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Agencies Press Play on Prescription Drug Machine-Readable File Requirement

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Last week, the Departments of Labor, Treasury and Health and Human Services rolled back two non-enforcement policies related to the machine-readable file requirements included in the transparency in coverage (TIC) final rules: (1) deferred enforcement of the requirement that health plans post a machine-readable file listing negotiated rates and historical net prices for covered prescription drugs, and (2) an enforcement safe harbor with respect to the requirement that dollar amounts be listed in the in-network rate machine-readable file for items and services for which it is difficult to ascertain dollar amounts in advance. The guidance was released in the form of FAQs, which can be viewed here.

By way of brief background, for plan years starting on or after July 1, 2022, non-grandfathered health plans are required to post three machine-readable files (updated monthly) covering the following: (1) in-network rates (expressed as a dollar amount) for covered items and services, (2) allowed amounts for covered items and services furnished by out-of-network providers, and (3) negotiated rates and historical net prices for covered prescription drugs.

While the machine-readable file requirements have been around for some time, the Departments have issued guidance along the way delaying or modifying enforcement of the requirements:

- In August 2021, the Departments delayed enforcement of the prescription drug machine-readable file requirement while they evaluated the potential overlap with the ***separate*** prescription drug reporting requirement for plans that was added by the Consolidated Appropriations Act, 2021 (which we blogged about here).
- In April 2022, for purposes of the in-network rate machine-readable file, the Departments provided an enforcement safe harbor for plans with respect to the requirement that in-network rates be expressed as dollar amounts for items and services covered by reimbursement arrangements that are not susceptible of being reported as dollar amounts in advance (*e.g.*, in the case of a "percentage-of-billed

charges" contract arrangement, where the dollar amount can be determined retrospectively only).

What happened?

On September 27, 2023, the Departments revoked both non-enforcement policies described above, subject to the following notes:

- **Prescription drug machine-readable file**: Having concluded that the prescription drug machine-readable file requirement is sufficiently different from the separate CAA prescription drug reporting obligation, the Departments rescinded their prior delayed enforcement policy. The Departments state they intend to release future technical guidance with an implementation timeline that "sufficiently accounts" for prior reliance by plan sponsors on the deferred enforcement policy, suggesting that plan sponsors may have some lead time to gather the necessary information to post the file.
- **In-network rate machine-readable file**: Going forward, the Departments state they intend to exercise enforcement discretion on a case-by-case basis with respect to the requirement that in-network rates be expressed as dollar amounts for items and services covered by arrangements that make it difficult to express the cost as a dollar amount prior to receipt of the item or service. Because the Departments do not mention future guidance or an implementation guideline, it appears that the revocation of this enforcement safe harbor is immediate.

Takeaways for plan sponsors and employers: 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. Plan sponsors currently relying on the enforcement safe harbor with respect to the requirement to list in-network rates as dollar amounts for items and service covered by arrangements that make it difficult to express the cost as a dollar amount will need to swiftly assess whether any changes are needed in light of the rescission of the safe harbor.

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