work product) regarding the quality and safety of health care delivery.

The Patient Safety Act requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers. (42 U.S.C. 299b–24(b)(1)(F)). The Patient Safety Act also authorizes the development of data standards, known as the Common Formats, to facilitate the aggregation and analysis of non-identifiable patient safety data collected by PSOs and reported to the network of patient safety databases (NPSD). (42 U.S.C. 299b–23(b)). The Patient Safety Act and Patient Safety Rule can be accessed at: *http://www.pso.ahrq.gov/legislation/.*

AHRQ has issued Common Formats for Event Reporting (CFER) for three settings of care—hospitals, nursing homes, and community pharmacies. AHRQ has also issued Common Formats for Event Reporting—Diagnostic Safety (CFER–DS) designed for use in all healthcare settings.

Federally listed PSOs can meet the requirement to collect patient safety work product in a standardized manner to the extent practical and appropriate by using AHRQ's Common Formats. The Common Formats are also available in the public domain to encourage their widespread adoption. An entity does not need to be listed as a PSO or working with one to use the Common Formats. However, the Federal privilege and confidentiality protections only apply to information developed as patient safety work product by providers and PSOs working under the Patient Safety Act.

Agenda, Registration, and Other Information About the Meeting

The Agency for Healthcare Research and Quality (AHRQ) will be hosting this fully virtual meeting to discuss implementation of the Common Formats with members of the public, including software developers and other interested parties. The agenda will include discussion on ways to improve the portion of the PSO Privacy Protection Center's website for Software Developers and Vendors: *https://www.psoppc.org/psoppc_web/publicpages/forDevelopersAndVendors.* Active participation and discussion by meeting participants is encouraged.

AHRQ requests that interested persons send an email to *SDMeetings@infinityconferences.com* for registration information. Before the meeting, an agenda and logistical information will be provided to registrants.

Dated: August 23, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–18486 Filed 8–26–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0103]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on September 1, 2022, from 10:00 a.m. to 5:00 p.m., EDT and September 2, 2022, from 10:00 a.m. to 12:00 p.m., EDT (dates and times subject to change, see the ACIP website for updates *http://www.cdc.gov/vaccines/acip/index.html*). The meeting will be webcast live via the World Wide Web. Written comments must be received on or before September 2, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0103, by either of the following methods.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329–4027, Attn: September 1–2, 2022, ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this Advisory Committee on Immunization Practices (ACIP) meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on use of COVID–19 vaccines booster doses. A recommendation vote(s) is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/index.html.*

The meeting will be webcast live via the World Wide Web; for more information on ACIP, visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to

public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before September 2, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment during the September 1–2, 2022, ACIP meeting must submit a request at *https://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m. EDT, August 30, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals by email on August 31, 2022, regarding their request to speak. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to three minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–18734 Filed 8–25–22; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

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 ZYNTEGLO (betibeglogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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 ZYNTEGLO (betibeglogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher. ZYNTEGLO is indicated for the treatment of adult and pediatric patients with ß-thalassemia who require regular red blood cell transfusions.

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about ZYNTEGLO, go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18519 Filed 8–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 28, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0746. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three