A Critical Analysis of Provisions of the Affordable Care Act Affecting the Life Sciences Industry

Thomas R. Barker*

I. Introduction

The Patient Protection and Affordable Care Act (“PPACA”)\(^1\) and the Health Care Education and Reconciliation Act (“HCERA”),\(^2\) collectively known and referred to as the “Affordable Care Act,” made sweeping reforms to the American health care system. Although significant public attention has been focused on the Act’s health insurance reforms and its promise to extend health insurance coverage to Americans who currently lack such coverage, as well as its cost and the scope of the federal government’s reach into the American health care system, the Affordable Care Act also fundamentally alters the life sciences industry. These changes increase assessments on pharmaceutical and medical device manufacturers, on the ostensible theory that increased numbers of Americans with health insurance will translate into increased business for these industry sectors; this increased business, it is believed, justifies these assessments.\(^3\) The legislation also changes the manner in which pharmaceutical

\* Thomas Barker is an adjunct professor of health law at the George Washington University School of Public Health and Health Services in Washington, D.C. and Suffolk University Law School, where he teaches an introductory health law course, as well as a course on legal issues in Medicare and Medicaid. Mr. Barker is also partner in the law firm of Foley Hoag LLP, where he is a member of the firm’s life sciences, health care, and government strategies practices. He represents health care providers, pharmaceutical, biological, and medical device manufacturers on complex CMS and FDA regulatory issues. Mr. Barker splits his time between the firm’s Washington, D.C. and Boston offices. Prior to joining Foley Hoag LLP, Mr. Barker served as a political appointee in the Administration of President George W. Bush. Most recently, Mr. Barker was the acting General Counsel of Health & Human Services from May of 2008 through the end of the Bush Administration.


\(^3\) \textit{See} Statement of the President, The President’s Proposal, The White House (Feb. 22, 2010),
products are covered by Medicaid and the Public Health Service Act section 340B program (“340B program”). Finally, the legislation liberalizes the Medicare Part D benefit first enacted under President George W. Bush’s Administration.

This article analyzes these changes. It describes the various assessments the statute enacts on the life sciences industry sector and discusses the legal issues that have arisen to date as these provisions have been analyzed and implemented. Next, the article illustrates the current Medicaid prescription drug rebate program and the 340B program; it then explains the revisions to those programs. Finally, it examines the revisions to the Medicare Part D program. Throughout, the article points out strategic considerations facing the life sciences industry in applying the new law.

II. Industry Assessments

The legislation imposes a series of excise taxes, or “fees,” on various sectors of the health care industry. Two, in particular, will affect the life sciences industry. The first is a fee on sales of branded pharmaceutical products to federal government health care programs. The second is an excise on sales of medical devices to all purchasers.

---

4 See Social Security Act § 1927, 42 U.S.C. § 1396r-8 (imposing rebates on outpatient prescription drugs covered by the Medicaid program) and Public Health Service Act § 340B 42 U.S.C. § 256b (establishing a federal drug-pricing program limiting the cost of out-patient drugs for certain covered entities) and amendments made by Patient Protection and Affordable Care Act of 2010 §§ 2501 and 2503 (to be codified at 42 U.S.C. § 1396r-8) and §§ 7101, 7102 (to be codified at 42 U.S.C. 256b) (expanding participation in and improving the “integrity” of the 340B program).


6 See generally Patient Protection and Affordable Care Act of 2010 § 9008 (to be amended as codified at 26 U.S.C. § 4001 note) (imposing an annual fee on “branded prescription pharmaceutical manufacturers and importers”).

7 See I.R.C. § 4191(b)(1) (2010) (imposing a tax on the sale of all “taxable medical device[8]”).
A. Fee on Branded Prescription Drug Sales

The fee on sales of branded pharmaceutical products is relatively straightforward. Under the statute, the Secretary of the Treasury determines the fee amount to assess each “covered entity” that manufactures or imports “branded prescription drugs” and has “branded prescription drug sales.” Thus, in order to know what entities are subject to the fee and its amount, one must know what is a covered entity, how the fee is determined, and what constitutes “branded prescription drug sales.”

Under the statute, a “covered entity” is “any manufacturer or importer with gross receipts from branded prescription drug sales.” Moreover, controlled groups are treated as one entity. Note that the fee is determined based on “gross receipts,” rather than gross income, adjusted gross income, or taxable income. As a result, it is possible that an entity with no income or a taxable loss may still be liable for the fee amount.

As indicated above, the fee is determined not by reference to the covered entity’s income, gross income, or taxable income, but rather, by the ratio of its gross receipts from branded prescription drug sales to the total of all gross receipts from branded prescription drug sales for all covered entities. This ratio is then multiplied by the amount intended to be raised by the assessment in the relevant year. The amount intended to be raised by the fee is $2.5 billion in 2011, increasing gradually until reaching a maximum of $4.1 billion in 2018, and decreasing to $2.8 billion in 2019 and

---


10 See id. § 9008(d)(2)(A) (to be codified as amended at 26 U.S.C. § 4001 note) (defining “controlled groups” as “persons treated as a single employer”).

11 See id. § 9008(b)(1) (to be codified as amended at 26 U.S.C. § 4001 note). Note that not all sales are taken into account when determining a covered entity’s gross receipts. Rather, for sales of $400 million or less in a year, only a sliding percentage of sales, with the first $5 million in sales being exempt, are taken into account. See id. § 9008(b)(2) (to be codified as amended at 26 U.S.C. § 4001 note). In this manner, Congress has lightened the burden of the assessment on small-covered entities. See id.

12 See Health Care Education and Reconciliation Act of 2010 § 1404(a)(2)(B) (amending PPACA to include the amount multiplied under section 9008(b)(4)).
subsequent years.\footnote{See id. (pre-determining the amount the branded prescription drug tax will raise).}

