will be enrolled in the study. Drivers will have a debriefing session if a driver chooses to withdraw from the study early or upon completion of the 8-month participation period.

Drivers who have a valid Class-A commercial driver's license (CDL) and work at the participating company in regional and long-haul operations for at least one year will be eligible for the study. A convenience sample of 180 eligible drivers will be recruited to participate in the study. The study sample will include approximately 90 regional and 90 long-haul drivers. There will be no required minimum number of female or minority drivers.

Data will be collected during each phase: (1) In the application, drivers will be asked to provide their name and contact information (home address, telephone number, and email address) to allow contact from the research team regarding their eligibility for the study. (2) In the briefing session, drivers will be asked to complete the Background Questionnaire. (3) During the study, information collection will occur through several streams: (a) A real-time fatigue monitoring system installed in the participating driver's vehicle; (b) Smart phone apps to collect data from a psychomotor vigilance test, the Karolinska Sleepiness Scale, a sleep log, a difficulty of drive scale, a degree of drive hazards scale, a fatigue scale, and a stress scale; (c) an electronic logging device which will record information about the driver's hours of service and driving; (d) a wrist actigraphy device to collect data on driver sleep and wake times. Drivers will be asked to synchronize the actigraph with a smartphone app daily; (e) smartphone or web-based questionnaires including an Exercise and Food Consumption Questionnaire, the quality of life short form 36 version-2 questionnaire (SF–36v2), Family Interactions Questionnaire, and Job Descriptive Index. These will be completed by drivers at four different intervals, including the beginning (1st week) and middle (2nd month) of the baseline phase, and the middle (5th month) and end (8th month) of the intervention phase; (f) A questionnaire to assess corporate practices and corporate safety climate will be given to managers at the participating carriers. These will be completed by managers at the beginning (1st week) of the study and end (8th month) of the intervention phase; and (g) During the field study, carriers will be asked to provide information concerning crashes and roadside violations occurring during each driver's period of study participation. Administrative cost information (*e.g.,* equipment, labor, etc.) will also be collected from the carrier to evaluate cost-benefit of the intervention.

OMB approval is requested for two years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 5,278 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Carrier Management	Participation Agreement	1	1	1
	Retrieval of Company Monthly Roadside Violations/Crash Reports.	1	8	90/60
	Retrieval of Company Administrative Costs	1	16	2
	Management Practice questionnaire (Time 1)	5	1	45/60
	Management Practice questionnaire (Time 2)	5	1	45/60
Drivers	Application to Participate	150	1	12/60
	Actigraph Training	90	1	10/60
	Background Questionnaire	90	1	45/60
	Daily Smartphone Questions	90	720	1/60
	PVT	90	720	3/60
	Exercise and Food Consumption Questionnaire.	90	4	20/60
	SF–36v2	90	4	30/60
	Family Interactions Questionnaire	90	4	15/60
	Safety Climate Questionnaire	90	4	10/60
	Job Descriptive Index	90	4	30/60
	Post-Study Questionnaire	90	1	1
	Phone Briefings	90	8	6/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Screening Tool for Unaccompanied Alien Children Program Staff and Visitors (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to continue use of a coronavirus (COVID–19) screening form for Unaccompanied Alien Children (UAC) program staff and visitors at ORR-funded programs. The form was originally approved under emergency approval for 6 months. ACF is requesting a 3-year extension of this information collection.

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 within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The COVID–19 risk questionnaire asks participants whether or not they display COVID–19 symptoms, whether or not they have had close contact with individuals known to test positive for COVID–19, and whether or not they have been tested for COVID–19. The questionnaire also requests temperature checks on individuals. This will help to reduce possible exposure to the virus and help protect the health and safety of both UAC and program staff.

Respondents: Staff and visitors at UAC program sites.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual responses per respondent	Average burden hours per response	Annual burden hours
UAC COVID–19 Risk Questionnaire	15,000	260	.033	128,700

Authority: 6 U.S.C. 279(b)(1)(B);(E).

Emily Ball Jabbour,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee. The general function of the committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

DATES: The meeting will take place virtually on October 22, 2020, from 10 a.m. Eastern Time to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at *www.fdalive.com/PEAC.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, *letise.williams@fda.hhs.gov,* 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 22, 2020, the committee will discuss and make recommendations on the topic ''Artificial Intelligence (AI) and Machine Learning (ML) in Medical Devices.'' Specifically, we will discuss the composition of the datasets on which the software ''learns'', components of the device information shared with patients, and factors that impact patient trust in the technology. Large clinical datasets are used to train and improve AI/ML algorithms, allowing transformational improvements in the diagnosis, clinical decision making, and treatment of patients. Devices using AI/ML technology will transform healthcare delivery by increasing efficiency of key processes in the treatment of patients. Health products powered by AI/ML are streaming into our lives, from virtual doctor apps to wearable sensors and drugstore chatbots to algorithms for detecting cancer in mammography and interpretations of chest X rays. Despite the rapid advancement and integration, AI/ML systems may have algorithmic biases, limited generalizability, and lack transparency in their assumptions based on potential limitations of training datasets. The recommendations provided by the committee will address the importance of including various demographic groups in AI/ML algorithm development. The recommendations will also address the impact of the user interface and transparency including what information and how the information about the devices could be communicated to foster patient trust in the AI/ML devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at *https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee.* Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations