agenda for the hearing and any other background materials will be made available 5 days before the hearing at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm572528.htm.*

If you need special accommodations because of a disability, please contact the Office of Combination Products at 301–796–8930 or *combination@fda.gov* at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live webcast of the hearing. To join the hearing via the webcast, please go to *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm572528.htm.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *https://www.fda.gov.*

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: September 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20521 Filed 9–25–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

COMPETES Reauthorization Act Challenge Competition

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration's (HRSA's) Maternal and Child Health Bureau (MCHB) announces a prize competition to support the development and testing of low-cost, scalable technology-based innovations to meet the needs of families and health care providers of children with special health care needs (CSHCN), particularly children with medical complexity (CMC), to improve the quality of care, patient empowerment, and family experiences while saving costs to the health care system.

FOR FURTHER INFORMATION CONTACT: James Resnick, Office of the Associate Administrator, MCHB, *JResnick@hrsa.gov,* (301) 443–3222, or Marie Mann, Division of Services for Children with Special Health Needs, MCHB, *MMann@hrsa.gov,* (301) 443–4925.

SUPPLEMENTARY INFORMATION: On January 4, 2011, the America COMPETES Reauthorization Act of 2010 was signed into law allowing the use of challenges and prize competitions increasing agencies' ability to promote and harness innovation. Competitions run by the federal government result in a number of benefits to the public, including the following:

(a) Increasing the number and diversity of the individuals, teams, and organizations that are addressing a particular problem or challenge of national significance;

(b) Improving the skills of the participants in the competition; and

(c) Directing attention to new market opportunities and stimulating private sector investment.

This challenge structured in three phases, reach a diverse population of innovators and solvers, including coders, public health experts, individuals affiliated with academic institutions, research and development communities in the private sector, and others. All submissions will be evaluated and separate prizes will be awarded for each of the three phases below.

Phase 1: Design
Phase 2: Development and Small Scale Testing
Phase 3: Scaling

Estimated dates for each phase are as follows:

Phase 1: Effective on January 22, 2018
Phase 1 Submission Period Ends: April 20, 2018, 11:59 p.m. ET
Phase 1 Judging Period: April 21–May 18, 2018
Phase 1 Winners Announced: May 25, 2018
Phase 2 Begins: May 29, 2018
Phase 2 Submission Period Ends: October 26, 2018
Phase 2 Judging Period: October 29–November 20, 2018
Phase 2 Winners Announced: December 4, 2018
Phase 3 Begins: December 7, 2018
Phase 3 Submission Period Ends: May 10, 2019
Phase 3 Winner Announced: May 30, 2019

Subject of Challenge Competition

MCHB is sponsoring the Making Technology Work for Care Planning and Coordination for Children with Special Health Care Needs Challenge. CSHCN, particularly CMC, often rely on multiple systems, services, and health professionals to maintain health and optimize well-being. Care coordination and care planning centered on the comprehensive needs of the child and family can lead to improved quality and experience of care, as well as more cost-effective care. Even with the presence of care coordinators and the development of shared care plans, communication and collaboration gaps remain because care coordinators and the shared care plans often are specific to providers and/or systems. Families have expressed frustration about working with the multiple systems and the lack of communication and coordination between them. They try to address the gap by assuming responsibility for their children's 24/7 care and care coordination. However, they often encounter numerous obstacles and barriers to fulfilling this role, including difficulty obtaining needed information or guidance from health professionals. They desire resources like electronic and informational tools to allow easy aggregation of information and sharing

from multiple providers to meet these expectations and responsibilities.

Health information technology can play a critical role in effecting care coordination and information sharing. Electronic tools can facilitate information sharing among families and their children's health care teams. Electronic care plans integrated into an electronic health record have the potential to facilitate information sharing between providers and families, particularly when coupled with patient/family portals. While electronic health records (EHR)-supported patient portals allow families access to the children's medical records, the information ''pushed'' to the patient/family portal reflects only care received from the specific providers or health systems. CSHCN and particularly CMC frequently receive care from multiple health systems and families must access multiple patient portals to obtain a full picture of the children's health information. Often the most complete information on CMC reside with their parents/caregivers, and a common need identified by families of CMC is improved and ready access to essential information for managing care, especially in urgent and emergency situations. This is particularly critical for families of CMC who reside in isolated or rural communities where the local health system is not able to care for the children.

