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Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for “Blockchain and Its Emerging Role in Healthcare and Health-related Research”

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

Award Approving Official: Karen DeSalvo, National Coordinator for Health Information Technology.

ACTION: Notice.

SUMMARY: The “Blockchain and Its Emerging Role in Healthcare and Health-related Research.” Ideation Challenge solicits white papers on the topic of Blockchain Technology and the potential use for Healthcare. Winners will be invited to present their submission at an upcoming industry-wide workshop co-hosted with the National Institute of Standards and Technology (NIST). The statutory authority for this Challenge is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358).

DATES:

- Submission period begins: June 20.
- Submission period ends: July 29.
- Evaluation begins: August 1.
- Evaluation ends: August 16.
- Winners notified: August 17.
- Winners Announced: August 20.
- Winner Presentation: September 26th–27th.

FOR FURTHER INFORMATION CONTACT:

Debbie Bucci, *debbie.bucci@hhs.gov* (preferred), (202) 690-0213.

SUPPLEMENTARY INFORMATION:

Subject of Challenge

A blockchain is a data structure that can be timed-stamped and signed using a private key to prevent tampering. There are generally three types of blockchain: Public, private and consortium. Potential uses include:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

Proponents of blockchain suggest that it could be used to address concerns

regarding the privacy, security and the scalability of health records. Critics ascertain that it would take enormous processing power and specialized equipment that far exceeds the benefits. Although most would acknowledge blockchain’s potential it is still evolving and maturing, especially with respect to its applicability to the health care.

This Ideation Challenge solicits White Papers on the topic of Blockchain Technology and the Potential for Its Use in Health IT and/or Healthcare Related Research Data.

This nationwide call may be addressed by an individual investigator or a investigator team. Interested parties should submit a White Paper no longer than 10 pages describing the proposed subject. Investigators or co-investigators may participate in no more than three submissions. A limited number of these submissions will be selected. The selection of a White Paper will result in an invitation to present at an upcoming industry-wide workshop on September 26th–27th at NIST Headquarters in Gaithersburg, MD.

Objective

The goal of this Ideation Challenge is to solicit White Papers that investigate the relationship between blockchain technology and its use in Health IT and/or Health Related research. The paper should discuss the cryptography and underlying fundamentals of blockchain technology, examine how the use of blockchain can advance industry interoperability needs expressed in the Nationwide Interoperability Roadmap, patient centered outcomes research (PCOR), precision medicine, and other health care delivery needs, as well as provide recommendations for blockchain’s implementation.

In lieu of a monetary award, challenge winners will be provided the opportunity to present their White Papers at an industry-wide “Blockchain & Healthcare Workshop” co-hosted by ONC and NIST.

Submission Requirements

Include a White Paper, not longer than ten (10) pages in length, that:

- Educates its audience on the technology; and
- Can be used to determine whether there is a place in Health IT and/or Healthcare related Research for the technology.
 - The paper should:
 - Describe the value of blockchain to the health-care system;
 - Identify potential gaps;
 - Discuss the effectiveness of the solution and the solutions ability to function in the “real world.” This

discussion may include information regarding meeting privacy and security standards, implementation and potential performance issues, and cost implications. Risk analysis and mitigation would be appropriate to include here as well.

- Discuss the solution’s link to the stated objectives in the Nationwide Interoperability Roadmap, PCOR, precision medicine and other national health care delivery priorities.

How To Enter

Challenge participants will have five (5) weeks from the date of the posting of this Notice. Those submissions must comply with the requirements provided above. Up to eight submissions may be selected as winners. The names of the winners will be posted on the *Challenge.gov* Web site, as well as the names of any participants receiving an honorary mention. Honorary mentions may be given to highly ranked submissions.

Eligibility Rules for Participating in the Challenge

To be eligible to win a prize under this Challenge, an individual or entity:

1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.
2. Shall have complied with all the stated requirements of the Blockchain and Its Emerging Role in Healthcare and Health-related Research Challenge.
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. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.
8. 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 Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

General Submission Requirements

In order for a Submission to be eligible to win this Challenge, it must meet the following requirements:

1. No HHS or ONC logo—The Solution must not use HHS' or ONC's logos or official seals and must not claim endorsement.
2. Functionality/Accuracy—A Solution may be disqualified if it fails to function as expressed in the description provided by the participant, or if it provides inaccurate or incomplete information.

Registration Process for Participants

To register for this Challenge, participants can access <http://www.challenge.gov> and search for "Blockchain and Its Emerging Role in Healthcare and Health-related Research."

Prize

Winners will be provided the following:

- Opportunity to present their paper at a Blockchain & Healthcare Workshop Hosted at NIST
- Paid travel to the Workshop;
- Paid room and board for the Workshop; and
- Paid Per Diem.

Payment of the Prize

Prize will be paid by contractor.

Basis Upon Which Winner Will Be Selected

The evaluation process will begin by removing those that are not responsive to this Challenge or not in compliance with all rules for eligibility. Judges will examine all responsive and compliant submissions, and rate the entries. Judges will determine the most meritorious submissions, based on these ratings and select up to eight (8) finalists. Honorable Mentions may be included and announced, along with the winners on Challenge.gov.

The judging panel will rate each submission based upon the effectiveness of the overall concept to help foster transformative change in the HealthIT culture, the viability of the proposed recommendations, the innovativeness of the approach, and its potential for achieving the objectives of ONC.

Up to eight (8) submissions will be selected as winners. Winners will be

awarded with the opportunity to present their White Paper at a two-day Blockchain & Healthcare Workshop. In lieu of a monetary prize, finalists will be provided with full expenses for travel to the Workshop, which will be held at the NIST Headquarters in Gaithersburg, MD.

At the end of the submission period, Submissions will be posted on the challenge Web site and will be reviewed, graded, and voted on by a steering committee.

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Each participant retains title and full ownership in and to their Submission. Participants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the Challenge, each entrant hereby irrevocably grants to the Government a limited, non-exclusive, royalty-free, perpetual, worldwide license and right to reproduce, publically perform, publically display, and use the Submission 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. This may also include displaying the results of the Challenge on a public Web site or during a public presentation.

Representation, Warranties and Indemnification

By entering the Challenge, each applicant represents, warrants and covenants as follows:

- (a) Participant is the sole author, creator, and owner of the Submission;
- (b) The Submission is not the subject of any actual or threatened litigation or claim;
- (c) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party;

Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of participant hereunder. The Federal Agency sponsors reserve the right to disqualify any Submission that, in their discretion,

deems to violate these Official Rules, Terms & Conditions.

Authority: 15 U.S.C. 3719.

Karen DeSalvo,
National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information: Opioid Analgesic Prescriber Education and Training Opportunities To Prevent Opioid Overdose and Opioid Use Disorder

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Request for information.

SUMMARY: Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain—have been increasingly implicated in drug overdose deaths over the last decade. Alarming, deaths related to opioid analgesic overdose have quadrupled since 1999, and this increase in deaths has been linked to parallel increases in opioid prescribing. As part of its comprehensive response to the opioid epidemic, HHS is actively working to stem overprescribing of opioids in a number of ways, including by providing clinicians with the tools and education they need to make informed prescribing decisions. In particular, HHS has developed a number of activities that support opioid analgesic prescriber education. This Request for Information (RFI) seeks comment on the most promising approaches in prescriber education and training programs and effective ways to leverage HHS programs to implement/expand them.

DATES: Comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2016.

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov>. Follow the