++ Confirm ACHC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the April 3, 2023, proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CfCs for ASCs. We received two (2) timely pieces of correspondence.

Comment: Two commenters expressed support for ACHC and their ASC accreditation program and encouraged CMS to approve them for continued recognition as a national AO for ASCs.

Response: We appreciate the support from commenters and agree that ACHC should be approved for continued recognition as a national AO for ASCs that wish to participate in the Medicare or Medicaid programs.

V. Provisions of the Final Notice

A. Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared ACHC's ASC accreditation requirements and survey process with the Medicare CfCs of part 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of ACHC's ASC accreditation application, which were conducted as described in section III of this notice, yielded the following areas where, as of the date of this notice, ACHC has completed revising its standards and certification processes in order to—

- Meet the standard's requirements of all the following regulations:

++ Section 416.44(a), to address that an ASC ''must provide a functional and sanitary environment for the provision of surgical services.''

++ Section 416.44(b)(2), to address the requirements regarding Life Safety Code (LSC) waivers.

++ Section 416.45(a), to address the regulatory language for granting privileges in accordance with recommendations from qualified medical personnel.

++ Section 416.54(d)(2), to clarify the cycle of testing for the ASC's emergency preparedness plans.

In addition to the standards review, CMS also reviewed ACHC's comparable survey processes, which were conducted as described in section III of this notice, and yielded the following areas where, as of the date of this notice, ACHC has completed revising its survey processes to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Revising the compliant policies and processes to align with the State Operations Manual, Chapter 5 guidance. In particular, ACHC's Administrative Review Offsite Investigation process to align with the triage process to track and trend for potential focus areas during the next onsite survey or complete an onsite complaint investigation.

++ Revising ACHC's ASC Accreditation Process policies to include the applicable sections of the Health Care Facilities Code (HCFC) National Fire Protection Agency (NFPA 99) in accordance with section 416.44(c).

++ Ensuring that all ASC LSC surveyors have received comparable, adequate training or have sufficient experience to make them qualified to survey health care facilities to both the 2012 LSC and 2012 NFPA 99 requirements.

++ Ensuring that each deficiency citation of the Medicare ASC CfCs is documented in such a way that is comparable to the state survey agencies conducting federal Medicare ASC surveys.

++ Ensuring that all findings of non-compliance, that crosswalk to a comparable Medicare CfC, is identified in the final survey report.

++ Providing guidance and instruction to surveyors on determining the appropriate level of citation for LSC deficiencies.

B. Term of Approval

Based on our review and observations described in section III and section V of this notice, we approve ACHC as a national accreditation organization for ASCs that request participation in the Medicare program. The decision announced in this notice is effective September 22, 2023, through September 22, 2027 (4 years). In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years.

While ACHC has taken actions based on the findings annotated in section V.A, of this notice, (Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of ACHC's ASC survey processes to ensure full implementation and sustained compliance. In keeping with CMS's initiative to increase AO oversight broadly and ensure that our requested revisions by ACHC are fully implemented, CMS expects more frequent review of ACHC's activities in the future.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,

Federal Register Liaison, Center for Medicare & Medicaid Services.

[FR Doc. 2023–19323 Filed 9–6–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Judicial, Court, and Attorney Measures of Performance: Feedback and Implementation (New Collection)

AGENCY: Children's Bureau, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children's Bureau, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new descriptive study, Judicial, Court, and Attorney Measures of Performance (JCAMP): Feedback and Implementation. This expands on earlier work around technical assistance, as approved under Office of Management and Budget (OMB) #: 0970–0593.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This study will expand on a collection from field testing sites that informed the development of a suite of measures and tools, which became the JCAMP (OMB #0970–0593 [1]). The information collection proposed here will further those efforts now that the suite of documents has been released. Specifically, this effort will (1) collect information from JCAMP implementation teams to understand their experiences with JCAMP implementation support, and (2) collect information from parents and children with child welfare cases, foster/kinship caregivers, judges, case workers, parent attorneys, children's attorneys, and child welfare agency attorneys to gather information for JCAMP measures selected for use by jurisdictions (jurisdictions will collect only the data elements relevant to them). This will be accomplished using eleven instruments:

JCAMP Feedback Survey: Members of JCAMP implementation teams will answer questions about their experiences with JCAMP written materials, technical assistance, and the eJCAMP online platform.

