Implementing Health Care Reform: Key Provisions Affecting the Pharmaceutical Industry

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The Affordable Care Act (also referred to as the "ACA") was enacted earlier this year culminating over a year of intense political negotiations, legislative drafting, and numerous Congressional hearings over whether, and how, to comprehensively reform the U.S. health care system. The ACA is made up of two pieces of legislation – the Patient Protection and Affordable Care Act, or "PPACA," Pub. L. No. 111-148, which President Obama signed on March 23, 2010, and the Health Care and Education Reconciliation Act, or "HCERA," Pub. L. 111-152, which President Obama signed on March 30, 2010.

This issue of the Health Law Reporter describes some of the sweeping changes the ACA makes to the way in which health care will be accessed, delivered, and paid for in the United States. The ACA has a broad reach, which will affect most Americans, as well as many, if not all, sectors of the U.S. health care system including health care providers, health insurers, and biomedical companies such as pharmaceutical and device manufacturers. While the law has been written, many details are yet to be decided upon as the departments and agencies—in particular, the Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS", or "Agency") and the Food and Drug Administration (FDA) —begin their work of implementing the law.

This article will focus on four aspects of the ACA that will significantly impact the biomedical and pharmaceutical industries. The sections below address, in turn, the issues of: closing the Part D coverage gap, expanding Medicaid drug rebates, expanding the Public Health Service Act Section 340B program, and creating an approval pathway for follow-on biologics.

The Part D Coverage Gap

The standard Part D benefit design contains a "gap" in coverage during which a Medicare beneficiary enrolled in Part D is fully liable for her prescription drug costs. Social Security Act § 1860D-2(b)(3)(A), 42 U.S.C. § 1395w-102(b)(3)(A). In plan year 2010, the coverage gap, or "donut hole," occurs for a beneficiary after she has incurred $2,830 in Part D prescription drug spending (split between the enrollee and the plan) and until the beneficiary incurs an additional $4,550 in true out-of-pocket (TrOOP) Part D spending (for a total generally equivalent to $6,440 in covered spending for covered Part D drugs under the plan).[1] Once the beneficiary has incurred the requisite amount of TrOOP costs, the beneficiary's "catastrophic coverage" begins wherein Medicare pays 95% of the cost and the beneficiary is responsible for the other 5%.[2]

Under the new law, which establishes the Medicare Coverage Gap Discount Program ("Coverage Gap Program"), in order for a pharmaceutical manufacturer's brand name drug, and in some cases, authorized generic drug, to be covered under Part D, the manufacturer must enter into an agreement with CMS stating that it will provide beneficiaries a 50% discount off of the negotiated price of the drug at the point of sale. Social Security Act § 1860D-14A(b)(1)(B). The 50% discount is treated as TrOOP spending for purposes of determining the level of the beneficiary's incurred costs.[3] *Id.* at § 1860D-2(b)(4)(E). The pharmacy will charge a Part D plan 50% of the negotiated price and the beneficiary the remaining 50%. The manufacturer will then be required to reimburse the Part D plan, generally within 38 days of receiving the invoice.[4]

In addition, beginning in 2011, the ACA gradually reduces the remaining 50% beneficiary coinsurance while the beneficiary is in the coverage gap. Thus, between the Coverage Gap Program described above and the reduction in coinsurance, the beneficiary's share for an applicable Part D drug while in the coverage gap will phase down to 25% by 2021.[5] At that point, the beneficiary's Part D coinsurance between the initial coverage limit and the catastrophic limit will be the same as it was before the initial coverage limit was reached under the standard Part D benefit design.

As with many aspects of the ACA, the Coverage Gap Program provi-

sions must be implemented by CMS. CMS began this process with initial guidance issued on April 30, 2010 explaining how the Agency plans to implement the new program.[6] The Agency received and considered public comments submitted to its initial guidance, and then issued a revised guidance on May 21, 2010 that included a draft Model Agreement which drug manufacturers will be required to enter into beginning January 1, 2011 for their applicable Part D drug to be covered by the Medicare Part D program.[7] On August 2, 2010 CMS issued the finalized model Manufacturer Agreement that prescription drug manufacturers must enter into by September 2010.[8] The CMS guidance and Model Agreement include key dates and requirements for manufacturers and Part D Plans, and describe critical aspects of the Coverage Gap Program such as how prescription drug event (PDE) data will be used to generate an invoice to be sent to the manufacturer from the CMS third party administrator (TPA) administering the Coverage Gap Program.

