DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Stakeholders Meeting To Provide Updates on NIOSH-Funded Research, Certification and Standards, Educate Participants on Resources To Reinforce the Proper Use of NIOSH-Certified Respirators, and Explore Personal Protective Technology Use in Industry Sectors

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of a public meeting.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), Personal Protective Technology (PPT) Program and National Personal Protective Technology Laboratory (NPPTL) will conduct a stakeholders meeting to provide updates on NIOSH-funded research, certification and standards, educate participants on resources to reinforce the proper use of NIOSH-certified respirators, and explore personal protective technology use in industry sectors. In addition, conformity assessment (certification and standards) needs and gaps relative to the personal protective technology will be discussed at this meeting.

DATES: The public meeting will be held 8 a.m. to 5 p.m., March 29, 2011.

ADDRESSES: The public meeting will be held at Hyatt Regency Pittsburgh International Airport, 1111 Airport Boulevard, Pittsburgh, PA 15231, telephone 724–899–1234.

FOR FURTHER INFORMATION CONTACT: Ed Fries, NPPTL, Office of the Director, P.O. Box 18070, Pittsburgh, PA 15236, telephone 412–386–6111, fax 412–386–4951, E-mail *npptlevents@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Status: The meeting will be open to the public, limited only by the space available. The meeting room accommodates approximately 200 people. Preregistration is recommended. This meeting will also be available through remote access capabilities (Microsoft Live Meeting), whereby participants simultaneously listen and view presentations over the internet. This option will be available to participants on a first-come, first-serve basis and is limited to the first 100 participants. Preregistration for this option is required.

Instructions: Registration and additional Information is available on the NIOSH NPPTL Web site, *http://www.cdc.gov/niosh/npptl* or by contacting NIOSH NPPTL Office of the Director, P.O. Box 18070, Pittsburgh, PA 15236, telephone 412–386–6111, fax 412–386–6617, E-mail *npptlevents@cdc.gov.*

Background: While this meeting will highlight the personal protective technology related to the four industries, the information and technology is relevant and can be transferred to other industries.

Discussions will highlight the following four occupational sectors:

1. Agriculture—Discussions will focus on identifying solutions to major barriers for appropriate PPE use practices that occur in pesticide handling in agricultural crop production. Discussions will use a process flow approach for focusing on each of the critical stages for PPE use in pesticide handling. Potential barriers and regulations, such as those identified from brainstorming meetings of the NIOSH PPE Surveillance and Intervention Program for Agricultural Pesticide Handlers, that may influence safe performance will be highlighted. Stakeholders will provide their input, clarify barriers and help identify solutions for future development. The goal of these discussions is to bring diverse stakeholders together to discuss barriers to appropriate PPE use and to jointly formulate and develop creative solutions.

2. Mining—One session will focus on technologies to improve current self-contained self-rescuer (SCSR) designs and mine rescue ensembles. Presentations from researchers, manufacturers, and users will focus on SCSR design improvements and technologies to address user needs. The second session will focus on best practices learned from ensemble users, performance requirements for mine rescue ensembles and identification of existing limitations and current best practices.

3. Healthcare—PPE use and usability issues in acute care and community healthcare settings and the alignment of current and recommended PPT research to narrow knowledge gaps, reduce exposures, and improve healthcare worker proper use and compliance will be emphasized. These sessions will explore respiratory protective equipment use and application issues as well as use and application issues with other types of PPE commonly used in healthcare, including integrated ensembles.

4. Public Safety—These sessions will focus on personal protective technology applications, performance/certification standards and use related to the fire service and law enforcement communities. Two breakout sessions will be conducted, one for fire service and one for law enforcement. The fire service-related breakout session will include issues and requirements related to the design, certification, inspection of firefighting personal protection ensembles, and NIOSH research supporting use of protective ensembles and respiratory protective equipment by the fire service. The law enforcement breakout session will address performance requirements and standards for law enforcement protective ensembles with a focus on CBRN hazards. The CBRN Protective Ensemble Standard for Law Enforcement released by the National Institute for Justice in late 2010 will be discussed.

Dated: December 21, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Development of Health Risk Assessment Guidance; Public Forum

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

ACTION: Notice of Public Meeting.

