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Client Alert

FDA & Life Sciences Practice Group

April 30, 2012

CMS Issues Final Rule on Changes to the Medicare Advantage Program and the Medicare Prescription Drug Benefit Program for Contract Year 2013

On April 12, 2012, the Centers for Medicare & Medicaid Services (CMS or the "Agency") published in the *Federal Register* a Final Rule with comment period entitled, "Changes to the Medicare Advantage Program and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes."[1] In the Final Rule, CMS made a number of programmatic and technical changes to the Medicare Advantage and Medicare Part D programs, many of which were contained in a Proposed Rule published on October 11, 2011.

According to CMS, the Final Rule makes changes to the Medicare Advantage and Medicare Part D programs that are designed to (1) implement statutory provisions; (2) strengthen beneficiary protections; (3) exclude plan participants that perform poorly; (4) improve program efficiencies; and (5) clarify program requirements. This Client Alert summarizes several of the key changes to these programs that are contained in the Final Rule, including:

- Codification of the Medicare Part D Coverage Gap Discount Program;
- Transparency requirements for Medicare Part D Pharmacy Benefit Managers (PBMs); and
- The authority of Medicare Advantage organizations to limit coverage of durable medical equipment (DME) to brands, items and supplies of "preferred" manufacturers.

Most of the provisions in the Final Rule are effective on June 1, 2012, although some are only applicable on January 1, 2013, given that health and drug plans under the Medicare Advantage and Part D programs operate under contracts with CMS that are applicable on a calendar year basis. CMS did not finalize its proposals regarding independence of long-term care (LTC) consultant pharmacists and will accept additional comments on these proposals until June 11, 2012.

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Codification of the Medicare Part D Coverage Gap Discount Program

Section 3301 of the Patient Protection and Affordable Care Act of 2010 (ACA) established the Medicare Part D Coverage Gap Discount Program ("Discount Program"), which is designed to phase out the Medicare Part D coverage gap, or "donut hole," for Medicare beneficiaries who do not already receive low-income subsidies from CMS. Through the Discount Program, manufacturer discounts equal to 50 percent of the negotiated price of applicable drugs are made available to Medicare Part D enrollees at the point-of-sale by Medicare Part D sponsors (on behalf of the manufacturer). CMS initially implemented the Discount Program through program instructions, but opted to codify most of the existing requirements in the Final Rule in order to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

In order for a manufacturer's branded drugs to be eligible for coverage under Medicare Part D, a manufacturer must: (1) participate in the Discount Program; (2) enter into a Discount Program Agreement with CMS; and (3) enter into an agreement with the Third Party Administrator (TPA) contractor for CMS responsible for administering the Discount Program. CMS has the authority to waive these conditions so that coverage of branded drugs is allowed without a Discount Program Agreement, however, if CMS has made a determination that the availability of the drug is essential to the health of Medicare beneficiaries. In the Final Rule, CMS recognized that it does not anticipate exercising such authority given the strong participation by manufacturers in the Discount Program since 2011 and the likely availability of therapeutic alternatives for many Medicare Part D drugs. Generic drugs continue to be covered under Medicare Part D irrespective of their manufacturers' participation in the Discount Program.

The Final Rule codifies in regulation a number of requirements pertaining to the operation of the Discount Program, many of which are already contained in the Discount Program Agreement to which drug manufacturers have already agreed. These requirements include:

- The term "applicable drug" for purposes of the Discount Program is defined to include all covered Part D drugs marketed under a new drug application (NDA) or a biologics license application (BLA) with the exception of certain drugs excluded from Part D coverage and Part D compounds.

- The term "negotiated price" for purposes of the Discount Program excludes discounts, rebates and other price concessions passed through to Part D enrollees at the point-of-sale, as well as dispensing fees and vaccine administration fees.

- The applicable discount must be applied before "other health or prescription drug coverage" that may be applicable to Medicare Part D enrollees is applied. Such other coverage includes that provided by state pharmaceutical assistance programs, AIDS drug assistance programs, Indian Health Service programs, supplemental coverage required by the Commonwealth of Puerto Rico, or employer group health or waiver plans (EGWPs) (the definition of "other health or prescription drug coverage" is applicable in January 2013).

- Manufacturers are responsible for reimbursing all applicable discounts provided by Medicare Part D sponsors on behalf of the manufacturer for all applicable drugs invoiced to the manufacturer within a maximum of three years of the date of dispensing. The TPA must invoice manufacturers on a quarterly

basis, and manufacturers must pay each Part D sponsor within 38 calendar days of receipt of an invoice or be subject to civil monetary penalties (unless the failure to timely submit payment is due to technical or other reasons beyond the control of the manufacturer). Civil monetary penalties include the amount that the manufacturer should have paid the Medicare Part D sponsor plus 25 percent of that amount. Manufacturers may appeal the imposition of civil monetary penalties using the existing appeals process for appealing civil monetary penalties in other Medicare programs.