Changes to the Medicaid Drug Rebate

Under current law, pharmaceutical manufacturers of "covered outpatient drugs" are required to enter into and have in effect an agreement with the Secretary of HHS ("Secretary") to provide a rebate as a condition of coverage of those drugs under a State Medicaid program or under Medicare Part B. Social Security Act § 1927(a)(1), 42 U.S.C. § 1395r-8(a)(1). Prior to the ACA, the "basic" rebate for innovator pharmaceutical products was calculated as the greater of: (1) 15.1% of the average manufacturer price (AMP) of the drug (also referred to as the "minimum rebate percentage"), or (2) the difference between the AMP for the drug, and the "best price" of the drug. *Id.* at subsection (c)(1). In addition to this basic rebate, a manufacturer must also provide an "additional" rebate to the extent that the price of its drug exceeds the increase in the consumer price index for urban consumers. *Id.* at subsection (c)(2)(A). Manufacturers must provide information about the AMP and best price to CMS.

The ACA makes several changes to the Medicaid drug rebate program. First, with respect to the basic rebate, the ACA increases the minimum rebate percentage for most branded pharmaceuticals from 15.1% to 23.1% of AMP.[9] Social Security Act § 1927(c)(1)(B). Further, the ACA provides that any increases in rebates attributable to the changes in minimum rebate percentage described above, taking into account the rebate extension to Medicaid managed care organizations (MCOs) and with respect to new formulations described below, are payable entirely to the federal government and not shared with the States under the usual FMAP principles that apply in Medicaid. *Id.* at subsection (b)(1)(C). The ACA provides, and CMS' guidance issued to State Medicaid Directors on April 22, 2010 further explains, that the federal government will apply this policy by offsetting Federal Medical Assistance Program (FMAP) payments to States by the increases in the amount of rebates the States receive as a result of the new policy.[10] *Id.* at clause (ii).

Second, the ACA applies the rebate requirement to "line extensions" of an existing single source drug or an innovator multiple source drug that is an oral solid dosage form. Social Security Act § 1927(c)(2)(C). The ACA provides that a drug is a "line extension" if it is a new formulation of the drug, such as an extended release formulation.[11] *Id.* Under the ACA, a drug that is a "line extension" of an innovator drug that is an oral solid dosage form is now subject to a rebate, which is calculated as the greater of: (1) the amount calculated under section 1927 of the Social Security Act for the new drug, or (2) the product of: (i) the AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, (ii) the highest additional rebate (calculated as a percentage of AMP) for any strength of the reference brand name drug, and (iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).[12] *Id.*

Third, the ACA applies the rebate to drugs dispensed to enrollees in Medicaid MCOs. Social Security Act § 1903(m)(2)(A)(xiii). Prior to the enactment of the ACA, rebates were only paid with respect to prescription drugs dispensed to enrollees in fee-for-service (FFS) Medicaid. The ACA mandates that State contracts with MCOs require that covered outpatient drugs dispensed to managed care enrollees are "subject to the same rebate required by the agreement entered into" with the manufacturer for prescription drugs dispensed to enrollees in FFS Medicaid. *Id.* Thus, regardless of whether the manufacturer is paying the rebate based upon the minimum rebate percentage or the difference between AMP and best price, that rebate must also be paid by the manufacturer to the State under the Medicaid drug rebate program for drugs dispensed to enrollees in Medicaid MCOs. It is notable that, since the legislation does not specify an effective date for extending the drug rebate

to Medicaid MCOs, this provision is effective upon enactment, March 23, 2010. This appears to require pharmaceutical manufacturers to re-negotiate their contracts with Medicaid MCOs in order to meet the new statutory requirement.

Further, many pharmaceutical manufacturers currently have private contracts with Medicaid MCOs whereby the manufacturer provides a rebate to the Medicaid MCO with respect to both the Medicaid and commercial lives enrolled in the plan, and which has been privately negotiated between the parties. The ACA does not address these private contracts. Rather, whether a manufacturer will have to continue to pay such a rebate to the Medicaid MCO – in addition to the new rebate required under the ACA – under a privately negotiated contract will depend on the contract and negotiations between the pharmaceutical manufacturer and Medicaid MCO. Thus, regardless of the result of these private negotiations, a pharmaceutical manufacturer will be liable to the State for the full Medicaid drug rebate, as expanded in the ACA. CMS is expected to issue further guidance on the MCO provision.

Fourth, the ACA revises the definition of "average manufacturer price" (AMP).[13] Social Security Act § 1927(k)(1). It is important to note that since the enactment of the ACA in March 2010, Congress has again made changes to the calculation of AMP.[14] Specifically, in legislation that was signed into law by the President on August 10, 2010, Congress amended the ACA to require that Medicaid rebates will be collected from prescription drug manufacturers of inhalation, infusion, instilled, implanted, or injectable drugs that are not generally sold at retail pharmacies.[15] The AMP definition affects the Medicaid drug rebate requirement because a rebate, as stated above, is determined by either one of the following two calculations: (1) 23.1% of AMP, or (2) AMP minus "best price"– whichever is larger. The new definition of AMP – because it will tend to raise the AMP of a pharmaceutical product – will result in increased rebates paid by manufacturers.

