II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization.” 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of “Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500051 to identify the guidance you are requesting.

IV. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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 801, regarding labeling have been approved under OMB control number 0910–0485.

V. Reference

The following reference is on display in the Division of Dockets Management (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at http://www.regulations.gov. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–04790 Filed 3–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Announcement of Requirements and Registration for the Opioid Overdose Prevention Challenge

AGENCY: SAMHSA, HHS.
ACTION: Notice.

SUMMARY: In summarizing the challenge that will be issued by your agency, please answer the following four questions:

(1) What action is being taken?
    The Substance Abuse and Mental Health Services Administration (SAMHSA) has issued a challenge to developers to help support patients in recovery who are receiving medication assisted treatment for opioid use disorder with an innovative app that provides features and information that support their recovery.

(2) Why is this action necessary?
    Addressing the opioid epidemic is a top priority for the U.S. Department of Health and Human Services and the Secretary is committed to evidence-informed interventions to turn the tide against opioid drug-related overdose and misuse. To that end, Substance Abuse and Mental Health Services Administration (SAMHSA) is issuing a three-month challenge to spur developers to create an app that provides additional recovery support to patients receiving outpatient medication-assisted treatment for opioid use disorder.

(3) What is the objective of the challenge?
    To provide support to people in recovery from opioid use disorder receiving medication assisted-treatment so that they can maintain treatment and achieve long-term recovery.

(4) What is the intended effect of this action?
    An increase in the number of individuals with opioid use disorders maintaining recovery; and a reduction in the number of deaths from opioid overdose.

DATES: The challenge starts on March 4, 2016 10:00 a.m. ET. The challenge ends on May 27, 2016 11:59 p.m. ET.

FOR FURTHER INFORMATION CONTACT: Danielle Tarino Rivkin, Health Information Technology Team, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, Public Health Advisor, SAMHSA/CSAT, 5600 Fishers Lane, Rockville, MD 20857, Phone: 240.276.2857, Email: Danielle.Tarino@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:
Subject of Challenge Competition: Opioid Recovery Support.

Eligibility Rules for Participating in the Competition

To satisfy the mandatory provisions of the COMPETES Act, use the following language:

A. The Competition is open only to:
(i) Individuals who are at least 18 years of age at the time of entry, and are citizens or permanent residents of the United States as of the time of entry;
(ii) teams of eligible individuals where each team member meets the eligibility requirements for individual Contestants; and
(iii) corporations (including not-for-profit corporations and other nonprofit organizations), limited liability companies, partnerships, and other legal entities that, at the time of entry, are domiciled (or incorporated) in the United States, have been duly organized or incorporated and validly exist, and employ no more than one hundred (100) people (“Organizations”).

B. Each team or Organization shall appoint one individual (the “Representative”) to represent and act, including entering a Submission, on behalf of said team or Organization. The Representative must meet the eligibility requirements for an individual Contestant and must be duly authorized to submit on behalf of the team or Organization. The Representative represents and warrants that: (i) He/she is duly authorized to act on behalf of the team or Organization; and (ii) each member of the team (or in the case of Organization, each participating member) has read the Official Rules and agrees to abide by these Official Rules. The Representative will ensure that each member of the team or Organization reads, agrees to, and complies with the Official Rules.
C. An individual may join more than one team or Organization, and an individual who is part of a team or Organization may also enter the Competition on an individual basis.

D. The following individuals, teams, and Organizations are not eligible regardless of whether or not they meet the criteria set forth above:

(i) The Sponsor, the Administrator, and any advertising agency, contractor or other organization involved with the design, production, promotion, execution, or distribution of the Competition (collectively “Promotion Entities”); all employees, representatives and agents of such Promotion Entities; and all members of any such employee, representative or agent’s immediate family or household;

(ii) any individual involved with the design, production, promotion, execution, or distribution of the Competition and each member of any such individual’s immediate family or household;

(iii) any company or individual that employs any Judge or that otherwise has a material business relationship or affiliation with any Judge;

(iv) any parent company, subsidiary, or other affiliate of any company described above.

E. This Challenge falls under the COMPETES Act. As such, if a Contestant is a federal grantee, they may not use federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

F. If Contestant is a federal contractor, they 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.

G. For purposes hereof:

(i) The members of an individual’s immediate family include such individual’s spouse, children and step-children, parents and step-parents, and siblings and step-siblings; and

(ii) the members of an individual’s household include any other person that shares the same residence as such individual for at least three (3) months out of the year.

