

The Future of the 340B Drug Pricing Program: Challenges and Opportunities

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Executive Summary

Since 1992, numerous “safety-net” health care providers have enjoyed the opportunity, guaranteed under federal law, to purchase outpatient pharmaceuticals at a significant discount from a manufacturer’s market price. This program, usually referred to in shorthand as “the Section 340B program” or “340B,” referring to the statutory provision under which it is established,¹ has grown significantly over the years, notwithstanding resistance from some quarters of the pharmaceutical industry. The availability of 340B drugs, in many cases, makes the difference between a safety-net provider being able to offer an effective pharmaceutical program to its patients (with the attendant benefits of monitoring compliance with drug regimens and avoiding potentially harmful drug interactions) and its patients having no access at all to affordable drugs. However, decreasing reimbursement, market forces, and the changes and uncertainties in federal health care reform and the federal administration of the program will present challenges, and likely opportunities, for providers participating in the 340B program.

Genesis of the 340B Program

Section 340B was enacted in the wake of the Omnibus Budget Reconciliation Act of 1990 (OBRA ‘90) which required pharmaceutical manufacturers to provide discounts, in the form of rebates, to state Medicaid agencies on drugs dispensed to Medicaid beneficiaries.² Congress was concerned that some manufacturers had responded to the rebate requirement by increasing prices for other federal purchasers, including the Department of Veterans Affairs and public health clinics, thereby nullifying the cost savings expected from the OBRA provisions.³ Section 340B was intended to prevent such cost shifting. In the words of Senator Kennedy:

The public health system has only a limited ability to absorb price increases. Their programs must compete for scarce Federal dollars. If they are forced to pay more for drugs, they have no choice but to cut back the services they provide.⁴

Section 340B requires drug manufacturers to charge no more than a calculated “ceiling price” for “covered outpatient drugs” that are sold to specific types of organizations identified in the statute. All of these organizations are either recipients

¹ The program was enacted under Section 602 of the Veterans Health Care Act of 1992, P.L.102-585 which added Section 340B to the Public Health Service Act, now codified at 42 U.S.C. § 256b.

² Pub. L. No. 101-508. The rebate provisions were added as Section 1927 of the Social Security Act, codified at 42 U.S.C. § 1396s.

³ 138 Cong Rec S 16117 (October 2, 1992).

⁴ *Ibid.*

of federal grant funds to carry out a specific health care mission or otherwise depend heavily on federal subsidies to provide health care to low income and uninsured patients and Medicaid beneficiaries. They are referred to in Section 340B as “covered entities.”

The Section 340B program is administered by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS).

340B Covered Entities

As enacted in 1992, the group of 340B covered entities included entities receiving federal grants authorized under provisions of the Public Health Service Act, including federally qualified health centers (FQHC), family planning projects, Ryan White Care Act grantees, state operated AIDS Drug Assistance Programs, comprehensive hemophilia diagnostic treatment centers, black lung clinics, Native Hawaiian Health Centers, urban Indian organizations receiving funds under the Indian Health Care Improvement Act, entities receiving federal funding relating to treatment of sexually transmitted diseases or tuberculosis and certain public acute care disproportionate share hospitals (DSH).⁵

Free-standing children’s hospitals were added as covered entities by the Deficit Reduction Act of 2005.⁶ However, because they were added through an amendment to the Social Security Act, as opposed to an amendment to Section 340B of the Public Health Service Act, HRSA did not establish a mechanism for them to actually participate in the 340B program until September, 2009. Children’s hospitals were expressly added to the 340B program through the federal health care reform legislation.⁷ In addition, PPACA added Critical Access Hospitals, Free-Standing Cancer Hospitals, Rural Referral Centers, and Sole Community Hospitals as 340B covered entities.⁸

Covered entities must enroll in the 340B program in order to be eligible to purchase at the 340B ceiling price. Enrollment is done electronically through the OPA web-site, which also serves as notice of their participation in the program to manufacturers and wholesalers. New enrollees are added quarterly.

⁵ Hospitals that treat a disproportionate number of indigent patients are entitled to receive federal funding for otherwise uncompensated care, including payment adjustments under both Medicaid and Medicare. A DSH hospital must have a DSH adjustment percentage of at least 11.75% in order to qualify as a 340B covered entity. 42 U.S.C. § 256b(a)(4)(L)(ii). Outpatient facilities of a DSH hospital that are an integral part of the hospital, *i.e.* are reported on the hospital’s Medicare cost report, may be included as a 340B covered entity. 59 *Fed. Reg.* 47884 (September 19, 1994).

⁶ Pub. Law 109-171.

⁷ The Patient Protection and Affordable Care Act, Pub. L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, referred to hereinafter as “PPACA.”

⁸ PPACA § 7101.

The 340B Ceiling Price

Under the statute, the “ceiling price” of a 340B covered drug is defined as the average manufacturer price (AMP) for the drug reduced by the 340B “rebate percentage.” The “rebate percentage,” in turn, is calculated by reference to the applicable Medicaid rebate paid on the drug.⁹ In short, the 340B ceiling price of a drug is equivalent to the price, after rebate, that state Medicaid agencies pay the manufacturer for the drug.

