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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Announcement of Requirements and Registration for Healthcare Associated Venous Thromboembolism Prevention Challenge

Authority: 15 U.S.C. 3719

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

Award Approving Official: Thomas R. Frieden, MD, MPH, Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) announces the launch of the Healthcare Associated Venous Thromboembolism (HA-VTE) Prevention Challenge on November 2, 2015. The challenge will be open until January 10, 2016.

Venous thromboembolism (VTE), blood clots occurring as deep vein thrombosis (DVT), pulmonary embolism (PE), or both, is an important and growing public health issue. Prevention of healthcare associated VTE (HA-VTE) is a national hospital safety priority. Many HA-VTEs can be prevented, but VTE prevention strategies are still not being applied regularly or effectively across the United States.

To support and promote HA-VTE prevention, HHS/CDC is announcing the 2015 HA-VTE Prevention Challenge. The challenge will bring prestige to organizations that invest in VTE prevention, improve understanding of successful implementation strategies at the health system level, and motivate health systems to strengthen their VTE prevention efforts. The top-judged organizations found to have implemented innovative and effective VTE prevention strategies will be recognized as HA-VTE Prevention Champions. HHS/CDC will document these successful strategies and highlight the systems, processes, and staffing that

contributed to exceptional VTE prevention outcomes achieved by Champions. Champions will receive a cash prize (if eligible) and other forms of recognition.

DATES: Contest begins on November 2, 2015 and ends on January 10, 2016.

FOR FURTHER INFORMATION CONTACT:

Michele Beckman, Division of Blood Disorders, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E-64, Atlanta, GA 30329, Telephone: 404-498-6474, Fax: 404-498-6799, Attention: HA-VTE Prevention Challenge, Email: havtechallenge@cdc.gov.

SUPPLEMENTARY INFORMATION: The challenge is authorized by Public Law 111-358, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act).

Subject of Challenge Competition

Entrants of the HA-VTE Prevention Challenge will be asked to describe the VTE prevention strategy and reasons that support the strategy choice developed by their organization. In addition, entrants will be asked to describe the specific intervention(s) (e.g. implementation of VTE protocols and order sets, risk assessment, electronic alerts, clinical decision support tools, performance monitoring systems and dashboards, patient and/or provider education and awareness, post-discharge follow-up, etc.), methods, and systems used to implement, support and evaluate the strategy. Entrants will be asked to submit at least one quantitative measure showing an increase of VTE prevention (e.g. number of patients assessed for VTE risk, number of at risk patients receiving appropriate VTE prevention, number of patients and/or providers receiving education on VTE prevention, etc.) and/or decrease in HA-VTE rates for the organization's population of interest. Each measure submitted must include two data points: One for the control or pre-intervention period and a second for the post-intervention period. Control/pre-intervention and post-intervention measures must cover a period of at least six months. This information collection is approved by the Office of Management and Budget under OMB Control Number 0990-0390, expiration April 30, 2018.

Eligibility Rules for Participating in the Competition

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

(1) Shall have completed and submitted the nomination form in its entirety to participate in the competition under the rules promulgated by HHS/CDC;

(2) Must be a hospital, multi-hospital system, hospital network or managed care organization, incorporated in and maintaining a primary place of business in the United States that provides inpatient medical care for patients.

(3) May not be a Federal entity or Federal employee acting within the scope of their employment (Federal entities or employees are eligible to participate in the challenge; however, they are not eligible to receive a monetary prize. Federal entities are eligible for non-monetary recognition only.);

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

(5) Shall not be an employee or contractor at HHS/CDC;

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

(7) 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;

(8) Must agree to participate in a data validation process to be conducted by an HHS/CDC-selected contractor. To the extent applicable law allows, data will be kept confidential by the contractor and will be shared with the CDC in aggregate form only; *i.e.*, the VTE prevention coverage rate for the practice not individual data;

(9) Must have a data management system (electronic or paper) that allows HHS/CDC or their contractor to check data submitted;

(10) Individual nominees and individuals in a group practice must be free from convictions or pending investigations of criminal and health care fraud offenses such as felony health care fraud, patient abuse or neglect; felony convictions for other healthcare-related fraud, theft, or other financial misconduct; and felony convictions relating to unlawful manufacture, distribution, prescription, or dispensing of controlled substances as verified through the Office of the Inspector General List of Excluded Individuals

and Entities. <http://oig.hhs.gov/exclusions/background.asp>

Individual nominees must be free from serious sanctions, such as those for misuse or mis-prescribing of prescription medications. Such serious sanctions will be determined at the discretion of the agency consistent with CDC's public health mission. HHS/CDC's contractor may perform background checks on individual clinicians or medical practices.

