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 December 3, 2018.

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, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–1326.

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–10391 Methods for Assuring Access to Covered Medicaid Services Under 42 CFR 447.203 and 447.204

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. *Title of Information Collection:* Methods for Assuring Access to Covered Medicaid Services Under 42 CFR 447.203 and 447.204; *Type of Information Collection Request:* Extension of a currently approved collection; *Use:* Current regulations at 42 CFR 447.203(b) require states to develop an access monitoring review plan (AMRP) that is updated at least every three years for: Primary care services, physician specialist services, behavioral health services, pre and post-natal obstetric services (including labor and delivery), and home health services. When states reduce rates for other Medicaid services, they must add those services to the AMRP and monitor the effects of the rate reductions for 3 years. If access issues are detected, a state must submit a corrective action plan to CMS within 90 days and work to address the issues within 12 months. Section 447.203(b)(7) requires that states have mechanisms to obtain ongoing beneficiary and provider feedback. A state is also required to maintain a record of data on public input and how the state responded to the input. Prior to submitting proposals to reduce or restructure Medicaid service payment rates, states must receive input from beneficiaries, providers, and other affected stakeholders on the extent of beneficiary access to the affected services.

The information is used by states to document that access to care is in compliance with section 1902(a)(30)(A) of the Social Security Act, to identify issues with access within a state's Medicaid program, and to inform any necessary programmatic changes to address issues with access to care. CMS uses the information to make informed approval decisions on State plan amendments that propose to make Medicaid rate reductions or restructure payment rates and to provide the necessary information for CMS to monitor ongoing compliance with section 1902(a)(30)(A). Beneficiaries, providers and other affected stakeholders may use the information to raise access issues to state Medicaid agencies and work with agencies to address those issues. *Form Number:* CMS–10391 (OMB control number: 0938–1134); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments); *Number of Respondents:* 51; *Number of Responses:* 212; *Total Annual Hours:* 12,262. (For questions regarding this collection contact Jeremy Silanskis at 410–786–1592.)

Dated: September 28, 2018.

William N. Parham, III,

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

[FR Doc. 2018–21587 Filed 10–3–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10008, CMS–R–234, and CMS–R–194]

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

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 November 5, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

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:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Eligibility of Drugs, Biologicals, and Radiopharmaceutical Agents for Transitional Pass-Through Status Under the Hospital Outpatient Prospective Payment System (OPPS); *Use:* Section 201(b) of the BBRA 1999 amended section 1833(t) of the Act by adding new section 1833(t)(6). This provision requires the Secretary to make additional payments to hospitals for a period of 2 to 3 years for certain drugs, radiopharmaceuticals, biological agents, medical devices and brachytherapy devices. Section 1833(t)(6)(A)(iv) establishes the criteria for determining the application of this provision to new items. Section 1833(t)(6)(C)(i) provides that the additional payment for drugs and biologicals be the amount by which the amount determined under section 1842(o) of the Act exceeds the portion of the otherwise applicable hospital outpatient department fee schedule amount that the Secretary determines to be associated with the drug or biological. Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108–173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we stated in the November 15, 2004 **Federal Register** (69 FR 65776), in CY 2005, we will pay under the OPPS for drugs, biologicals and radiopharmaceuticals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Public Law 108–173 at a rate that is equivalent to the payment these drugs and biologicals will receive in the physician office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule final rule. Information on Average Sales Price is found at *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/.* The intent of these provisions is to ensure that timely beneficiary access to new pharmacological technologies is not jeopardized by inadequate payment levels. *Form Number:* CMS–10008 (OMB control number 0938–0802); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 480. (For policy questions regarding this collection contact Raymond Bulls at 410–786–7267).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Subpart D—Private Contracts; *Use:* Section 4507 of the Balanced Budget Act of 1997 (BBA 1997) amended section 1802 of the Social Security Act (the Act) to permit certain physicians and practitioners to opt-out of Medicare and to provide through private contracts services that would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the supporting regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455, counters the effect of certain provisions of Medicare law that, absent section 1802 of the Act, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits. The most recent approval of this information collection request (ICR) was issued by the Office of Management and Budget on March 2, 2016. We are now seeking to renew this approval before it expires on March 31, 2019. We have made no changes to the information being collected. We updated our burden estimate to reflect changes in the number of physicians and practitioners who have opted out and refinements to our methodology for estimating the burden associated with contracts. We have also updated the cost estimate to account for the current Bureau of Labor Statistics (BLS) wage estimates and to include the estimated costs for Medicare Advantage plans. *Form Number:* CMS–R–234 (OMB control number 0938–0730); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 57,722; *Total Annual Responses:* 57,722; *Total Annual Hours:* 23,557. (For policy questions regarding this collection contact Frederick Grabau at 410–786–0206).

3. *Type of Information Collection Request:* Reinstatement without a change of a previously approved collection; *Title of Information Collection:* Medicare Disproportionate Share Adjustment Procedures and Criteria; *Use:* Section 1886(d)(5)(F) of the Social Security Act established the Medicare disproportionate share adjustment (DSH) for hospitals, which provides additional payment to hospitals that serve a disproportionate share of the indigent patient population.

This payment is an add-on to the set amount per case the Centers for Medicare and Medicaid Services (CMS) pays to hospitals under the Medicare Inpatient Prospective Payment System (IPPS). Under current regulations at 42 CFR 412.106, in order to meet the qualifying criteria for this additional DSH payment, a hospital must prove that a disproportionate percentage of its patients are low income using Supplemental Security Income (SSI) and Medicaid as proxies for this determination. This percentage includes two computations: (1) The ''Medicare fraction'' or the ''SSI ratio'' which is the percent of patient days for beneficiaries who are eligible for Medicare Part A and SSI and (2) the ''Medicaid fraction'' which is the percent of patient days for patients who are eligible for Medicaid but not Medicare. Once a hospital qualifies for this DSH payment, CMS also determines a hospital's payment adjustment based on these two fractions. 42 CFR 412.106 allows hospitals to request that the Medicare fraction of the DSH adjustment be calculated on a cost reporting basis rather than a federal fiscal year. Once requested, the hospital must accept the result irrespective of whether it increases or decreases their DSH payment. The routine use procedure and the DUA allows hospitals to request the detailed Medicare data so they can make an informed choice before deciding whether to request that the Medicare fraction be calculated on the basis of a cost reporting period rather than a federal fiscal year. *Form Number:* CMS–R–194 (OMB control number 0938–0691); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Emily Lipkin at 410–786–3633.)

Dated: September 28, 2018.

William N. Parham, III,

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

[FR Doc. 2018–21590 Filed 10–3–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1721]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

DATES: Submit either electronic or written comments on the collection of information by December 3, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 3, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 3, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2014–N–1721 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Applications.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- 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