FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collections Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of existing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). On August 22, 2013, (78 FR 52194), the FDIC requested comment for 60 days on a proposal to renew the following information collections: Interagency Guidance on Asset Securitization, 3064–0137, and The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions, 3064–0148. No comments were received. The FDIC hereby gives notice of its plan to renew the following information collections: Interagency Guidance on Asset Securitization, 3064–0137, and The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions, 3064–0148. No comments were received. The FDIC hereby gives notice of its plan to renew the following information collections: Interagency Guidance on Asset Securitization, 3064–0137, and The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions, 3064–0148.

DATES: Comments must be submitted on or before November 27, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- Email: comments@fdic.gov Include the name of the collection in the subject line of the message.
- Hand Delivery: Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.
- All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper, at the FDIC address above.

SUPPLEMENTARY INFORMATION:
Proposal to renew the following currently-approved collections of information:

1. Title: Interagency Guidance on Asset Securitization
   OMB Number: 3064–0137.
   Form Number: None.
   Frequency of Response: On occasion.
   Affected Public: Insured State Nonmember Banks.
   Estimated Number of Respondents: 22
   Estimated Time per Response: 7.5 hours.
   Total estimated annual burden: 164 hours.
   General Description of Collection: The Interagency Guidance on Asset Securitization Activities informs bankers and examiners of safe and sound practices regarding asset securitization. The information collections contained in the Interagency Guidance are needed by institutions to manage their asset securitization activities in a safe and sound manner. Bank management use this information as the basis for the safe and sound operation of their asset securitization activities and to ensure that they minimize operational risk in these activities.

2. The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions
   OMB Number: 3064–0148.
   Form Number: None.
   Frequency of Response: Annual.
   Affected Public: Insured State Nonmember Banks.
   Estimated Number of Respondents: 6
   Estimated Time per Response: 25 hours.
   Total estimated annual burden: 150 hours.
   General Description of Collection: The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions describes the types of internal controls and risk management procedures that the Agencies believe are particularly effective in assisting financial institutions to identify and address the reputational, legal, and other risks associated with complex structured finance transactions.

Request for Comment

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC’s functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 23rd day of October, 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

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).

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

ACTION: Notice.

SUMMARY: The deadline for all submissions to the “System for Locating People Using Electricity Dependent Medical Equipment During Public Health Emergencies” Ideation Challenge is extended from October 20, 2013, to October 31, 2013 at 11:59 p.m. 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 until October 31, 2013 at 11:59 p.m.
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 resiliency 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 compiled 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

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: October 22, 2013.

Nicole Lurie,
Assistant Secretary for Preparedness and Response.
[PR Doc. 2013–25280 Filed 10–25–13; 8:45 am]
BILLING CODE 4150–37–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–1147]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our guidance...