H. A Contestant will 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 available to all Contestants participating in the competition on an equitable basis.

Registration Process for Participants

(i) Beginning on March 4, 2016 at 10:00 a.m. Eastern Time, visit http://samsnnpioioidercoveryapp.devpost.com/ (the “Competition Web site”) and click “Sign Up” to create a Devpost account, or click “Log In” and log in with an existing Devpost account. There is no charge for creating a Devpost account. (ii) After a Contestant signs up on the Competition Web site, a confirmation email will be sent to the email address provided by the Contestant. The Contestant should use the confirmation email to verify their email address.

(iii) Contestant should indicate their agreement in participating by clicking “Register” on the Competition Web site in order to receive important Competition updates.

(iv) In the event of a dispute pertaining to this Competition, the authorized account holder of the email address used to sign up for the Devpost account used to enter the Submission will be deemed to be the Contestant (in case of an individual) and the Contestant’s Representative, in the case of a team or Organization. The “authorized account holder” is the natural person or legal entity assigned an email address by an Internet access provider, online service provider or other organization responsible for assigning email addresses for the domain associated with the submitted address. Contestants generally and potential winners may be required to show proof of being the authorized account holder.

Amount of the Prize: 1st prize: $15,000 cash; 2nd prize: $7,500 cash; 3rd prize: $5,000 cash. Payment of the Prize: Payment will be paid by contractor.

Basis Upon Which Winner Will Be Selected

A. All eligible Submissions will be judged by an expert panel of impartial judges (the “Judges”) selected by the Sponsor. The internal panel will judge these Submissions on the criteria identified in these Official Rules to select finalist Submissions. Finalist Submissions will then be judged by the expert judging panel determined by the Sponsor. The judging panel is not required to test the Application and may choose to judge based solely on the text description and video provided in the Submission. The Sponsor and the Administrator reserve the right to divide and assign the criteria identified below in these Official Rules among different members of the internal and expert judging panels. The Sponsor and the Administrator reserve the right to substitute or modify the judging panel at any time for any reason.

B. All Judges shall be and remain fair and impartial. Any Judge may recuse him or herself from judging a Submission if the Judge, the Sponsor or the Administrator considers that it is inappropriate, for any reason, for the Judge to evaluate a specific Submission or group of Submissions.

C. A Contestant’s likelihood of winning will depend primarily on the number and quality of all of the Submissions, as determined by the Judges using the criteria in these Official Rules. The judging period is May 30, 2016 at 10:00 a.m. Eastern Time through July 1, 2016 at 11:59 p.m. Eastern Time (the “Judging Period”).

D. Criteria:

Judging Criteria:

a. Quality of Idea (Includes the degree to which the proposed app can support patient recovery by addressing the required and optional insights, the creativity of the idea and the innovation of the proposed app to support recovery).

b. Implementation of Idea (Includes how well the idea was implemented including the user experience, design and technical functionality).

c. Potential Impact (Includes the patient value and potential impact the application can have for individuals in recovery).

E. If deemed necessary by the judging panel, each of the top five finalists may be asked to participate in a virtual or in-person meeting with federal staff to discuss their Application and demonstrate its operation. The purpose of these meetings will be to further evaluate the Contestant’s product, provide any additional information to SAMHSA, and clarify any concerns or questions raised by the review panel.

F. Tie Breakers. In the event of a tie between two or more Submissions, the panel of Judges will vote on the tied submissions.

G. The Sponsor reserves the right, in its sole discretion, to

a. cancel, suspend, or modify the Challenge, and/or

b. not award any prizes if no submissions are deemed worthy.

H. All decisions made by the Sponsor regarding adherence to contest rules are final.

I. All selection of contest winners is final.

Additional Information

B. Submission

(i) Contestants must create a working software application. Apps must be developed as either:

a. iOS or Android, as a downloadable app.

b. The app can be developed for just one operating system.
(OS) but the 1st place winner must develop for both iOS and Android within six months of winning the prize.

OR

b. an HTML5 mobile web application accessible via a mobile browser (Chrome or Safari) on the device.

