the comments. This guidance supersedes ''Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff; Humanitarian Device Exemption (HDE) Regulation: Questions and Answers,'' issued July 8, 2010 (available at: *https://www.fda.gov/media/74307/download*).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the Humanitarian Device Exemption Program. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Humanitarian Device Exemption Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17040 and complete title of the guidance in the request.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part, guidance, or FD&C Act section	Topic	OMB control No.
807, 812, 814	Acceptance of Data from Clinical Investigations for Medical Devices	0910–0741
814	Pediatric Uses of Devices	0910–0748
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
803	Medical Devices; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
520(m) of the FD&C Act	Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements.	0910–0661
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
56	Institutional Review Boards	0910–0130
10	Administrative Practices and Procedures	0910–0191
54	Financial Disclosure by Clinical Investigators	0910–0396

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19290 Filed 9–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about ACHDNC and the agenda for this meeting can be found on the ACHDNC website at: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: September 24, 2019, 10:00 a.m.–1:00 p.m. Eastern Time (ET).

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* The deadline for online registration is 12:00 p.m. ET on September 23, 2019. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive

services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the September meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include a discussion of the role of health information technology within state newborn screening programs and general updates on ACHDNC projects focused on newborn screening. Agenda items are subject to changes as priorities dictate and the final meeting agenda will be available on ACHDNC's website: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Information about the ACHDNC, a roster of members, as well as past meeting summaries are also available on the ACHDNC website.

Members of the public will have the opportunity to provide comments. Requests to offer oral comments will be accepted in the order they are requested and may be limited as time allows. Public participants may also submit written statements. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on September 19, 2019. Visit the ACHDNC website for information on registration, *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.,* parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–19260 Filed 9–5–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request; Information Request Title: 340B Drug Pricing Program Reporting Requirements, OMB Number 0915–0176—Extension

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection, the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR must be received no later than October 7, 2019.

ADDRESSES: Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

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

Information Collection Request Title: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—[Extension].

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act ''Limitation on Prices of Drugs Purchased by Covered Entities''), which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program) and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data reported by manufacturers to the Centers for Medicare & Medicaid Services. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

Section 340B(a)(5)(C) of the PHS Act permits the Secretary of HHS and manufacturers of a covered outpatient drug to conduct audits of covered entities in accordance with by procedures established the Secretary related to the number, duration, and scope of the audits. Manufacturers are permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer notifies the covered entity in writing when it believes the covered entity has violated these provisions of the 340B Program. If the problem cannot be resolved, the manufacturer will then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to HRSA, Healthcare Systems Bureau, Office of Pharmacy Affairs (OPA) for review. OPA will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General (OIG).

In response to the statutory mandate of section 340B(a)(5)(C) to permit the Secretary or manufacturers to conduct audits of covered entities and because of the potential for disputes involving covered entities and participating drug manufacturers, OPA developed an informal voluntary dispute resolution process for manufacturers and covered