The significance of this feature of the fee cannot be overstated. A covered entity will have absolutely no way of knowing the amount of its assessment in a year until the Secretary of the Treasury announces the denominator of the ratio.\footnote{See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 9008(b)(3), (g), 124 Stat.119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (to be codified as amended at 26 U.S.C. § 4001 note). The Secretary of the Treasury will determine the denominator of the ratio based upon the submission of reports pertaining to sales made by all covered entities to Medicare Part D, Medicare Part B, Medicaid, the Department of Veterans Affairs, the Department of Defense, and TRICARE. See id. Commentators have noted that the method of calculation contemplated by PPACA will result in uncertainty regarding not only the dollar value of the ultimate figure, but also its accuracy. See, e.g., Peter S. Reichertz, New Taxes for Pharmaceutical and Medical Device Manufacturers/Importers/Distributors, FDA LAW UPDATE BLOG, (Apr. 19, 2010), http://www.fdalawblog.com/2010/04/articles/legislation/new-taxes-for-pharmaceutical-and-medical-device-manufacturersimportersdistributors (last visited Mar. 26, 2011).} Presumably, a covered entity will know its own gross receipts attributable to branded prescription drug sales (although given the definition of branded prescription drug sales, to be discussed \textit{infra}, this may not be a safe presumption), but a covered entity will have no way of knowing the total amount of gross receipts from branded prescription drug sales from all covered entities until the Secretary of the Treasury announces what that amount is.\footnote{See Patient Protection and Affordable Care Act of 2010 § 9008(a)(1), amended by Health Care and Education Rehabilitation Act of 2010 § 1404(a)(1) (to be codified as amended at 26 U.S.C. § 4001 note). The fee is payable on “the annual payment date of each calendar year” beginning after 2010. \textit{Id}. In turn, this term is defined as occurring no later than September 30. See \textit{id}. § 9008(a)(2). Thus, by September 30, 2011, the fee for calendar year 2011 must be paid, based on events occurring in 2010. \textit{See id}. Congress has given the Secretary of the Treasury broad discretion to determine the amount of the fee. See \textit{id}. § 9008(b)(3) (granting discretion to the Secretary to “calculate the amount of each covered entity’s fee”). The IRS has announced that the fee will be based on sales data occurring in the year that is two years prior to the year in which the fee is paid, with an adjustment in subsequent years. See I.R.S. Notice 2011-9, 4, 2011-6 I.R.B (Feb. 7, 2011). This is apparently because the Centers for Medicare and Medicaid Services (“CMS”) data are not available the year immediately preceding the payment year. See \textit{id}. Entities subject to the fee must file Form 8947 by February 11, 2011, from which the IRS will announce the preliminary fee determination on May 16, 2011. See \textit{id}. The final fee determination will be sent on August 15, 2011. See \textit{id}. at 8-9.} A “branded prescription drug” is any prescription drug that was approved by the U.S. Food and Drug Administration (“FDA”) as a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b), or any
biologic product approved by the FDA pursuant to a license submitted under section 351(a) of the Public Health Service Act, 42 U.S.C. § 262(a).17

Critically, note that the fee is not assessed with respect to all sales of branded prescription drugs in the United States; rather, it is assessed just on sales to government programs.18 The statute defines these programs as consisting of Medicare Part D, Medicare Part B, the Medicaid program, the Department of Veterans Affairs, the Department of Defense health care programs, and the TRICARE program.19 Thus, receipts from commercial sales are exempt from the fee.

A few other features of the fee bear mention for purposes of complying with the assessment. First, for federal income tax purposes, the fee is not deductible for determining taxable income.20 Second, sales by manufacturers to federal government programs are determined not by the manufacturers, but by the respective federal government agencies that operate the programs.21 Although this removes a significant

17 Id. § 9008(e)(2)(A)(i), (ii).
18 Id. § 9008(e)(1).
19 Id. § 9008(e)(4)(A)-(F). The full language of the relevant provisions reads:
   The term “specified government program” means --
   (A) the Medicare Part D program under part D of title XVIII of the Social Security Act,
   (B) the Medicare Part B program under part B of title XVIII of the Social Security Act,
   (C) the Medicaid program under title XIX of the Social Security Act,
   (D) any program under which branded prescription drugs are procured by the Department of Veterans Affairs,
   (E) any program under which branded prescription drugs are procured by the Department of Defense, or
   (F) the TRICARE retail pharmacy program under section 1074g of title 10, United States Code.

21 See Patient Protection and Affordable Care Act of 2010 § 9008(g) (to be codified as amended at 26 U.S.C. § 4001 note) (imposing a reporting requirement on federal government agencies including the Secretary of Health and Human Services for the Medicare Part D, Medicare Part B
paperwork and reporting burden from manufacturers, it also leaves them dependent on reports from federal government agencies, not their own records, for tax compliance purposes. This is a relatively uncommon feature in federal income tax law.

It is not difficult to envision the likelihood of litigation arising from the fee based on any number of disputes that could arise. First, covered entities may dispute their share of the fee based on a disagreement about the numerator of the ratio. As noted, supra, section 9008(g) of PPACA imposes the reporting requirement on the amount of sales by a particular covered entity on the government program, not the covered entity’s own records. Second, covered entities may dispute the Secretary of the Treasury’s calculation of the denominator of the ratio—i.e., the total branded prescription drug sales.22 Because each of the factors that go into a particular covered entity’s economic burden of the fee are not determined by the covered entity, but rather, by multiple federal government agencies, covered entities must rely on the accuracy of those agencies’ records. Disputes over the accuracy could potentially lead to litigation.

B. Excise Tax on Medical Device Sales

In addition to the fee on branded prescription drug sales, the Affordable Care Act also imposes an excise tax on sales of medical devices. Unlike the fee on branded prescription drug sales, which is not drafted as part of the federal income tax code, the tax on medical device sales is codified at section 4191 of the Internal Revenue Code of 1986 (“IRC”).23 Also, unlike the assessment on branded prescription drug sales, under which the assessment varies based upon the payer’s relative proportion of gross receipts

and Medicaid Programs, the Secretary of Veterans Affairs for Department of Veterans Affairs programs, and the Secretary of Defense for Department of Defense programs and TRICARE); see generally Thomas C. Fox et al., HEALTH CARE FIN. TRANSACTIONS MANUAL § 21:57.5 (Nov. 2010) (noting that the share of the fee assessed to each manufacturer or importer is determined by “the ratio of (1) its ‘branded prescription drug sales’ (as defined in the ACA) in a taxable year to specified government programs, to (2) that of the aggregate ‘prescription drug sales’ of all manufacturers and importers to such programs in such year (i.e., roughly based on its market share”).
22 See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 9008(f)(2), 124 Stat.119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 9008(b)(3), 124 Stat. 1029 (to be codified as amended at 26 U.S.C. § 4001 note) (stating that the Treasury Secretary will determine branded prescription drug sales on the basis of reports in section 9008(g) and “the use of any other source of information available to the Secretary of the Treasury”); see also supra note 15 and accompanying text (discussing how the Secretary of the Treasury calculates fees).
from branded prescription drug sales, the tax on medical device sales is imposed in a flat amount, thereby giving the payer of the tax greater certainty as to its liability for the tax.24 That said, the structure of the tax also leaves several unanswered questions.

Under IRC section 4191(a), a tax is imposed on the sale of a “taxable medical device” in an amount equal to 2.3% of the sales price of the device.25 A “taxable medical device” is any medical device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h).26 The statute contains four exemptions from the definition of “taxable medical device”; eyeglasses, contact lenses, hearing aids, and medical devices the Secretary of the Treasury determines to be “of a type” the general public typically purchases at retail.27

25 I.R.C. § 4191(a).
26 See id. § 4191(b). The Federal Food, Drug, and Cosmetic Act defines a medical device, in relevant part, as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and . . . which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

27 See I.R.C. § 4191(b)(2)(A)-(D) (enumerating exemptions). The United States Food and Drug Administration (“FDA”) categorizes medical devices into three classes based on their level of complexity and potential to cause harm to human beings. See 21 U.S.C. § 360c (a)(1)(A) – (C); see also Riegel v. Medtronic, 552 U.S. 312, 315-17 (2008). A Class I medical device is a device that needs little regulation because it is generally safe to use as intended and poses little to no risk to its users. See Riegel, 552 U.S. at 315-17. Examples of Class I medical devices include “elastic bandages and examination gloves.” Id. at 316-17. A Class II medical device is a device that needs an enhanced level of regulation and FDA review before the product can be introduced into interstate commerce. See id. FDA review for Class II medical devices is typically granted through the section 510(k) process, which permits the introduction of Class II medical devices into interstate commerce if they are “substantially equivalent” to medical devices currently on the market. See id. at 317-19 (contrasting section 510(k) review process to standard premarket approval process); Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79 (1996) (outlining the section 510(k) review process). Examples of Class II medical devices include “powered wheelchairs and surgical drapes.” See Riegel, 552 U.S. at 315-17. Finally, Class III medical devices are those devices that pose the most risk to humans. Id. Examples of Class III medical devices include “heart valves, implanted cerebella stimulators, and pacemaker pulse generators.” Id. Such
The fourth exemption from the definition of “taxable medical device” will likely generate the most significant legal issues because Congress failed to define the phrase “generally purchased by the general public at retail.”

28 From the context, it seems clear that most Class I medical devices would meet this definition; for example, bandages, splints, cotton ear cleaners, gauze pads, and ear plugs are all Class I medical devices and can all be purchased at any drug store. Indeed, an earlier version of the legislation contained a similar exemption. 29 Moreover, there are also many Class II devices that would seem to meet the definition; for instance, a wheelchair or a walker can be purchased in the retail setting.

But what about a power wheelchair such as those advertised on television and that are not sold at a retail establishment? One could argue that these are nevertheless “retail” sales in the sense that they are sales to the general public and are not intended for resale. The Internal Revenue Service (“IRS”) has recently issued a request for guidance on this issue. 30 Were the IRS to conclude that these more complex products devices must usually be approved through either the FDA’s pre-market approval process or through the section 510(k) substantial-equivalence process. See id. at 317-19; Medtronic, Inc., 518 U.S. at 478-80; Mark Herrmann et al., The Meaning of the Parallel Requirements Exception Under Lohr and Riegel, 65 N.Y.U. ANN. SURV. AM. L. 545, 548-52 (2010) (noting that medical devices “sold before the passage of the MDA are grandfathered and may be marketed until the FDA promulgates a regulation requiring approval through the [premarket approval] process”); see also U.S. FOOD AND DRUG ADMINISTRATION, General and Special Controls, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last visited Mar. 26, 2011); U.S. FOOD AND DRUG ADMINISTRATION, Overview of Device Regulation, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm (last visited Mar. 26, 2011).

28 See I.R.C. § 4191(b)(2)(D) (providing an exemption for “generally purchased by the general public at retail”); see also IRS Notice 2010-89, IRB 2010-52 (Dec. 27, 2010) (“Comments are specifically requested on the exemption in section 4191(b)(2)(D) for any medical device ‘determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use’”).

29 See H.R. 3962, 111th Cong., § 552 (1st Sess. 2009) (adding proposed I.R.C. section 4062(b)(2)(B), exempting sales of medical devices at retail establishments if the device is “of a type . . . which is purchased by the general public”).

30 See IRS Notice 2010-89, supra note 28 (soliciting comments on fourth exemption). Note that some Class II medical devices meet the definition of durable medical equipment in the Medicare program under the Social Security Act. See Social Security Act § 1861(n), 42 U.S.C. § 1395x(n) (2006). Some items of durable medical equipment are never purchased by a Medicare beneficiary, in the sense that the beneficiary does not take title to the device. See Social Security Act § 1834(a)(7)(A)(i), 42 U.S.C. § 1395m(a)(7)(A)(i), (providing for payment on a rental basis only for some items of durable medical equipment). Because a Medicare beneficiary would not take title to the device, one could argue that it does not meet the definition of a “sale” in section 4191, at least as that term is defined in the Uniform Commercial Code. See Uniform Commercial Code Article II, § 2-206(1) (defining “sale” as consisting of “the passing of title from the seller to
that are not available in retail stores are ineligible for the exemption, disputes will likely ensue from manufacturers of, for example, power wheelchairs, who may have a strong argument that their product is sold “at retail” and therefore exempt from the tax.

III. Medicaid and PHSA 340B

A. Medicaid Rebates

As a condition of Medicaid coverage of outpatient prescription drugs in a State, a prescription drug manufacturer is required to pay a rebate to the State with respect to a “covered outpatient drug.”31 Under the normal Medicaid shared financing principles, the federal government and the states share the rebate.32 Prior to the enactment of the Affordable Care Act, the rebate was the greater of 15.1% of the average manufacturer price (“AMP”) of the drug, also called the “minimum rebate percentage,” or the difference between the AMP and the “best price” for the drug.33 Clearly, a few definitions are in order.

The AMP for a drug was, prior to the enactment of the Affordable Care Act, “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”34 The AMP is

31 Social Security Act § 1927(a)(1), (b), 42 U.S.C. § 1396r-8(a)(1), (b). The term “covered outpatient drug” is defined as a drug that can only be dispensed pursuant to a prescription and that is FDA approved as safe and effective. See id. § 1396r-8(k)(2)(A)(i) (defining term). Certain drugs sold in the United States prior to 1962, for which the FDA did not require FDA approval for efficacy at the time, are also included in the definition. See id. § 1396r-8(k)(2)(A)(ii)(l).

32 Id. § 1396r-8(b)(2). States incur expenditures for medical assistance, and the federal government matches those expenditures according to the state’s federal medical assistance percentage (“FMAP”). Id. § 1396b(a)(l). A state’s FMAP varies in inverse proportion to the per capita income of the state. Id. § 1396d(b).


