

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for “System for Locating People Using Electricity Dependent Medical Equipment During Public Health Emergencies Ideation Challenge”

AGENCY: Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services (HHS).

ACTION: Notice.

Authority: 15 U.S.C. 3719.

Award Approving Official: Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response.

SUMMARY: The “System for Locating People Using Electricity Dependent Medical Equipment During Public Health Emergencies” Ideation Challenge seeks ideas to establish a system for monitoring the location and status of life-sustaining durable medical equipment (DME) during a prolonged power outage or disaster situation. This information would be used by a network of family and friends, formal caregivers, emergency responders and others responding to a disaster to better assist individuals who are dependent on DME. The current Challenge focuses on obtaining information about DME; however, this is part of a larger effort to ensure that these people get the necessary help as quickly as possible. Submissions can be existing applications, or applications developed specifically for this challenge. The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES: Submissions will be accepted for 30 calendar days from the date this posting is published in **Federal Register**.

FOR FURTHER INFORMATION CONTACT:
Adam DeVore, (202) 401–2361.

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition:
The Office of the Assistant Secretary for Preparedness and Response (ASPR), in collaboration with the Federal Emergency Management Agency (FEMA), seeks ideas for a system for monitoring the location and status of life-sustaining durable medical equipment (DME) during a prolonged power outage or disaster situation. Many in-home patients require the daily use of a piece of electrically powered DME. During a disaster or other event that leads to a prolonged power outage, these patients often end up at shelters

or emergency rooms looking for sources of power or alternate ways to manage their medical needs. For example, during recent natural disasters and weather related emergencies, many people who were dependent on electricity and battery-powered DME—such as oxygen concentrators and ventilators—and who typically care for themselves at home, were forced to evacuate their homes and go to a shelter or health care facility to power and re-supply their equipment. This not only has the potential to adversely impact the health outcomes for individuals who rely on DME, but it also stresses the local health care system and reduces a community’s resilience and capability to rapidly recover from an emergency. During an emergency, communities could better meet the needs of individuals who rely on DME if they had access to real-time, remotely transmittable information about the locations and remaining battery life of life-sustaining medical devices. In addition, this information could be beneficial to an individual, their caregivers, and family members on a routine basis during non-emergent events.

ASPR has identified a need for a reliable system available to identify, locate, and assist these individuals in a timely fashion. This information would be used by a network of family and friends, formal caregivers, emergency responders, and others responding to a disaster to better assist individuals who are dependent on DME. Currently, there is no reliable system to simultaneously and rapidly identify the locations of individuals who rely on DME, to understand the power status of their life-sustaining devices. Developing and integrating a system that automatically monitors and transmits the status and location of a device will provide caregivers and responders with actionable information to support emergency planning and response operations, such as deploying a charged replacement battery or prioritizing power restoration.

ASPR is committed to developing a comprehensive action plan to provide emergency aid to people in need. Proposals should be detailed and implementable. The current Challenge focuses on obtaining information about DME; however, this is part of a larger effort to ensure that these people get the necessary help as quickly as possible. This is an Ideation Challenge with a guaranteed award for at least one submitted solution.

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 the Office of Assistant Secretary for Preparedness and Response;

(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; and

(6) Shall not be in the reporting chain of Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response.

Federal grantees may not use federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award. Federal contractors 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.

An individual or entity 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 available to all individuals and entities participating in the competition on an equitable basis.

Registered participants shall be required to 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 their participation in a competition, whether the injury, death, damage, or loss arises through negligence or otherwise, and to indemnify the federal government against third party claims for damages arising from or related to competition activities.

Participants shall be required to obtain liability insurance or demonstrate financial responsibility for claims by—

(1) A third party for death, bodily injury, or property damage, or loss

resulting from an activity carried out in connection with participation in a competition, with the federal government named as an additional insured under the registered participant's insurance policy and registered participants agreeing to indemnify the federal government against third party claims for damages arising from or related to competition activities; and

(2) The federal government for damage or loss to government property resulting from such an activity.

Registration Process for Participants

To register for this challenge participants may do any of the following:

(1) Access the www.challenge.gov Web site, search for the "System for Locating People Using Electricity Dependent Medical Equipment During Public Health Emergencies Ideation Challenge," and follow the link to the registration page; or

(2) Access the InnoCentive challenge Web site at www.innocentive.com/ar/challenge/9933433.

All participants are required to consent to the rules upon or before submitting an entry.

Amount of the Prize

This is an Ideation Challenge, which has the following features:

- There is a guaranteed award. The awards will be paid to the best submission(s) as solely determined by the judge. The total payout will be \$10,000, with at least one award being no smaller than \$5,000 and no award being smaller than \$1,000.

- Additional Award: In addition to the direct monetary awards, some of the winner(s) of this Challenge may be invited (at the ASPR's sole discretion) to a unique opportunity to present their idea to high-profile thought leaders at an upcoming event in Atlanta, GA, USA on April 1–4, 2014. This opportunity includes a \$1,000 stipend to defray the cost of travel and accommodations.

