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E-ALERT | Health Care

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HEALTH CARE REFORM: MEDICARE PART D DONUT HOLE AND PROTECTED CLASSES

On March 23, 2010, President Obama signed into law Pub. L. No. 111-148, the Patient Protection and Affordable Care Act (PPACA). Shortly afterwards, on March 30, 2010, President Obama signed into law Pub. L. No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010 (the Reconciliation Amendments), amending PPACA. PPACA, as now amended by the Reconciliation Amendments (collectively the Act), will have far-reaching effects for the entire health care sector.

This alert, part of a series explaining the impact of the Act on life sciences companies, will summarize the provisions of the Act relating to: (1) the coverage gap, or "donut hole," under Medicare Part D, and (2) protected classes of drugs under Part D. These provisions can be found in sections 3301, 3307, and 3314 of PPACA and section 1101 of the Reconciliation Amendments.

Executive Summary

- The Act authorizes the Centers for Medicare & Medicaid Services (CMS) to provide a $250 rebate to Medicare Part D beneficiaries who enter the donut hole in 2010.
- Beginning in 2011, the Act will phase out the coverage gap by gradually reducing the coinsurance for brand name and generic drugs purchased in the donut hole until it reaches 25% by 2020.
- The Act directs CMS to promulgate regulations that establish criteria for identifying protected categories and classes of drugs "of clinical concern." Every drug in such a category or class must be included on Part D formularies unless CMS makes a specific exception.
- Until CMS establishes such criteria, prescription drug plans (PDPs) and Medicare Advantage plans with prescription drug benefits (MA-PDs) must continue to provide coverage for all drugs in the following classes: (1) anticonvulsants; (2) antidepressants; (3) antineoplastics; (4) antipsychotics; (5) antiretrovirals; and (6) immunosuppresants for the treatment of transplant rejection.

Closing the Medicare Part D Donut Hole

The donut hole refers to the gap in coverage after a beneficiary's spending exceeds the initial coverage limit ($2,830 for 2010), but before the beneficiary has incurred sufficient "true out-of pocket" (TrOOP) costs to qualify for catastrophic coverage ($4,550 for 2010).

- COVERAGE GAP REBATE IN 2010. The Act authorizes CMS to provide a single payment of $250 directly to any Medicare Part D beneficiary who enters the donut hole in any quarter in 2010. CMS must pay the rebate by the 15th day of the third month following the end of the quarter in which the beneficiary enters the donut hole.

- **CLOSING THE COVERAGE GAP BY 2020.** Beginning in 2011, the Act will phase out the donut hole by gradually reducing the amount of beneficiary cost sharing for brand name and generic drugs purchased in the coverage gap until such cost sharing reaches 25% by 2020. This closing of the donut hole will be partially financed by the creation of a new Medicare coverage gap discount program (the Discount Program) under which manufacturers will agree, as a condition of participation in Medicare Part D, to provide a 50% discount off the negotiated price of brand name drugs (excluding dispensing fees) while a beneficiary is in the donut hole. Discounts on generic drugs will be paid for by the federal government.
  - *Brand name drugs.* Beginning in 2011, beneficiaries in the donut hole will receive a 50% discount on brand name drugs. In 2013, the federal government will begin to further subsidize the cost of brand name drugs, providing an additional 2.5% discount in 2013 and 2014; 5% discount in 2015 and 2016; 10% discount in 2017; 15% discount in 2018; 20% discount in 2019; and 25% discount in 2020 and beyond. By 2020, the combined discounts from manufacturers and the government will amount to 75%. Beneficiaries will be responsible for the remaining 25% -- the same amount of cost sharing as in the initial coverage phase.
  - *Generic drugs.* In 2011, the federal government will begin to subsidize the cost of generic drugs purchased in the donut hole by providing a 7% subsidy. (In other words, in 2011, the maximum amount of coinsurance in the donut hole will be 93%.) The government will cover an additional 7% in subsidies each year until, in 2020 and beyond, the subsidy will reach 75% of the cost of the drug. As with brand name drugs, the beneficiary will be responsible for the remaining 25% of the cost of the drug.
- **INCLUSION OF DRUGS FROM MANUFACTURERS NOT PARTICIPATING IN THE DISCOUNT PROGRAM.** Under the Act, there is an exception to the rule requiring manufacturers to participate in the Discount Program as a condition of receiving coverage for their drugs under Part D if: (1) CMS has made a determination that the availability of the drug is essential to the health of Part D beneficiaries; or (2) CMS determines that, in the period beginning on January 1, 2011 and ending on December 31, 2011, there were extenuating circumstances.
- **DISCOUNT AGREEMENTS.** Within 180 days of enactment, the Act requires CMS, in consultation with manufacturers, to establish a model agreement for use under the Discount Program. Manufacturers who participate in Part D, in turn, must enter into agreements with CMS within 30 days of release of the model agreement (210 days after enactment). Each manufacturer with an agreement in effect under the Discount Program must collect and have available data that will demonstrate compliance with Discount Program requirements. Agreements will be effective for an initial period of at least 18 months and will be automatically renewed for a period of at least one year, unless terminated by CMS or the manufacturer.
- **PROVISION OF THE DISCOUNT.** The Act provides that beneficiaries will receive the benefit of the drug discount at the pharmacy or mail order service point-of-sale, and throughout the entire coverage gap. Manufacturers must pay the discount no later than 14 days after the date of dispensing a discounted drug. When the entire amount of the negotiated price for an applicable drug does not fall within the coverage gap, the manufacturer may provide the discounted price on only the portion that falls within the gap. And, where a beneficiary has supplemental benefits with respect to drugs under a PDP or MA-PD, the beneficiary will not receive a discounted price under the Discount Program until after the supplemental benefits have been applied to the drug.
- **EFFECT ON TROOP COSTS.** The Act provides that the manufacturer discount will count as an "incurred cost" for purposes of the TrOOP threshold for determining access to catastrophic coverage; however, the federal subsidies will not count for such purposes. In addition, the Act provides that costs for drugs paid for by a state Pharmaceutical Assistance Program, an AIDS

Drug Assistance Program, or the Indian Health Service are to be treated as incurred costs for purposes of the TrOOP threshold.

