oversight of covered entity compliance with the requirements of the 340B Program. In particular, PPACA strengthens procedures to

prevent drug diversion and violations of the duplicate discount provisions and requires the Secretary to:²⁰

- Develop procedures to enable and require covered entities to regularly update information maintained on the HHS website and a system for the Secretary to verify the accuracy of such information.
- Develop more detailed guidance describing acceptable methodologies and options for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts.
- Establish a single, universal, and standardized identification system by which manufacturers can identify covered entity sites.
- Revise potential sanctions to require return of discount and interest when a covered entity violates the prohibition on diversion and expand penalties for a knowing and intentional violation to include the payment of a monetary penalty to manufacturers, permanent disqualification (in the event the violation was systemic and egregious), and referral to other appropriate federal authorities for appropriate action.

Within 180 days of enactment, PPACA also requires the Secretary to promulgate regulations to establish and implement an administrative dispute resolution process to address compliance concerns of covered entities and manufacturers regarding overcharges and possible diversion.²¹

Conclusion

The 340B Program provides certain covered entities with access to substantial discounts on outpatient pharmaceuticals. PPACA expanded access to the 340B Program to certain critical access hospitals, rural referral centers, sole community hospitals, free standing cancer hospitals and children's hospitals. Given the cost savings available to 340B Program participants, newly eligible entities should explore participation in the 340B Program and familiarize themselves with program requirements.

C. Frederick Geilfuss, II is a partner of Foley & Lardner LLP in the firm's Milwaukee office. He co-chairs the Health Law section's Transactions Work Group and is a member of the firm's Critical Access Hospital and Rural Provider Team. Mr. Geilfuss has been recognized as one of the country's top health care transactions attorneys. He can be reached at (414) 297-5650 or fgeilfuss@foley.com.

Maureen Kwiecinski is an associate attorney at Foley & Lardner LLP in the firm's Milwaukee office. She is a registered nurse and member of the firm's Critical Access Hospital and Rural Provider Team. Ms. Kwiecinski counsels hospitals, providers and payors regarding transactional, general compliance, medical staff governance and regulatory matters, including hospital/physician affiliations, medical staff governance, human subject research, and billing/reimbursement issues. She can be reached at (414) 319-7325 or mkwiecinski@foley.com.

¹ 42 U.S.C. § 256(b).

² SSA, 42 U.S.C. § 1396r-8.

³ See 42 U.S.C. § 256b(a)(10).

⁴ Mathematica Policy Research, Inc., Policy Analysis Brief, "The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities" (2004)

⁵ NORC Walsh Center for Rural Health Analysis Report, "Rural Hospitals Experience with the 340B Drug Pricing Program" (September, 2007), available at http://www.shepscenter.unc.edu/rural/pubs/finding_brief/FB82.pdf

⁶ The Deficit Reduction Act of 2005 added children's hospitals to the list of covered entities eligible to access the 340B Program. It did so amending section 1927(a) of the Social Security Act, but without also amending section 340B of the PHSA (which contains many of the requirements covered entities must meet). PPACA fixed this incongruity by amending section 340B of the PHSA to include certain children's hospitals.

⁷ 42 U.S.C. § 256b(a)(4)(L)(iii).

⁸ 42 U.S.C. § 256b(a)(4)(M)-(O).

⁹ See <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>

¹⁰ H.R. 4213, Section 340B-1.

¹¹ The PSSC website at <http://pssc.aphanet.org/about/registrationprocess.htm#health> contains detailed registration information. For newly eligible entities, at this time, the PSSC has not yet identified the recommended registration form.

¹² Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (October 24, 1996).

¹³ *Id.*

¹⁴ Pub.L. 101-508, 104 Stat. 1388, enacted November 5, 1990)

¹⁵ 42 U.S.C. § 256b(a)(5)(A).

¹⁶ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

¹⁷ *Id.*

¹⁸ Report of HHS Office of Inspector General, "Review of 340B Prices," July 2006.

¹⁹ 42 U.S.C. § 256b(d)(1)(B).

²⁰ 42 U.S.C. § 256b(d)(2).

²¹ 42 U.S.C. § 256b(d)(3).