Although the ceiling price is established by law, a drug manufacturer’s participation in the 340B program, and the terms of that participation, is established through a Pharmaceutical Pricing Agreement (PPA) between the manufacturer and HHS. A manufacturer must enter into a 340B PPA in order to have its drugs covered by Medicaid.¹⁰

Currently, the Medicaid minimum rebate percentages are as follows:

- Brand name drugs - 23.1%
- Brand name clotting factors and pediatric drugs - 17%
- Generics (non-innovator multisource) – 13%¹¹

The 340B ceiling price is, therefore, a calculated price based on manufacturer pricing data. The mechanics of this calculation is complex and has been criticized by the HHS Office of Inspector General (OIG).¹² In short, manufacturers calculate the ceiling price (based on the statutory formula) for purposes of sales to covered entities. HRSA also calculates a ceiling price from information that manufacturers provide to the Centers for Medicare and Medicaid Services for purposes of the Medicaid drug rebate program. The ceiling price is calculated quarterly based on retrospective data.

However, OBRA '90 prohibits the government from disclosing the pricing information that manufacturers provide to it. As a result, HRSA does not make the calculated ceiling price available to covered entities nor to the 340B Prime Vendor and manufacturers typically do not do so.¹³ Covered entities customarily purchase covered drugs through wholesalers at a contract price which includes both the drug cost and the wholesaler’s distribution fee. The drug sales price cannot legally exceed the ceiling price, although it could be lower than the ceiling price. But, without access to the ceiling price, covered entities have no way of gauging the accuracy of the price they are being charged by the wholesaler and no way to effectively negotiate distribution fees with the wholesaler. In sum, 340B is a discount program wherein the end purchasers, *i.e.* the covered entities, cannot ascertain the actual discount price at any particular time. This problem is exacerbated by the fact that 340B pricing

⁹ 42 U.S.C. § 256b(a)(1) and (2).

¹⁰ See 42 U.S.C. § 256b(a)(1) and 42 U.S.C. § 1396r-8(a).

¹¹ PPACA § 2501. Prior to PPACA the percentages were 15.1%, 15.1%, and 11% respectively..

¹² See OIG report OEI-05-02-00072, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, October, 2005.

¹³ GlaxoSmithKline voluntarily began to provide its calculated ceiling price to the Prime Vendor in 2005.

typically is provided to covered entities through a system of charge backs/credits from wholesalers. As discussed below, PPACA contains provisions intended to promote pricing transparency.

While the statute requires manufacturers to sell covered outpatient drugs to covered entities at no more than the calculated ceiling price, covered entities may negotiate prices lower than the ceiling price. To promote the availability of sub-ceiling pricing to covered entities, the statute directs HHS to establish a prime vendor program (PVP).¹⁴ The statute does not require a covered entity to purchase any of its covered outpatient drugs through the 340B program or through the PVP. However, the federal standards for procurements paid for with federal grant funds require that grantees purchase in the most cost effective manner. HRSA policy, as stated on HRSA grant awards, is that purchasing outpatient drugs at 340B pricing and through the PVP demonstrates prudent purchasing.¹⁵

340B Beneficiaries

Although the 340B Program is designed as a discount program for covered entities, there is no question that the patients of the covered entities are also beneficiaries, albeit indirectly, of the program. Clearly, the most vulnerable members of society benefit from having increased access to needed prescription drugs. Congress intended that savings realized from participating in the program help “stretch Federal resources as far as possible, to reach more eligible patients and provide more comprehensive services.”¹⁶

In that regard, the statute provides that a covered entity may not “resell or otherwise transfer the drug [acquired at the 340B ceiling price] to a person who is not a patient of the entity.”¹⁷ However, the statute does not define “patient.” In 1996, HRSA published patient definition guidelines that provide that a person is a “patient” of a covered entity only if:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g.

¹⁴ 42 U.S.C. § 256b(a)(8). Currently the HRSA Prime Vendor is Apexus, Inc. www.340bvpv.com

¹⁵ See 65 *Fed. Reg.* 6383 (February 9, 2000).

¹⁶ HHS Office of Inspector General Report OEI-05-02-00070 (June, 2004); H.R. Rpt. 102-384, 102nd Cong., 2nd session, pt.2 at 12 (1992).

¹⁷ See 42 USC § 256b(a)(5)(B). A covered entity that dispenses or otherwise sells or transfers a drug in violation of this provision is liable to the manufacturer of the drug for the amount of the 340B discount on the drug. 42 U.S.C. § 256b(a)(5)(D).

referral for consultation) such that the responsibility for the care provided remains with the covered entity; and

3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

4. An individual will not be considered a “patient” of the entity for purposes of 340B if the only health service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.¹⁸

These guidelines generally have worked well for the program. However, the flexibility HRSA built into the definition in order to accommodate the individuals served by the diverse group of 340B covered entities sometimes has led to arrangements that stretch the definition and that have led to an actual, or perceived, abuse of the program. Problematic arrangements typically focus only on one element of the patient definition in order to justify dispensing 340B drugs to an individual, as opposed to the actual relationship between those individuals and the covered entity. For example, under the so-called “case management” model, a covered entity contracts to oversee the pharmaceutical needs of a person and “maintains records” of that service as required by the first prong of the definition. Another example involves self insured covered entities that dispense 340B drugs to their employees, without providing the underlying care that generates the prescription. They argue that since they have financial “responsibility” for the care, that responsibility satisfies the second prong of the definition.

The most prominent case of 340B diversion, and the only one on public record to date, involved an Aliquippa, Pennsylvania DSH hospital. In 2004 HRSA excluded the hospital from the 340B program for prescribing practices that violated the patient definition guidelines. The hospital had dispensed 340B drugs to individuals who enrolled, for a fee, in the hospital’s Physician Medicine Assist Program, but who did not receive any other health care services from providers associated with the hospital.

In response to the Aliquippa hospital case, and, nominally, to correct other perceived abuses, in January, 2007, HRSA published proposed revisions to the 1996 patient definition guidelines. Those guidelines, in effect, would have completely replaced the existing and well-understood guidelines, and would have required covered entities to abandon many established relationships with patients that were in no way abusive of

¹⁸ 61 *Fed. Reg.* 55157 (October 21, 1996). State-operated or funded AIDS drug purchasing assistance programs are excepted from this definition.

the 340B program.¹⁹ Not surprisingly, the proposed guidelines generated substantial opposition from covered entities. They were never adopted. In early 2011, HRSA officially withdrew the 2007 proposal and submitted a new proposal for review by the Office of Management and Budget (OMB). Those proposed guidelines were subsequently cleared for publication by OMB, but, as of August, 2011 HRSA had not published them. As discussed below, HRSA's re-definition of "patient" is likely to be the most significant issue that 340B covered entities will have to address in the foreseeable future.

Dispensing 340B Drugs

In order to accommodate the numerous covered entities that did not have an in-house dispensing pharmacy, in August, 1996, HRSA issued guidelines regarding the circumstances and conditions under which a covered entity could contract with a commercial pharmacy to dispense drugs to their patients.²⁰ These guidelines allowed a covered entity to contract with only one commercial pharmacy to serve an individual service delivery site. Moreover, a covered entity could not ordinarily operate both an in-house pharmacy and also contract with a commercial pharmacy. However, more expansive dispensing models frequently were authorized through HRSA-approved Alternative Method Demonstration Projects (AMDP).

In April, 2010, HRSA issued revised contract pharmacy guidelines that significantly expanded the permissible contract pharmacy arrangements. A covered entity now may contract with multiple commercial pharmacies (including chain pharmacies) to serve any and all of its delivery sites while maintaining an in-house pharmacy.²¹ However, HRSA declined to provide a blanket authorization for a covered entity to dispense 340B drugs to patients of another covered entity. Those arrangements, which can significantly improve patient access to 340B drugs, still require HRSA approval through an AMDP.

Reimbursement for 340B Drugs

There is nothing in the statute that governs the amount that a covered entity can charge a patient (or be reimbursed by third party payers) for Section 340B drugs. However, some covered entities must comply with specific program requirements governing their charges to patients and third party payers.²² Otherwise, covered

¹⁹ 72 *Fed. Reg.* 1543 (January 12, 2007).

²⁰ 61 *Fed. Reg.* 43549 (August 23, 1996).

²¹ 75 *Fed. Reg.* 10272 (March 5, 2010).

²² For example, FQHCs are required to establish a schedule of charges for their services, designed to cover their costs and consistent with the locally prevailing fee for the service. They must establish a schedule of discounts from those charges, based on a patient's ability to pay, for uninsured patients whose income is between 100% and 200% of the federal poverty income guidelines (FPL). Uninsured patients with income below 100% of FPL must be provided a full discount or charged only a "nominal" fee. Uninsured patients with income above 200% FPL are not eligible for a discount, provided that no patient can be denied services on account of inability to pay. FQHCs may not provide a discount from their established charges to

entities generally are free to establish their charges for 340B drugs pricing, with one exception that derives from the relationship between 340B program and the Medicaid drug rebate program.

As noted previously, drug manufacturers are required to provide discounts (in the form of a rebate) to state Medicaid agencies when a covered outpatient drug is dispensed to a Medicaid beneficiary. Accordingly, if the drug were dispensed by a covered entity that acquired it at the 340B ceiling price, the manufacturer would be burdened by both the reduced Section 340B sales price and the subsequent rebate obligation, a so called “duplicate discount.”

