• Assembling and sharing an information base of ''best practices'' for helping consumers evaluate health coverage options.

• Building and leveraging existing community infrastructures for information, counseling, and assistance.

• Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of May 20, 2019 are: Robert Blancato, President, Matz, Blancato & Associates; Dale Blasier, Professor of Orthopaedic Surgery, Department of Orthopedics, Arkansas Children's Hospital; Deborah Britt, Executive Director of Patient Services, Piedmont Fayette Hospital; Deena Chisolm, Associate Professor of Pediatrics and Public Health, The Ohio State University College of Medicine, The Research Institute at Nationwide Children's Hospital; Robert Espinoza, Vice President of Policy, Paraprofessional Healthcare Institute; Louise Scherer Knight, Director, Harry J. Duffey Family Patient and Family Services Program, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center; Cathy Phan, Business Development Coordinator, Asian American Health Coalition dba HOPE Clinic; Kamilah Pickett, Director, Community Health Compass; Alvia Siddiqi, Medical Director, Advocate Physician Partners; and Tobin Van Ostern, Co-Founder, Young Invincibles Advisors.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the July 16, 2019 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (April 10, 2019) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Security, Building, and Parking Guidelines

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at the number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held in a federal government building, the Hubert H. Humphrey (HHH) Building; therefore, federal security measures are applicable.

The REAL ID Act of 2005 (Pub. L. 109–13) establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits federal agencies from accepting an official driver's license or ID card from a state for any official purpose unless the Secretary of the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into federal buildings. The current list of states from which a federal agency may accept driver's licenses for an official purpose is found at *http://www.dhs.gov/real-id-enforcement-brief*.

We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

• Presentation of a government-issued photographic identification to the Federal Protective Service or Guard Service personnel.

• Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into HHH Building, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.

IV. Collection of Information

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. Chapter 35).

Authority: Sec. 1114(f) of the Social Security Act (42 U.S.C. 1314(f)), sec. 222 of the Public Health Service Act (42 U.S.C. 217a), and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR part 102–3).

Dated: June 21, 2019.

Seema Verma,

Administrator Centers for Medicare & Medicaid Services.

[FR Doc. 2019–13658 Filed 6–26–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Behavioral Interventions To Advance Self-Sufficiency Next Generation (BIAS–NG) (0970–0502)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) in the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) requests Office of Management and Budget (OMB) approval to modify the previously approved pilot generic clearance (0970–0502) to collect data as part of rapid cycle testing and evaluation, in order to inform the design of interventions informed by behavioral science and to better understand the mechanisms and effects of such interventions. Interventions have been and will continue to be developed in the program area domains of Temporary Assistance for Needy Families (TANF) and child welfare, and this revision

would also allow for collection of data in the Early Head Start/Head Start program area. These interventions are intended to improve outcomes for participants in these programs.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning 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 directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OPRE is conducting the Behavioral Interventions to Advance Self-Sufficiency Next Generation (BIAS–NG) project. This project uses behavioral insights to design and test interventions intended to improve the efficiency, operations, and efficacy of human services programs. The BIAS–NG project is applying and testing behavioral insights to ACF programs including TANF and Child Welfare, and intends to expand these efforts to Early Head Start/Head Start. This notice is a revision to a previously approved collection, which included data collection to design and test interventions in the TANF and Child Welfare domains. Under the approved pilot generic clearance, OPRE plans to work with approximately six sites, and will conduct one or more tests per site, for a total of approximately 9 tests of behavioral interventions. At least one of these sites will be in the newly added program area of Head Start/Early Head Start. The design and testing of BIAS–NG interventions is rapid and, to the extent possible, iterative. Each specific intervention is designed in consultation with agency leaders and launched as quickly as possible. To maximize the likelihood that the intervention produces measurable, significant, positive effects on outcomes of interest, rapid cycle evaluation techniques will be employed in which proximate outcomes will be measured to allow the research team to more quickly iterate and adjust the intervention design, informing subsequent tests. Due to the rapid and iterative nature of this work, OPRE sought and received generic clearance to conduct this research. Following standard OMB requirements for generic clearances, once instruments requiring burden are tailored to a specific site and the site's intervention, OPRE submits an individual generic information collection request under this umbrella clearance. Each request includes the individual instrument(s), a justification specific to the individual information collection, a description of the proposed intervention, and any supplementary documents. Each specific information collection includes up to two submissions: One submission for the formative stage research and another submission for any further data collection requiring burden during the testing phase. The type of information to be collected and the uses of the information is described in the supporting statements, found here: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201707-0970-005.*

This Notice is specific to expanding the program area domains to include Early Head Start/Head Start, in addition to the previously approved domains of Child Welfare and TANF.

Respondents: (1) Program Administrators, (2) Program Staff and (3) Program Clients.

TOTAL BURDEN ESTIMATES

[TANF, CW, Third Domain]

Instrument	Previously approved respondents for TANF and CW	Total number of respondents (TANF, CW, EHS/HS)	Number of responses per respondent	Average burden hours per response	Total burden hours with 3rd Domain
Diagnosis and Design					
Administrator interviews/focus groups	24	48	1	1	48
Staff interviews/focus groups	48	378	1	1	378
Client interviews/focus groups	48	348	1	1	348
Client survey	600	840	1	.25	210
Staff Survey	120	144	1	.25	36
Evaluation					
Administrator interviews/focus groups	48	96	1	1	96
Staff interviews/focus groups	96	756	1	1	756
Client interviews/focus groups	96	696	1	1	696
Client survey	6,000	10,800	1	.25	2,700
Staff Survey	120	600	1	.25	150

Estimated Total Burden Hours: 5,418.

Authority: 42 U.S.C. 1310.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–13701 Filed 6–26–19; 8:45 am]

BILLING CODE 4184–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5372]

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.'' This final guidance provides detailed recommendations for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers, and includes guidance describing the types of modifications to a diagnostic ultrasound device for which FDA does not intend to enforce the requirement for a new premarket notification (510(k)).

DATES: The announcement of the guidance is published in the **Federal Register** on June 27, 2019.

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–2017–D–5372 for ''Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Marketing Clearance of Diagnostic Ultrasound Systems and Transducers'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shahram Vaezy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4227A, Silver Spring, MD 20993–0002, 301–796–6242; or Keith Wear, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2114, Silver Spring, MD 20993–0002, 301–796–2538.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides detailed recommendations for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. This guidance supersedes FDA's guidance entitled ''Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers'' dated September 9, 2008, regarding FDA's approach to the regulation of certain diagnostic ultrasound devices.

In addition to outlining regulatory approaches for certain diagnostic ultrasound devices, this guidance describes the types of modifications to a diagnostic ultrasound device for which FDA does not intend to enforce the requirement for a new 510(k). As