

## E-ALERT | Health Care

August 3, 2010

### CMS RELEASES FINAL DISCOUNT PROGRAM MODEL AGREEMENTS

The Centers for Medicare & Medicaid Services (CMS) has released final versions of the [model manufacturer agreement](#) and [third-party administrator \(TPA\) agreement](#) for the [Medicare Coverage Gap Discount Program](#) (Discount Program), established under the Affordable Care Act (ACA) (Pub. L. 111-148, as amended by Pub. L. 111-152). CMS previously released, and accepted public comment on, [drafts](#) of these agreements.

This alert summarizes some of the significant requirements in the final agreements.

#### MODEL MANUFACTURER AGREEMENT

- **Timeframe for Payment.** The model manufacturer agreement requires manufacturers to pay each Part D sponsor within “38 calendar days [an increase from the 14 days provided in the draft agreement] of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information[.]” Receipt of the invoice will be considered to be one calendar day after the TPA electronically transmits the invoice to the manufacturer, or otherwise notifies the manufacturer that the invoice is available.
- **Medicare Part D Discount Information.** The quarterly discount invoice sent to the manufacturer must include the following data elements: (1) date of service; (2) service provider identifier qualifier; (3) service provider identifier; (4) prescription/service reference number; (5) product/service identifier; (6) quantity dispensed; (7) days supply; (8) fill number; and (9) reported gap discount. Additional data elements from the prescription drug event (PDE) records, such as the ingredient cost paid and total amount attributed to sales tax, will be available upon audit only.
- **Payment and Notice to TPA.** The manufacturer must pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer. Within five days of an electronic funds transfer to Part D sponsors, the manufacturer must provide the TPA with electronic documentation in a manner specified by CMS that demonstrates that the manufacturer sent the payments, and includes the date and amount of the payments.
- **National Drug Code.** References to National Drug Code (NDC) in the agreement generally are to the 11-digit NDC (inclusive of 5-digit labeler code, 4-digit product code, and 2-digit package size code).
- **Penalties.** The agreement provides that CMS may impose a civil monetary penalty on a manufacturer that fails to pay applicable discounts. A manufacturer will be deemed to have failed to pay applicable discounts if “payment has not been transmitted within 38 calendar days of receipt of the applicable invoice for each identified Part D sponsor.” The penalty for each failure will be the amount of the discount, plus an additional 25% of that amount.
- **Dispute Resolution.** The agreement provides that the manufacturer must provide written notice of a dispute within 60 days of receipt of information that is the subject of the dispute. The

manufacturer cannot withhold any invoiced discount payments pending dispute resolution, except the manufacturer may withhold invoiced amounts for applicable drugs manufactured under labeler codes not subject to the agreement. The agreement also describes, and provides deadlines for, the process for requesting an independent review and review by the CMS administrator.

- **Audits.** Both parties have the right to conduct periodic audits (no more often than annually). The party requesting the audit must provide 60-days notice of the reasonable basis of the audit and a description of the information required for the audit. The TPA will determine an audit schedule for manufacturers based on available resources. The manufacturer has the right to audit the data and information provided on the invoice (discussed above) for a statistically significant sample size of PDEs used to determine the applicable discounts. The manufacturer may audit only information made available to the TPA; it cannot audit CMS records or the records of Part D sponsors.
- **Confidentiality.** CMS cannot disclose, in a form that identifies the manufacturer, any information shared by the manufacturer in connection with the agreement, except as necessary to carry out the Discount Program or as otherwise required by law. Moreover, information disclosed to manufacturers pursuant to the agreement can be used only for purposes of paying the discounts under the Discount Program.
- **Data Use.** The agreement includes, as an exhibit, provisions governing the use of data received by manufacturers for purposes of the Discount Program. Among other things, the exhibit requires manufacturers to ensure the confidentiality of the data by complying with all applicable law, including the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA), and to limit the use of Discount Program information to those uses necessary to perform functions governed by the agreement (which uses are not further described or specified). In addition, the exhibit requires the manufacturer to retain Discount Program files for a period of 10 years from the date of payment of the invoice and to destroy them at the end of the 10-year period. However, the manufacturer may retain the data beyond this period if the data is the subject of an unresolved audit, government investigation, or litigation, or if required by another applicable law, and if the manufacturer notifies CMS of such matter and promptly destroys the data once the pending matter is resolved. The exhibit also requires the manufacturer to report to CMS, within one hour of discovery, any incident in which it inadvertently receives individually identifiable health information, or any breach of Discount Program information.

## TPA AGREEMENT

- **Manufacturer Responsibilities.** The TPA agreement requires the manufacturer to establish and maintain a point-of-contact (POC) responsible for maintaining connectivity between the manufacturer and the TPA. If the manufacturer contracts with a third-party for file transmission, the manufacturer maintains ultimate responsibility for adhering to the TPA agreement and the manufacturer agreement. The manufacturer also must provide electronic connectivity and receive Discount Program information from and send the information to the TPA using CMS-approved record formats.
- **TPA Responsibilities.** The TPA agreement obligates the TPA to provide customer support to the manufacturer, provide and maintain connectivity between the manufacturer and the TPA, and facilitate audits by the manufacturer.
- **Mutual Obligations.** Both the manufacturer and the TPA have responsibilities relating to testing, data transmission accuracy, and data transmission security. The security access codes that the TPA issues to the manufacturer must be legally sufficient to verify the identity of the

transmitter and to authenticate the Discount Program data transmission, so as to establish the validity of the data transmission.

The CMS website states that the deadline for returning signed agreements is [September 1, 2010](#). Please contact one of the attorneys listed below if you have questions about how the Discount Program agreements will affect your business.

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

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