Parent Experience Survey: A brief survey that collects data post-hearing about parent experiences in court including, strategies used by judges to engage families, satisfaction with their legal representation, and collects demographic information.

Parent Court Experience Question Bank: This question bank includes options for items to include on a survey of parents with child welfare cases. Sites will select items that align with their chosen JCAMP measures. It is expected that surveys created from this bank will include up to 30 questions.

Parent Focus Group Guide: This focus group guide includes questions for parents with child welfare cases about their experiences with the child welfare court process.

Youth Post-Hearing Short Survey: This brief survey asks youth about their experiences immediately following hearings and collects demographic information (for example to allow assessment of equity aspects of judicial and legal practice and differences among age groups).

Youth Experience Survey: This survey collects information from youth with child welfare cases about their experiences with the child welfare court process and collects demographic information (for example to allow assessment of equity aspects of judicial and legal practice and differences among age groups).

Youth Court Experience Question Bank: This question bank includes options for items to include on a survey of youth with child welfare cases. Sites will select items that align with their chosen JCAMP measures. It is expected that surveys created from this bank will include up to 30 questions.

Youth Focus Group Guide: This focus group guide includes questions for youth with child welfare cases about their experiences with the child welfare court process.

Caregiver Survey: This survey collects information from adults caring for children with child welfare cases about their experiences with the child welfare court process and demographic information.

Stakeholder Survey: This survey collects data regarding judges' and attorneys' experiences in court including, persons present at hearings, judicial engagement strategies used with parents, children, and caregivers, the practices of parent, child, and agency attorneys during hearings, typical timelines to permanency, and case processing activities.

Stakeholder Focus Group Guide: This focus group guide asks judges, parent attorneys, children's attorneys, and child welfare agency attorneys their perceptions of the child welfare court system, including how families are engaged, how families receive due process, the quality of legal representation, safety decision-making, and permanency decision-making.

Respondents: Respondents consist of Court Improvement Program administrators and staff, parents, youth, adults caregivers, judges, case workers, parent attorneys, children's attorneys, and agency attorneys.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
JCAMP Feedback Survey	100	1	0.25	25
Parent Experience Survey	250	1	0.17	42.5
Parent Court Experience Question Bank	250	1	0.17	42.5
Parent Focus Group Guide	80	1	1	80
Youth Post-Hearing Survey Short	250	1	0.08	20
Youth Experience Survey	250	1	0.17	42.5
Youth Court Experience Question Bank	250	1	0.17	42.5
Youth Focus Group Guide	80	1	1	80
Caregiver Survey	250	1	0.08	20
Stakeholder Survey	1,500	1	0.17	255
Stakeholder Focus Group Guide	400	1	1	400

[1] *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202203-0970-010.*

Estimated Total Annual Burden Hours: 1,050.

Authority: Sec. 5106, Public Law 111–320, the Child Abuse Prevention and Treatment Act Reauthorization Act of 2010, and titles IV–B and IV–E of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–19228 Filed 9–6–23; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2607]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that VEOPOZ (pozelimab-bbfg), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that VEOPOZ (pozelimab-bbfg), approved on August 18, 2023, and manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a priority review voucher. VEOPOZ (pozelimab-bbfg) injection is indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about VEOPOZ (pozelimab-bbfg), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19287 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1190]

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Sickle Cell Disease

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 Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. On October 31, 2023, the Committee will discuss and make recommendations on biologics license application (BLA) 125787 from Vertex Pharmaceuticals, Inc. for exagamglogene autotemcel (exa-cel). The applicant has requested an indication for the treatment of sickle cell disease in patients 12 years and older with recurrent vaso-occlusive crises. 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 October 31, 2023, from 9 a.m. to 5 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.*

The online web conference meeting will be available at the following link on the day of the meeting at *https://youtube.com/live/M90IjjxOdQg.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–1190. The docket will close on October 30, 2023. 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 October 30, 2023. 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 October 24, 2023, will be provided to the Committee. Comments received after that date and on October 30, 2023, 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