



BRIEFING | TRANSPARENCY IN COVERAGE

Prescription Drug File Briefing: Transparency in Coverage Final Rules

DATE

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AUTHOR

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BRIEFING SUMMARY

Bottom line

The Prescription Drug File now has a date. The Departments of Health and Human Services, Labor, and the Treasury expect plans and issuers to publish it in December 2027 and monthly thereafter, using a schema they plan to finalize around May 2027.

Three points matter most for third-party administrators (TPAs) and health plans:

- 1 The data requirements did not change.** The file still requires negotiated rates and historical net prices for every covered drug, by National Drug Code (NDC) and by pharmacy. The regulatory definition of net price is inclusive of rebates, discounts, chargebacks, fees, and other price concessions, data a plan may need from its pharmacy benefit manager (PBM).
- 2 The accountability requirements did change.** The final rules place the Prescription Drug File inside the new attestation requirement. A named senior official stands behind each file as true, accurate, and complete.
- 3 The December 2027 date comes from a CMS announcement, not from the regulation.** The published rule text contains no drug file schema or publication date. Treat December 2027 as the planning date and expect the binding detail in guidance.

THE DATA QUESTION

The file requires net prices at the NDC and pharmacy level. A plan or TPA that does not hold that data will need it from its PBM or another vendor before it can publish a complete file or attest to it.

This briefing summarizes federal rules and agency statements as of the date above. It is not legal advice. Confirm obligations for your plans with counsel.

What was announced

On October 5, 2026, the Departments finalized amendments to the Transparency in Coverage (TiC) rules. The rules were published in the Federal Register on October 6, 2026 (91 FR 63748, CMS-9882-F) and take effect December 7, 2026.

Most of the rulemaking addresses the In-network Rate and Out-of-network Allowed Amount machine-readable files (MRFs). The Prescription Drug File is addressed in two places, and they carry different legal weight.

STATEMENT	WHERE IT APPEARS	WEIGHT
Schema development begins November 2026	CMS press release, October 5, 2026	Agency plan
Schema finalized "on or around May 2027"	CMS press release	Agency plan
Plans and issuers "expected to publish" starting December 2027, monthly thereafter	CMS press release	Agency expectation
Departments "plan to begin working to implement the prescription drug file in short order"	Final rule preamble, section I.A	Preamble statement, no date
Attestation and named senior official apply to the Prescription Drug File	Final rule, paragraph (b)(1)(iv)	Binding regulation
Text file and footer link cover the Prescription Drug File	Final rule, paragraphs (b)(2)(iii) and (b)(3)(iii)	Binding regulation
Prescription Drug File stays on a monthly update cadence	Final rule, paragraph (b)(4)(ii)	Binding regulation

The schema and publication dates appear only in the press release. We searched the full text of the published rule and found none of the three dates. The Departments also said they are still weighing comments from their June 2025 request for information on the drug file, so content changes through later guidance or rulemaking remain possible.

How we got here. The 2020 TiC rules required three files. The Departments deferred enforcement of the drug file in August 2021 (FAQs Part 49), withdrew that deferral in September 2023 in favor of case-by-case enforcement (FAQs Part 61), and requested public input in June 2025. The requirement has been on the books since 2020. What has been missing is a schema and a date.

Key dates

December 2027 is the date to plan against. Two regulatory dates fall before it and both reach the Prescription Drug File.

DATE	WHAT HAPPENS	DRUG FILE IMPACT	SOURCE
November 2026	Departments begin developing the initial Prescription Drug File schema	Schema work for the other files runs on the CMS GitHub repository	CMS press release
December 7, 2026	Final rules take effect	None directly	Final rule
March 6, 2027	Phase 1 applies: In-network Rate and Allowed Amount file changes, quarterly cadence, attestation, open-access and single-format rules	Attestation paragraph covers the drug file by its terms. Any drug file posted must be reachable by any person, script, or web crawler with no login, CAPTCHA, or download limit	Final rule, paragraph (c)(1)
Around May 2027	Departments finalize the Prescription Drug File schema	Build specification becomes fixed. About seven months remain to first publication	CMS press release
September 6, 2027	Phase 2 applies: Text File, footer link, Taxonomy and Utilization Files	Text File and "Price Transparency" footer link must lead to all MRFs, the drug file included. The rule's example timing table shows the first Text File posting on October 1, 2027	Final rule, paragraph (c)(1)
December 2027	Plans and issuers expected to publish the Prescription Drug File on the new schema	First publication, then monthly updates	CMS press release

One related date sits outside the drug file. For plan years beginning on or after January 1, 2027, cost-sharing information from the self-service tool must also be available by phone, on request.

Attestation: a named official behind every file

Each Prescription Drug File must carry an attestation and the name of a senior official.

What the regulation requires. Paragraph (b)(1)(iv) applies to the In-network Rate, Allowed Amount, Prescription Drug, Utilization, and Taxonomy Files. In each one, the plan or issuer must:

1 Attest that, to the best of its knowledge and belief, it has included all applicable information and that the information is "true, accurate, and complete as of the date in the file."