Similarly, while a majority of child health professionals have adopted the EHR, a significant number do not have a fully functional EHR with added pediatric functionality. Lack of pediatric functionality requires that clinicians perform tasks outside the EHR or develop workarounds adding to workload and reducing productivity and efficiency. Clinicians report feeling overburdened and express frustration at not having adequate support for the increased demand to adopt processes for coordinating care and sharing information. For the time being, the primary ''solution'' for fragmented providers and systems communication and coordination has become the responsibility of the families of CSHCN and CMC, with their 3-ring binders that contain important information and care plans from the various providers and systems; these binders are cumbersome, and it is difficult and time-consuming to keep them current.

MCHB seeks innovations to address how to make technology work to improve care coordination and planning for CSHCN, their families, and the child health professionals who care for them. The solution allows for the electronic exchange of the children's shared plans of care across multiple providers and care sites and consolidation of health information in a single user interface that supports access anytime, anywhere, with families maintaining control over who can modify or see this critical information. Information from the care plans could be extracted, compiled, and aggregated on a mobile platform so families can have 24/7 access to such information, specifically the information that lets parents/caregivers know when they need to call their primary care and/or specialty care providers and for what reason (*i.e.,* the information needed to manage emergencies). This responsive platform should have the potential to integrate with existing platforms. Additionally, the challenge will bring forth multiple solutions (products/services) that could better scale and enhance healthcare services and family experiences with care.

Key design features of the innovations include:

- Low-cost and scalable;
- Intuitively designed with needs of families in mind and information organized in a manner that makes sense to them;
- Control of the information resides with families;
- Engages child health professionals;
- Employs Office of the National Coordinator for Health Information Technology (ONC) certified standards, where appropriate;
- Advanced security architecture—HIPPA enabled; and
- Broadly applicable to CSHCN/CMC and not confined to a population of children with a specific condition.

Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by HRSA and the U.S. Department of Health and Human Services (HHS).

(2) Shall have complied with all the requirements under this section.

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(4) May not be a federal entity or federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) May not be employees of HRSA or any other company, organization, or individual involved with the design, production, execution, judging, or distribution of the Challenge and their immediate family (*i.e.,* spouse, parents and step-parents, siblings and step-siblings, and children and step-children) and household members (*i.e.,* people who share the same residence at least 3 months out of the year).

(7) In the case of a federal grantee, may not use federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) In the case of a federal contractor, may not use federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

(9) Shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made equitably available to all individuals and entities participating in the competition.

(10) Must agree to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from the participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

(11) Must also agree to indemnify the federal government against third party claims for damages arising from or related to competition activities.

(12) Shall not be currently on the Excluded Parties List (*https://www.epls.gov/*).

Submission Requirements

The Challenge has three phases.

Phase 1—Design

The first stage of the prize competition aims to attract a large set of ideas and innovators. The target product of the first stage will be the conceptualization of the most promising innovations to meet the care planning and coordination needs of families and health care providers of children with special health care needs (CSHCN), particularly children with medical complexity (CMC).

The submissions should aim to demonstrate that the proposed intervention will be accessible across

diverse backgrounds and easily implemented by users.

The Phase 1 Submission shall include:

1. A comprehensive description of the proposed intervention in five pages or less, including:

a. A one-paragraph executive summary that clearly states the question to be solved;

b. Background information linking the evidence to support the intervention;

c. A descriptive analysis of how the applicant arrived at their idea;

d. Descriptions of the methods and technologies involved in implementation of the intervention

e. An assessment describing the applicant's ability to execute the proposed solution in Phases 2 and 3.

Phase 2—Development and Small Scale Testing

The winners of Phase 1 of the prize competition will then advance to a second stage focused on prototyping the intervention, and testing the effectiveness of the intervention. Using support from the Phase 1 prize funding, intervention developers will test the efficacy of their models to show that the proposed intervention demonstrates an impact on the outcomes for CSHCN and their families. The applicants should demonstrate both the evidence base for the intervention and its usability. Mentors will be available to help participants design appropriate testing methodologies and learn more about the evidence base.