(i) The 1st place winner will need to host the HTML5 mobile web app for at least 2 years from delivery of signed affidavit by prizewinner

(ii) During the Competition Submission Period, Contestant must visit the Competition Web site and confirm that he or she has, or if Contestant is a Representative, all members of their team or Organization have, read and agree to the Official Rules. Then, Contestant must submit its Submission by providing the following items included in subsections a-n below:

a. The name of the Application;

b. a brief text description (no more than 350 words) of the Application and how it functions; including a list of the features and how they address the insights provided in Attachment A. If any additional resources have been provided in the Application by the Contestant, the Contestant will submit an Excel or .csv file with a list of all the additional resources that includes the title of the resource; the source of the resource; and a link to the resource if applicable. Additionally, if Application uses any additional copyrighted material, contestant must have written consent to use it. The Administrator and/or Sponsor reserves the right to request additional documentation from Contestants to verify this information.

c. a text description of testing instructions for the app;

d. at least one image (screenshot) of the working Application;

e. a link to a video uploaded to Devpost.com and YouTube.com that clearly demonstrates the Application’s functionality and features (by walking through the Application);

f. the Application platform (iOS, Android, HTML5 Web);

g. for Android applications: The Android APK file and any other associated files needed to run the app or a link to the app in the Google Play store;

h. for iOS applications:

If your Application is available on the iTunes App Store provide a link in the "Web site URL" field on “Enter a Submission” form. If you charge a fee for downloading your Application, you must provide a promo code.

If your Application is not yet publicly available on the iTunes App Store, you must send a test build to the Administrator before the end of the Challenge Submission Period using one of the following methods: The iOS App file registered to the reviewers unique device ID (UDID), the Sponsor will provide UDIDs upon request (see contact info at the end of the rules section). For more details see: https://developer.apple.com/library/ios/documentation/IDEs/Conceptual/AppDistributionGuide/

TestingYouriOSApp/

TestingYouriOSApp.html.

OR, provide a link to the app in the Apple iTunes store;

OR contestants can use one of the following options:

B. Text Description, Image and Video Requirements

A. Language Requirements

All Submission materials must be in English.

B. Text Description, Image and Video Requirements

(i) The text description must describe the Application’s key features and functionality, and must outline how the features address the insights specified by the Administrator in Attachment A.

(ii) The image(s) must be photographs or screenshots of your working Application.

(iii) The video portion of the Submission:

a. Should be no longer than five (5) minutes;

b. must clearly demonstrate the Application’s features and functionality, especially those that address the required assets and insights; and

c. must not include music or other copyrighted material or use third party trademarks unless the Contestant has written permission to use such material.

(iv) If the video is primarily promotional rather than a demonstration of the Application’s functionality and features (by walking through the Application), the...
Submission may be disqualified at the Sponsor’s and/or Administrator’s sole discretion.

(v) Please provide a description of ideas for how you could promote the app if you are a prizewinner (350 words max).

C. Content Requirements

(i) The Submission must only address insights provided.

(ii) The Submission must include the required information contained in the INSERT ASSET FILE NAME. This includes APIs and resources. The ASSET FILE NAME will indicate whether content is optional or required. Entries may not substantially alter the meaning, intent, or otherwise misrepresent the content in whole or in part. The intention of this clause is to ensure that the integrity of the content is maintained.

(iii) The Submission must target individuals in recovery from opioid misuse who are receiving outpatient medication-assisted treatment.

(iv) The submission features should be designed to encourage repeat usage of the app.

(v) A Submission must not include an audio or visual performance, including but not limited to music, dance, or other performing art, third-party copyrighted material or trademarks, unless the Contestant has written permission to use such material.

(vi) The Submission must not use HHS’s or SAMHSA’s logos or official seals and must not claim endorsement.

D. Application Requirements

In addition to the requirements described above in Sections 5(A)–5(C):

(i) The Application must be able to be successfully installed and capable of running consistently as described on the platform for which it is intended.

(ii) Applications may be newly created or existing applications modified to meet the requirements of the Competition.

(iii) Applications must be designed for use with existing modern smartphones.

(iv) Applicants using HTML5 should limit the data burden on users and where possible the submissions should leverage local storage and client-side cache options.

(v) Applications must not collect or store personally identifiable information (PII) or protected health information (PHI) as defined in 45 CFR 160.103.