- **DISCOUNT ADMINISTRATION.** CMS is required, under the Act, to enter into a contract with one or more third parties to administer CMS's requirements for carrying out the Discount Program. The contract must require the third party to: (1) receive and transmit information among CMS, manufacturers, and other appropriate individuals; (2) facilitate the distribution of funds from manufacturers to appropriate individuals in order to meet manufacturers' contractual obligations; (3) provide adequate and timely information to manufacturers; and (4) permit manufacturers to conduct periodic audits of the data and information used by the third party to determine discounts for applicable drugs.
- **ENFORCEMENT.** Manufacturers participating in the Discount Program will be subject to periodic audits, and those that fail to provide applicable discounts will be subject to civil money penalties assessed and collected by CMS. The penalties will be commensurate with the amount the manufacturer would have paid under the agreement (which will then be used to pay the discounts the manufacturer failed to provide), along with an additional penalty equal to 25% of the discount amount.

Protected Classes of Drugs under Part D

- **REGULATORY CRITERIA.** The Act directs CMS to develop, through notice-and-comment rulemaking, criteria for identifying drug "classes of clinical concern." All covered Part D drugs included in such classes must be included in Part D formularies. Previously, under section 176 of the Medicare Improvements for Patients and Providers Act of 2008, the statute specified two statutory criteria that CMS must use in identifying classes of clinical concern: (1) restricted access to the drugs in the class would have major or life-threatening clinical consequences for individuals with a disease or disorder treated by drugs in such class; and (2) there is a significant need for such individuals to have access to multiple drugs within a class due to unique chemical actions and pharmacological effects of the drugs within a class. The Act eliminates these statutory criteria and leaves the process to CMS's discretion. CMS recently announced, in a final rule published on April 15 covering several aspects of the Medicare Part D and Medicare Advantage programs, that it will not adopt previously proposed criteria for identifying protected classes and related definitions. CMS stated that, in light of the many provisions in the Act affecting Medicare Part D beneficiaries, it wishes to take time to further consider how best to establish appropriate criteria.
- **FORMULARY REQUIREMENTS.** The Act requires PDP and MA-PD sponsors to include "all" covered part D drugs in the classes identified by CMS as classes of clinical concern. Previously, CMS required a sponsor to cover "all or substantially all" covered Part D drugs in protected classes.
- **EXISTING PROTECTED CLASSES.** The Act provides that, until CMS issues regulations establishing criteria for identifying protected classes, protection must be maintained for the following classes of drugs, which are already protected under existing CMS guidance: (1) anticonvulsants; (2) antidepressants; (3) antineoplastics; (4) antipsychotics; (5) antiretrovirals; and (6) immunosuppressants for the treatment of transplant rejection.
- **EXCEPTIONS PROCESS.** The Act also authorizes CMS to create, through regulation, a process for a PDP or MA-PD sponsor to seek permission to exclude from its formulary a particular drug in a protected class, or limit coverage for such a drug (including through prior authorization or utilization management). In the final rule described above, CMS stated that it will be retaining the exceptions process that it proposed prior to the Act. Under this process, exceptions would include: (1) drug products that are determined to be therapeutic equivalents under the Food and Drug Administration (FDA) Orange Book; (2) edits that limit the quantity of drugs due to safety;

and (3) other drugs CMS may specify through a process based upon scientific evidence and standards of practice (and, in the case of antiretroviral medications, is consistent with agency guidance) and which permits public notice and comment.

Effective Dates

Provision	Date
Medicare Part D Donut Hole $250 Rebate	2010 plan year only
CMS Model Agreement for Medicare Part D Coverage Gap Program	By September 27, 2010
Manufacturer Agreements with CMS for Part D Coverage Gap Program	By October 27, 2010
Medicare Part D Coverage Gap Discount Program	Begins January 1, 2011
Inclusion in TrOOP of costs for drugs paid for by a state Pharmaceutical Assistance Program, an AIDS Drug Assistance Program, or the Indian Health Service	Costs incurred on or after January 1, 2011
Part D Protected Classes	Plan year 2011 and beyond

Outstanding Issues and Implementation Challenges

- Given that the implementation date of January 1, 2011 is rapidly approaching, manufacturers must move quickly to develop and implement new policies and systems for complying with Discount Program requirements. It is likely, however, that many of the specific requirements and mechanics of the Discount Program will not become known until they are set forth in the model agreement developed by CMS, which might not be issued until September 27, 2010.
- Manufacturers will have only 30 days after CMS releases the model agreement to enter into an agreement with CMS under the Discount Program and may have only three months to put in place systems that comply with Discount Program requirements.
- Manufacturers may want to consider revising their Part D agreements with PDP and MA-PD sponsors to account for the new Discount Program and avoid "double dipping" caused by existing discount arrangements.
- The Discount Program agreement is likely to lead to False Claims Act litigation such as those flowing from the Medicaid Drug Rebate Program.
- The Act provides no guidance to CMS regarding how the agency should develop criteria for identifying protected classes of drugs under Part D, and CMS has stated that it will not be adopting the approaches it was previously considering. Thus, CMS's approach to this rulemaking remains unknown.

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There are many detailed changes in the Act. We would be pleased to discuss these changes and their potential impact on your industry, company, or customers.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

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