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E-ALERT | Health Care

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UPDATE ON THE MEDICARE COVERAGE GAP DISCOUNT PROGRAM

The Centers for Medicare & Medicaid Services (CMS) has taken a number of steps over the past few weeks to implement the Medicare coverage gap discount program (Discount Program), established under section 3301 of the Patient Protection and Affordable Care Act (PPACA), as amended by section 1101 of the Health Care and Education Affordability Reconciliation Act of 2010. On May 21, CMS issued revised guidance to Part D sponsors, which included CMS's responses to public comments on the draft guidance issued April 30. That same day, CMS issued for comment a draft model agreement between CMS and manufacturers under the Discount Program (Model Agreement). On May 25, CMS issued additional guidance to Part D sponsors regarding coverage for generic drugs in the coverage gap. And, on June 1, CMS held a meeting to discuss the draft Model Agreement.

This alert summarizes the draft Model Agreement, the June 1 meeting, the revised guidance to Part D sponsors, and the guidance on generic drugs.

DRAFT MODEL AGREEMENT

At the June 1 meeting, CMS stated that the draft Model Agreement was modeled on the National Drug Rebate Agreement under the Medicaid program. CMS also stated, in the preamble to the draft Model Agreement, that it intends to use the Model Agreement as a standard agreement and that it will not negotiate amendments with individual manufacturers. The draft Model Agreement addresses definitions, the manufacturer's responsibilities, CMS's responsibilities, penalties, payment amount dispute resolution, confidentiality, and nonrenewal and termination. The specific requirements generally track the requirements in the CMS guidance to Part D sponsors, but there are a few provisions worth noting.

- **Dispute Resolution Process.** The draft Model Agreement provides that, in the event a manufacturer disputes any information on the discount invoices, the manufacturer must provide written notice of the disputed information, by National Drug Code (NDC) number, to CMS and its contractor within 60 days of receipt of the information. The notice must be supported by material, specific evidence related to the dispute. The manufacturer is not permitted to withhold disputed amounts pending dispute resolution. If the dispute is not resolved within 60 days, CMS will provide for an independent review within 120 days of receipt of notification. If the manufacturer disagrees with the determination under the independent review, the manufacturer may request review by the CMS Administrator, whose decision CMS will consider to be final and binding.
- **Timeframe for Payment.** The draft Model Agreement requires the manufacturer to pay each Part D sponsor "within 14 days of being invoiced" by the CMS contractor.
- **Transfer of Ownership.** The draft Model Agreement provides that, in the event of a transfer in ownership of a manufacturer or product, the agreement is automatically assigned to the new owner, and all terms and conditions of the agreement will remain in effect. Manufacturers who acquire or divest products may want to address in the related agreements how discounts will be paid during the transition period.

CMS will accept public comment on the draft Model Agreement until 5 p.m. on June 21, 2010. We would be pleased to assist you in preparing comments or in understanding how the agreement will affect your business.

JUNE 1 MEETING

At the June 1 meeting, CMS officials provided an overview of, and answered questions about, the draft Model Agreement and the administration of the Discount Program. CMS also heard from panels of pharmaceutical manufacturers, Part D plan sponsors/pharmacy benefits managers (PBMs), and beneficiary advocates. Materials from the June 1 meeting are available here.

- **Timeline for Model Agreements.** CMS offered the following timeline for implementation of the Model Agreements.

July 15, 2010	Target date for final Model Agreement
August 15, 2010	Target effective date of Model Agreements (30-day timeframe for manufacturers to sign begins to run)
September 15, 2010	Target date for signed Model Agreements

- **Manufacturer Contact Information.** CMS stated that, by June 11, it expects to issue a template that manufacturers can use to submit their contact information. CMS will use this information for purposes of administering the Discount Program (*e.g.*, to send out the execution copy of the final Model Agreement).
- **Third-Party Administrator Agreement.** In addition to the Model Agreement between CMS and a manufacturer, CMS expects to issue in July a model agreement between a manufacturer and the CMS contractor (TPA Agreement). CMS explained that the TPA Agreement will relate to operational details of the program; the important policy determinations will be made through the process of finalizing the Model Agreement between the manufacturers and CMS.
- **Discounts versus Rebates.** CMS emphasized that the coverage gap discounts should not be considered rebates, as the discounts are for the benefit of the beneficiaries. A commenter pointed out, however, that some manufacturers are being advised by financial and accounting experts to treat the discounts as rebates.
- **Labeler Codes.** CMS plans to publish a list of labeler codes covered by manufacturer agreements by October 1. This list will be inclusive, as opposed to exclusive. The agency expects that manufacturers will list all of their labeler codes in their agreements with CMS.
- **Data on Invoices.** CMS stated that it plans to design discount invoices that will include the "minimum data necessary" to enable manufacturers to pay the discounts -- less than manufacturers typically receive under other programs. The data likely will include, at the NDC level, units, and the discount amount. (Although the revised guidance indicates that invoices will be itemized at the NDC-11 level, this was not incorporated into the draft Model Agreement or confirmed at the June 1 meeting.) CMS specifically requested comments on why manufacturers believe prescription-level data is necessary for the Discount Program, as opposed to other programs or requirements.
- **Payment Period for Invoices.** CMS believes that a 14-day payment period is consistent with Part D sponsor payments to pharmacies, and is feasible for manufacturers. CMS acknowledged, however, that it will need to clarify when exactly the 14-day period will begin to run, and whether