(vi) Applications must not collect or require input of end user email addresses within the Application.

(vii) The Prizewinners must offer the Application to the public for free for a period of at least one (1) year. Each Application must be available free of charge for testing, evaluation and use by the Competition Sponsor, Administrator and judges during the Competition and until the Judging Period ends at 11:59 p.m. Eastern Time on July 1, 2016. For one year following the prize distribution, prize winners will be required to provide to the Sponsor a report of monthly data on the number of app downloads.

(viii) Contestants must acknowledge, as a prerequisite to any subsequent acquisition by federal contract or other method, they may be required to make their product compliant with Section 508 accessibility and usability requirements at their own expense. Any electronic information technology that is ultimately obtained by HHS for its use, development, or maintenance must meet Section 508 accessibility and usability standards. Past experience has demonstrated that it can be costly for solution-providers to “retrofit” solutions if remediation is later needed. The HHS Section 508 Evaluation Product Assessment Template, available at www.hhs.gov/od/vendors/index.html, provides a useful roadmap for developers to review. It is a simple, Web-based checklist utilized by HHS officials to allow vendors to document how their products do or do not meet the various Section 508 requirements.

(ix) Submissions requiring approval from a third party, such as an app store, in order to be accessible to the public, must be submitted to such third party or app store for review before the end of the Competition Submission Period. For any software that is not a web or mobile Web Application run on a web browser (tablet and desktop Applications), Contestants will be required to provide an installation file containing the Application.

E. General Requirements

(i) Submissions must not:
   a. Violate any law or regulation;
   b. depict hatred;
   c. be in bad taste;
   d. denigrate (or be derogatory towards) any person or group of persons or any race, ethnic group or culture;
   e. threaten a specific community in society, including any specific race, ethnic group or culture;
   f. incite violence or be likely to incite violence;
   g. contain vulgar or obscene language or excessive violence;
   h. contain pornography, obscenity or sexual activities of
      i. disparage the Sponsor or Administrator.

(ii) Submissions must not attempt to duplicate a prior Submission already submitted in this Competition. Sponsor or Administrator reserves the right in its sole discretion to disqualify any Submission that is a duplicate or substantially similar to another Submission.

(iii) Submissions must be free of malware. Contestant agrees that the Sponsor and/or the Administrator may conduct testing on the Application to determine whether malware or other security threats may be present. Submissions not complying with these requirements may be disqualified.

(iv) Each Application will be tested by the Administrator, the Sponsor or their designees. Submissions may be disqualified if the Application does not function as depicted in the video or expressed in the text description, at the Sponsor’s and/or Administrator’s sole discretion.

(v) Prizewinners may be required to submit the source code and any relevant data of their Application to the Administrator and/or Sponsor upon request at any time.

(vi) A Contestant may submit more than one Submission. However, each Submission must be unique, as determined by Sponsor and/or the Administrator in their sole discretion. If a Contestant enters two or more Submissions that are substantially similar, the Sponsor and Administrator reserve the right to disqualify Submissions or require the Contestant to choose one Submission to enter into the Competition.

(vii) Submissions must not include any email addresses, phone numbers, addresses, or social security numbers in the Submission name, text description, video, or images.

(viii) Contestants must not imply endorsement of their Application by the Sponsor in any of the Submission components or in any advertising or media, including Web sites and app stores, featuring the Contestant’s Application.

(ix) Submissions must: (a) Be the original work product of the Contestant; (b) be solely owned by Contestant and with no other person or entity having any right or interest in it; and (c) not violate the Intellectual Property rights or other rights including but not limited to copyright, trademark, patent, contract, and/or privacy rights, of any other person or entity. A Contestant may contract with a third party for technical assistance to create the Submission provided the Submission components are solely the Contestant’s work product and the result of the Contestant’s ideas.
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–10]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in National Coalition for the Homeless v. Veterans Administration, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency’s needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for “off-site use only” recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 58–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the Federal Register, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; NASA: Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management, Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).


Brian P. Fitzmaurice,
Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 03/04/2016

Suitable/Available Properties

Land

New Jersey

49 Acres

Woodbridge Avenue

Edison NJ 08817

Landholding Agency: GSA

Property Number: 54201610006

Status: Excess

GSA Number: NJ–0944–AA

Comments: 49 acres, contact GSA for more information.