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Transparency in Coverage “Enforcement Safe Harbor” Rescinded for Prescription Drug Reporting

To help address rising healthcare costs, various transparency and reporting laws and regulations have been enacted in the past few years. One of these regulations is the Transparency in Coverage Rule (“TiC”), which directed group health plans, in part, to publicly provide machine readable data files (“MRFs”) containing prescription drug cost information.

As noted in our [prior Client Alerts](#), the TiC requirements went into effect for plan years beginning or after January 1, 2022. However, due to potentially duplicative and overlapping reporting requirements under the Consolidated Appropriations Act, 2021 (“CAA”), on August 20, 2021 the Departments of Labor, Health and Human Services, and Treasury (“Departments”) announced the deferral of MRF enforcement for prescription drugs pending further consideration. Later, on April 19, 2022, the Departments announced an “enforcement safe harbor” for plans that were unable to satisfy the prescription drug reporting requirements.

On September 27, 2023 the Departments announced they were ending the policy of deferring enforcement of the prescription drug MRF reporting rules rather than address the conflict through additional rulemaking. The Departments found no meaningful conflict between the reporting requirements of the CAA and the TiC Final Rules. Plans must now ensure they are providing the prescription drug MRF in accordance with the TiC rules. Civil enforcement penalties for TiC violations can reach \$100 per day, per violation, per person affected.

The Departments intend to exercise enforcement discretion with respect to the prescription drug MRF requirements on a case-by-case basis without any “safe harbor.” If plans come under review for potential violations, the Departments have stated they are unlikely to pursue enforcement action if plans can demonstrate that compliance with the relevant provisions of the TiC Final Rules would have been extremely difficult or impossible.

If you have questions about the price transparency requirements imposed by TiC or the potential compliance and enforcement impacts of these regulations, please reach out to a member of the Kutak Rock [Employee Benefits and Executive Compensation Group](#).

