[4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS-0056-IFR]

RIN 0938-AU19

Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA), National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard; Updates to Compliance and Other Related Dates

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Interim final rule.

SUMMARY: This document updates compliance and other dates presented in the final rule that appeared in the December 13, 2024 **Federal Register** titled "Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard" to conform with the subsequent final rule that appeared in the February 11, 2025 **Federal Register.**

DATES: These regulations are effective August 20, 2025.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

We published a final rule that appeared in the December 13, 2024, **Federal Register** (89 FR 100763) titled "Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs

(NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard," (hereinafter referred to as the December 2024 final rule). That final rule adopted updated versions of the retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These updated versions are modifications to previously adopted standards for the following retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. This final rule also adopted a modification to the standard for the Medicaid pharmacy subrogation transaction. Subsequently, we determined this final rule contained a technical error regarding the 8-month transition period before full compliance with retail pharmacy and Medicaid pharmacy subrogation standards, so references to August 11, 2027, should have, instead, read June 11, 2027. We published a subsequent final rule that appeared in the February 11, 2025, **Federal Register** (90 FR 9289) titled Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard; Delay of Effective Date, (hereinafter referred to as the February 2025 final rule). That final rule delayed by 60 days the effective date of the December 2024 final rule, to April 14, 2025, which delay was necessary to give agency officials the opportunity to further review and consider the new regulation, consistent with the January 20, 2025, Presidential memorandum titled "Regulatory Freeze Pending Review." This final rule also mentioned the technical date error that appeared in the December 2024 final rule.

The February 2025 final rule (90 FR 9290) acknowledged the impact of this delayed effective date on compliance and transition periods for covered entities and state Medicaid agencies. The December 2024 final rule initially specified a compliance date 36 months after its effective date, with an 8-month transition starting 28 months after the effective date and running to the compliance date. The February 2025 final rule altered the effective date to April 14, 2025,

resulting in a new compliance date of April 14, 2028, with the 8-month transition period running from August 14, 2027, to April 14, 2028.

II. Provisions of the Interim Final Rule

This interim final rule (IFR) updates compliance and other dates in the preamble and regulations text of the December 2024 final rule in accordance with the delay of effective date changes finalized in the February 2025 final rule. As a result of the changes published in the February 2025 final rule, the following provisions of the December 2024 final rule are updated as follows:

- The "Dates" section of the December 2024 final rule:

++ Effective Date: April 14, 2025.

++ Compliance Date: April 14, 2028.

- Summary of effective and compliance dates (section I.C. of the December 2024 final rule):

++ Beginning August 14, 2027, all covered entities, as agreed to by trading partners, may use either Version D.0 and Version 1.2, or Version F6 and Version 15, for 8 months as a transition period prior to full compliance, which begins 36 months after the effective date of the February 2025 final rule.

++ All covered entities must be in compliance with Version F6 and Version 15 beginning April 14, 2028.

++ Beginning August 14, 2027, state Medicaid agencies, as agreed to by trading partners, may use Version 3.0 or Version 10 for 8 months as a transition period prior to full compliance, which begins 36 months after the effective date of the February 2025 final rule.

++ State Medicaid agencies must be in compliance with Version 10 beginning April 14, 2028.

- Compliance Date for Version F6 and Version 15 (section III.C.1. of the December 2024 final rule)--The final transition and compliance dates for Version F6 and Version 15 at §§

162.1102, 162.1202, 162.1302 and 162.1802:

++ All covered entities may, as agreed to by trading partners, use either Version D.0 and Version 1.2, or Version F6 and Version 15, beginning August 14, 2027.

++ All covered entities must comply with only Version F6 and Version 15 beginning April 14, 2028.

● Compliance Date for Version 10 (section III.C.2. of the December 2024 final rule) -- At § 162.1902, we are finalizing the compliance date for Version 10 as beginning April 14, 2028, which aligns with the timeline we are adopting for Version F6 and Version 15. In addition, at § 162.1902, we are finalizing that, beginning August 14, 2027, which is 8 months before the compliance date, state Medicaid agencies may, as agreed to by trading partners, use either Version 3.0 or Version 10 for Medicaid pharmacy subrogation transactions.

