d. date of birth (required)
e. gender (required)
f. social security number (SSN) (required)
g. requested qualified health plan (QHP) coverage effective date (required)
h. requested QHP coverage end date (required)
i. State identification (required)
j. transaction ID (required)

Data provided by VHA to CMS:

a. SSN (required)
b. start/end date(s) of enrollment period(s) (when match occurs)
c. a blank date response when a non-match occurs
d. a blank date when a match is made but VHA's record contains a date of death
e. enrollment period(s) is/are defined as the timeframe during which the individual was enrolled in a VHA Health Care Program.

System(s) of Records

The records used in the matching program will be disclosed from the following systems of records, as authorized by routine uses published in the system of records notices (SORNs) cited below:

A. System of Records Maintained by CMS

CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018). Routine use 3 authorizes CMS' disclosures to VHA.

B. Systems of Records Maintained by VHA

54VA10NB3 Veterans and Beneficiaries Purchased Care Community Health Care Claims, Correspondence, Eligibility, Inquiry and Payment Files—VA, published at 80 FR 11527 (March 3, 2015). Routine use 25 authorizes VHA's disclosures to CMS.

[FR Doc. 2023–19481 Filed 9–8–23; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–21 and CMS–8003]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by November 13, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–R–21 Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31
CMS–8003 1915(c) Home and Community Based Services (HCBS) Waiver Application

Under the 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 requires Federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31; *Use:* Certain Medicaid providers that are subject to offsets for the collection of Medicaid overpayments may terminate or substantially reduce their participation in Medicaid, leaving the State Medicaid agency unable to recover the amounts due. Recovery procedures allow for determining the amount of overpayments and offsetting the overpayments by withholding the provider's Medicare payments. To effectuate the withholding, the State agency must provide their respective CMS regional office with certain documentation that identifies the provider and the Medicaid overpayment amount. The agency must also demonstrate that the provider was notified of the overpayment and that demand for the overpayment was made. An opportunity to appeal the overpayment determination must be

afforded to the provider by the Medicaid State agency. Lastly, Medicaid State agencies must notify CMS when to terminate the withholding; *Form Number:* CMS–R–21 (OMB control number: 0938–0287); *Frequency:* Occasionally; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 54; *Total Annual Responses:* 27; *Total Annual Hours:* 81. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* 1915(c) Home and Community-Based Services (HCBS) Waiver Application; *Use:* We use the application to review and adjudicate individual waiver actions. The application is also used by States to submit and revise their waiver requests. *Form Number:* CMS–8003 (OMB control number 0938–0449); *Frequency:* Yearly; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 47; *Total Annual Responses:* 71; *Total Annual Hours:* 6,005. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

Dated: September 6, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–19500 Filed 9–8–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3391]

Clinical Pharmacology Considerations for Peptide Drug Products; Draft 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 draft guidance for industry entitled ''Clinical Pharmacology Considerations for Peptide Drug Products.'' This guidance describes FDA's recommendations regarding clinical pharmacology considerations for peptide drug product development programs, including hepatic impairment, drug-drug interactions (DDIs), assessing QTc prolongation risk, and immunogenicity risk and impact on the pharmacokinetics (PK), safety, and efficacy assessment. The intent of this draft guidance, when finalized, is to assist industry in the conduct of these development programs.

DATES: Submit either electronic or written comments on the draft guidance by December 11, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–3391 for ''Clinical Pharmacology Considerations for Peptide Drug Products.'' 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 the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Daphne Guinn, Center for Drug