To prevent this from occurring, the statute forbids a covered entity from requesting payment under Medicaid for a drug that a manufacturer has agreed to sell at the 340B price “if the drug is subject to the payment of a rebate to the State...²³ (Emphasis added). The statute further requires HHS to establish a mechanism to ensure that covered entities comply with the prohibition on duplicate discounts.²⁴ The mechanism that HRSA adopted requires covered entities to indicate on the OPA website if they purchase drugs at 340B pricing to dispense to Medicaid patients. That, in turn, puts the state Medicaid agency on notice not to request a rebate from manufacturers for those drugs.²⁵ Commercial pharmacies that contract with covered entities to dispense 340B drugs are likely to dispense drugs to Medicaid beneficiaries in their own right in addition to dispensing 340B drugs on behalf of contracting covered entities. Therefore, HRSA contract pharmacy guidelines state that a covered entity may not use a contract pharmacy to dispense to Medicaid beneficiaries unless that contracted pharmacy has reached agreement with the state Medicaid agency with respect to a method to prevent a duplicate discount situation from occurring.²⁶

In order to ensure that state Medicaid agencies were not financially disadvantaged when a covered entity dispensed a 340B drug to a Medicaid beneficiary (thereby causing the Medicaid agency to forego a rebate on the dispensed drug), in 1994 HRSA took the position that covered entities could bill Medicaid only for the acquisition cost of the drug plus the state allowed dispensing fee.²⁷ In 2000, HRSA stated that it was reconsidering the policy requiring billing at the actual acquisition price, and instructed covered entities to follow whatever billing rules the respective Medicaid agencies adopted.²⁸ Covered entities have the option of purchasing outpatient drugs for dispensing to their Medicaid patients outside of the 340B program (the so-called “carve-out” option) thereby avoiding restrictive billing requirements but also losing the benefit of 340B purchasing.

Medicare, Medicaid, or any other third party payer. See 42 U.S.C. § 254b(k)(3)(G); 42 C.F.R. § 303(f) and (g).

²³ 42 U.S.C. § 256b(a)(5)(A)(i).

²⁴ 42 U.S.C. § 256b(a)(5)(A)(ii).

²⁵ 58 *Fed.Reg.* 34058 (June 23, 1993) clarifying 58 *Fed. Reg.* 27293 (May 7, 1993).

²⁶ 75 *Fed. Reg.* 10278 (March 5, 2010).

²⁷ 59 *Fed. Reg.* 25112 (May 13, 1994).

²⁸ 65 *Fed. Reg.* 13984 (March 15, 2000).

The 340B Program: Looking Forward

There is no doubt that the 340B program has been a highly successful policy initiative, certainly from the point of view of covered entities and, presumably, patients of covered entities. According to OPA, there were over 16,000 covered entity sites participating in the program as of early 2011, and 6,500 contract pharmacies.²⁹ While there is no reliable data on the total savings that the 340B program generates for covered entities, the Congressional Budget Office has estimated that the 340B ceiling price is, on average, 51% of the list price (AWP) of covered drugs.³⁰ Nevertheless, as the 340B program approaches its twentieth anniversary, covered entities face new challenges, and some opportunities, in their utilization of the program.

Impact of Federal Health Care Reform

Congress enacted numerous statutory provisions in PPACA amending section 340B. Many are currently in effect. Other provisions could have a significant future impact depending on the outcome of the pending federal court cases challenging the Constitutionality of the individual mandate provisions of PPACA, one of which has invalidated the entire statute. If upheld by the Supreme Court, even the new 340B provisions that currently are in effect presumably would be nullified.

The GAO Study

Congress directed the Government Accountability Office (GAO) to undertake a study to make recommendations on improving the 340B program and to report its findings to Congress no later than September, 2011 (<http://www.gao.gov/new.items/d11836.pdf>).³¹ GAO examined “whether those individuals served by the covered entities [under the 340B Program] are receiving optimal health care services.” Specifically, GAO was directed to make recommendations as to:

- (1) Whether the 340B program should be expanded since it is anticipated that the 47,000,000 individuals who are uninsured as of the date of enactment of [PPACA] will have health care coverage once [the] Act is implemented;

²⁹ CDR Krista M. Pedley, Director, OPA, Seventh Annual 340B Coalition Winter Conference, February 10, 2011.

³⁰ *Prices for Brand –Name Drugs Under Selected Federal Programs*, June, 2005.

³¹ PPACA, § 7103.

(2) Whether mandatory sales of certain products by the 340B program could hinder patients [sic] access to those therapies through any provider;

(3) Whether income from the 340B program is being used by the covered entities under the program to further the program objectives.

GAO initiated its study in 2010, including interviews with the various 340B stakeholders, and it is believed that the report is on schedule for release in the fall of 2011. Obviously the tone of the questions presented to GAO is not particularly friendly to the 340B program. In responding to the GAO, covered entities emphasized that 340B would continue to play an important role post health care reform, noting, among other things, that the CBO estimated that nearly 21 million persons would remain uninsured. It is difficult to predict the outcome of the study, or how it might influence policymakers, particularly if the pending litigation results in the demise of all or significant parts of PPACA, thereby negating the promise of nearly universal health insurance.