- Awards may be subject to federal income taxes and HHS will comply with IRS withholding and reporting requirements, where applicable.

Basis Upon Which Winner Will Be Selected

Winning solution proposals to this Challenge will at a minimum meet the following Requirements:

(1) System is capable of capturing essential data from durable medical equipment (DME), including, but not limited to:

- Loss of external power;

- Power level and status of internal battery, including remaining battery life time, if appropriate;

- Unique identifier of the DME or at minimum, brand and model;

- GPS location;

- Current time/date;

- Device diagnostic information to determine operational status of DME; and

- User identifying information.

- (2) System is capable of securely sending all captured data over various spectrums:

- Send information over medical body area network (MBAN);

- Robustly transmit over at least two communication methods/technologies; e.g. Ethernet, Wi-Fi, Mobile (CDMA, GSM, LTE), Amateur Radio, ZigBee;

- Ability to switch between/rollover spectrum/technologies depending on resource availability;

- Ability to send data automatically or upon manual command (e.g. at specified intervals of time, on-demand, or when triggered by external events);

- No interference with the operation of the DME;

- Securely transmit "read only" data collected from DME; and

- Data need to be distributed to a predetermined list of responders in a format defined by ASPR.

- (3) System is accessible to all in-home patients with DME:

- Easy to install and set up user defined characteristics;

- Simple registration process; and

- Simple to use, particularly for elderly or frail individuals.

A solution may include the use of a device(s). If this is the case, these additional specifications must be met:

- (1) Low-power consumption transmitter:

- Ideally be constructed of readily available open source components;

- Consumes low level of standby power;

- If integrated into DME, consumes minimal power with no impact upon DME performance; and

- Alternatively, has its own power source separate from the DME.

ASPR is currently working to develop a piece of open source hardware capable of executing these functionalities. While the hardware is near completion, coding software is still needed and additional methods (e.g., mobile and social media apps) are required to establish the infrastructure needed to support information transmission using multiple channels. Hence, ASPR is interested in additional types of hardware, a combination of hardware and software, or a non-technical solution.

Include in your submission a detailed description of the system (process and/

or device) that will be used under routine and emergency conditions to:

- Uniquely identify DME;

- Report the current power status of the device, to include remaining battery time;

- Report the location of the device;

- Determine the operational status of DME; and

- Identify a way to contact the DME user.

Be sure to include the rationale for the solution and specific ideas to address the following questions.

- How would people obtain the system?

- How could they register?

- How will data be transferred to recipients?

The solution most likely includes a device, but ASPR is interested in a versatile submission that would benefit people from all socioeconomic backgrounds.

Submitted proposals along with all relevant supporting data should include the information described in the Detailed Description of the Challenge.

Submitted proposals should not include any personal identifying information the participants do not want to make public, or any information the participant may consider as their intellectual property that they do not want to share.

After the Challenge deadline, a review panel of technical advisers will complete the review process and make a decision with regards to the winning solution(s). All participants that submit a proposal will be notified about the status of their submissions; however, no detailed evaluation of individual submissions will be provided.

Additional Information

Ownership of intellectual property is determined by the following:

- Each entrant retains title and full ownership 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 sponsor and administrator a perpetual, non-exclusive, royalty free, worldwide license and right to reproduce, publicly perform, publicly display, and use the submission to the extent necessary to administer the challenge, and to publicly perform and publicly display the submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

About ASPR

ASPR leads HHS in preparing the nation to respond to and recover from adverse health effects of emergencies, supporting communities' ability to withstand adversity, strengthening health and response systems, and enhancing national health security. To learn more about ASPR and preparedness, response, and recovery from the health impacts of disasters, visit the HHS public health and medical emergency Web site, www.phe.gov.

Dated: September 13, 2013.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2013-22854 Filed 9-19-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3287-PN]

Medicare and Medicaid Programs; Application from the Compliance Team for Initial CMS-Approval of its Rural Health Clinic Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Compliance Team for initial recognition as a national accrediting organization for rural health clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 21, 2013.

ADDRESSES: In commenting, please refer to file code CMS-3287-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways:

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.regulations.gov>. Follow the "submit a comment" instructions.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3287-PN, P.O. Box 8016, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3287-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments to the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lisa Sullivan, (410) 786-2841; Cindy Melanson, (410) 786-0310; or Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. Referencing the file code CMS-3287-PN and the specific "issue identifier" that precedes the section on which you choose to comment will assist us in fully considering issues and developing policies.

Inspection of Public Comments: All comments received before the close of the comment period are available for

viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a Rural Health Clinic (RHC) provided certain requirements are met. Section 1861(aa), and 1905(l)(1) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488, subpart A. The regulations at 42 CFR part 491, subpart A specify the minimum conditions that a RHC must meet to participate in the Medicare program. The conditions for Medicare payment for RHCs are set forth at 42 CFR 405, subpart X.

Generally, to enter into an agreement, a RHC must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 491 of our regulations. Thereafter, the RHC is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any