SUMMARY: On November 16, 2010, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), published a notice in the **Federal Register** (75 FR 70009) requesting public comment to assist development of guidance for Health Risk Assessments (HRAs). Section 4103 of the Affordable Care Act (ACA) (Pub. L. 111–148) requires that a Health Risk Assessment be included in the annual wellness visit benefit authorized for Medicare beneficiaries under the ACA. CDC is collaborating with the Centers for Medicare and Medicaid Services (CMS), also located within HHS, in the development of guidance for this type of assessment. This guidance is also intended to be useful for HRAs

conducted in other patient populations, including those persons covered by employer healthcare plans. In the November 16, 2010 notice, CDC also announced that it would hold a public forum in early February 2011 to obtain additional public comment. Today's notice announces the public forum.

DATES: The public forum will be held on:

Tuesday, February 1, 2011, from 9 a.m. to 5 p.m. EST and Wednesday, February 2, 2011, from 9 a.m. to 5 p.m. EST.

ADDRESSES: The Public Forum will be held at the Centers for Disease Control and Prevention, Roybal Campus, Tom Harkin Global Communications Center, Building 19, Auditorium A, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Upon entering the campus visitors must stop at the CDC Visitor's Center parking guard station. Visitors will be asked for identification and the purpose of the visit. Please be aware that your vehicle is subject to search before being allowed to enter the facility. A government-issued photo ID is required for entry for all adults over the age of 16. Acceptable forms of identification include a valid driver's license, a passport or a state-issued photo identification card. Parking spaces for visitors are available in the parking lot adjacent to the CDC Visitor's Center (Building 19). Once inside the CDC Visitor's Center, visitors will be asked to show their picture ID again and a visitor's badge will be issued. Those who have registered in advance will have a visitor's badge waiting and entry will be expedited. Non-U.S. citizens (including permanent residents) must register in advance. Please note, this is a working Federal Facility. Please follow the guards' directions. Backpacks, suitcases or large containers are prohibited and photography is restricted.

Please visit our Web site for additional information on security and for directions to the facility *(http://www.cdc.gov/museum/security.htm*).

CDC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paula Staley at (404) 639–0210 at least 7 days in advance of the meeting.

Registration: Participants are encouraged to pre-register for the Public Forum. On-line registration and a draft agenda is available at: *http://www.cdc.gov/policy*. As space is limited, registration by January 7, 2011 is strongly encouraged.

FOR FURTHER INFORMATION CONTACT: Paula Staley, Office of Prevention through Healthcare, Office of the Associate Director for Policy, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, Georgia 30333; *phone:* (404) 639–0210.

SUPPLEMENTARY INFORMATION: Section 4103 of the Affordable Care Act (ACA) requires that a Health Risk Assessment (HRA) be included in the annual wellness visit benefit authorized for Medicare beneficiaries under the ACA. CDC is collaborating with the Centers for Medicare and Medicaid Services (CMS) in the development of guidance for this type of assessment. This guidance is also intended to be useful for HRAs conducted in other patient populations such as privately insured populations, including those persons covered by employer healthcare plans. Currently there is considerable variation in available HRAs, with the majority created to support employer-based health and wellness programs. Several instruments have been created for use in research and are not available in the marketplace; and the scientific rigor of HRA tools is not always evident. Therefore, the development of HRA guidance is essential for effective implementation of this part of the Medicare wellness visit and to support broader HRA use within primary care.

Agenda: The meeting will open with presentations related to background information on the elderly population, HRAs and the HRA guidance development. The meeting will consist of panel presentations for each of the areas of emphasis which are listed in this notice as well as in the November 16, 2010 **Federal Register** notice. Participants attending the public forum will be invited to provide comment at the end of each half day of the meeting. The final agenda and panelists' presentations will be made available to the public no later than two business days before the meeting. If CDC is unable to post the presentations on its Web site prior to the meeting, the material will be made publicly available at the location of the meeting. The final agenda and panelists' presentations will be available at *http://www.cdc.gov/policy*. The agenda is subject to change without notice.