there will be a penalty for late payments. (Note that the revised guidance states that manufacturers must pay invoiced amounts "within 14 days of receipt.")

- **Payment to Part D Sponsors.** CMS reiterated its belief that the statute does not permit CMS to distribute funds under the Discount Program and, therefore, the agency will not allow manufacturers to make payments to the CMS contractor instead of to Part D sponsors. CMS indicated that this is a final decision that it does not plan to revisit.
- **Part D Drugs.** CMS discussed the definition of an "applicable Part D drug" -- *i.e.*, one that is approved under a New Drug Application (NDA) under the Food, Drug, and Cosmetic Act, or, in the case of a biological product, licensed under Public Health Service Act, and that is on the formulary or treated as if it is on the formulary. CMS stated that this may include some authorized generics, and asked for specific comments on this point.
- **Pharmaceutical Manufacturer Panel.** The panel of pharmaceutical manufacturers informed CMS about the need to include detailed prescription-level data on the invoices to enable them to validate the data, scrub for duplicates, conduct due diligence, and approve payments. The panelists also expressed strong concern about the 14-day period for processing payments, pointing out that it is unclear when this period begins and whether it refers to business or calendar days. Some of the panelists urged CMS to reconsider its decision to require manufacturers to pay the Part D sponsors instead of the contractor, which would be more efficient. They also asked CMS to reconsider the decision to require manufacturers to "pay and chase" disputed amounts, an approach that is disfavored by the Office of the Inspector General. In addition, some of the panelists asked CMS to release the TPA Agreement in conjunction with the Model Agreement. They also asked CMS to clarify how the Discount Program will account for repackagers and whether a manufacturer whose first applicable drug is approved mid-year will be permitted to execute a Discount Program agreement with CMS so that the drug will be eligible for coverage under Part D.
- **Part D Plan Sponsor/PBM Panel.** Panelists on the Part D sponsor/PBM panel asked CMS to monitor the impact that the Discount Program has on the Part D program; and, specifically, potential movement from generic drugs to brand name drugs. They also asked CMS to develop clear and consistent messaging about the Discount Program. Panelists expressed concern about whether all manufacturers will participate; what information will be included on the pharmacy receipts; the administrative costs associated with the Discount Program; and the integration of the Discount Program with health information technology, among other topics. One panelist urged manufacturers to keep in mind that if they decrease rebates in the coverage gap, member premiums will increase.
- **Beneficiary Advocate Panel.** The panel of beneficiary advocates urged CMS to develop simple, clear, and accurate information about the Discount Program that can be provided to beneficiaries (e.g., how the discounts are calculated, what counts toward true out-of-pocket costs, etc.). Panelists urged that CMS ensure that trusted intermediaries, such as prescribers and pharmacists, are trained about the Discount Program and can deliver clear and accurate information to beneficiaries. The beneficiary advocates also emphasized that beneficiary information should be kept as confidential as possible and information about drug prices should be as accurate as possible.

REVISED GUIDANCE TO PART D SPONSORS

- **Payment of Discounts to Part D Sponsors.** CMS disagreed with commenters who indicated that requiring manufacturers to pay invoiced amounts to Part D sponsors directly would be administratively burdensome, and that CMS instead should require manufacturers to pay the invoiced amounts to the CMS contractor. CMS stated that the statute allows the agency to

contract with the CMS contractor to "receive, distribute, **or** facilitate the distribution of funds of a manufacturer" (emphasis in original). CMS therefore concluded that it is consistent with the intent of the statute to have the contractor facilitate the distribution of payments, but not actually receive the payments on behalf of the Part D sponsors. Moreover, CMS does not believe the requirement to pay Part D sponsors will be overly burdensome for manufacturers.