- CMS provides monthly interim coverage gap payments to Part D sponsors as necessary to advance coverage gap discounts to beneficiaries. These estimated interim coverage gap discount payments are then reconciled with actual Discount Program costs. This reconciliation process occurs after Medicare Part D payment reconciliation.

- Manufacturers may conduct periodic audits, directly or through contracts, of the data and information used by the TPA to determine discounts for applicable drugs of the manufacturer under the Discount Program. Manufacturers are also subject to periodic audits by CMS.

- Manufacturers may dispute quarterly discount amounts through a three-stage appeals process. First, the manufacturer must provide notice (accompanied by supporting evidence) to the TPA within 60 days of receipt of the information that is subject to dispute. Next, the manufacturer may appeal an unfavorable determination of the TPA to an independent review entity contracted by CMS within 30 days of the unfavorable determination (or within 90 days after the TPA's receipt of the notice of dispute if the dispute is not resolved within 60 days, whichever is earlier). Finally, a manufacturer or CMS may request the CMS Administrator to review an unfavorable determination of the independent review entity within 30 days of receipt of such determination. The decision of the CMS Administrator is final and binding. Beneficiaries may utilize the Medicare Part D coverage determination and appeals process for disputes involving the availability and amount of applicable discounts under the Discount Program.

- Manufacturers must maintain updated electronic listings of all National Drug Codes (NDCs) of the manufacturer that are currently in distribution in the Food and Drug Administration (FDA) NDC directory and with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Manufacturers must provide CMS with any new NDCs no later than three business days after learning that the NDC has been assigned by FDA.

- Manufacturers must collect and have available appropriate data (as determined by CMS) pertaining to its participation in the Discount Program and must maintain such information for no less than 10 years.

- Manufacturers must enter into (or renew) a Discount Agreement no later than January 30 of the year preceding the calendar year in which the Discount Agreement is to be effective. All Discount Program agreements must have an initial period of 24 months, with automatic renewal for a period of one year each January 1 thereafter, unless terminated. CMS may terminate a Discount Agreement for a knowing and willful violation of its requirements or other good cause shown. Such termination may be challenged through an administrative hearing and subsequent review by the CMS Administrator. Manufacturers may terminate a Discount Agreement for any reason.

Transparency Requirements for Medicare Part D PBMs

Section 6005 of the ACA requires Part D sponsors and entities that provide pharmacy benefit management services for Medicare Part D enrollees to report various data elements to CMS. Pursuant to this statutory authority, CMS codified in regulation the following data elements that must be reported to CMS by a Part D sponsor (PBMs must transmit information to Part D sponsors that then report the information to CMS):

1. The total number of prescriptions that were dispensed;
2. The percentage of all prescriptions provided through retail pharmacies compared to mail order pharmacies;
3. The percentage of prescriptions for which a generic drug was available and dispensed, by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract;
4. The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees) that the PBM negotiates that are attributable to patient utilization under the plan;
5. The aggregate amount of rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions dispensed; and
6. The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

CMS defined "bona fide service fees" in this context to mean fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. Although the Proposed Rule contained specific examples of bona fide service fees, CMS declined to include these examples in the Final Rule as such services are subject to change and are not appropriate for inclusion in the regulation. CMS indicated that it would elaborate on the definition of bona fide service fees, as well as the definitions of the various pharmacy types, in subregulatory guidance.

Information disclosed to CMS under the above requirements is confidential and must not be disclosed by CMS or the Part D sponsor receiving the information, except in certain limited circumstances in which CMS may disclose the information in a non-identifiable form (*e.g.*, review by the Comptroller General or the Congressional Budget Office). Part D sponsors and PBMs that fail to provide the required information in a timely manner or knowingly provide false information are subject to the penalties that are applicable for untimely and false submission of pricing data in the Medicaid Drug Rebate Program.