(11) Health systems must have a written policy in place that conducts periodic background checks as described in (10) on all providers and takes appropriate action accordingly. In addition, a health system background check may be conducted, as deemed necessary, by HHS/CDC or an HHS/CDC contractor that includes a search for The Joint Commission sanctions and current investigations for serious institutional misconduct (e.g., attorney general investigation). HHS/CDC's contractor may also request the policy and any supporting information deemed necessary.

(12) Must agree to accept the monetary prize and be recognized if selected, and agree to participate in an interview to develop a success story that describes the systems and processes that support VTE prevention. Champions will be recognized on HHS/CDC Web sites. Strategies used by Champions that support VTE prevention may be written into a success story, placed on HHS/CDC Web sites, and attributed to Champions.

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 equal basis.

By participating in this challenge, an individual or organization agrees to assume any and all risks related to participating in the challenge. Individuals or organizations also agree to waive claims against the Federal Government and its related entities, except in the case of willful misconduct, when participating in the challenge, including claims for injury; death; damage; or loss of property, money, or profits, and including those risks caused by negligence or other causes.

By participating in this challenge, individuals or organizations agree to protect the Federal Government against third party claims for damages arising from or related to challenge activities.

Entrants who are a U.S. federal hospital, multi-hospital system, hospital

network or managed care organization that provides inpatient medical care for patients may apply for non-monetary recognition. No monetary prize will be awarded.

Entrants who are an international hospital, multi-hospital system, hospital network or managed care organization that provides inpatient medical care for patients may apply for non-monetary recognition. No monetary prize will be awarded.

Registration Process for Participants

To participate, interested parties will navigate to www.challenge.gov. On this site, nominees will have access to the nomination form. Information required of the nominees on the nomination form includes:

- The organization name, address, and contact information of the nominee.

- The size, scope, and general demographic characteristics of the nominees' patient population.

- Details regarding the nominee's VTE prevention strategy and implementation including the population(s) observed, intervention, and methods of implementation. Examples of strategies include implementation of sustainable systems or processes that support VTE prevention. These may include but are not limited to implementation of VTE protocols and order sets, risk assessment, electronic alerts, clinical decision support tools, performance monitoring systems and dashboards, patient and/or provider education and post-discharge follow-up.

- A description of the observed results of the VTE prevention strategy including the pre-implementation and post-implementation measures for the observed VTE prevention activity. Examples of outcome measures include but are not limited to the number of patients assessed for VTE risk, the number of at risk patients receiving appropriate VTE prevention, and the number of patients and/or providers receiving education on VTE prevention.

- A brief summary of the barriers and successes to implementation.

The VTE prevention rates achieved should be for the organizations entire patient population observed as outlined in their strategy and intervention methods, not limited to a sample. Data on subpopulations is allowed, but must be inclusive of all patients seen during the stated time period of study. Examples of ineligible data submissions include VTE prevention interventions limited to treatment cohorts from clinical trials of novel anticoagulant drugs.

The estimated burden for completing the nomination form is 30 minutes to 1 hour.

Amount of the Monetary Prize

An estimated 7 of highest scoring U.S. hospitals, multi-hospital systems, hospital networks and managed care organizations will be recognized as HA-VTE Prevention Champions and will receive a cash award of \$10,000. A maximum of \$70,000 will be awarded in this challenge. Additional honorable mention awards, pending availability of funds, may be made if the judges identify more than 7 deserving entries. Federal and international winners will receive non-monetary recognition but no prize.

Payment of the Monetary Prize

Monetary prizes awarded under this challenge 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 Upon Which Winner Will Be Selected

Challenge submissions will be evaluated by a panel of three to five judges (CDC, HHS agencies such as the Agency for Healthcare Research and Quality and the Centers for Medicare and Medicaid Services, and external industry experts) using the information provided on, and in accordance with, the nomination form. The judges will score the nomination form using a rubric based on the following evaluation criteria: methods (30% of score); results (50% of score); and feasibility/utility (20% of score) of the strategy and interventions associated with the intended outcome of interest. Nominees with the highest score will be required to participate in a process to verify their data. Final selection will take into account all the information from the nomination form, the background check, and data verification. Geographic location and population treated may be used to break any ties in the event of tie scores at any point in the selection process. An estimated 7 organizations will be recognized as prize winners.