34 Social Security Act § 1927(k)(1)(A), 42 U.S.C. § 1396r-8(k)(1)(A). The phrase “retail pharmacy class of trade” is not defined in the statute, but is defined in agency regulations. See 42 C.F.R. §
calculated so that it reflects the true economic price at which the drug changes hands. Thus, the AMP is determined without regard to customary prompt pay discounts. Under federal regulations, the AMP includes all sales, as well as associated price concessions provided by the manufacturer for drugs distributed in the retail pharmacy class of trade, unless expressly exempted by statute or regulations.

The “best price” for a drug is, essentially, the price at which the drug is sold to a favored vendor. In the words of the statute, it is the “lowest price available from the manufacturer . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.” The provision offers State Medicaid agencies the best commercially-negotiated discount for drugs that manufacturers have granted in the marketplace. For example, if the AMP of a drug is $100 per 30-day supply, but the manufacturer has agreed to sell it to a favored vendor at $25 per 30-day supply, all State Medicaid agencies must also be granted the $25 price, even though the minimum rebate percentage would otherwise dictate a price of $84.90 per 30-day supply (i.e., $100 – (15.1% x $100), or $100 - $15.10 = $84.90).

Certain sales are exempted from the definition of “best price.” The effect of these exclusions is to permit certain “socially-favored” purchasers to purchase drugs at an even better price than the Medicaid price. Examples include community health

447.504(e) (2010) (repealed 2010) (including in the definition virtually any entity, including mail order pharmacies, that purchase drugs from manufacturers and re-sell to the public). CMS’ regulation was repealed in November 2010. See 75 Fed. Reg. 69571, 69591-97 (Nov. 15, 2010).


37 Examples of sales exempted from the calculation of AMP are sales at a nominal price. Id. § 1396r-8(c)(1)(C)(i)(III). Other examples of exemptions include sales to certain federal government entities, to State entities, to long-term care facilities, and sales outside of the United States. Id. § 1396r-8(c)(1)(C)(i) – (VI). The aim of excluding these sales is to increase AMP, and accordingly, the amount of the rebate manufacturers pay.

38 Id. § 1396r-8(c)(1)(C)(i).

39 Id.

40 Id.


42 See H.R. REP. NO. 102-384, pt. 2, at 11-13 (1992) (Conf. Rep.). According to the sponsors of the provision, raising drug prices adversely affects public hospitals that serve large numbers of low-income and uninsured patients. Id. The exemption of public hospitals, among others, from
centers, hospitals that serve a disproportionate share of low-income individuals, Indian Health Service facilities and other governmental entities, State pharmacy assistance programs, and the Medicare Part D program. As a practical matter, however, most manufacturers sell to these entities at the Medicaid price rather than providing a supplemental rebate or discount.

In addition to the base rebate (i.e., 15.1% of AMP or AMP minus the best price), manufacturers must pay an additional rebate if they raise their prices to State Medicaid agencies in an amount greater than the rate of inflation. Under the statute, the amount of the additional rebate is equal to the number of units of the drug sold to State Medicaid programs, multiplied by the AMP for the drug, less the AMP for the drug when it first went on the market trended forward by the consumer price index. Under this formula, then, any increase in price in excess of the rate of inflation is recaptured in rebates and must be paid over to State Medicaid agencies.

The Affordable Care Act makes significant changes to the statutory regime governing the drug rebate program. First, it increases the minimum rebate percentage, and in doing so, the Act alters the traditional shared financing arrangement applicable in the Medicaid program. Second, it modifies the definition of AMP. Third, it alters the calculation of the additional rebate attributable to price increases. Fourth, it expands the reach of the rebate program to capture additional drug sales. Each provision is described in greater detail below.

The law increases the minimum rebate percentage from 15.1% of the AMP to 23.1% of the AMP. In addition, and presumably in a response to the desperate need the “best price” calculation allows them to continue to provide health care to underserved populations. Id. 43 Social Security Act § 1927(c)(1)(C)(I) – (VI), 42 U.S.C. § 1396r-8(c)(1)(C)(I) – (VI) (2006). The list of entities excluded from the definition of “best price” demonstrates the inter-relationship of pharmacy reimbursement provisions throughout the Medicaid and Medicare programs. See infra text accompanying notes 78-99 (describing the section 340B program) and 100-123 (describing the Medicare Part D program).

45 See id. (describing formula).
46 See CONGRESSIONAL BUDGET OFFICE, PUB. NO. 4228, SELECTED CBO PUBLICATIONS RELATED TO HEALTH CARE LEGISLATION 2009-2010, 66-76 (2010), available at http://www.cbo.gov/ftpdocs/120xx/doc12033/12-23-SelectedHealthcarePublications.pdf. The office estimates that in 2019, the average nationwide value for benefits accumulated through rebates and other additional payments will be close to $67 per member per month. See id.
for revenue to demonstrate that the legislation was ostensibly fully paid for, the legislation alters the longstanding financing principles applicable in the Medicaid program. As noted, under the current drug rebate program, the federal government and States share manufacturer rebates in accordance with the federal medical assistance percentage otherwise applicable in the program. Under the Affordable Care Act, the federal government retains the entire amount of rebates attributable to the increase in the minimum rebate percentage. It is likely that States objected to this rather dramatic change in the Medicaid shared financing scheme.

In addition to the increase in the minimum rebate percentage, the Affordable Care Act also modifies the definition of AMP. Under the new definition, the concept of drugs distributed to the “retail pharmacy class of trade” is replaced with sales to “wholesalers for drugs distributed to retail community pharmacies,” as well as sales directly to “retail community pharmacies that purchase drugs directly from the manufacturer.” Recall that program regulations defined “retail pharmacy class of trade” as including sales to mail-order pharmacies. Thus, the new statutory definition for generic drugs is also increased, to thirteen percent. Patient Protection and Affordable Care Act of 2010 § 2501(b) (to be codified as amended at 42 U.S.C. § 1396r-8(c)(3)(B)(iii)).


See Patient Protection and Affordable Care Act of 2010 § 2501(a) (to be codified as amended at 42 U.S.C. § 1396r-8(b)(1)(C)(i)(II)) (reducing State payments by amounts “affected by” the Affordable Care Act changes). This “clawback” applies not only to the increase in the minimum rebate percentage as in this instance, but to other rebate changes as well. See infra text accompanying notes 51-66; Memorandum from Cindy Mann, Director of Centers for Medicare and Medicaid Services, CHIP, and Survey & Certification, to the State Medicaid Directors (Apr. 22, 2010), available at https://www.cms.gov/smdl/downloads/SMD10006.pdf (noting that the Federal Medicaid office plans to offset the non-Federal share of the difference between the rebate percentage in effect in December 2009 and the new rebate percentage in January 2010).

