

for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* State child support agencies are required to establish and operate a federally approved statewide Automated Data Processing (ADP) and information retrieval system to assist in child support services. The APD process, established at 45 CFR part 95, subpart F, is the procedure by which states request and obtain approval for Federal Financial Participation (FFP) in their cost of acquiring ADP equipment

and services. The ACF OCSS Division of State and Tribal Systems (DSTS) oversees this process.

States are required to submit an initial APD, containing information to assist the Secretary of the Department of Health and Human Services (HHS) in determining if the state computerized support enforcement project planning and implementation meets federal certification requirements for approving FFP. States are then required to submit annual APD updates to HHS to report project status and request ongoing FFP for systems development, enhancements, operations, and maintenance. As-needed APDs are also submitted to acquire FFP when major milestones are missed or significant changes to project schedules occur.

Based on an assessment of the information provided in the APD, states that do not meet the federal requirements necessary for approval are required to conduct periodic independent verification and validation services for high-risk project oversight.

In addition to the APDs providing HHS/ACF/OCSS with the information necessary to determine the allowable level of federal funding for state systems projects, states also submit associated procurement and data security documents, such as requests for proposals (RFPs), contracts, contract amendments, and the biennial security review reports.

*Respondents:* State child support agencies.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
RFP and Contract .....	50	4.5	4	900	300
Emergency Funding Request .....	21	1	2	42	14
Biennial Reports .....	54	1.5	1.5	121.5	40.5
Advance Planning Document .....	44	3.6	120	19,008	6,336
Operational Advance Planning Document .....	10	3	30	900	300
Independent Verification and Validation (ongoing) .....	3	12	10	360	120
Independent Verification and Validation (semiannually) .....	4	6	16	384	128
Independent Verification and Validation (quarterly) .....	10	12	30	3,600	1,200
System Certification .....	3	3	240	2,160	720

*Estimated Total Annual Burden Hours:* 9,158.50.

*Authority:* 45 CFR part 95, subpart F.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2024-02166 Filed 2-2-24; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2024-N-0018]

**Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and

recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on March 15, 2024, from 8:30 a.m. to 5:30 p.m. eastern time.

**ADDRESSES:** All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-0018. The docket will close on March 14, 2024. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. eastern time at the end of March 14, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be

considered timely if they are received on or before that date.

Comments received on or before March 1, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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-2024-N-0018 for "Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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, 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." FDA 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 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 the 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.

#### FOR FURTHER INFORMATION CONTACT:

Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 240-402-5343, email: [ODAC@fda.hhs.gov](mailto:ODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

#### SUPPLEMENTARY INFORMATION:

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. During the morning session, the Committee will discuss supplemental biologics license application (sBLA) 125746.74 for CARVYKTI (ciltacabtagene autoleucel), suspension for intravenous infusion, submitted by Janssen Biotech, Inc. The proposed indication for this product is for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide. The Committee will have a general

discussion focused on the overall survival data in the Study MMY3002 (CARTITUDE-4) and the risk and benefit of ciltacabtagene autoleucel in the intended population. During the afternoon session, the Committee will discuss sBLA 125736.218 for ABECMA (idecabtagene vicleucel), suspension for intravenous infusion, submitted by Celgene Corp., a Bristol-Myers Squibb Co. The proposed indication is for the treatment of adult patients with relapsed or refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The Committee will have a general discussion focused on the overall survival data in the Study MM-003 (KarMMa-3) and the risk and benefit of idecabtagene vicleucel in the intended population.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before March 1, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 11:10 a.m. to 11:40 a.m. and 4 p.m. to 4:30 p.m. eastern time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 22, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may

conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 23, 2024.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: January 30, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-02229 Filed 2-2-24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection

**Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Small Health Care Provider Quality Improvement Program, OMB No. 0915-0387—Extension**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than April 5, 2024.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Small Health Care Provider Quality Improvement Program, OMB No. 0915-0387—Extension.

*Abstract:* This program is authorized by the Public Health Service Act, section 330A(g) (42 U.S.C. 254c(g)). This authority permits the Federal Office of Rural Health Policy (FORHP) to award Small Health Care Provider Quality Improvement grants that expand access to, coordinate, and improve the quality of basic health care services, and enhance the delivery of health care, in rural areas. Specifically, FORHP may award grants to provide for the planning and implementation of Small Health Care Provider Quality Improvement activities, including activities related to increasing care coordination, enhancing chronic disease management, and improving patient health outcomes.

The purpose of the Small Health Care Provider Quality Improvement Grant Program is to provide support to rural primary care providers for implementation of quality improvement activities. The goal of the program is to promote the development of an evidence-based culture and delivery of coordinated care in the primary care setting. Additional objectives of the program include improved health outcomes for patients, enhanced chronic disease management, and better engagement of patients and their caregivers. Organizations participating

in the program are required to use an evidence-based quality improvement model, perform tests of change focused on improvement, and use health information technology (HIT) to collect and report data. HIT may include an electronic patient registry or an electronic health record and is a critical component for improving quality and patient outcomes. With HIT it is possible to generate timely and meaningful data, which helps providers track and plan care. HRSA collects information from grant recipients that participate in this program using an OMB-approved set of performance measures and seeks to extend its approved information collection.

*Need and Proposed Use of the Information:* For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to FORHP, including: (1) access to care, (2) population demographics, (3) staffing, (4) consortium/network, (5) sustainability, and (6) project specific domains. All measures will speak to FORHP's progress toward meeting the goals set. FORHP collects this information to quantify the impact of grant funding on access to health care, quality of services, and improvement of health outcomes. FORHP uses the data for program improvement and grantees use the data for performance tracking. No changes are proposed from the current data collection effort, but FORHP estimates fewer respondents to align with the current cohort of grantees.

*Likely Respondents:* The respondents would be the grant recipients (program grantees, not patients who receive health care services) of the Small Health Care Provider Quality Improvement Program grants.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden