

Categories of Records

Records exchanged under the matching program include beneficiary identifying information, enrollment information, claims information, provider identifiers, diagnosis and procedure information, dates of service, payment information, and other data elements necessary to identify duplicate payments for medical services.

The data used in the match include the following:

VHA Beneficiary Finder File Data:

- a. Transaction type: VA Unique Person Identifier
- b. SSN
- c. Medicare Claim Number (if available)
- d. Date of Birth
- e. Beneficiary First Name
- f. Beneficiary Last Name
- g. Beneficiary Sex
- h. Enrollment time frames: effective date and/or, when applicable, end date
- i. Date of death (if applicable)

CMS Response File Data:

- a. Action type: VA Unique Person Identifier
- b. SSN
- c. MBI
- d. Date of Birth
- e. Beneficiary First Name
- f. Beneficiary Last Name
- g. Beneficiary Sex code
- h. Medicare Enrollment time frames: Effective and termination dates
- i. Date of death

Based on the results in each response file identifying the beneficiaries who are dual enrolled, VHA will provide CMS with a file containing medical claims that VHA paid in full or in part for those dually enrolled beneficiaries. CMS will match the records to its own claims and payment systems and return to VHA a response file containing claims that CMS paid in full or in part for the same service. This exchange includes the following data:

VHA Claims File Data Fields:

- a. Patient Information from Matched Beneficiary File (e.g., SSN, Date of Birth, Name, Sex)
- b. Claim Identification Fields (e.g., Claim Number, Claim Line)
- c. Service Identification Fields (e.g., Service Date, Type, Place)
- d. Additional Claim Relevant Identification Fields (e.g., Revenue Codes)
- e. Billing Provider Identification Fields (e.g., Name, National Provider Identification number).
- f. Additional Relevant Provider Identification Fields (e.g., Rendering Provider, Attending Provider)

- g. Procedure Codes and Modifiers
- h. Diagnosis Codes and Qualifiers
- i. Payment Identification Fields (e.g., Date, Amount, Units, Payment Authority)

CMS Claims File Data Fields that are Added to the VA File for Matched Claims:

- a. Patient Information from Matched Beneficiary File (e.g., SSN, Date of Birth, Name, Sex)
- b. Claim Identification Fields (e.g., Claim Number, Claim Line)
- c. Service Identification Fields (e.g., Service Date, Type, Place)
- d. Additional Claim Relevant Identification Fields (e.g., Revenue Codes)
- e. Billing Provider Identification Fields (e.g., Name, National Provider Identification number).
- f. Additional Relevant Provider Identification Fields (e.g., Rendering Provider, Attending Provider)
- g. Procedure Codes and Modifiers
- h. Diagnosis Codes and Qualifiers
- i. Payment Identification Fields (e.g., Date, Amount, Units)

System(s) of Records

The data used in this matching program will be disclosed from the following systems of records, based on the routine uses identified:

CMS

- Common Working File (CWF), System No. 09–70–0526
- Medicare Beneficiary Database (MBD), System No. 09–70–0536
- Integrated Data Repository (IDR), System No. 09–70–0571
- National Claims History (NCH), System No. 09–70–0558

Department of Veterans Affairs

- Enrollment and Eligibility Records—VA (147VA10)
- Non-VA Care (Fee) Records—VA (23VA10NB3)

[FR Doc. 2026–21491 Filed 10–20–26; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2482]

Regulatory Considerations for Prescription Drug Use-Related Software; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry titled “Regulatory Considerations for Prescription Drug Use-Related Software.” This final guidance describes FDA’s application of its drug labeling authorities to certain software outputs that are disseminated by or on behalf of a drug sponsor for use with a prescription drug product or a prescription drug-led, drug-device combination product that is assigned to the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research as the lead center. This guidance finalizes the draft guidance of the same title issued on September 19, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on October 21, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2023–D–2482 for “Regulatory Considerations for Prescription Drug Use-Related Software.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division

of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3314, Silver Spring, MD 20993–0002, 301–796–2500, CDEROMP@fda.hhs.gov; Aneesh Deoras, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5540, Silver Spring, MD 20993–0002, 240–402–4363, digitalhealth@fda.hhs.gov; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911, industry.biologics@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry titled “Regulatory Considerations for Prescription Drug Use-Related Software.” This guidance describes how FDA intends to apply its drug labeling authorities to certain software outputs that are disseminated by or on behalf of a drug sponsor for use with a prescription drug product or a prescription drug-led, drug-device combination product. As explained in this final guidance, prescription drug use-related software generally includes software that (1) is disseminated by or on behalf of a drug sponsor and (2) produces an end-user output that supplements, explains, or is otherwise textually related to one or more of the sponsor’s drug products regardless of whether the software is regulated as a device¹ under the Federal Food, Drug,