Phase 3—Scaling

The winners of Phase 2 will move to the final phase of the incentive prize, which will involve testing the most promising models at greater scale through rollout at the program or community level. This will test the scalability of the device at low-cost, the feasibility of implementation, and the impact on the intended outcomes.

Registration Process for Participants

Participants will be able to register and submit an entry at the Making Technology Work for Care Planning and Coordination for Children with Special Health Care Needs Challenge Web site. Participants can find out more information at *https://www.challenge.gov/list/.*

Prizes

- Total: $375,000 in Prizes
  - Phase 1: 7–10 winners; up to a total of $100,000 in prizes
  - Phase 2: 3–5 winners; up to a total of $125,000 in prizes
  - Phase 3: 1 winner; up to a total of $150,000 prize

Payment of the Prizes

Prize payments will be paid by a contractor. Phase 1 winners may be expected to use a portion of the prize money for travel and lodging to attend a 2-day meeting in Washington, DC, to demonstrate their innovation to the judges.

Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis for Winner Selection

A review panel composed of HHS employees and experts will judge challenge entries in compliance with the requirements of the COMPETES Act and HHS judging guidelines: *http://www.hhs.gov/idealab/wp-content/uploads/2014/04/HHS-COMPETITION-JUDGING-GUIDELINES.pdf.*

The review panel will make selections based upon the following criteria:

Phase 1

In Phase 1, proposed interventions to be judged on the following criteria:

Accessibility

- Is the proposed intervention easily utilized by families of diverse economic, social, and cultural backgrounds? Is it functional across disciplines/users?

Measurability

- How easily will the proposed intervention be evaluated in order to determine its efficacy (in both lab testing and in the real world)? Is the proposed intervention measurable among various audiences?

Sustainability

- Does the proposed intervention compel users to utilize the technology often and/or for long periods of time (''sticky'')? Does it fit into daily life? Is it easy to use?

Impact

- Does the applicant present a theory or explanation of how the proposed intervention would inspire coordination and collaboration between families and providers?

Phase 2

In Phase 2, interventions will be judged on the following criteria:

Impact

- How did the intervention impact families and child health professionals? Were desired outcomes achieved?

Evidence Base

- Is the intervention grounded in existing science and patient/family/clinician preferences?

Sustainability

- Was the intervention ''sticky'' among users? Did users want to continuously engage with the development, testing, and scaling of the innovation?

Implementation

- How feasible is the intervention? How much support for implementation will the intervention require (estimated financial and time commitment).

Phase 3

In Phase 3, interventions will be judged on the following criteria:

Impact

- How effective was the intervention when implemented at scale? Did the impacts from Phase 2 remain consistent?

Implementation

- How feasible was the intervention on a larger scale? How much support for implementation did the model require (financial and time commitment). How challenging was the actual program implementation?

Scalability

- How costly was the intervention in a real-world setting? How likely are cost efficiencies for program delivery at greater scale? Can the device be used in existing platforms?

Additional Information

General Conditions

- HRSA reserves the right to cancel, suspend, and/or modify the contest, or any part of it, for any reason, at HRSA's sole discretion.
- The interventions submitted across all phases should not use the HHS or HRSA logos or official seals in the submission, and must not claim endorsement.

Intellectual Property

- Each entrant retains full ownership and title in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement.
- By participating in the challenge, each entrant hereby irrevocably grants to HRSA a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publically perform, publically display, and use the submission for internal HHS business

and to the extent necessary to administer the challenge, and to publically perform and publically display the submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

• Record Retention and FOIA: All materials submitted to HRSA as part of a submission become HRSA records and cannot be returned. Any confidential commercial information contained in a submission should be designated at the time of submission. Participants will be notified of any Freedom of Information Act requests for their submissions in accordance with 45 CFR 5.65.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (COMPETES Act, Pub. L. 111–358) as amended by section 401(b) of the American Innovation and Competitiveness Act, Public Law 114–329.

Dated: September 19, 2017.

George Sigounas,

Administrator.

[FR Doc. 2017–20536 Filed 9–25–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Challenge Competition: Using Technology to Prevent Childhood Obesity in Low-Income Families and Communities

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration's (HRSA's) Maternal and Child Health Bureau (MCHB) announces a prize competition to support the development of low-cost, scalable technology-based innovations to promote healthy weight for low-income children and families in the socio-cultural and environmental contexts of their communities.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010.

This challenge, structured in three phases, will reach a diverse population of innovators and problem solvers, including families, coders, public health experts, community leaders, individuals affiliated with academic institutions, research and development communities in the private sector, and others.

All submissions will be evaluated and separate prizes will be awarded for each of the three phases below.

Phase 1: Design
Phase 2: Development and Small Scale Testing
Phase 3: Scaling

Estimated dates for each phase are as follows:

Phase 1: Effective on January 2, 2018
Phase 1 Submission Period Ends: January 31, 2018, 11:59 p.m. ET
Phase 1 Judging Period: February 1-February 28, 2018
Phase 1 Winners Announced: March 12, 2018
Phase 2 Begins: March 13, 2018
Phase 2 Submission Period Ends: July 11, 2018
Phase 2 Judging Period: July 12-August 12, 2018
Phase 2 Winners Announced: August 20, 2018
Phase 3 Begins: August 21, 2018
Phase 3 Submission Period Ends: February 21, 2019
Phase 3 Winner Announced: March 1, 2019

FOR FURTHER INFORMATION CONTACT: Meredith Morrissette, Division of Maternal and Child Health Workforce Development, MCHB, *MMorrissette@hrsa.gov,* (301) 443–6392, or James Resnick, Office of the Associate Administrator, MCHB, *JResnick@hrsa.gov,* (301) 443–3222.

SUPPLEMENTARY INFORMATION: On January 4, 2011, the America COMPETES Reauthorization Act of 2010 was signed into law allowing the use of challenges and prize competitions increasing agencies' ability to promote and harness innovation. Competitions run by the federal government result in a number of benefits to the public, including the following:

(a) Increasing the number and diversity of the individuals, teams, and organizations that are addressing a particular problem or challenge of national significance;

(b) Improving the skills of the participants in the competition; and

(c) Directing attention to new market opportunities and stimulating private sector investment.

Subject of Challenge Competition

Secretary Price identified reducing childhood obesity as a priority for the Department of Health and Human Services (HHS), acknowledging this is a growing epidemic in the United States. Since 1980, childhood obesity rates for 2- to 19-year-olds have tripled, with rates of obesity in 6- to 11-year-olds more than doubling, and rates of obesity in 12- to 19-year-olds quadrupling. While improved eating behaviors and increased physical activity play a large role in obesity prevention, additional public health factors such as limited access to affordable, healthy food options, social and cultural norms, and limited availability of safe places to play also impact childhood obesity rates. While existing apps and tools address individual behaviors, such as exercise and nutrition, their uptake in underserved communities is limited because they are not tailored to the needs, challenges, and barriers to healthy weight in these communities. The goal of this challenge is to make technology work for the family as a unit within the reality of their larger community environment.

Addressing childhood obesity from a population-based, public health perspective as a complement to the individual clinical perspective requires innovative, community-based solutions and partnerships. A challenge will maximize competition and spur innovation for communities in a cost-effective and accelerated timeframe. It will reach a broad stakeholder group and allow involvement of non-traditional partners who are knowledgeable about the strengths and challenges affecting the community, and who can bring new ideas towards addressing this issue. A challenge will provide support for the development of several innovative ideas through a pay-for-results mechanism, ultimately leading to the development of multiple novel and scalable interventions.

Potential areas of focus include, but are not limited to:

• Promoting access to healthy, affordable food;

• Supporting community-owned solutions that increase families' knowledge and skills related to healthy eating and nutrition;

• Finding innovative ways that increase physical activity, such as gamification, while accounting for environmental barriers to physical activity in underserved communities; and

• Empowering families to achieve healthy eating practices, healthy lifestyles, and sustainable changes in the home environment, while accounting for limited access to healthy foods in under-resourced communities.

Key design features of the innovations may address one or more of the following:

• Be at low-cost to families and scalable;