See generally N.C. Aizenman & Julie Appleby, Expansion of Medicaid, WASH. POST, Oct. 19, 2010, http://www.washingtonpost.com/wpdyn/content/article/2010/10/18/AR2010101804768.html (last visited Mar. 26, 2011). Manufacturers are likely to object as well, given that States may respond to the loss in revenue by demanding “supplemental” rebates from manufacturers. Depending on a manufacturer’s market power and desire for favorable formulary placement, it may be forced to grant the additional rebates if it wishes to maintain competitive in the state’s market. See generally Letter to Cindy Mann, Director of Centers for Medicare and Medicaid Services, CHIP, and Survey & Certification re. Rebates, NATIONAL ASSOCIATION OF STATE MEDICAID DIRECTORS (May 18, 2010), available at http://hsd.aphsa.org/home/doc/lettertoCMSRebates.pdf (voicing concern over the ACA recapture provision).


Id.

42 C.F.R. § 447.504(e)(2010); see supra note 34 (noting recent repeal of CMS’ regulation).
clearly excludes mail-order pharmacies from the definition. The effect of the new definition will be to raise the AMP, since the sales price of drugs to mail order pharmacies is generally lower than the sales price of drugs to retail pharmacies.

The Affordable Care Act also works to address a perceived abuse in the additional rebate calculation—that is, the additional rebate attributable to price increases. Recall that under current law, State Medicaid programs are protected against price increases that exceed the consumer price index (“CPI”) because any price increase in excess of that amount is recaptured by States as an additional rebate. Manufacturers arguably avoided paying this additional rebate by securing FDA approval of a new formulation of an existing drug (e.g., an extended-release form of an existing drug taken twice a day) and then charging a premium price for the new drug far in excess of the CPI-only price increase for the existing drug. The Affordable Care Act, however, moves to curtail this perceived abuse by imposing new rebate obligations on a “line

---


55 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 2503(a), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (to be codified as amended at 42 U.S.C. § 1395r-8(e)(5)) (defining use of AMP in upper payment limits). As a result, manufacturer rebates will increase because the minimum rebate amount will be 23.1% of a higher number or because the spread between the AMP and the best price will be greater. See id. At the same time, reimbursement to pharmacies will increase because the upper limit of Medicaid reimbursement to pharmacies is based off of a percentage of AMP. See id. Congress likely enacted the provision both to increase rebates from manufacturers, as well as to appease community pharmacies that had objected to the prior reimbursement regime. See Nat’l Ass’n of Chain Drug Stores v. Leavitt, 631 F. Supp. 2d 17, 28 (D.C. Cir. 2009) (order amending preliminary injunction). Recently the federal government and pharmacies agreed to dismiss the suit, likely in response to the enactment of the Affordable Care Act. See John Schultz, CMS’ New Take on AMP Rule Assessed by NACDS, CHAIN DRUG REV. Oct. 25, 2010, http://www.chaindrugreview.com/inside-this-issue/news/10-25-2010/cms-new-take-on-amp-rule-assessed-by-nacds (last visited Mar. 26, 2011).

56 Social Security Act § 1927(c)(2)(A), 42 U.S.C. § 1396r-8(e)(2)(A) (2006). The statute provides that the rebate will be increased by the product of (1) the total units of the dosage for which payments were made under the State plan and (2) the amount that the average manufacturers price for the dosage exceeds the average manufacturer’s price beginning in 1990 adjusted by the CPI. Id.

57 AMERICAN HEALTH CARE ASSOCIATION, Reed Smith Health Care Reform Review (Apr. 2010), available at http://www.ahcancal.org/advocacy/Documents/Reed%20Smith%20Health%20Care%20Reform%20Review.pdf. The review explains that because each product is unique for “purposes of the rebate statute, a new formulation of a product can effectively establish new launch period and reduce the amount of the ‘additional’ rebate” that manufacturers were required to pay. Id. at 14.
“line extension” of existing drugs.\textsuperscript{58}

Under the new provision, for any drug that is a “line extension” of a branded drug that is an oral solid dosage form, the applicable rebate is the greater of two amounts. The first amount is the rebate calculated under the existing rebate calculation.\textsuperscript{59} The second amount for a unit is the product of the AMP of the line extension and the additional rebate (i.e., rebates attributable to price increases in excess of the CPI), calculated as a percentage of the AMP of the reference product.\textsuperscript{60} In this way, the statute effectively ends the purportedly abusive practice of manufacturers escaping the additional rebate by re-formulating an existing drug.

The statute defines “line extension” as “a new formulation of the drug, such as an extended-release formulation.”\textsuperscript{61} Clearly, additional guidance is necessary given the relative vagueness of this definition. The Centers for Medicare & Medicaid Services (“CMS”), which regulates the rebate program, will likely issue either a State Medicaid Directors letter or perhaps a regulation further defining the term.\textsuperscript{62}

Finally, the Affordable Care Act expands the rebate to capture sales of drugs that are dispensed to Medicaid managed care enrollees.\textsuperscript{63} Since the inception of the rebate program in 1990, rebates have only been imposed with respect to drugs dispensed to Medicaid beneficiaries in traditional State Medicaid programs. Prior to the enactment of the Affordable Care Act, no rebates were imposed on drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care plans.\textsuperscript{64} As a practical matter, this


\textsuperscript{59} See id.


\textsuperscript{61} Id.

\textsuperscript{62} CMS has already issued guidance on the rebate changes. See Memorandum from Cindy Mann, supra note 49; Letter from Cindy Mann, Director, Centers for Medicaid and Medicare Services, to State Medicaid Directors (Apr. 22, 2010), available at http://www.cms.gov/smdl/downloads/SMD10006.pdf


\textsuperscript{64} Christopher Weaver, Federal Officials Confirm a Shift in Medicaid Drug Rebates, KAISER HEALTH NEWS (Apr. 22, 2010), http://www.kaiserhealthnews.org/Stories/2010/April/22/Medicaid-drug-rebates.aspx (last visited Mar. 26, 2011) (discussing federal government’s change in the Medicaid drug rebate program to include Medicaid managed care plans and its fiscal effect on both state governments and the federal government).
means drugs dispensed to elderly or disabled Medicaid beneficiaries were subject to rebates, while drugs dispensed to managed care enrollees, who were typically not elderly and not disabled, were not.\(^65\)

