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Manufacturers Affected by Recent Medicare Part D Rule

CMS formalizes its Medicare Part D Coverage Gap Discount Program rules as part of an omnibus Medicare Part C and Part D rulemaking.

In a rule (the Rule) affecting both the Medicare Part C and Medicare Part D programs, the Centers for Medicare & Medicaid Services (CMS) has recently implemented changes that impact the relationship between pharmaceutical manufacturers and the Medicare Part D program. The Rule was published in the *Federal Register* on April 12. The changes are effective June 1, 2012. Manufacturers should take note of the following key aspects of the rule.

What the Rule Covers

The Rule covers a vast array of topics relating both to Medicare Advantage plans authorized under Medicare Part C and to Medicare Prescription Drug Plans authorized under Medicare Part D. Some of the provisions reflect statutory changes enacted under the Affordable Care Act, but others reflect changes from far less recent legislation.

Medicare Part D Coverage Gap Discount Program

Pursuant to statutory changes made by the Affordable Care Act, the Medicare Part D Coverage Gap Discount Program requires that manufacturers of innovator products (and their licensees) pay half of the negotiated price of their drugs for patients in the coverage gap (also called the "donut hole") in their Medicare prescription drug program as a pre-condition to coverage of their drugs under Medicare Part D. Although CMS has previously issued instructions, and has had manufacturers sign a model agreement, CMS is still codifying key requirements in regulation. Some of the specific provisions are as follows:

Definition of "Applicable Drug." The Rule identifies that the drugs to which the program applies are those that are authorized under a New Drug Application (NDA) or a Biologics License Applications (BLA). It is irrelevant if those drugs are treated as generics by a particular Part D plan. Furthermore, the Rule expressly excludes compounded products. Even though such products might qualify as Part D drugs, no Part D coverage gap discount obligations attach to such utilization.

Definition of "Manufacturer." A manufacturer is defined as any entity with a unique labeler code included in the National Drug Code (NDC) of applicable drugs. In other words, the entity that physically "manufactures" a product may not actually have any rebate liability. That liability is associated with the owner of the labeler code.

Definition of "Negotiated Price." CMS defines this term for purposes of the program as the total amount the pharmacy has agreed to receive for a drug (or if out of network, the allowed amount), minus any price concessions passed along to the beneficiary at the point of sale, and excluding any dispensing fees or vaccine administration fees. Manufactures intending to reduce the "negotiated price" of their products through rebates to Part D plans should be very specific in their agreements as to the Part D plan's responsibility to make the discount available at the point of sale.

Definition of "Other Health or Prescription Drug Coverage." CMS distinguishes between Medicare Part D benefits and non-Medicare benefits. Medicare Part D benefits are applied before calculating the manufacturer's

coverage gap liability, and non-Medicare benefits are applied afterward. CMS has determined that employer group waiver plan (EGWP) benefits are considered non-Medicare benefits, which are also known as "other health or prescription drug coverage." In other words, any supplemental benefits furnished to employees and retirees in an employer-based EGWP do not reduce a manufacturer's Part D coverage gap liability. Note that these benefits' identification as non-Medicare benefits means that beneficiaries are not entitled to any protections in connection with these benefits, such as appeal rights. It is quite likely that, in addition to manufacturers, entities that protect workers' rights, such as unions, will find CMS's interpretation of this term to be less than ideal.

Implications of Decision Not to Sign Agreement. Although a manufacturer will find no coverage of its "applicable drugs" if it fails to sign an agreement, CMS has decided to eschew the "plainest reading" of the statute, which would preclude coverage even of generics manufactured by a manufacturer. Instead, any drug approved under an Abbreviated New Drug Application (ANDA) will be allowed coverage, even if the manufacturer fails to execute an agreement for its "applicable drugs." Such an interpretation may be of benefit to entities that sell few drugs approved by NDAs or BLAs, but do sell large volumes of drugs approved under ANDAs.

Manufacturer Responsibilities. There are several key responsibilities manufacturers have under their agreements with CMS. One is to make payment to each Part D plan within 38 days of receiving its invoice, even if the amount is disputed. Another is that the manufacturer adds any new labeler codes the Food and Drug Administration (FDA) assigns to it within three business days of FDA's assignment. A manufacturer must retain for 10 years from any payment date information regarding manufacturer labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, and utilization and pricing information relied on by the manufacturer in disputes. One other requirement that is included in the agreement, and now memorialized in regulation, relates to uses of the data received on manufacturer invoices. Manufacturers must stringently protect the privacy of this data and ensure that its use is limited to determining the manufacturer's liability under the Coverage Gap Discount Program. Manufacturers should make sure that their operations are set up to comply with all of these requirements, including their policies and procedures regarding record retention and privacy of information received from CMS.

Timing and Length of Agreement. Agreements must be entered into by January 30 of the year preceding the year in which a drug is to be covered under Part D. The initial term for such agreements is 24 months. Once entered into, they are automatically renewed for one-year periods. CMS has the ability to terminate the agreement for cause. It is unclear what process a manufacturer must follow to terminate an agreement.

Dispute Resolution. There is both a formal dispute process and an audit process. The dispute process involves three levels of review. The first is with the program's third party administrator (TPA), and must be formally launched within 60 days of the invoice. Disagreements not resolved at this initial level are elevated to an independent review entity, and then finally the CMS Administrator reviews remaining disputes. Launching a dispute entails submitting material evidence that the invoice is wrong, as CMS presumes that its data, which is sanitized using several screens for aberrations, is accurate. Manufacturers are separately allowed to audit the TPA's records, but such audit can only occur annually and must happen onsite at the TPA. Only work papers may be brought out of the audit, and no claims-specific information may be copied or maintained. The work papers as well cannot be shared with anyone other than the auditor, who is only allowed to share his or her conclusion as to the accuracy of the invoices. Given the limited audit right and the degree of specificity CMS is requiring with respect to disputes, manufacturers should have a fully developed strategy for pursuing an appeal before they submit a request to dispute or audit questionable data.

Civil Monetary Penalties. Manufacturers that fail to timely pay their invoices, even by a day, must pay the amount otherwise due plus an additional 25% of such amount. The only exception applies if there were technical difficulties beyond the manufacturer's control. Manufacturers are allowed to appeal determinations of any such liability.

Definition of "Bona Fide Service Fee"

The concept of a bona fide service fee is an important one for Part D plans, as well as manufacturers doing business with them. If a manufacturer pays a Part D plan a bona fide service fee, that amount need not be viewed

as a price concession, or reported as such in cost statements Part D plans submit to CMS. As these cost statements form the basis of payments from CMS to the Part D plans, characterizing a payment as a bona fide service fee instead of as a price concession results in increased income to the Part D plan. CMS has defined "bona fide service fees" consistent with its definition for Average Sales Price reporting purposes. As now defined, fees must be (a) paid at fair market value, (b) for itemized services that the manufacturer would otherwise need to perform for itself, and (c) not passed on to any of the Part D plan's clients or customers. It is important for a manufacturer when signing rebate agreements with Part D plans to ensure that it only allows fees to be considered "administrative fees" rather than rebates when these criteria have been met so as to avoid even the implication that the manufacturer aided a Part D plan in submitting a false claim to CMS.

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