

I. Background and Summary of Errors

In FR Doc. 2020–12195 of July 1, 2025 (90 FR 28749), there were typographical and technical errors. This document corrects those errors.

II. Correction of Errors

In FR Doc. 2025–122195 of July 1, 2025 (90 FR 28749), make the following corrections:

1. On page 28751,
 - a. Second column,

(1) Third bulleted paragraph, lines 1 through 5, the paragraph “• Epidural Steroid Injections for Pain Management excluding facet joint injections (L39015, L33906, L39036, L39240, L39242, L36920, L38994, L39054)” is corrected to read “• Epidural Steroid Injections for Pain Management (L39015, L39240, L36920) excluding Facet Joint Interventions”.

(2) Fourth bulleted paragraph, lines 2 through 5, the phrase “Vertebral Compression Fracture (VCF) (L33569, L34106, L34228, L38201, L34976, L35130, L38737, L38213)” is corrected to read “Vertebral Compression Fracture (VCF) (L38201, L34228, L35130)”.

(3) Fifth bulleted paragraph, lines 1 through 3, the phrase “Fusion (L39741, L39799, L39770, L39758, L39762, L39793, L39773, L39788)” is corrected to read “Fusion (L39741, L39758, L39793)”.

(4) Seventh bulleted paragraph, lines 2 through 4, the phrase “Apnea (L38276, L38307, L38398, L38387, L38310, L38312, L38385, L38528)” is corrected to read “Apnea (L38307, L38310, L38385)”.

(5) Eleventh bulleted paragraph, lines 1 through 4, the paragraph “• Skin and Tissue Substitutes (LCDs below)—only applicable to MAC jurisdictions and states that have an active LCD in place” is corrected to read “• Skin and Tissue Substitutes (LCDs below): Only applicable to selected WISeR MAC jurisdictions and states with an active LCD in place during the WISeR performance years starting on January 1, 2026.”

b. Third column, first full paragraph, lines 23 and 24, the phrase “Additional information about the WISeR model is available” is corrected to read “Additional information about the WISeR model and the most current WISeR items and services and their affiliated NCDs and LCDs are available”.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign

this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–06617 Filed 4–3–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–416 and CMS–10628]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 6, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; *Use:* The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility) who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state’s results in attaining the participation goals set for the state. The information gathered from this report permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. *Form Number:* CMS–416 (OMB control number 0938–0354); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,128. (For policy questions regarding this collection

contact Deirdra Stockmann at 410-786-2433.)

2. *Type of Information Collection Request*: Revision of a previously approved collection; *Title of Information Collection*: Initial Request for State Implemented Moratorium Form; *Use*: Congress has enacted section 1866 (j)(7) of the Social Security Act, which allows for the imposition of temporary moratorium. CMS promulgated 42 CFR 424.570 in order to comply with that statute, which requires that prior to implementing state Medicaid moratoria the state Medicaid agency must notify the Secretary in writing, including all of the details of the moratoria, and obtain the Secretary's concurrence with the imposition of the moratoria.

The Initial Request for State Medicaid Implemented Moratorium, named the "Initial Request for State Medicaid Implemented Moratorium" has been created to collect that data, in a uniform manner, which the states report to CMS when they request a moratorium. Currently, CMS is collecting this data on an ad-hoc basis, however this process needs to be standardized so that moratoria decisions are being made based on the same criteria each time. The form may be used by states and territories who wish to impose a Medicaid or Children's Health Insurance Program moratorium. CMS will use this information as a standardized method to collect and track state-imposed moratoria requests. *Form number*: CMS-10628 (OMB control number: 0938-1328); *Frequency*: Occasionally; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 5; *Number of Responses*: 5; *Total Burden Hours*: 25. (For questions regarding this collection contact Alisha Sanders at 410-786-0671).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026-06570 Filed 4-3-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1280]

Electronic Submission of Postmarketing Individual Case Safety Reports to the Food and Drug Administration Adverse Event Monitoring System Using International Council of Harmonisation E2B(R3) Data Standards; Regional Data Elements and Implementation Schedule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an updated data standard requirement for the submission of postmarketing individual case safety report (ICSR) submissions for human drug products, biological products, and drug- or biologic-led combination products to the FDA Adverse Event Monitoring System (AEMS) database (formerly FDA Adverse Event Reporting System (FAERS)) via the Electronic Submissions Gateway Next Generation (ESG NextGen). Starting October 1, 2026, postmarketing ICSRs must be reported using the data standards adopted by FDA in the International Council for Harmonisation (ICH) guidance for industry entitled "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide—Data Elements and Message Specification" (ICH E2B(R3) Implementation Guidance), which incorporates by reference regional implementation guides (collectively ICH E2B(R3) data standards).

DATES: For postmarketing ICSRs for human drug products, biological products, and drug- or biologic-led combination products submitted via ESG NextGen, beginning October 1, 2026, the ICSRs must be submitted to the AEMS database using ICH E2B(R3) data standards.

FOR FURTHER INFORMATION CONTACT: For information concerning drug products and biological products regulated by the Center for Drug Evaluation and Research: Quocbao Pham, Center for Drug Evaluation and Research (HFD-430), Food and Drug Administration, 10903 New Hampshire Ave., Building 22, Rm. 4491, Silver Spring, MD 20993-0002, (301)-796-5384, aemsesub@fda.hhs.gov.

For information concerning biological products regulated by the Center for

Biologics Evaluation and Research: Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, (240)-402-7911.

SUPPLEMENTARY INFORMATION: FDA is announcing an updated data standard requirement for the submission of postmarketing ICSR submissions for human drug products, biological products, and drug- or biologic-led combination products to the AEMS database via the ESG NextGen. Starting October 1, 2026, postmarketing ICSR submissions for human drug products, biological products, and drug- and biologic-led combination products to the AEMS database via ESG NextGen must be reported using the data standards provided in the ICH E2B(R3) Implementation Guidance (available at <https://www.fda.gov/media/81904/download>), which incorporates by reference the guidance for industry and technical specifications document entitled "FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products" (ICH E2B(R3) FDA Regional Implementation Guidance) (available at <https://www.fda.gov/media/180748/download>). The ICH E2B(R3) Implementation Guidance and ICH E2B(R3) FDA Regional Implementation Guidance were issued to improve the quality of data in ICSR submissions and to enable improved handling and analyses of ICSRs. Differences between ICH E2B(R2) and ICH E2B(R3) include, for example: new, changed, and expanded data elements; assessment of seriousness at the event level, rather than the case level; and embedding of attachments in the ICSR rather than providing separately.

FDA postmarketing safety reporting regulations for human drug and biological products require that persons subject to mandatory postmarketing reporting requirements for human drug products, biological products, and drug- or biologic-led combination products submit ICSRs in an electronic format that FDA can process, review, and archive. See 21 CFR 4.102, 230.220(c)(1), 310.305(e)(1), 314.80(g)(1), 314.81(b)(3)(v)(F)(1), 314.98, 329.100(c)(1), and 600.80(h)(1). The regulations explain that FDA will issue guidance on how to provide the electronic submission of safety reports, including ICSRs and ICSR attachments.

In the guidance for industry entitled "Providing Submissions in Electronic Format—Postmarketing Safety Reports" (eSRR Guidance) (available at <https://www.fda.gov/media/71176/download>), FDA provides two options for electronic