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HEALTH LAW ALERT
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CMS Publishes Final Amendments to MA/Part D Rules

PBM Transparency, Plan Termination Among Issues Addressed

Today, the Centers for Medicare and Medicaid Services (CMS) published final amendments to the Medicare Advantage and Part D Rules (42 C.F.R. Parts 422 and 423) designed to implement provisions of the Affordable Care Act as well as to "improve the program[s] through modifications that reflect experience [CMS has] obtained in administering the programs and/or address requests for clarification received from stakeholders." The amendments address a variety of issues, including additional transparency requirements for pharmacy benefit managers, termination of Medicare Advantage organization/Part D Plan Sponsor contracts for failure to maintain at least a three-star rating, and making a prescribing provider's National Provider Identifiers (NPIs) a mandatory data element in prescription drug event records.

Although the amendments generally are effective on June 1, 2012, several provisions are not applicable until January 1, 2013, recognizing Medicare Advantage organizations' and Part D Plan Sponsors' contractual commitments. The final amendments are published at 77 *Federal Register* 22072 (click here).

Click here (or see the "Resources" page at tbixbylaw.com) for my compilation of the Medicare Advantage and Part D Rules incorporating these amendments (see the last two lines under "Compiled Rules").

Some of the issues addressed by the amendments are:

- **PBM Transparency.** The amendments will require PBMs to provide information on rebates, discounts, and other price concessions arising from Medicare Part D business, including the total amount of such price concessions and the amount passed on to Plan Sponsors. PBMs must report to CMS the generic dispensing rate by pharmacy type—independent, chain, supermarket, and mass merchandiser pharmacies. Plan Sponsors and PBMs are subject to substantial financial penalties for failure to timely provide the required information and for knowingly providing false information.

- **Plan Termination.** CMS will be able to terminate its contracts with MA organizations and Plan Sponsors that fail to maintain a three-star rating for three consecutive years. CMS explains that entities that fail to meet the three-

star standard for three years "have demonstrated that they have substantially failed to meet the requirements of the [Medicare Advantage and Part] D programs and failed to take timely and effective corrective action."

- **Broker Compensation.** The amendments permit MA organizations and Plan Sponsors to set broker compensation annually based on a fair market value amount published by CMS each year. This change is to "level the playing field" between entities that have been in the market for several years, which have been required to base compensation on rates established in 2009, with new entrants, which are permitted to base compensation on fair market value.

- **First Tier & Downstream Entity Contract Requirements.** CMS revised language in the Rules to clarify that MA organizations and Plan Sponsors must engage first tier entities in binding "contracts" that include flow-down provisions—CMS was concerned that the current Rules did not provide sufficient clarity that flow-down provisions must be enforceable obligations of first tier entities. First tier entities will similarly be required to engage downstream entities in enforceable "contracts."

- **Prescriber NPIs in Prescription Drug Records.** Part D Sponsors will be required to obtain "active and valid" NPIs for health care providers who prescribe medications to Part D enrollees and include the NPIs in prescription drug records (PDEs) reported to CMS. Moreover, the Part D Sponsor is prohibited from allowing "the lack of an active and valid individual prescriber NPI [to] unreasonably delay a beneficiary's access to a covered Part D drug." The amendment outlines steps the Plan Sponsor must take in the event that, at the point of sale, the pharmacy submits an NPI that is not active or invalid. CMS explains this requirement is for purposes of the Federal Government's fraud prevention efforts.

- **DME Coverage.** The amendments clarify that an MA organization may limit coverage of durable medical equipment to preferred brands and manufacturers, provided that the MA organization meets several beneficiary-protection requirements. For example, enrollees must have access to all medically-necessary DME brands, items, and supplies offered by non-preferred manufacturers and the MA organization must treat denials of non-preferred manufacturers' DME brands, items, and services as organization determinations, with appropriate appeal rights.

- **Coverage Gap Discount Program.** The amendment adds a new Subpart W, which describes the coverage gap discount program that will eliminate the "donut hole," as required by the Affordable Care Act. The amendment does not make significant changes to the program initially described in CMS guidance. Rather CMS explains that it is codifying the program in the Part D

Rule "to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements."

- **Daily Cost-Sharing Rate.** Beginning in 2014, Part D Sponsors must provide a daily cost-sharing rate that will reduce out-of-pocket costs for short-term prescriptions so enrollees will have the incentive "to ask their prescribers whether less than a month's supply of a drug would be appropriate."

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