- **Payment Period for Manufacturer Invoices.** The revised guidance retains CMS's original proposal that manufacturers pay the invoiced amounts within 14 days of receipt, despite numerous comments indicating that manufacturers will need a longer payment period to review, validate, and pay the invoiced amounts. CMS did indicate, however, that it will consider these comments when developing the final Model Agreement.
- **Data Provided on Manufacturer Invoices.** Several commenters recommended that the CMS contractor provide detailed claim-level data to manufacturers to facilitate efforts to validate the invoiced discount amounts. The revised guidance provides that the invoices will be itemized at the 11-digit NDC level as determined by CMS and provide certain claim-level data. (As discussed above, CMS did not indicate clearly in the draft Model Agreement or at the June 1 meeting that data will be provided at the NDC-11 level.) The agency plans to provide, in subsequent guidance, additional information regarding the data that will be provided on manufacturer invoices.
- **Payment of Disputed Invoiced Amounts.** Although numerous commenters requested that CMS remove the requirement that manufacturers pay disputed invoiced amounts, CMS determined that this requirement is necessary to ensure that discounts are paid in a timely manner. If invoiced discount amounts are later found to be improper, CMS stated, the revisions will be reflected on future manufacturer invoices as a negative adjustment reducing the total discount payment.
- **Labeler Codes Covered by Manufacturer Agreements.** In the revised guidance, CMS stated that a manufacturer must specify all of its labeler codes in the discount agreement so that all of the manufacturer's applicable drugs will be covered under the agreement. CMS will maintain an updated list of labeler codes covered by agreements, distribute the list to Part D sponsors, and post it on the CMS website. The 2011 list is expected to be made public by October 1, 2010.
- **Exceptions for Drugs Not Covered under Agreements.** Reversing its position from the draft guidance, CMS stated that it expects all manufacturers of applicable drugs to sign discount agreements so there will be no reduction in availability of covered Part D drugs. CMS will notify Part D sponsors if any applicable drug not covered by a manufacturer agreement has been determined to be essential for the health of Part D enrollees and exempt from the manufacturer agreement requirement. CMS does not intend to apply the "extenuating circumstances" exception in a blanket manner for 2011. Moreover, CMS will not permit transition coverage for drugs that potentially become excluded from Part D for failure of a manufacturer to sign a discount agreement.
- **Relationship Between Gap Discounts and Underlying Rebate Agreements.** According to CMS, Congress did not intend for the coverage gap discounts to replace rebates currently available to Part D sponsors. The agency stated that it expects that manufacturers will continue to "negotiate" with Part D sponsors and other entities to provide rebates on Part D drugs purchased throughout the Part D benefit and specifically in the coverage gap. In addition, CMS reminded Part D sponsors that they will have an opportunity to make some formulary changes during the August update window if necessary to address contracting changes that could otherwise affect their formularies.
- **Submission of PDE Records.** CMS stated that Part D sponsors must submit PDE records for the Discount Program within the current PDE submission deadlines for the Part D program -- on

average, within 30 days of claim receipt. For the Part D Discount Program payment reconciliation, Part D sponsors must submit their PDE records within five months after the end of the contract year.

- **Employer Group Waiver Plans (EGWPs).** After specifically requesting and receiving comments on how the Discount Program should be applied to EGWPs, CMS determined that EGWPs are included in the Discount Program because the definition of "applicable beneficiary" includes all Part D plan enrollees not eligible for a low income subsidy. In order for an EGWP to participate in the Discount Program in 2011, however, CMS will require it to attest or otherwise demonstrate that its beneficiaries have cost sharing between the initial coverage limit (ICL) and the catastrophic threshold and that they will apply any supplemental benefits before determining the applicable threshold that will be reported on the PDE records.
- **Retroactive Changes to Applicable Discounts.** Commenters persuaded CMS to change its position and permit retroactive changes to applicable discounts when necessary to reflect the retroactive changes to the claim or beneficiary eligibility.
- **Reconciliation Process.** In future guidance, CMS plans to provide additional information about the reconciliation process and the timing of the reductions to prospective Part D payments.

GUIDANCE ON GENERIC DRUGS

- **Generics on Non-Generic Formulary Tiers.** According to CMS, the newly-mandated 7% standard coverage of generic drugs in the gap in 2011 (*i.e.*, the federal subsidy) will apply to all generics treated as formulary drugs in the ICL phase, regardless of tier placement. This includes generic drugs residing on non-generic formulary tiers (*e.g.,* brand tier or specialty tier), as well as generic drugs obtained through the exceptions process.
- **Part D Excluded Drugs.** Generic Part D excluded drugs covered through the gap by enhanced plans will not be subject to the new provision for generic gap coverage; only those Part D drugs treated as formulary drugs will be subject to the new benefit.
- **Additional Gap Coverage.** CMS provided guidance with respect to enhanced alternative plans offering additional gap coverage, clarifying that Part D sponsors may elect, but are not required, to provide additional gap coverage for generic drugs on certain tiers or subsets of tiers. CMS also stated, among other things, that enhanced alternative plans offering such additional gap coverage of generics may also apply cost sharing through the gap. However, such gap coverage will be above and beyond the mandated 7% standard coverage of generic drug costs in the gap.

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

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