Expansion of 340B Program

The 340B Drug Pricing Program ("340B program"), provides that "covered entities" that purchase "covered outpatient drugs" (any drug used in the outpatient setting, excluding vaccines) receive discounted prices for such covered outpatient drugs."[16] Public Health Service Act § 340B, 42 U.S.C. § 256b.

The ACA makes two main changes to the 340B program: (1) it expands the definition of a "covered entity," and (2) it adds new program integrity requirements for pharmaceutical manufacturers and 340B covered entities. Notably, the ACA does not include an expansion of the 340B program to covered drugs provided to inpatients. An earlier version of PPACA proposed to expand the 340B program to inpatients, but this provision was deleted in HCERA. That said, Congress may make further changes to the 340B program through future legislation.[17]

With respect to the definition of a "covered entity," which currently refers to certain socially favored health care providers, such as community health centers, disproportionate share hospitals, and AIDS drug assistance programs,[18] the ACA adds the following new "covered entities": pediatric hospitals that are excluded from the Medicare inpatient prospective payment system (IPPS) and that would have had a disproportionate share adjustment percentage of greater than 11.75% ("DSH threshold") if they were subject to the IPPS, cancer hospitals that are excluded from the Medicare IPPS and that meet the 11.75% DSH threshold, rural referral centers that have a disproportionate share adjustment percentage equal to or greater than 8%, critical access hospitals that treat Medicaid patients, and sole community hospitals that have a disproportionate share adjustment percentage equal to or greater than 8%. Public Health Service Act § 340B(a)(4).

With respect to program integrity, the ACA added requirements for both pharmaceutical manufacturers and covered entities aimed to strengthen the 340B program by increasing the Secretary's oversight of manufacturers and covered entities. *Id.* at paragraph (d). The ACA also establishes a dispute resolution process for administratively handling disputed claims. *Id.*

Follow-On Biologics

Prior to the enactment of health care reform, there was no FDA approval pathway for "follow-on" biologics (FOBs) as there is for generic small molecule drugs. The ACA amends the Public Health Service Act to create a new regulatory pathway for FDA approval of FOBs – products that are "biosimilar" to a reference product that is approved by the FDA under a biological license application (BLA).[19] Public Health Service Act § 351(k). To do so, the ACA creates a new abbreviated biological product application (aBPA) for "biosimilar" biological products, and requires the Secretary to grant an aBPA if she determines that the product is "biosimilar" to the reference product and that the FOB

has made the requisite clinical and safety showings. *Id.*

Further, the ACA provides for 12 years of data exclusivity for the innovator product. *Id.* at subsection (k)(7). Thus, under the ACA, the FDA cannot approve a biosimilar product until 12 years after the BLA for the reference product was approved. Regarding the first approved interchangeable FOB for a reference product, the ACA provides one year of exclusivity. *Id.* at subsection (k)(6).

The ACA includes a number of other provisions related to the follow-on biologics approval pathway, for example, applying the risk evaluation and mitigation strategies (REMS) requirement to FOBs. *Id.* at subsection (k)(5)(C). It also leaves open issues that must be worked out in the implementation phase, such as the handling of the application and information that could have implications in patent infringement cases. *Id.* at subsection (l). Another issue to be addressed in implementation is the development of user fees for biosimilar biologic products. The ACA provides for a public process with all stakeholders, including industry, scientific and academic experts, Congress, patient representatives and health care professionals, to develop appropriate user fees and FDA performance and safety goals for FOBs, to be implemented October 1, 2012. *See* ACA, § 7002(f). The public process must be started no later than October 1, 2010. The statute also provides for data collection on the cost of reviewing aBPA applications from the date of enactment through October 1, 2010. *Id.*

In addition to creating the approval pathway for FOBs, the ACA provides for a separate billing code for Part B biosimilar products, and mandates that reimbursement for biosimilar products covered under Medicare Part B is 100% ASP of the biosimilar product plus 6% of the ASP for the reference product. Social Security Act § 1847A(b)(1).

Conclusion

The ACA includes numerous provisions that must be implemented through regulatory or subregulatory guidance by federal departments and agencies, in particular HHS and CMS. The implementation process for some provisions has already begun and for all provisions the process will unfold and expand over the next several years. Stakeholders should pay close attention to the statutory deadlines as well as departmental and agency actions for developments that will impact their industries.