The Affordable Care Act eliminates this distinction. Effective with respect to drugs dispensed on or after the date of enactment of the Affordable Care Act, March 23, 2010, drugs dispensed to enrollees in Medicaid managed care plans are subject to all of the section 1927 rebate requirements.\(^66\) The enactment of this provision has raised concerns for manufacturers regarding liabilities for additional rebates.\(^67\) It is likely that Medicaid managed care plans were already, on their own initiative, imposing rebates for drugs dispensed to plan enrollees.\(^68\) It does not automatically follow, however, that now that States are imposing rebates on these same drugs, plans will forego rebate revenue. More likely is the possibility that manufacturers will now have to re-negotiate rebate agreements with Medicaid managed care plans to avoid paying double rebates for the same population of enrollees.\(^69\)

\(^{65}\) See id. Since 1997, States have been able to enroll Medicaid beneficiaries in managed care programs without obtaining approval of the Secretary of HHS. See Social Security Act § 1932(a)(1)(A)(i), 42 U.S.C. § 1396u-2(a)(1)(A)(i) (2006). However, children with special needs, elderly or disabled individuals, and Indians are exempt from this broad grant of permissive enrollment. See id. § 1396u-2(a)(2)(A), (B), (C). States must receive a waiver from HHS in order to enroll such individuals in managed care programs. Id. § 1315(a) (permitting the Secretary to waive otherwise-applicable requirements of the Medicaid program if doing so would “promot[e] the objectives” of Medicaid). Prior to 1997, States sought, and HHS frequently granted, waivers of the prohibition on managed care enrollment. See id. § 1396u-2(a)(2)(A), (B), (C).


\(^{67}\) See Report: Health Reform to Cut Pharma Revenues by $112 Billion Over 10 Years, 7 FDA NEWS DRUG DAILY BULLETIN 96 (May 17, 2010) (stating new rebates provided by health care law will reduce drug company profits); see also Allison Bell, PPACA: CBO Looks at Effects on Drugs, NAT’L UNDERWRITER CO., Nov. 4, 2010, at NEWS 11 (stating provisions in new health care law require drug manufacturers to offer new discounts and rebates). The article also suggests that manufacturers may have an incentive to raise drug prices to counteract the additional required discounts the new law calls for, thus creating a net raise in prices. See Bell, supra. Such a strategy would seem to be counter-productive, however, in light of the inflation penalty. See supra notes 44-46 and accompanying text.

\(^{68}\) See CHUCK MARR ET AL., SENATE FINANCE COMMITTEE HEALTH REFORM BILL IS FISCALLY RESPONSIBLE, CTR. ON BUDGET & POLICY PRIORITIES, 7 (Oct. 13, 2009), available at http://www.cbpp.org/files/9-16-09health.pdf (discussing the ability of managed care plans to negotiate discounted drug prices); THE LEWIN GROUP, EXTENDING THE FEDERAL DRUG REBATE PROGRAM TO MEDICAID MCOs: ANALYSIS OF IMPACTS 2 (May 29, 2003), available at http://www.communityplans.net/LinkClick.aspx?fileticket=Vl3ZKz5DBgM%3D&tabid=60&mid=686&forcedownload=true (explaining that at that time, Medicaid managed care organizations (“MCOs”) had to enter into separate negotiations with drug manufacturers to obtain rebates).

\(^{69}\) See id.
these negotiations, of course, depends on the manufacturer’s market power, product, and desire for favorable formulary placement.

These are the major changes the Affordable Care Act enacts to the Medicaid prescription drug rebate scheme: an increase in the minimum rebate percentage, a revised definition of AMP, a new rebate calculation for re-formulations of brand name drugs, and a new rebate on drugs dispensed to Medicaid managed care enrollees.70 Each provision increases the cost of doing business with government programs, so each manufacturer will have to evaluate its exposure in these markets.71 On the other hand, the Affordable Care Act will likely lead to significant new markets for brand name prescription drugs, and some might argue that the increased rebates are the price of accessing these new markets.72

B. Expansion of the Public Health Service Act Section 340B Program

Integrally related to the Medicaid prescription drug rebate program is the Public Health Service Act section 340B program, which favors certain entities with socially encouraged missions by allowing them to purchase drugs from manufacturers at the Medicaid price or cheaper.73 Participation in the 340B program is mandatory as a condition of a manufacturer’s drugs being covered in State Medicaid programs.74 Under the 340B program, a manufacturer must agree to sell “covered drugs” to “covered entities” for no more than the Medicaid price for the drug.75 The term “covered

---

70 See supra notes 33, 49, 64, 67 and accompanying text.
71 See supra notes 34, 37, 50, 54-56 and accompanying text.
75 Public Health Service Act § 340B(a)(1), 42 U.S.C. § 256b(a)(1). Manufacturers are protected from paying double rebates (i.e., granting section 340B pricing to a covered entity that will then
entity”—i.e., those entities that are able to purchase covered drugs at favorable prices—contained, prior to the enactment of the Affordable Care Act, twelve entities: (1) federally-qualified health centers; (2) patient navigator organizations; (3) family planning projects; (4) entities providing outpatient early intervention services for HIV disease (“Ryan White programs”); (5) AIDS Drug Assistance Programs (“ADAP”); (6) black lung clinics; (7) hemophilia diagnostic treatment centers; (8) Native Hawaiian Health Centers; (9) urban Indian organizations; (10) HIV health care services programs; (11) organizations providing treatment for sexually-transmitted diseases; and (12) certain disproportionate share hospitals. In addition, pediatric bill a State Medicaid plan for the drug. See id. § 256b(a)(3) (exempting drugs paid for by Medicaid from section 340B sales price requirement).

76 Id. § 256b(a)(4)(A). A “federally-qualified health center” is an entity that receives a grant under section 330 of the Public Health Service Act, while simultaneously receiving funding from such a grant under a contract with the recipient of such a grant, and as an entity, is not owned, controlled, or operated by another entity. See 42 U.S.C. §§ 1905(l)(2)(B), 1396d(l)(2)(B) (defining term).

77 Public Health Service Act, 42 U.S.C. § 256b(a)(4)(B). A patient navigator organization is an entity receiving a grant from the Health Resources and Services Administration under section 340A of the Public Health Service Act to improve health outcomes. See id. § 256a.


80 Public Health Service Act § 340B(a)(4)(E), 42 U.S.C. § 256b(a)(4)(E). A metropolitan area is eligible for an AIDS Drug Assistance Program if the Centers for Disease Control and Prevention has confirmed more than two thousand cases of AIDS during the last five years in that area. Id. § 300ff-11(a). An identified area will remain eligible for such a program until the area fails to meet the requirements as outlined for three consecutive fiscal years. Id. § 300ff-11(b).

