copies to the Division of Dockets Management. If you do not wish your name and contact information to 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 this 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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:

I. Background

FDA is announcing the availability of a draft document entitled ''Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271; Draft Guidance for Industry.'' The document provides certain establishments that manufacture HCT/Ps, regulated solely under section 361 of the PHS Act and the regulations under 21 CFR part 1271, with recommendations and relevant examples for complying with the requirements under 21 CFR 1271.350(b) to report HCT/P deviations. The examples provided in the draft guidance are intended to illustrate those HCT/P deviations that have been most frequently reported to FDA, CBER.

The draft guidance does not apply to reproductive HCT/Ps or to HCT/Ps regulated under 21 CFR part 1270 and recovered before May 25, 2005. The draft guidance does not apply to health professionals who implant, transplant, infuse, or transfer HCT/Ps into recipients. The draft guidance also does not apply to HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, nor does it apply to investigational HCT/Ps subject to an investigational new drug application or an investigational device exemption.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue Based Products Regulated Solely Under section 361 of the Public Health Service Act and 21 CFR part 1271. 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Other Issues for Consideration

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32323 Filed 12–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Class Deviation from Competition Requirements for the Health Center Program; Notice of Class Deviations from the Requirements for Extensions, Administrative Supplements, and for Announcing these Deviations in the **Federal Register** for the Health Center Program.

SUMMARY: In accordance with the Awarding Agency Grants Administration Manual (AAGAM) Chapter 1.03.103, the Bureau of Primary Health Care (BPHC) has been granted class deviations from the requirements for extensions contained in the AAGAM Chapter 2.04.104B–4A.I.a(5)(b) and the requirements for administrative supplements contained in AAGAM Chapter 2.04.104B–4A.4.b to provide additional grant funds during extended budget periods in excess of the allowed maximum. The deviations prevent interruptions in the provision of critical health care services for a funded service area until a new award can be made to an eligible Service Area Competition (SAC) applicant and to conduct an orderly phase-out of Health Center Program activities by the current award recipient. BPHC has also been granted a deviation that allows it to annually announce via the **Federal Register** the Health Center Program award recipients that received a low cost extension and/or administrative supplement under the above described deviations.

SUPPLEMENTARY INFORMATION: Intended Recipient of the Award: Health Center Program award recipients for service areas that are threatened with a lapse in services due to transitioning award recipients.

Amount of Non-Competitive Awards: Varies annually.

Period of Supplemental Funding: Awards made beginning in fiscal year 2016 and ongoing.

CFDA Number: 93.224

Authority: Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

Justification: Targeting the nation's neediest populations and geographic areas, the Health Center Program currently funds more than 1,300 health centers that operate approximately 9,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. More than 23 million patients, including medically underserved and uninsured patients, received comprehensive, culturally competent, quality primary health care services through the Health Center Program award recipients.

Approximately one-third of current award recipients' service areas are scheduled to be competed each year via SACs. SACs are also held prior to a current grant's project period end date when (1) a grant is voluntarily relinquished or (2) a program noncompliance enforcement action taken by HRSA terminates the grant. If a SAC draws no fundable applications, BPHC may extend the current award recipient's budget period to conduct an orderly phase-out of Health Center Program activities and prepare for a new competition for the service area.

The amount of additional grant funds is calculated by pro-rating HRSA's existing annual funding commitment to the service area. The average Health Center Program grant amount is over $2 million. Approximately 6 months is required to announce and conduct a SAC. BPHC's extensions and administrative supplements are generally for a minimum of 90 days, which is at least 25 percent of the annual grant amount, thereby typically exceeding the allowed maximum. Through the deviations, award recipients receive consistent levels of funding to support uninterrupted primary health care services to the nation's most vulnerable populations and communities during service area award recipient transition.

FOR FURTHER INFORMATION CONTACT: Olivia Shockey, Expansion Division Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration at 301–443–9282 or *oshockey@hrsa.gov*.

Dated: December 17, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–32355 Filed 12–23–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on November 1, 2015, through November 30, 2015. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed