

Federal Healthcare Law Update – July 2023

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FEDERAL HEALTHCARE LAW UPDATE



CMS Proposes Changes to Medicaid Drug Rebate Program

The Centers for Medicare & Medicaid Services (CMS) has proposed extensive changes to the Medicaid Drug Rebate Program. The changes primarily focus on drug misclassification, drug pricing, and product data misreporting by pharmaceutical manufacturers. Program integrity and administrative changes affecting manufacturers would include limitations on the timeframe for manufacturers to initiate audits of state Medicaid plan drug rebate obligations, clarification on accumulating price concessions, and the establishment of drug price verification and transparency through data collection. CMS is aiming to enhance transparency in prescription drug costs by verifying reported prices through an annual Medicaid Drug Price Verification Survey. This transparency initiative and the disclosure of non-proprietary drug price information are intended to give state Medicaid agencies greater negotiating power with drug manufacturers, particularly for high-cost drugs.

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CMS Adopts Updated Notice of Non-Coverage Form

The Centers for Medicare & Medicaid Services recently adopted an updated Advance Beneficiary Notice of Noncoverage (ABN) Form, [Form CMS-855-N](#). Providers, including independent laboratories, home health agencies, skilled nursing facilities, hospices, physicians, practitioners, and suppliers to Medicare fee for service beneficiaries, typically issue this Form to patients in situations where Medicare payment is expected to be denied. The Form serves as a means to transfer potential financial liability to the Medicare beneficiary in certain instances. The Form must be provided to a patient prior to the commencement of services, and if the patient chooses to proceed with the service and signs the Form, the Provider may bill the patient if Medicare does not cover the cost of the service.

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OIG Provides New Guidance for ASCs that are Unable to Satisfy the One-Third Income Test Under the ASC Safe Harbor

In March 2023, the U.S. Department of Health and Human Services Office of Inspector General (OIG) published a [frequently asked questions page](#) (the FAQ) that, among other things, provides new guidance on how the OIG will evaluate a physician's ownership of an Ambulatory Surgery Center (ASC) where the physician-owner is unable to satisfy the one-third income test under the ASC safe harbor to the Federal Anti-Kickback Statute (AKS).