Endnotes

1 Under the statute, only spending incurred by the beneficiary "or by any other person, such as a family member, on behalf of the individual" counts as incurred costs. Social Security Act § 1860D-2(b)(4)(C)(ii). CMS regulations interpret the phrase "any other person" as including a family member, a bona-fide charity, and a State pharmacy assistance program. *See* definition of "incurred costs" at 42 C.F.R. § 423.100. *See also* discussion at 70 Fed. Reg. 4193, 4239 (Jan. 28, 2005).

2 These dollar amounts are indexed each year for inflation. Social Security Act § 1860D-2(b)(3)(A)(ii).

3 Spending by AIDS drug assistance programs and by the Indian Health Service are also treated as incurred costs. Social Security Act § 1860D-2(b)(4)(C)(iii)(III) and (IV).

4 CMS Medicare Coverage Gap Discount Program Manufacturer's Agreement, available at http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf; see also, CMS, Center for Medicare, Memorandum to All Part D Sponsors, "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" (May 21, 2010), *available at* http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised%20Guidance%20052110.pdf.

5 *See* Social Security Act, § 1860D-14A (implementing 50% discount in PPACA) and § 1860D-43 (phasing out the coverage gap).

6 CMS, Center for Medicare, Memorandum to All Part D Sponsors, "Medicare Coverage Gap Discount Program beginning in 2011" (April 30, 2010), *available at* http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_043010.pdf.

7 CMS, Center for Medicare, Memorandum to All Part D Sponsors, "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" (May 21, 2010), *available at* http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised%20Guidance%20052110.pdf; Medicare Program; Medicare Coverage Gap Discount Program Model Manufacturer Agreement and Announcement of the June 1, 2010 Public Meeting, 75 Fed. Reg. 29555 (May 26, 2010), available at http://edocket.access.gpo.gov/2010/pdf/2010-12559.pdf.

8 CMS Medicare Coverage Gap Discount Program Manufacturer's Agreement, available at http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf.

9 The minimum rebate percentage for clotting factors and outpatient drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications only increases to 17.1% of AMP. CMS will issue further guidance on the process it will use to identify clotting factors and drugs with pediatric indications. *See* CMS, Center for Medicaid, CHIP, and Survey & Certification, Memorandum to State Medicaid Directors (April 22, 2010), *available at* https://www.cms.gov/smdl/downloads/SMD10006.pdf.

10 CMS, Center for Medicaid, CHIP, and Survey & Certification, Memorandum to State Medicaid Directors (April 22, 2010), *available at* https://www.cms.gov/smdl/downloads/SMD10006.pdf.

11 CMS is expected to issue further guidance on the process that will be used to identify "line extensions" of existing drugs.

12 See also CMS, Center for Medicaid, CHIP, and Survey & Certification, Letter to State Medicaid Directors, Re: Medicaid Prescription Drug Rebates (April 22, 2010), available at http://www.cms.gov/Reimbursement/08_MedicaidPrescriptionDrugsundertheAffordableCareAct.asp#TopOfPage.

13 The new definition of AMP enacted in the ACA includes in the calculation of AMP the average price paid by wholesalers to manufacturers of the drug with respect to drugs distributed to retail pharmacies, which in effect, removes mail order sales from the calculation of AMP. In addition, the legislation includes in the calculation of AMP the average price paid by retail pharmacies that purchase covered outpatient drugs directly from the manufacturer; and excludes from the calculation of AMP prompt pay discounts extended to wholesalers, bona fide service fees paid by manufacturers to wholesalers or community pharmacies, reimbursement or other charges for damaged drugs, and payments or rebates to non-retail pharmacies, including HMOs, PBMs, mail order pharmacies, and other entities.

14 The Aviation Safety and Investment Act of 2010 (also referred to as the "Education Jobs and Medicaid Funding bill"), H.R. 1586, enacted on August 10, 2010 as Pub. L. 111-226.

15 See Colloquy on Medicaid Pharmacy Reimbursement, H.R. 1586, § 202, between Senate Majority Leader Reid, Senator Lincoln and Senator Murray (Aug. 4, 2010),
Enacted in the Veterans Health Care Act of 1992, Pub. L. 102-585.

16 The American Jobs and Closing Tax Loopholes Act of 2010, H.R. 4213, 111th Cong. (2010), includes an expansion of the 340B program to include drugs dispensed to hospital inpatients who do not have insurance. The House of Representatives passed H.R. 4213 on May 28, 2010 with a vote of 245 – 171. At the time of this article's writing, the Senate had not yet voted on this legislation.

17 See Public Health Service Act § 340B(a)(4) (describing "covered entities.").

18 The statute defines a "biosimilar" product as a product that is "highly similar" to the reference product "notwithstanding minor difference in clinically inactive components," and for which there are "no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product." Public Health Service Act § 351 (k)(2)(i).