● Regulations text of the December 2024 final rule. In the regulations text of this interim final rule, §§ 1162.1102, 162.1202, 162.1302, 162.1802, and 162.1902 are revised to reflect the transition and compliance dates (August 14, 2027 and April 14, 2028, respectively) noted previously.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) and (c) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register**, provide interested parties an opportunity to comment or otherwise participate in the rulemaking process, and consider this input prior to finalization. Exceptions to these requirements are available under section 553(b)(A) and (B) of the APA when a rule is interpretative, a general statement of policy, or concerns agency organization, procedure or practice; or when the agency for good cause finds that notice and comment are impracticable, unnecessary, or contrary to public interest. In addition, section 553(d) of the APA requires a 30-day delay in effective date after issuance or publication of a rule, with exceptions available under sections 553(d)(1) through (d)(3) of the APA that allow the agency to proceed without the required 30-day delay in effective date where:

a rule grants an exemption or relieves a restriction; a rule is an interpretative rule or statement of policy; or, otherwise provided by the agency for good cause with a statement published with the rule.

This interim final rule does not constitute a rule that would be subject to notice and comment. However, to the extent that 5 U.S.C. 553 applies to this action, it is exempt from its requirements because it constitutes a general statement of policy under 5 U.S.C. 553(b)(A). As described previously, the February 2025 final rule's delay in the effective date was intended to give agency officials the opportunity to further review and consider the December 2024 final rule. Here, we simply state the new compliance and other related dates for the requirements previously finalized in the December 2024 final rule that arose pursuant to the February 2025 final rule's delay of the effective date.[1] This document does not change any of the requirements previously finalized in the December 2024 final rule, which was the product of notice and comment rulemaking. The compliance date and transition period start date for the December 2024 final rule requirements remain unchanged at, respectively, 36 months and 28 months from the effective date of the rule; this document states those dates taking into account the delay in the effective date published in the February 2025 final rule.

Moreover, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures just to incorporate the updated dates in this document, or further delaying the effective date, would be contrary to the public interest, as covered entities have requested that the updated dates be published in a timely manner in order to reduce confusion among the industry regarding the actual compliance and transition period dates. Additional notice and comment procedures and further delay in the effective date of this interim final rule are unnecessary as we are not altering our policies, but,

[1] As we noted in the February 2025 final rule at 90 FR 5290, the December 2024 final rule, in the regulations text, contained a technical error pertaining to the 8-month transition period (erroneously allowing just a 6-month period), so references to August 11, 2027 should have read June 11, 2027.

rather, simply stating the updated compliance and other dates that had previously been proposed and subjected to notice and comment, and then finalized in the December 2024 final rule. We find that, should the notice, comment, and effective date requirements have been applicable, we have good cause to waive these requirements because they are unnecessary and contrary to the public interest.

IV. Collection of Information Requirements

This document does not impose new information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The requirements and burdens associated with the information collection requirements contained and were finalized in the December 2024 final rule. Therefore, the one-time burden was previously approved and accounted for in the information collection request previously approved under OMB control number 0938-0866 and titled "CMS-R-218: HIPAA Standards for Coding Electronic Transactions."

OMB has determined that the establishment of standards for electronic transactions under HIPAA (which mandate that the private sector disclose information and do so in a particular format) constitutes an agency-sponsored third-party disclosure as defined under the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 et seq.) (see 65 FR 50350 (August 17, 2000)). OMB's previous determination for electronic transaction standards under HIPAA obviates the need for further OMB review under the PRA. This document merely finalizes updates in the compliance and other dates for requirements previously finalized in the December 2024 final rule to conform with the delayed effective date published in the February 11, 2025, final rule, and, therefore does not implicate the PRA.

Should our assumptions be incorrect, this information collection request will be revised and reinstated to incorporate any additional transaction standards and modifications to

transaction standards that were previously covered in the PRA package associated with OMB approval number 0938-0866.

V. Regulatory Impact Statement

A. Statement of Need

As discussed in more detail in section II. of this interim final rule, consistent with the Presidential memorandum of January 20, 2025, "Regulatory Freeze Pending Review," we delayed for 60 days the effective date of the December 2024 final rule to provide the Administration sufficient time to review any questions of fact, law, and policy. This interim final rule updates compliance and other dates in the preamble and regulations text of the December 2024 final rule in accordance with the delay of effective date changes finalized in the February 2025 final rule.[2]

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (Pub. L. 96 354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4); Executive Order 13132, "Federalism"; and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages, and distributive impacts). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more in any one year, or adversely affect in a

[2] *See* footnote 1; this interim final rule specifies the correct transition dates, accounting for the delayed effective date, and corrects the technical error in their calculation in the December 2024 final rule regulations text that erroneously provided a 6-, not 8-, month transition period.

material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues for arising out of legal mandates, or the President's priorities.