81 Id. § 256b(a)(4)(F).

82 Id. § 256b(a)(4)(G).

83 Id. § 256b(a)(4)(H).


85 Id. § 256b(a)(4)(J).

86 Id. § 256b(a)(4)(K).

87 Id. § 256b(a)(4)(L). Hospitals that treat a “disproportionate number” of low-income individuals receive an add-on to their Medicare payments. See Social Security Act § 1886(d)(5)(F)(i)(I), 42 U.S.C. § 1395ww(d)(5)(F)(i)(I) (2006) (describing formula). Additionally, hospitals that are located in an urban area, have more than one hundred beds, and whose net
hospitals meeting a disproportionate share percentage threshold also qualify for the section 340B pricing. 88

The Affordable Care Act rather dramatically expanded the number of covered entities eligible to receive the section 340B pricing. In particular, the following new entities were added as covered entities: (1) pediatric hospitals and freestanding cancer hospitals meeting a disproportionate share percentage threshold; 89 (2) critical access hospitals that participate in the Medicaid program; 90 and (3) rural referral centers and sole community hospitals that participate in the Medicaid program and that meet a disproportionate share percentage threshold. 91 The Affordable Care Act changes resulted in a significant expansion of covered entities and liability for pharmaceutical

88 Social Security Act § 1927(a)(5)(B), 42 U.S.C. § 1396r-8(a)(5)(B). The disproportionate share percentage threshold is the same as for acute hospitals, as described in section 340B. See Public Health Service Act, 42 U.S.C. § 256b(a)(4)(L)(ii). Likely for jurisdictional reasons, Congress did not include pediatric hospitals as covered entities in the Public Health Service Act and amended the Social Security Act only, although, as will be discussed infra, this provision was modified in the Affordable Care Act.


90 See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (to be codified as amended at 42 U.S.C. § 256b(a)(4)(N)). The amended section will read, “(N) An entity that is a critical access hospital . . . .” Id.; see also Social Security Act § 1820(c)(2)(B)(i), 42 U.S.C. § 1395i-4(c)(2)(B)(i) (defining a critical access hospital as one that is located more than thirty-five land miles from another hospital or is designated by the State as being a necessary provider of services in a community).

91 See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (to be codified as amended at 42 U.S.C. § 256b(a)(4)(O)). The amended section will read, “(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (I)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.” Id.
manufacturers, due in large part to the potential inclusion of over one thousand critical access hospitals in the United States.\textsuperscript{92}

Congress imposed new compliance requirements on both manufacturers and covered entities because Congress was further concerned that there was little enforcement of compliance with the 340B program requirements.\textsuperscript{93} Nonetheless, one particular concern of manufacturers is that the legislation left unaddressed the fact that there is no prohibition on the entity’s ability to re-sell the drug to patients at a higher rate; whereas a covered entity must be able to purchase a drug at a favored price.\textsuperscript{94} For the first time, however, requirements for compliance, coupled with the possibility of civil monetary penalties for noncompliance, were included into the statute.

The Affordable Care Act provisions are the largest expansion of section 340B since the program’s creation in 1990. Although this expansion is potentially negative for manufacturers, on the positive side, the new law creates some new markets for covered entities, including critical access hospitals. In addition, it creates some new markets for

\textsuperscript{92} See \textit{DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF PHARMACY AFFAIRS, GROWTH OF 340B COVERED ENTITY SITES FROM 01/1998 TO PRESENT}, http://opanet.hrsa.gov/opa/Report/StatisticalReport.aspx (last visited Mar. 26, 2011) (noting that there are approximately 13,000 section 340B covered entities); see generally Thomas C. Fox, \textit{HEALTH CARE FIN’L TRANSACTIONS MANUAL}, § 21:57.5 (2010) (describing generally how the health care reform act impacts various entities in health care). Fox briefly explains in section 21 how the section 340B drug discount program has been expanded to include a number of new covered entities, including critical access hospitals. \textit{Id.} Not all critical access hospitals will qualify as covered entities, but it is likely that at least several hundred will. See \textit{DEPARTMENT OF HEALTH AND HUMAN SERVICES, supra}.\textsuperscript{93} See \textit{Public Health Service Act} § 340B(d)(1), (2), 42 U.S.C. § 256b(d)(1), (2) (2006). Fines for pharmaceutical manufacturers may be up to $5000 for each instance of overcharging a covered entity. \textit{Id.} § 256b(d)(1)(B)(vi)(II). Any abuse of compliance by a covered entity may include paying the manufacturer interest on the sum of improper payments induced by the covered entity, as well as the Secretary having the power to remove the covered entity from the drug discount program for whatever time period the Secretary deems necessary. \textit{Id.} § 256b(d)(2)(B)(v)(I), (II). The compliance guidelines are generally based on regular reporting requirements, as well as periodic audits to ensure compliance with the regulations. \textit{Id.} § 256b(d)(2)(B)(i)-(iv). The Secretary’s authority to audit covered entities is found in section 340B(a)(5)(D) of the Act, which is codified at 42 U.S.C. § 256b(a)(5)(D), and the Act references that authority in section 340B(d)(3)(A), codified at 42 U.S.C. § 256b(d)(3)(A). \textit{Id.} §§ 256b(a)(5)(D), 256b(d)(3)(A).\textsuperscript{94} See \textit{Public Health Service Act} § 340B(a)(5)(B), 42 U.S.C. § 256b(a)(5)(B) (prohibiting re-sale of drugs to individuals who are not patients of the covered entity). The statute clearly permits re-sales to patients; however, for patients, presumably those most in need of the protection of section 340B, pricing is not protected from price gouging by covered entities. \textit{Id.} However, an auditing mechanism exists that allows the Secretary and the manufacturer to request a review of the covered entity’s records pertaining to compliance with the requirements described in subparagraphs (A) and (B) with respect to the covered drugs. See \textit{id.} § 256b(a)(5)(C).
manufacturers.

IV. Medicare Part D

Perhaps the most significant health care legislation enacted during the Administration of President George W. Bush was the Medicare Prescription Drug Program, codified at Part D of title XVIII of the Social Security Act. Part D adds a prescription drug benefit to the Medicare program, and it became effective on January 1, 2006. Part D is unlike the rest of the Medicare program in the sense that the only way for a Medicare beneficiary to access the benefit is through a private health insurance plan; there is no “government-run” Medicare Part D.

Part D plans are thus required to offer enrollees coverage that meets a standard benefit design, although plans may offer actuarially equivalent coverage. The standard benefit design also contains a “coverage gap” in which Medicare beneficiaries with high drug expenditures are fully exposed to the cost of covered Part D drugs after the plan has incurred a specified level of coverage for Part D drugs, referenced in the statute as the initial coverage limit. Once reaching the initial coverage limit, Part D enrollees must incur a total of $3,600 in true out-of-pocket spending before qualifying for catastrophic coverage. The beneficiary must incur the costs herself; generally, payments by insurers or other individuals do not count as true out-of-pocket spending. However, once beneficiaries make it through the coverage gap and begin catastrophic coverage, their cost sharing is very low.

