Healthcare Alert - CMS Guidance on Implementation of Reduction in Coverage Gap

May 3, 2010

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I. Overview

As initially enacted, standard prescription drug coverage under Medicare Part D contains a "gap" in coverage during which a Part D enrollee is fully liable for their prescription drug costs. Social Security Act § 1860D-2(b)(3)(A), 42 U.S.C. § 1395w-102(b)(3)(A). In plan year 2010, once a beneficiary incurs $2,830 in Part D spending (split between the enrollee and the plan), Part D coverage will cease until the beneficiary incurs true out-of-pocket spending of $4,550.[1] At this point, Part D catastrophic coverage begins. [2]

The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act (HCERA) (collectively referred to in this memorandum as the Health Care Reform Legislation) reduces the coverage gap by 50% beginning in 2011, and phases it down to 25% by 2021. [3] Under the new law, pharmaceutical manufacturers that wish to have their drugs covered under Part D must agree to provide a discount of 50% of the negotiated price of the drug to Part D enrollees at the point of sale. Social Security Act § 1860D-14A(b)(1)(B). The 50% discount is treated as true out-of-pocket spending for purposes of determining the level of the beneficiary's incurred costs.[4] Id. at § 1860D-2(b)(4)(E). On April 30, 2010, CMS issued a guidance document explaining how it would implement the new provisions. This memorandum analyzes that guidance document.

II. The CMS Guidance Document

The health care reform legislation permits CMS to implement the coverage gap discount program through program instructions and does not require the agency to go through the rulemaking process. Social Security Act § 1860D-14(d)(5). In the April 30 document, CMS states that it will accept public comment through May 14, 2010.

CMS begins the guidance document by re-iterating the statutory requirement that a manufacturer must sign an agreement with CMS under which it agrees to participate in the discount program. Manufacturers who do not sign the agreement may not have their drugs covered under Part D. Social Security Act § 1860D-43(a)(1) and (2); CMS April 30 Guidance at 2. The Guidance Document states that manufacturers must grant the discount at the point of sale, and that CMS will coordinate the payment of the discount from the manufacturer to the Part D plan sponsor.

CMS notes that in order to adjudicate the discount, four pieces of information are necessary:

- Whether the drug is eligible for the discount;
- Whether the beneficiary is eligible for the discount;
- Whether the claim is wholly or partially in the coverage gap; and
- The amount of the discount (taking into account other payers that may be liable for a portion of the claim).

CMS has concluded that only the Part D plan sponsor has access to all four pieces of information; thus, it is the Part D sponsor that is liable to make payment of the 50% discount.

CMS states that it considered using a third party administrator to adjudicate claims, but ultimately concluded that HIPAA billing standards did not support the transfer of all information necessary to adjudicate the claim. Thus, beginning on January 1, 2011, Part D sponsors must calculate the discount amount and pay it to the pharmacy. CMS states that it will begin the process of revising contracts to require Part D sponsors to provide the discount at point of sale. The pharmacy must be reimbursed pursuant to CMS timely payment requirements. CMS Guidance Letter at § 30.1, p. 3 – 4.

CMS will make monthly prospective payments to Part D sponsors for the manufacturer discounts made available to enrollees under the discount program. These payments will be calculated based on the sponsor's plan bid and its current enrollment. CMS Guidance Letter at § 30.2, p. 4. These prospective amounts will then be offset based on payments received based on invoices sent to manufacturers of covered Part D drugs. Id. This offset will, of course, ensure that Part D sponsors do not receive duplicate payments for the discounts. A year-end reconciliation process will coordinate payments made by, and to, Part D plan sponsors. Id. at § 30.3. Part D plan sponsors must include the administrative costs of the discount program in their plan bids. Id. at § 30.4, p. 5.

Part D plan sponsors will be required to report information regarding the discount program on the prescription drug event (PDE) records. The April 30 guidance lists the data sets that will be added to the PDE records. Id. at § 30.5, p. 5. CMS goes on to say that it will list additional guidance on this process this year.

As stated earlier in the guidance, CMS intends to invoice manufacturers, and will coordinate the collection of discount payments from manufacturers and payments to Part D plans. The process will begin by a CMS contractor that will verify the accuracy of discounts reported by Part D plans. The contractor will then invoice the manufacturer quarterly on behalf of the Part D sponsor. The invoices will be itemized at either the 9-digit or 11-digit National Drug Code (NDC) level. Manufacturers will be required to pay the invoice directly to Part D plan sponsors within 15 days of receipt, including any amounts in dispute. CMS is specifically soliciting comments on this aspect of the guidance. CMS Guidance Letter at § 40.1, p. 6.

Section 50.1 of the Guidance Document explains further how CMS will enforce the requirement that Part D drugs can only be covered if the manufacturer signs an agreement with CMS to provide the discount. CMS states that it will implement this

agreement by having the manufacturer specify in the discount agreement the labeler codes (i.e., the first five digits of the products NDC) that are covered under the agreement. CMS Guidance Letter at § 50.1, p. 6. Beginning in 2012, Part D sponsors must notify enrollees if a manufacturer has not signed an agreement with respect to a specific drug. Id.

Under the statute, CMS must permit coverage of Part D drugs without a signed agreement in 2011 if CMS determines that there are "extenuating circumstances." Social Security Act § 1860D-43(a)(3). In the April 30 Guidance Document, CMS has determined that there are extenuating circumstances in 2011. This is because Part D formularies for 2011 were due in April, 2010, and at the time Part D plans developed their formularies for 2011, there was no way for the plan to know whether the manufacturer would have signed an agreement for the drug. Thus, CMS notes that it may be (i.e., in the case of a manufacturer that has not signed an agreement) that coverage will be available in 2011 for a drug, and no discount will be available for the drug. Id.

CMS notes in the Guidance Document that the statute defines those beneficiaries who are eligible for the discount program. These are beneficiaries who:

- Are enrolled in a Part D plan or a Medicare Advantage Part D plan;
- Are not enrolled in a qualified retiree drug plan;
- Are not entitled to the low-income subsidy; and
- Has reached or exceeded the initial coverage limit in a year, but has not begun catastrophic coverage.

If a Part D plan offers supplemental coverage, supplemental coverage must be exhausted before the plan can apply the discount program. If the supplemental coverage eliminates the coverage gap (e.g., a PACE plan), the plan is excluded from the discount program. Coverage Document at § 70.1, p. 8. The applicable date for determination of applicability of the discount program is the date of dispensing of the Part D drug. Id. at § 70.4, p. 9.

III. Conclusion

As noted, the comment period on this guidance document ends on Friday, May 14, 2010. The rapid timeframe is necessary because of Part D program requirements related to bid submissions for the 2011 plan year.

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[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). The 2010 dollar amounts are set forth in Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 37.

[3] See Pub. L. No. 111-148 § 3301 (implementing 50% discount in PPACA) and Pub. L. No. 111-152 § 1101 (phasing out coverage gap in HCERA).

[4] The health care reform legislation also treats spending by AIDS drug assistance programs and by the Indian Health Service as incurred costs. Social Security Act § 1860D-2(b)(4)(C)(iii)(III) and (IV).