insurance coverage. In this matching program, VHA provides CMS with data when a state administering entity (AE) requests it and VHA is authorized to release it, verifying whether an individual who is applying for or is enrolled in private health insurance coverage under a qualified health plan through a federally-facilitated health insurance exchange is eligible for coverage under a VHA health plan. CMS makes the data provided by VHA available to the requesting AE through a data services hub to use in determining the applicant's or enrollee's eligibility for financial assistance (including an advance tax credit and cost-sharing reduction, which are types of insurance affordability programs) in paying for private health insurance coverage. VHA health plans provide minimum essential coverage, and eligibility for such plans usually precludes eligibility for financial assistance in paying for private coverage. The data provided by VHA under this matching program will be used by CMS and AEs to authenticate identity, determine eligibility for financial assistance, and determine the amount of the financial assistance.

Categories of Individuals

The categories of individuals whose information is involved in the matching program are:

• Veterans whose records at VHA match data provided to VHA by CMS (submitted by AEs) about individuals who are applying for or are enrolled in private insurance coverage under a qualified health plan through a federally-facilitated health insurance exchange.

Categories of Records

The categories of records used in this matching program are identity records and minimum essential coverage period records, consisting of the following data elements:

Data provided by CMS to VHA:

a. First name (required)
b. middle name/initial (if provided by applicant)
c. surname (applicant's last name) (required)
d. date of birth (required)
e. gender (optional)
f. SSN (required)
g. requested qualified health plan (QHP) coverage effective date (required)
h. requested QHP coverage end date (required)
i. transaction ID (required)

Data provided by VHA to CMS:

a. SSN (required)
b. start/end date(s) of enrollment period(s) (when match occurs)
c. a blank date response when a non-match occurs
d. if CMS transmits request and a match is made, but VA's record contains a date of death, VA will respond in the same manner as a non-match response, with a blank date
e. enrollment period(s) is/are defined as the timeframe during which the individual was enrolled in a VHA health care program

Systems(s) of Records

The records used in this matching program will be disclosed from the following systems of records, as authorized by routine uses published in the system of records notices (SORNs) cited below:

A. System of Records Maintained by CMS

• CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR. 6591 (Feb. 14, 2018). Routine use 3 authorizes CMS' disclosures to VHA.

B. Systems of Records Maintained by VHA

• 147VA10NF1 Enrollment and Eligibility Records—VA, published at 81 FR 45597 (July 14, 2016). Routine use 14 authorizes VHA's disclosures to CMS.

• 54VA10NB3 Veterans and Beneficiaries Purchased Care Community Health Care Claims, Correspondence, Eligibility, Inquiry and Payment Files—VA, published at 80 FR 11527 (March 3, 2015). Routine use 25 authorizes VHA's disclosures to CMS.

[FR Doc. 2018–21506 Filed 10–2–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of Intent To Issue an OPDIV-Initiated Supplement to BCFS Health and Human Services Under the Standing Funding Opportunity Announcement Number HHS–2017–ACF–ORR–ZU–1132, Residential (Shelter) Services for Unaccompanied Children

AGENCY: Unaccompanied Alien Children's (UAC) Program, Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of intent to issue an OPDIV-Initiated Supplement.

SUMMARY: Administration for Children and Families, Office of Refugee Resettlement, announces the intent to issue an OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, TX, in the amount of up to $6,500,000. ORR has been identifying additional capacity to provide shelter for potential increases in apprehensions of Unaccompanied Children at the U.S. Southern Border. Planning for increased shelter capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter for Unaccompanied Alien Children referred to its care by the Department of Homeland Security (DHS). To ensure sufficient capacity to provide shelter to unaccompanied children referred to HHS, BCFS proposed to the continuation of services to ORR with 222 variance licensed beds.

DATES: Supplemental award funds will support activities until January 31, 2019.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Deputy Director for Children's Programs, Office of Refugee Resettlement, 330 C Street SW, Washington, DC 20201. Phone: 202–401–4997. Email: *DCSProgram@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: ORR is continuously monitoring its capacity to shelter the unaccompanied children referred to HHS, as well as the information received from interagency partners, to inform any future decisions or actions.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The continuation of services of the existing program and its services through this supplemental award is a key strategy for ORR to continue to meet its responsibility to provide shelter for Unaccompanied Children referred to its care by DHS and so that the U.S. Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States. The award to BCFS will be made as two OPDIV-initiated supplements.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and

Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Karen Shields,

Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2018–21454 Filed 9–28–18; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1175]

Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs.'' This guidance addresses FDA's current thinking about the relevant age groups to study and how early in drug development applicants should incorporate pediatric patients for development of systemic drugs for atopic dermatitis (AD). This guidance finalizes the draft guidance of the same name issued on April 9, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on October 3, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2018–D–1175 for ''Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs.'' Received comments 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.

- 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.'' The Agency 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 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: *https://www.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dawn Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5168, Silver Spring, MD 20993–0002, 301–796–5376; or Stephen Ripley, 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 guidance for industry entitled ''Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs.'' This guidance addresses FDA's current thinking about the relevant age groups to study and how early in drug