Medicare Advantage Plans May Limit Coverage of DME

Effective January 1, 2013, Medicare Advantage organizations may limit enrollee access to certain DME brands, items and supplies of preferred manufacturers provided certain requirements are met. These requirements include:

- Enrollees must have access to all categories of DME under Medicare Part B.
- Contracts with DME manufacturers or suppliers must ensure that enrollees have access to all DME brands, items and supplies of preferred manufacturers.
- Enrollees must have access to all DME brands, items and supplies of non-preferred manufacturers that are medically necessary.
- Enrollees must have continued access to DME products of non-preferred manufacturers during the first 90 days of coverage under a Medicare Advantage plan, and repairs to such products must also be provided.
- Medicare Advantage organizations must not make any negative changes (*e.g.*, elimination of coverage) to the DME products of preferred manufacturers during a plan year. Positive changes, including the addition of DME with innovative new technologies, or the addition of suppliers that would increase brands and manufacturers available to enrollees, are permitted mid-year.
- Medicare Advantage organizations must include in the annual description of benefits to enrollees and on a plan website the DME coverage limitations and enrollee appeal rights in the event of a denial of coverage (denials of coverage for DME products of non-preferred manufacturers are considered organization determinations for purposes of the appeals process).
- Medicare Advantage organizations must provide full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories annually determined by CMS to require full coverage (*e.g.*, emerging new technologies or items typically tailored to meet individual needs).

Other Changes to the Medicare Advantage and Medicare Part D Programs

The Final Rule also makes a number of other technical and programmatic changes to the Medicare Advantage and Medicare Part D programs, including:

- Effective January 1, 2013, the definition of "Part D drug" is amended to include benzodiazepines, and barbiturates used in the treatment of epilepsy, cancer, or a chronic mental health disorder, as required by Section 175 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

- CMS codified the longstanding policy that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law.

- Beginning in January 2014, to encourage prescribers and enrollees to limit the quantities of solid oral drugs dispensed when less than 30-days' quantity is required, Medicare Part D sponsors must create a daily cost-sharing rate equal to the enrollee's monthly co-payment divided by 30 or 31 and rounded to the nearest lower dollar amount. The daily cost-sharing rate is not applicable to solid oral doses of antibiotics

or drugs that are dispensed in their original container as indicated by FDA or otherwise customarily dispensed in their original packaging to assist patient compliance.

- Effective January 1, 2013, only prescription drug event (PDE) records containing an active and valid National Provider Identifier (NPI) may be submitted to CMS by Part D sponsors. If a valid NPI cannot be determined at the point-of-sale and there is no indication of fraud, Part D sponsors are instructed to pay the claim but must acquire a valid NPI before the PDE data may be submitted to CMS.

- Effective January 1, 2013, a prescriber acting on behalf of an enrollee may request reconsideration by an Independent Review Entity of an adverse coverage decision by a Medicare Part D plan sponsor.

- If a Medicare Advantage or Part D plan fails to maintain a Plan Rating System score of at least 3 (out of 5) for three consecutive years, CMS may terminate plan sponsor's Medicare contract. CMS may also deny applications submitted by Medicare Advantage organizations and Part D sponsors that have performed so poorly that CMS has terminated or not renewed a contract with the organization previously.

CMS Seeks Additional Comment on Proposals for Independence of LTC Consultant Pharmacists

LTC facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the needs of each resident. LTC pharmacies are required by regulation to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services to the facility, including a drug regimen review at least once a month for each facility resident. As a result of this role, CMS recognized that LTC consultant pharmacists may exercise significant influence over the drugs that LTC residents receive, and the lack of independence of the consultant pharmacist from the interests of the LTC pharmacy or related organizations may lead to recommendations that steer LTC facilities to recommend or use certain drugs for their residents. This could result in the overprescribing of medications, the prescribing of drugs that may be inappropriate for LTC residents, or the use of unnecessary or inappropriate therapeutic substitutions.

In the Proposed Rule, CMS indicated that it was considering requiring that LTC consultant pharmacists be independent of any affiliations with LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities. CMS expressed its view that such a requirement would be necessary to ensure that consultant pharmacist decisions are objective, unbiased, and in the best interest of LTC facility residents. Based on the comments submitted to the Proposed Rule, however, CMS declined to finalize this provision and instead is accepting additional comments in the following three areas to better define the problem and frame a more comprehensive solution to address the Agency's concerns: (1) enhancing medication management and the effectiveness of medication review in LTC facilities; (2) collection and use of data regarding the connection of inappropriate use of drugs in LTC facilities and consultant conflicts of interest; and (3) increasing transparency in order to address conflicts of interest. The deadline for submission of comments on these issues is June 11, 2012.

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The Final Rule may be accessed at: https://www.federalregister.gov/articles/2012/04/12/2012-8071/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit.

If you have questions regarding the Final Rule or would like assistance in submitting comments to the LTC consultant pharmacy provisions, please contact us.

[1] 71 Fed. Reg. 22072 (Apr. 12, 2012).