Weekly Digest

• *October 10, 2023* •

Agencies Press Play on Prescription Drug Machine-Readable File Requirement

"Subject to the implementation timeline set to be announced by the Departments in future guidance, plan sponsors will need to work with service providers to put together a game plan to gather the required information and post the prescription drug machine-readable file." **Full Article**

Proskauer Rose LLP

Biden-Harris Administration Moves Forward with Medicare Drug Price Negotiations to Lower Prescription Drug Costs for People with Medicare

"All 10 drug companies whose drugs were selected for price negotiation with Medicare for the first cycle of the program have decided to participate in those negotiations. These selected drugs accounted for $50.5 billion in total Part D gross covered prescription drug costs, or about 20%, of total Part D gross covered prescription drug costs between June 1, 2022 and May 31, 2023. Medicare enrollees taking the 10 drugs covered under Part D selected for negotiation paid a total of $3.4 billion in out-of-pocket costs in 2022 for these drugs." **Full Article**

U.S. Department of Health and Human Services

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The Proposed MHPAEA Regulations' 'Meaning of Terms' Part Two: Processes, Strategies, Evidentiary Standards and Other Factors

"The 2013 final MHPAEA regulations use -- but do not define -- the terms, 'processes,' 'strategies,' 'evidentiary standards' or 'other factors.' The Departments now propose to define these other terms. Under the proposal, 'processes' relate to the application of an NQTL, while "strategies" relate to their design. Evidentiary standards are not themselves considered factors; rather, they are considered or relied upon in designing or applying a factor. This invites the question: What happens when a plan or issuer only relies upon a single evidentiary standard to design or apply an NQTL?" **Full Article**

McDermott, Will & Emery

The ERISA Edit: More Coverage Mandates and TiC Enforcement Ahead

"Current agency guidance interpreting statutory and regulatory requirements states that preventive products that are generally available without a prescription, such as folic acid, contraception sponges, and spermicides, must be covered without co-sharing only when such products are prescribed by a healthcare provider. The **September 29 RFI** signals that the Departments are considering future rulemaking or new guidance that would eliminate the prescription requirement." **Full Article**

Miller & Chevalier Chartered

Court Ruling Calls Into Question Whether Plans and Issuers Can Exclude Coupons Towards the MOOP

"The 2021 Notice of Benefit and Payment Parameters (2021 NBPP) permitted (but did not require) plans and issuers to count direct support offered by drug manufacturers for prescription drugs toward the ACA's annual cost-sharing limit (MOOP). The court concluded that the 2021 NBPP interpretation of 'cost sharing' conflicts with the statutory and regulation definition of 'cost sharing' under the ACA and remanded the amendments back to HHS for further consideration." **Full Article**

Groom Law Group

Fiduciary Governance: Evaluating, Selecting, and Contracting with Pharmacy Benefit Managers

"The authors posit that the lack of compliance monitoring is not for lack of interest but rather because of the complexity of the landscape to which the regulation applies. As such, in this piece, we lay the groundwork for compliance studies by outlining the agencies responsible for enforcing compliance with the TiC rule, delineating the universe of entities that are required to comply with it, and discussing how compliance might be assessed." **Full Article**

Nixon Peabody