Areas of Emphasis:

Content and Design

- Risk assessment domains—What are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age?
- How should literacy and other cultural appropriateness factors be factored into the design?
- Should the HRA instrument support shared decision-making by provider and patient? If so, how?

Mode of Administration

- How will individuals access the HRA (*e.g.,* via kiosk or some other means in the physician's office, internet, mail-in paper form, other non-traditional healthcare locations, such as, kiosk in a pharmacy)?
- What are the cultural appropriateness factors in patient HRA access?

Primary Care Office Capacity

- What primary care office capacity (personnel, Information Technology (IT), *etc.*) is required to utilize HRA data effectively in support of personalized prevention planning?
- Is training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?
- What are potential or demonstrated community care transition linkages—follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?
- What is the current practice of HRA in medical practices of various sizes, particularly those with five or fewer physicians?

Consumer/Patient Perspective

- How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?
- What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?

Data

- With respect to IT, how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?
- Are there standardized and certified tools available to support this data migration from multiple data entry sources?

Certification

- What certification tools and processes should complement the HRA standards and how should they be made available to support primary care office selection of an HRA instrument?

Evaluation and Quality Assurance

• How should the HRA standards be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?

Procedure: Interested persons may present data, information, or views orally or in writing, on topics listed in this **Federal Register** notice. Written submissions for the public comment period may be made to the contact person on or before January 18, 2011. Oral presentations from the public will be scheduled during 30-minute public comment periods at the end of each half day of proceedings, *i.e.,* from 11:30 a.m. to 12 noon and 4:30 p.m. to 5 p.m. on Tuesday, February 1, 2011 and Wednesday, February 2, 2011. Those individuals interested in making formal oral comments should notify the contact person and submit a brief statement of the general nature of the comments they wish to present and the names and addresses of proposed participants on or before January 11, 2011. Each commenter will be limited to 3–5 minutes. The CDC is not responsible for providing access to electrical outlets.

Individuals who have not submitted comments ahead of time will have the opportunity to sign up to comment during registration on the day of the forum. However, if time does not allow for all interested parties to comment, individuals who have submitted their comments ahead of time will be given preference. If the number of participants requesting to comment is greater than can be reasonably accommodated, the CDC may conduct a lottery to determine the speakers for the scheduled open public comment sessions. The contact person will notify interested persons regarding their request to comment by January 18, 2011.

Public forum participants not receiving an opportunity to comment during the open public comment period may submit their comments to OPTH mailbox at: *http://www.cdc.gov/policy*. CDC will make all comments it receives available to the public without change, including personal information you may provide, which includes the name of the person submitting the comment or signing the comment on behalf of an organization, business, or any such entity. If anyone does not wish to have this information published, then that information should not be included when submitting the comment.

Dated: December 21, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Consolidated Vaccine Information Materials for Multiple Infant Vaccines

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

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa–26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on a proposed new vaccine information statement that consolidates the six vaccine information statements for the following childhood vaccines: DTaP, *Haemophilus influenzae* type b, inactivated polio vaccine, pneumococcal conjugate vaccine, hepatitis B, and rotavirus. This consolidated Vaccine Information Statement is available to be used by vaccination providers as an alternative to providing the six individual Vaccine Information Statements for the same vaccines.

DATES: Written comments are invited and must be received on or before February 28, 2011.

ADDRESSES: Written comments should be addressed to Jennifer Hamborsky, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E–52, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe, National Center for Immunization and Respiratory Diseases, Mailstop E–52, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–8809.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) A concise description of the benefits of the vaccine,

(2) A concise description of the risks associated with the vaccine,

(3) A statement of the availability of the National Vaccine Injury Compensation Program, and

(4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, hepatitis A, meningococcal conjugate and polysaccharide, rotavirus, human papillomavirus (HPV), and trivalent influenza vaccines have subsequently been added to the National Vaccine Injury Compensation Program. Use of the Vaccine Information Statements applicable to all of these vaccines, except meningococcal, rotavirus and HPV, is also required. (Interim versions of Vaccine Information Statements for meningococcal, rotavirus and HPV vaccines are available for discretionary use pending completion of the statutory process for finalizing VISs applicable to those vaccines.) Instructions for use of the vaccine information materials and copies of the materials can be found on