Medicaid Rebates/AMP Calculations

PPACA increased the Medicaid minimum rebate percentages, retroactive to January 1, 2010. Since the 340B discount is tied to the Medicaid rebate, the increase in the rebate percentage should lower the 340B ceiling price. However, Congress also enacted changes to the method of calculating AMP which are likely to raise the AMP for certain drugs, thereby diluting some of the benefit of the increased rebate percentage.³² CMS has yet to adopt regulations for computing AMP under the new law. Because of the complexities in calculating AMP and the 340B ceiling price (which for brand name drugs must take into account the manufacturer's best price (as defined by law) as well as the minimum rebate percentage) the post-PPACA ceiling price for any particular drug likely will be a function of the manufacturer's marketing strategy and the pricing history of the drug.

Medicaid Managed Care

PPACA extended the mandatory Medicaid rebate to drugs dispensed to individuals enrolled in Medicaid managed care organizations (MCO).³³ Drugs subject to Section 340B discounts, *i.e.* those dispensed to patients of covered entities are exempt from the rebate requirement. This essentially leaves covered entities contracting with MCOs in the same position as they were under prior law. As there is no possibility of a duplicate discount occurring, covered entities should be free to charge MCOs their usual and customary fee without any need to pass on their 340B savings to the MCO. Covered entities should also have the opportunity to negotiate with MCOs for mutually beneficial reimbursement arrangements. However, manufacturers

³² PPACA § 2503, as amended by Pub. L. 111-226.

³³ PPACA § 2501(c).

frequently pay rebates to MCOs and are not likely to want to pay rebates on 340B drugs dispensed by contracting covered entities. Thus, covered entities may find themselves subject to the same pressures from MCOs facing diminished revenues as they are encountering from commercial payers, as discussed below.

Price Transparency

PPACA requires HHS to take measures to prevent manufacturer overcharges and other violations of the 340B pricing requirements.³⁴ To that end, HHS is required to develop a system to enable it to verify the accuracy of ceiling prices calculated by manufacturers, which must include:

- Developing and publishing precisely defined standards and methodology for calculating ceiling prices
- Regularly comparing the ceiling prices calculated by HHS with the quarterly price that the manufacturers report to HHS
- Spot checking sales transactions by covered entities
- Inquiring into indentified price discrepancies and taking, or requiring the manufacturers to take, appropriate corrective action
- Developing procedures for manufacturers to issue refunds to covered entities in the event of an overcharge
- Developing a mechanism by which rebates and discounts provided to manufacturers obtained subsequent to the sale of 340B drugs are reported to HHS and appropriate credits or refunds are provided to covered entities if the rebate or discount has the effect of lowering the ceiling price
- Selective auditing of manufacturers and wholesalers

The statute also authorizes HHS to impose sanctions up to \$5000.00 for each instance of a manufacturer knowingly and intentionally charging an amount exceeding the ceiling price.

However, the most important “transparency” provision in PPACA is that HHS is required to allow covered entities to access the applicable ceiling prices, as calculated and verified by HHS, through a secure HHS web-site.³⁵ This process, if properly implemented, would go far toward ensuring that covered entities receive the correct

³⁴ PPACA § 7102(a).

³⁵ The statute requires HHS to adopt security measures that adequately assure that privileged pricing data is protected from unauthorized disclosure.

ceiling price and remove lingering suspicions of manufacturer overcharges. Pricing transparency might also encourage covered entities that do not participate in the 340B program to do so, as price comparisons could easily be made. Unfortunately, it is not clear when, or if, these benefits will be realized. Although PPACA authorized appropriations to support this effort, funds to actually implement transparency measures have yet to be appropriated, and whether they will be is questionable in the current climate of budget cutting in Congress.

Program Integrity

PPACA added measures intended to improve the ability of manufacturers to identify eligible covered entities and for HHS to verify the information that covered entities provide to HHS in enrolling.³⁶ Of more significance to covered entities, Congress instructed HHS to establish an administrative dispute resolution process to address disputes regarding alleged manufacturer overcharges and alleged diversion or duplicate discount violations by covered entities. This was designed to remedy the virtual absence of any effective means to resolve such issues under prior law. Whether this procedure, once adopted, will have a significant impact on the program remains to be seen. To date, manufacturers have been extremely reluctant to audit covered entities for diversion or duplicate discount violations, which will remain a pre-condition to using the new administrative process. Further, given the difficulty and expense of proving an intentional overcharge case (taking into account the complex data elements that come in to play); it is doubtful that a covered entity will want to take on anything but the most egregious case of overcharging. Perhaps more telling, the statute requires HHS to issue regulations establishing the administrative process within 180 days of its enactment. As of August, 2011, HHS had not even published proposed regulations, although in a September, 2010 Advance Notice of Proposed Rulemaking it solicited input from 340B stakeholders as to the features that should be included in the administrative procedure.³⁷

Health Benefit Exchanges

PPACA provided for the establishment of state based health benefits exchanges designed to facilitate the individual and group purchase of qualified health plans (QHP) certified by HHS. Among other requirements, a QHP must include within its network “essential community providers. . . that serve predominantly low-income, medically underserved individuals such as health care providers [defined in Section 340B]. . . [unless the] provider refuses to accept the generally applicable payment rates of such plan.”³⁸ The risk to covered entities, of course, is that QHPs will offer them lower reimbursement in an effort to extract the benefit of the 340B discount. However, in response to a request for public comment on the appropriate

³⁶ PPACA § 7102.