This interim final rule is not a significant regulatory action under section 3(f) of Executive Order 12866. The temporary delay in the effective date until April 14, 2025, published in the February 2025 final rule (90 FR 9290), was necessary to give agency officials the opportunity for further review and consideration of the new regulation, consistent with the memorandum described previously. We estimate this temporary delay in the effective date could result in annualized net cost savings for the industry of approximately $992,500 and $1.04 million at the 7 percent and 3 percent discount rates, respectively. Additional details regarding the economic impacts can be found in the regulatory impact analysis in section VI. of the December 2024 final rule (89 FR 100773 through 100787).

C. Regulatory Flexibility Act Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity.

As stated earlier, this interim final rule updates compliance and other dates in the preamble and regulations text of the December 2024 final rule in accordance with the 60-day delay of effective date changes finalized in the February 2025 final rule. The temporary delay in the effective date until April 14, 2025, published in the February 2025 final rule (90 FR 9290), was necessary to give agency officials the opportunity for further review and consideration of the new regulation, consistent with the memorandum described previously. As a result, the Secretary

has certified that this interim final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For the purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This interim final rule will not significantly impact the operations of a substantial number of small rural hospitals, as these entities are not involved in the exchange of retail pharmacy transactions. Therefore, the Secretary has certified that this interim final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

D. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending more in any 1 year than threshold amounts in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This interim final rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of more than $187 million in any 1 year.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule will not impose substantial direct requirement costs on State and local governments, preempt State law, or otherwise have Federalism implications.

F. Executive Order 14192

Executive Order 14192, titled "Unleashing Prosperity Through Deregulation," was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This interim final rule is expected to be an E.O. 14192 deregulatory action. We estimate that this interim final rule would generate $992,500 in annualized cost savings at a 7 percent discount rate, discounted relative to the year 2024, over a perpetual time horizon.

List of Subjects in 45 CFR Part 162

Administrative practice and procedures, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 162 as set forth below:

PART 162—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

Authority: 42 U.S.C. 1320d—1320d-9 and secs. 1104 and 10109 of Pub. L. 111-148, 124 Stat. 146-154 and 915-917.

§ 162.1102 [Amended]

2. Section 162.1102 is amended by:

a. In paragraph (c), removing the date "August 11, 2027," and adding in its place the date "August 14, 2027,";

b. In paragraph (d), removing the date "August 11, 2027," and adding in its place the date "August 14, 2027,";

c. In paragraph (e) introductory text, removing the dates "August 11, 2027 through February 11, 2028," and adding in its place the dates "August 14, 2027 through April 14, 2028,"; and

d. In paragraph (f), removing the date “February 11, 2028” and adding in its place the date “April 14, 2028,”.

§ 162.1202 [Amended]

3. Section 162.1202 is amended by:

a. In paragraph (c), removing the date “August 11, 2027,” and adding in its place the date “August 14, 2027,”;

b. In paragraph (d) introductory text, removing the dates “August 11, 2027 through February 11, 2028,” and adding in its place the dates “August 14, 2027 through April 14, 2028,”; and

c. In paragraph (e), removing the date “February 11, 2028” and adding in its place the date “April 14, 2028,”.

§ 162.1302 [Amended]

4. Section 162.1302 is amended by:

a. In paragraph (c), removing the date “August 11, 2027,” and adding in its place the date “August 14, 2027,”;

b. In paragraph (d), removing the date “August 11, 2027,” and adding in its place the date “August 14, 2027,”;

c. In paragraph (e) introductory text, removing the dates “August 11, 2027 through February 11, 2028,” and adding in its place the dates “August 14, 2027 through April 14, 2028,”; and

d. In paragraph (f), removing the date “February 11, 2028” and adding in its place the date “April 14, 2028,”.

§ 162.1802 [Amended]

5. Amend § 162.1802 by:

a. In paragraph (c), removing the date “August 11, 2027,” and adding in its place the date “August 14, 2027,”;

b. In paragraph (d), removing the date “August 11, 2027,” and adding in its place the date “August 14, 2027,”;

c. In paragraph (e) introductory text, removing the dates “August 11, 2027 through February 11, 2028,” and adding in its place the dates “August 14, 2027 through April 14, 2028,”;

d. In paragraph (f), removing the date “February 11, 2028” and adding in its place the date “April 14, 2028,”.

§ 162.1902 [Amended]

6. Amend § 162.1902 by:

a. In paragraph (a), removing the date “August 11, 2027--” and adding in its place the date “August 14, 2027--”;

b. In paragraph (b) introductory text, removing the dates “August 11, 2027 through February 11, 2028--” and adding in its place the dates “August 14, 2027 through April 14, 2028--”; and

c. In paragraph (c), removing the date “February 11, 2028” and adding in its place the date “April 14, 2028”.

Robert F. Kennedy, Jr.,
Secretary,
Department of Health and Human Services.
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