Some Champions will participate in a post-challenge telephone interview. The interview will include questions about the strategies employed by the organization to achieve high rates of VTE prevention, including barriers and facilitators for those strategies. The interview will focus on systems and processes and should not require preparation time by the Champion. The estimated time for the interview is one

hour, which includes time to review the interview protocol with the interviewer, respond to the interview questions, and review a summary report about the Champion's practices. The summary will be written as a success story and will be posted on the CDC Web site.

Additional Information

Information received from nominees will be stored in a password protected file on a secure server. The challenge Web site may post the number of nominations received but will not include information about individual nominees. The database of information submitted by nominees will not be posted on the Web site. Personal information collected and stored from nominees will only include general details, such as the organization name, address, and contact information of the nominee. This type of information is generally publically available. The nomination form and submission will collect and store only aggregate clinical data through the nomination process; no individual identifiable patient data will be collected or stored. Confidential or proprietary data, clearly marked as such, will be secured to the full extent allowable by law.

Information for selected Champions, such as the hospital or health system's name, location, VTE prevention outcomes, and practices that support HA-VTE prevention will be shared through press releases, the challenge Web site, social media, and other HHS/CDC resources. Summary data on the types of systems and processes used to increase VTE prevention will be shared in documents or other communication products that describe generally used practices for successful VTE prevention. HHS/CDC will use the summary data only as described.

Compliance With Rules and Contacting Contest Winners

Finalists must comply with all terms and conditions of these official rules, and winning is contingent upon fulfilling all requirements herein. The finalists will be notified by email, telephone, or mail after the date of judging.

Privacy

Personal information provided by entrants on the nomination form through the challenge Web site will be used to contact selected finalists. Information is not collected for commercial marketing. Winners are permitted to cite that they won this challenge.

The names, cities, and states of selected Champions will be made

available in HHS/CDC's educational materials on VTE prevention and at recognition events.

General Conditions

HHS/CDC reserves the right to cancel, suspend, and/or modify the challenge, or any part of it, for any reason, as HHS/CDC's sole discretion.

Dated: September 15, 2015.

Sandra Cashman,

Acting Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 80 FR 34643-34644, dated June 6, 2015) is amended to reflect the reorganization of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and function statements for the *Division of Respiratory Disease Studies (CCH)* and insert the following:

Respiratory Health Division (CCH). The Respiratory Health Division (RHD) seeks to advance protection against work-related hazards and exposures that cause or contribute to respiratory illness, injury, and death and to promote workplace-based interventions that improve respiratory health. To accomplish its mission, the Division gathers and synthesizes information, makes recommendations, and delivers products and services to a range of stakeholders, including partners able to effect prevention. Specifically, RHD: (1) Prevents work-related respiratory disease and improves workers' respiratory health by generating new knowledge and transferring that knowledge into practice; (2) plans, designs, and conducts a national research program relevant to preventing

occupational respiratory disease and optimizing workers' respiratory health; (3) upon request, conducts hazard evaluations and provides technical assistance to address challenges, including emerging issues, in occupational respiratory disease; (4) plans, designs, and conducts a national surveillance program for occupational and work-related respiratory disease; (5) communicates study findings to prevent occupational respiratory disease and optimize workers' respiratory health, and evaluates the effectiveness of these communications; (6) administers a program of legislatively mandated medical monitoring services for coal miners under the Federal Mine Safety and Health Act of 1977; and (7) provides rewarding educational and training opportunities in occupational and work-related respiratory disease prevention to visiting scientists, Epidemiologic Investigations Service Officers, fellows, residents, interns, students and others through a variety of temporary assignments in various Division activities.

Office of the Director (CCH1). Directs and manages the operations of the Respiratory Health Division.

Field Studies Branch (CCHB). (1) Plans, designs, and conducts short- and long-term field investigations relevant to preventing occupational respiratory diseases and optimizing workers' respiratory health; (2) responds to requests for health hazard evaluations and technical assistance relevant to occupational respiratory disease; (3) conducts morbidity and mortality studies relating to occupational respiratory diseases in selected worker populations and the general population in order to identify causal agents and other risk factors, quantify exposure effect relationships, and evaluate prevalence and severity of specific respiratory diseases; (4) conducts environmental studies, medical test evaluations, industrial hygiene research, laboratory research, demonstrations of workplace exposures and controls, and studies the challenges created by new technologies; (5) provides statistical design and implements data analysis and verification for Division research projects; and (6) develops and evaluates research methods of data collection, processing, and statistical analysis that are relevant to the Division mission, including medical tests, sampling approaches and equipment, sample analyses, exposure and dose assessment and modeling (including dermal exposure), bioavailability of exposures, biomarkers of exposure and health effects, and protective measures.