³⁷ 75 *Fed.Reg.* 57223. HRSA also sought comments on how it should implement its authority to impose civil monetary penalties on manufacturers conferred under PPACA. 75 *Fed. Reg.* 57230 (September 20, 2010).

³⁸ PPACA § 1311(c)(1)(C).

certification criteria to apply,³⁹ 340B covered entities argued that HHS ought to require QHPs to reimburse covered entities at market rates, unless otherwise agreed by the parties. Of course, reimbursement will be moot if the Supreme Court throws out this part of PPACA.

Trends in Reimbursement for 340B Drugs

Although a covered entity has the benefit of a substantial discount in purchasing covered drugs that is of little value if it cannot dispense the drugs to its patients. In short, purchasing is only one part of an effective pharmacy program. Dispensing, medication management, and other pharmacy services also are critical components. Covered entities are, by definition, safety-net providers that typically serve large uninsured and underinsured populations, but also are legally obligated to serve their “target” populations without regard to individual income or insurance coverage. In short, in order to have an effective 340B pharmacy program there must be sufficient revenue to support all elements of the program. The notion that covered entities could generate revenue from the margin on 340B drugs was implicit in the enactment of the statute, and HRSA has embraced this concept in published guidance.⁴⁰ Nevertheless, covered entities now are facing increased challenges to financial sustainability.

Third Party Payers

Many third party payers, including Pharmacy Benefit Managers (PBM) that manage pharmacy benefit programs for insurers and employers, are reducing reimbursement to covered entities. There are several explanations offered for this trend. One is that PBMs typically negotiate rebates with manufacturers in exchange for their drugs being included in the PBM’s formulary. Manufacturers are less inclined to pay that rebate when they also are selling the drug at the 340B discount. The other, simply put, is that some PBMs and payers seek to improve their own bottom line by paying covered entities less.

This trend is likely to continue. Moreover, the ability of PBMs/third party payers to identify prescriptions filled with drugs acquired at 340B pricing will be made much easier when a new telecommunications standard developed by the National Council for Prescription Drug Programs (NCPDP) becomes effective.⁴¹ This standard will describe how pharmacy billing software should be written to allow identification of claims when 340B drugs are dispensed, both at the point of sale and retroactively. As PBMs cannot now easily distinguish claims filled with 340B drugs, some manufacturers have declined to pay rebates on any drugs dispensed by covered entities so as to avoid a potential duplicate discount. The standard nominally is intended to allow PBMs to identify non-340B claims for which they might claim the

³⁹ 75 *Fed. Reg.* 45584 (August 3, 2010).

⁴⁰ *See* 61 *Fed.Reg.* 43551 (August 23, 1996).

⁴¹ NCPDP is a nonprofit standard setting organization for the pharmaceutical industry.

customary commercial rebate. However, that information also can be used to identify 340B claims for purposes of ratcheting down covered entity reimbursement. The new standard is set to take effect January 1, 2012, although it will not be used until October, 2012.

Medicaid

The original HRSA guidance on billing for 340B drugs dispensed to Medicaid beneficiaries limited reimbursement to the covered entity's actual acquisition cost plus a "reasonable" dispensing fee established by the state Medicaid agency.⁴² Typically, the state-allowed dispensing fee was relatively low and insufficient alone to cover the overhead costs of a pharmacy program. Section 340B covered entities, not being permitted to "mark-up" the price on the drug ingredients, were disadvantaged in that regard because, under the applicable reimbursement rules, commercial pharmacies are permitted to earn some margin on Medicaid prescriptions in addition to the dispensing fee. Covered entities retained the option of purchasing drugs for their Medicaid patients at commercial rates and, accordingly, receive the same reimbursement as other Medicaid pharmacy providers.

However, states sometimes find it to their advantage to encourage covered entities to purchase drugs at 340B prices for Medicaid beneficiaries as opposed to "carving out" Medicaid from their 340B pharmacy program. While they must forgo the manufacturer rebate on those drugs, the 340B savings are an up-front discount, essentially eliminating the delay in obtaining the savings as well as avoiding the administrative cost (and potential errors) in submitting rebate claims. The inducement offered to covered entities to use 340B drugs for Medicaid patients is to increase their reimbursement significantly above what an acquisition cost plus dispensing fee reimbursement model would realize. Generally, this is a win-win situation for the state and for 340B providers.