2 Encode the name of its chief executive officer, president, or the senior official designated to oversee the encoding of that data.

Who can attest. A plan or issuer may have another party, such as a TPA, make the attestation and encode the name of that party's own senior official. This is allowed only where a written agreement has that party producing the files under the rule's special provisions.

WHAT THE DEPARTMENTS SAID ABOUT IT

- The requirement is modeled on the Hospital Price Transparency attestation.
- The attester is expected to consult the staff who build the files.
- Passing the schema validator does not satisfy it. The validator checks format, not accuracy.
- It does not change the underlying duty to publish accurate and complete data. It attaches a name to that duty.
- The rule sets no attestation-specific penalty and no safe harbor. The only qualifier is "to the best of its knowledge and belief."

A DISCREPANCY TO KNOW ABOUT

The CMS fact sheet lists the attestation statement for four files and omits the Prescription Drug File, while listing it for the named official. The regulatory text and the preamble include the drug file for both. The regulation controls.

TIMING

The attestation paragraph applies beginning March 6, 2027, nine months before the expected first drug file. The rule does not say how that date applies to a file whose schema is not yet final. Confirm this point with counsel.

Who is responsible

Responsibility follows the type of plan, and a contract moves the liability in only one case: a fully insured plan whose issuer has agreed in writing to publish.

ARRANGEMENT	WHO PUBLISHES	WHO IS IN VIOLATION IF THE FILE IS MISSING, INACCURATE, OR INCOMPLETE
Fully insured plan with a written agreement requiring the issuer to provide the information	Issuer	The issuer, not the plan
Self-funded plan with a written agreement with a TPA or other third party	TPA or third party	The plan
Issuer that contracts with a third party	Third party	The issuer

For TPAs. A TPA can publish the drug file, host the Text File on its own site for plans that have no public website, serve as the point of contact, and make the attestation in its own senior official's name. None of that moves regulatory liability off the self-funded plan. The Departments kept this liability structure after commenters raised concerns about plan sponsors that rent a network, and told plans to address vendor capability in their contracts.

For health plans and issuers. An issuer carries the obligation for its insured business directly and, where it agrees in writing, for the fully insured group plans it covers.

PBM data access. The regulation names a pharmacy benefit manager as an example of a party that may provide the required information under a written agreement, with liability staying on the plan or issuer if the PBM falls short. The final rules do not discuss rebates and create no new right to obtain data from a vendor. The Departments instead pointed plans to the existing gag clause prohibition in the Consolidated Appropriations Act, 2021, which bars agreements that restrict a plan's electronic access to de-identified claims and encounter data.

Whether a given PBM contract delivers net price by NDC and pharmacy is a contract question.

Enforcement. The Departments said they will prioritize compliance and enforcement through existing authorities and make enforcement actions visible to the public. The tools cited are corrective action, civil monetary penalties, and equitable relief. The Department of Labor is the primary enforcer for private employer plans, states for insured coverage with HHS as backstop, and HHS for non-federal governmental plans. No new penalty schedule was adopted.

What is not yet settled

Six questions remain open. Each one affects build scope or contract language, and none is answered in the published rule.

1

Is December 2027 binding?

The date is a stated expectation in a press release. The published rule sets no publication or enforcement date for the drug file.

2

Will the schema change the data elements?

The Departments are still weighing the 2025 request for information, which asked about existing data elements and whether plans can obtain the data. The schema could narrow, clarify, or restructure what is reported.

3

How is historical net price computed at the pharmacy level?

The definition calls for "reasonably allocated" rebates and other concessions. The final rules do not describe an allocation method for an NDC at a single pharmacy.

4

Can a TPA publish one drug file across many self-funded plans?

The new aggregation rules cover the other two files only. Until guidance says otherwise, plan on drug files organized by coverage option.

5

How does the March 6, 2027 attestation date apply to a file with no schema until May 2027?

The rule does not address the interaction.

We will update this briefing when the draft schema posts and when the Departments issue guidance.

How TALON is supporting clients

TALON will track the schema from first draft to final and brief clients at each step. Our platform was demonstrated to the federal government's Health Policy Team in 2018 and served as the model for the Transparency in Coverage rule.

Schema monitoring. We will review the draft schema when it posts and send clients a plain-language summary of what it requires and what changed.

Client questions. Send questions about this briefing or your plans' readiness to your TALON account team.

SOURCES

[Transparency in Coverage final rules, 91 FR 63748 \(October 6, 2026\): regulatory text and preamble, checked against the official govinfo PDF](#)

[CMS press release, October 5, 2026: Prescription Drug File schema and publication timeline](#)

[CMS fact sheet, CMS-9882-F: summary of provisions and applicability dates](#)

[Request for Information on the Prescription Drug File, 90 FR 23303 \(June 2, 2025\)](#)

[45 CFR 147.210: definitions of negotiated rate and historical net price](#)

[FAQs Part 61 \(September 27, 2023\) and FAQs Part 49 \(August 20, 2021\): enforcement history](#)



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