and Cosmetic Act (FD&C Act). A software function is a distinct purpose of the prescription drug use-related software, and end-user output is any material (content) that the prescription drug use-related software presents to the end user (e.g., a patient, caregiver, or health care practitioner). As discussed in this final guidance, FDA considers end-user output to be a type of prescription drug labeling.

This final guidance clarifies (1) how FDA intends to apply its drug labeling authorities to end-user output of prescription drug use-related software, (2) how the FDA-required labeling, in particular the Prescribing Information (PI), should describe prescription drug use-related software functions, and (3) when and how sponsors should submit end-user output to FDA for review. Generally, the recommendations provided in this final guidance are intended to align with ongoing Agency initiatives across all product centers, including digital health initiatives at the Center for Devices and Radiological Health. In developing this guidance, FDA has considered existing Agency policies to ensure consistent regulation of device software and efficient, coordinated review in instances when prescription drug use-related software is reviewed by the Agency as a device.

This guidance finalizes the draft guidance titled “Regulatory Considerations for Prescription Drug Use-Related Software” issued on September 19, 2023 (88 FR 64443). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include (1) clarifying the considerations for standalone software functions; (2) introducing a decision tree to guide sponsors through labeling determinations; (3) providing illustrative examples of PI language for both device-connected software and standalone software; and (4) recommending the addition of a statement in the PI for device-connected software functions for which there is no meaningful improvement in a clinical outcome. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Regulatory Considerations for Prescription Drug Use-Related Software.” It does not establish any rights for any person and is not binding on FDA or the public.

¹ Under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act, “the term ‘device’ (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term ‘device’ does not include software functions excluded pursuant to section 520(o).”

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be neither an E.O. 14192 regulatory action nor an E.O. 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.2 and 601.12 for biologics license applications and supplemental applications have been approved under OMB control number 0910–0338. The collections of information in Form FDA 2253 have been approved under OMB control number 0910–0001. The collections of information for prescription drug product labeling requirements in 21 CFR 201.56 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 202.1 for prescription drug advertisements have been approved under OMB control number 0910–0686.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21516 Filed 10–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report, OMB No. 0915–0172—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 20, 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 Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915–0172—Revision.

Abstract: The Title V Maternal and Child Health (MCH) Services Block Grant to States Program is authorized by Sections 501–509 of Title V of the Social Security Act (42 U.S.C. 701–709). HRSA is updating the *Title V Maternal and*

Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report (Guidance). This Guidance is used annually by the 50 states and nine jurisdictions (the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands; hereafter referred to as “state”) in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. The updates being proposed by HRSA for this edition of the Guidance continue to support the federal-state partnership that is supported by the Title V MCH Services Block Grant and the state's role in developing a 5-Year Action Plan that addresses its individual priority needs. Updates to this edition of the Guidance are editorial and technical revisions based on feedback from the states in using the Guidance and Forms since January 2024, and by comments received from State Title V program leadership, national MCH leaders, other MCH stakeholders, and the public.

A 60-day notice published in the **Federal Register** on May 19, 2026, vol. 91, No. 96; pp. 29140–41 (91 FR 29140). The 60-day **Federal Register** Notice (FRN) stated that minor editorial corrections and clarifications were made to Form 7, Form 10, Form 12 instructions and the Glossary, and that updates were made to the short and long titles of the National Performance Measures to improve title accuracy and fulfill Government Accountability Office recommendations and align National Performance Measures with other HRSA program measures. However, the reference to Form 12 instructions in the 60-day FRN was a technical error; instead, the FRN should have referred to Form 11, to which additional minor clarifications were made.

HRSA received comments from five respondents (state Title V programs and other MCH stakeholders) on the proposed updates to the eleventh edition of the Guidance. The submitted responses included multiple comments. Of the five respondents, four respondents provided comments related to implementation of the guidance or the Title V Information System (TVIS) that would be addressed most effectively in the form of technical assistance, rather than adjusting the guidance instructions. Two respondents recommended expanding the definitions of budget-related glossary terms to