While several of these so-called "shared savings" models continue, some states, most notably California, have taken a different and somewhat Draconian tack toward extracting savings from the 340B program. In 2009, California adopted legislation that requires 340B covered entities to purchase drugs at 340B prices as a condition of participating in Medi-Cal, the state Medicaid program, thereby eliminating the "carve out" option. Moreover, covered entities are reimbursed only for their 340B acquisition cost plus dispensing fee.⁴³ This has put a significant financial strain on 340B providers.

Other states have removed outpatient pharmaceuticals from their Medicaid managed care program, presumably because in returning to a fee-for-service approach they will have a better opportunity to realize savings from the 340B program rather than allowing the benefit to accrue to managed care plans and 340B covered entities. With

⁴² 59 *Fed. Reg.* 25112 (May 13, 1994).

⁴³ Healthcare Trailer Bill A.B. X4-5.

state budgets under pressure, one might expect further state initiatives to capture the savings afforded by the 340B program. Moreover, it is widely believed that some CMS officials support the notion that the 340B program should be administered in a way that ensures that state Medicaid agencies reap the maximum savings from the 340B program, for example, by eliminating any “shared savings” option for states.

In that regard, in PPACA, Congress directed HHS to develop “more detailed” guidance describing the methodologies and options available to covered entities for billing 340B covered drugs to state Medicaid agencies in a manner that avoids duplicate discounts.⁴⁴ 340B covered entities have urged HHS to allow states flexibility (but not to permit other states to take California’s approach). It is not clear how HHS will deal with this issue.

Market Forces

The 340B ceiling price undoubtedly will continue to be extremely important for access to expensive name brand drugs and for patients requiring high cost therapies, such as clotting factor. But generic drugs typically comprise a substantial part of safety-net providers’ drug formularies. The savings on these drugs is less significant and, in some cases, covered entities are able to purchase generics on the open market at less than the 340B ceiling price. Moreover, as the patents expire on frequently prescribed name brands and substitute generics become available, the overall value of the 340B discount will decline for some covered entities. They may find it more advantageous to purchase outside of the program and avoid the limitations on patient eligibility and the federal and manufacturer oversight that is part of the 340B program. In addition, covered entities have reported that a drug is sometimes not available at the ceiling price, due to a purported shortage, but that the same drug is readily available at commercial pricing. This practice appears to be a subversion of the statute and, if left unchecked, will undermine the value of the program.

Legislation, Oversight, and Policy Implications

Except for the addition of children’s hospitals in 2005, there were no legislative changes to the 340B program in the eighteen years preceding PPACA. In 2005, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce conducted hearings focusing on price transparency and accuracy issues highlighted in a 2005 OIG report.⁴⁵ Subsequently, bills were introduced in both houses of Congress that attempted to address those issues. Most, but not all, of the features of those bills, were included in the PPACA amendments. Most notably, PPACA, as originally enacted, extended 340B pricing to inpatient pharmaceuticals and removed a provision in the law that prohibits DSH hospitals from purchasing 340B drugs through a Group Purchasing Organization (GPO). Both of these provisions were

⁴⁴ PPACA § 7102.

⁴⁵ Report No. 109-108 (December 15, 2005). *See also* note 12 above.

removed in the final bill. The prospects for significant legislative expansion of the 340B program in the near future seem unlikely.⁴⁶

However, critics of the 340B program undoubtedly will continue to make their case to Congress and the Administration. In particular, the National Community Pharmacists Association has complained that covered entities should not be permitted to dispense 340B drugs to insured patients. According to the Association, covered entity pharmacies are able to provide discounts to insured patients thereby attracting business that otherwise would go to the community pharmacies.⁴⁷ This challenge seems odd in that federally qualified health centers, which represent the second largest group of covered entities, are prohibited by statute from providing a discount to third party payers or to any insured person with income over 200% of the Federal Poverty Income level. Moreover, there are now approximately 6500 commercial pharmacies that contract with covered entities to dispense 340B drugs,⁴⁸ many of which are community pharmacies, providing a service to patients (and business for local pharmacies) that likely would not exist if it were not for the 340B program in the first place. Nevertheless, this complaint is evidence that the “battleground” for 340B will be, as it has been throughout the history of the program, on the scope of the individuals who are eligible for 340B drugs.

In short, expansion (other than through the addition of new covered entities) or contraction of the program primarily is a function of the scope of individuals to who covered entities may dispense 340B drugs. Because the statute essentially gives HRSA discretion to define who is a “patient” for 340B purposes, HRSA has the primary jurisdiction (short of legislation) to expand or contract the program. Accordingly, how HRSA now chooses to define “patient” will significantly affect the value of the program for 340B covered entities and their ability to provide the persons they serve with access to low cost drugs.

Documenting Compliance: Some Recommended Best Practices

Concern has been expressed in recent years relative to the 340B program: 1) that the program has a negative financial impact on small community pharmacies, 2) that the program is not fulfilling its original objectives, and 3) that compliance with 340B program requirements is lacking.