---

96 Id. § 1395w-101(a)(2). Prior to the enactment of Part D, Medicare only paid for prescription drugs that were administered incident to a physician’s service and that were not usually self-administered. Id. § 1395x(s)(2)(A) (defining “medical and other health services”). Prior to Part D, Medicare also covered prescription drugs in other rare instances, such as prescription drugs used in immunosuppressive therapy and erythropoiesis stimulating agents for dialysis patients. Id. §§ 1395x(s)(2)(J), § 1395x(s)(2)(O). But until the enactment of Part D, normal prescription drug maintenance therapy, such as hypertension medication, was not covered.
97 See Social Security Act § 1860D-1(a)(1)(A), (B), 42 U.S.C. § 1395w-101(a)(1)(A), (B) (providing that Part D benefits are only available through prescription drug plans or a Medicare Advantage plan).
98 Id. § 1395w-102(a)(1)(A), (B).
99 Id. § 1395w-102(b)(3).
100 Id. § 1395w-102(b)(4)(B)(i)(I). The $3,600 level is for 2006 and increases each year for inflation. Id. § 1395w-102(b)(4)(B)(i)(II).
102 Id. § 1395w-102(b)(4)(A). The beneficiaries pay the greater of two specified values, either “a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug . . . and $5
The Affordable Care Act phases out the Part D coverage gap in two ways so that by Plan Year 2021, standard Part D cost sharing for beneficiaries will only be twenty-five percent throughout the entire benefit design. Under the first component of the coverage gap elimination, manufacturers of covered Part D drugs that wish to have their drugs covered under Part D must participate in the coverage gap discount program. Under this program, manufacturers must agree to provide discounts to Part D enrollees for the manufacturer’s covered Part D drugs. The discounts are to be provided at the point of sale. Under the statute, the discount must equal fifty percent of the “negotiated price” of the drug. The manufacturer's discount will count as true for any other drug or . . . coinsurance that is equal to 5 percent.” Id. These amounts are indexed for inflation.

---


105 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 3301(b), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (to be codified as amended at 42 U.S.C. § 1395w-114a(b)(1)(B)) (imposing requirement that beneficiaries receive applicable drugs for discounted price at point of sale). CMS has described this requirement in greater detail so that its operation is seamless to Part D enrollees. See Memorandum, CMS, Medicare Coverage Gap Discount Program beginning in 2011, § 30.1 (Apr. 30, 2010), available at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_043010.pdf. When a Part D enrollee shows up at a pharmacy counter, the pharmacist will have sufficient information to adjudicate the discount at that point. See id. The beneficiary will pay any cost sharing that remains after the discount, the Part D plan reimburses the pharmacy, and the manufacturer reimburses the Part D plan for the amount of the discount. See id. §§ 30.2, 30.3. According to CMS, this approach was chosen because of all parties to the transaction, only the Part D sponsor has all the necessary data elements to process the discount. See id. § 30.

out-of-pocket spending for the Part D enrollee. In addition, the statute makes clear that the discounts are permissible under the federal anti-kickback statute. Finally, the price of the drug after applying the discount does not count toward a manufacturer’s “best price” under the Medicaid drug rebate program.

Under the second component of the coverage gap elimination, the federal government subsidy to Part D plans gradually increases over the next ten years so that by 2020, beneficiaries are only liable for twenty-five percent coinsurance until reaching catastrophic coverage. Under the new benefit design, therefore, cost sharing during the coverage gap will be applied in accordance with the following table:

---

108 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 3301(c), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (to be codified as amended at 42 U.S.C. § 1395w-102(b)(4)(E)). This provision, of course, helps the Part D enrollee exit the coverage gap in half the time that it would have otherwise taken. Id.

109 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 3301(d)(1), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (to be codified as amended at 42 U.S.C. § 1320a-7b(b)(3)(j)). Assuming the requisite intent, the federal anti-kickback statute makes it a crime for any entity to provide an inducement, in cash or in kind, for an enrollee in a Federal health care program to choose a particular item or service that may be reimbursed under the program. Social Security Act § 1128B(b)(1)(A), 42 U.S.C. § 1320a-7b(b)(1)(A) (2006). Absent the inclusion of the new language in the Affordable Care Act, one could construe the granting of the discount as a prohibited inducement subjecting the manufacturer to criminal liability. See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL ADVISORY OPINION 06-04 (Apr. 20, 2006) (finding that a pharmaceutical manufacturer’s grant of financial assistance to Part D enrollees for Part D cost sharing could potentially generate prohibited remuneration under the anti-kickback statute); see also ADVISORY OPINION 06-09 (Aug. 25, 2006) (similar conclusion for program assisting patients with kidney disease); ADVISORY OPINION 06-13 (Sept. 25, 2006) (similar conclusion for program assisting patients with kidney disease); ADVISORY OPINION 06-03 (Apr. 18, 2006) (same, even where charity is dispensing free drugs rather than financial assistance). In all cases, the Inspector General announces that it will not impose civil monetary penalties because of the structure of the financial assistance program. See ADVISORY OPINION 06-04, 06-09, 06-13, 06-03, supra.


The new benefit design, when fully phased in, is a significant shift in financial liability away from Part D enrollees to the federal government and to pharmaceutical manufacturers.

112 See Social Security Act § 1860D-15(e)(3)(C)(i)(III), 42 U.S.C. § 1395w-115(e)(3)(C)(i)(III). A more accurate description is that the federal government bears this obligation, since the Part D plan obligation is paid for it by the subsidy payment to Part D plans. See id. § 1395w-115(a)(1)(A) (providing that the federal government payment to a plan is equal to its bid for basic prescription drug coverage). The Secretary will provide a subsidy payment to PDP sponsors that offer MA-PD plans in accordance with the subsidies in section 1395w-115. See id. §1395w-115(a). The goals of this subsidy are to reduce premium levels for qualified part D drug coverage individuals, to reduce adverse selection among prescription drug plans, and to promote participation of PDP sponsors in this section. See id.


V. Conclusion

The Affordable Care Act, most notable in the popular press for the Act’s re-structuring of the American health care system, contains provisions of significant interest to the life sciences industry. These include the new assessment on pharmaceutical manufacturers and medical device manufacturers, revisions to the Medicaid prescription drug rebate program, the expansion of the Public Health Service Act section 340B program, and adjustments to the Medicare Part D prescription drug benefit. These changes create both challenges and strategic business opportunities for pharmaceutical manufacturers.