With over 6500 commercial pharmacies now contracting with covered entities to dispense drugs, many of which are community pharmacies, the supposed ‘harm to

⁴⁶ Post PPACA, Congress amended Section 340B to remove a provision added by PPACA that prohibited children’s hospitals from obtaining 340B pricing on “orphan” drugs. Section 204 of the Medicare and Medicaid Extenders Act of 2010, Pub.L. 111-309. “Orphan” drugs are those that are developed specifically to treat a rare disease or condition. Manufacturers are afforded special incentives to produce such drugs under the Orphan Drug Act, Pub. L. 97-414.

⁴⁷ Letter to Rep. Darrell Issa, Chairman, House Committee on Oversight and Government Reform, January 12, 2011

⁴⁸ See note 29 above.

pharmacy' argument is without merit. Second, the 340B program is fulfilling its original objectives as intended by Congress: namely to help safety-net providers' stretch scarce federal resources and provide vulnerable populations access to affordable drugs. Last, with regard to program integrity, there are market-based solutions that can ensure accountability and program integrity and that do not jeopardize access to 340B drugs for safety-net providers. It is assumed that covered entities understand that diversion of 340B drugs can trigger manufacturer claims for the amount of the discount. Moreover, HRSA may impose additional penalties depending on the degree of the violation.

Covered entities participating in the 340B program are obligated to establish auditable systems. The necessary complexity or extent of these systems is a function of the entity type and a function of the entity's means of implementing the program. In other words, the less complex the system - the simpler the audit procedures.

Examples:

1. An FQHC that administers or dispenses drugs exclusively to its patients only needs to maintain dispensing records, 340B invoices, and health records.
2. An STD or TB clinic needs to meet the same conditions but is also limited by the scope of its federally funded grant. For example, a clinic operating out of a health department could provide primary care that is outside the scope of the STD or TB grant. In order to qualify for 340B drugs provided outside the TB or STD grant (Example: treatment for hypertension) the services would either have to be covered under other qualifying grant(s) or those drugs would have to be carved out of the health department's 340B purchases.
3. Other 340B entity types such as ADAPs (AIDS Drug Assistance Programs) must meet audit requirements that provide information on patient qualifications, drug formulary specifications and provide details necessary to access 340B prices or 340B rebates.
4. 340B hospitals must be able to provide an audit trail that can be used to differentiate 340B qualified outpatient drugs from all other drug utilization. The most complex audit requirements generally apply to hospitals because of mixed use settings that include on-campus outpatient departments, emergency departments that process inpatient admissions, outpatient surgery departments and units that cannot be considered either acute inpatient or outpatient, such as SNFs and other sub-acute units.

The complexity of maintaining an auditable record trail obviously increases if a covered entity utilizes contract pharmacies to dispense to its patients. Nonetheless, it is imperative that all covered entities participating in the 340B program not only

comply with program requirements but also be able to document compliance with those requirements in the event of an audit. The cost of technology to support compliance no longer is prohibitive even for small covered entities.

An auditor must be able to link 340B purchase items to the scope of services provided under a grant or other restrictions such as orphan drug rules. An audit (conducted by a manufacturer or HRSA) is likely to involve the following steps:

1. Identifying the responsible 340B covered entity in the OPA Database.
2. Identifying the responsible contract pharmacy. Currently, only sites listed on the database are eligible.
3. Identifying the responsible provider's relationship with the covered entity and the patient (covered entity health record and employment/credential file).
4. Verifying that for the date and time of service generating the prescription, the individual was a "patient" of the covered entity under then applicable HRSA patient definition guidelines. (Covered entity health record within the data set utilized by the dispensing covered entity or its contract pharmacy).
5. Verifying [when applicable] that the service generating the prescription for the 340B drugs dispensed is within the scope of services for which grant funding is provided. (Diagnoses in health record as verified by covered entity or contract pharmacy).
6. Verifying that GPO and Orphan Drug requirements are met. (Health record as verified by the covered entity or contracted pharmacy).

Manual vs. Electronic Systems

If covered entity electronic systems are not available or are not interactive, the covered entity is responsible for providing paper records. Manufacturers recognize that they have no authority to mandate that 340B covered entities have electronic information systems available for audits. However it is strongly recommended that 340B covered entities have these systems in place because it facilitates record keeping and documentation necessary to assure compliance.

Comment:

The federal 340B program has been a significant value to safety net providers by helping ensure that patients have access to affordable medications. However, to ensure the longevity of the program, covered entities and pharmaceutical manufacturers share responsibility for demonstrating their commitment to compliance. Covered entities deserve accurate and transparent ceiling pricing, and

manufacturers deserve assurance, through reasonable documentation, that the drugs are dispensed only to eligible patients and that there are no duplicate discounts.

The challenges in the 340B program have been and continue to be significant. For those of us who believe that every new challenge represents opportunities to strengthen not expand the 340B program, I encourage readers to consider the arguments set forth in this White Paper. While there may be disagreement, the objective here is to discuss and determine ways to strengthen the existing 340B program.