DEPARTMENT OF HEALTH AND HUMAN SERVICES

Stakeholder Listening Session in Preparation for the 66th World Health Assembly

Time and date: May 6, 2013, 3 p.m.–4:30 p.m. EST.
Place: Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.
Status: Open, but requiring RSVP to OGA.RSVP@hhs.gov.

Purpose
The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 66th World Health Assembly—will hold an informal Stakeholder Listening Session on Monday, May 6, 3–4:30 p.m., in the Great Hall of the HHS Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. The Stakeholder Listening Session will help the HHS’s Office of Global Affairs prepare for the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 66th World Health Assembly. Your input will contribute to US positions as we negotiate these important health topics with our international colleagues.

The listening session will be organized around the interests and perspectives of stakeholder communities, including, but not limited to:
- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

It will allow public comment on all agenda items to be discussed at the 66th World Health Assembly http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_1-en.pdf.

RSVP
Due to security restrictions for entry into the HHS Hubert H. Humphrey Building, we will need to receive RSVPs into the HHS Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health Partnership Opportunity on a Research Project To Evaluate the Performance of Isolation Gowns

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

ACTION: Notice of opportunity to support research.

SUMMARY: The NIOSH National Personal Protective Technology Laboratory is initiating a research study in support of American Society for Testing and Materials (ASTM) International standards development to establish minimum performance requirements for isolation gowns for health care workers. NIOSH is seeking to identify currently marketed isolation gown products. All manufacturers are requested to submit samples to NIOSH free of charge for testing. There will be no cost to the manufacturers for testing. Not all submitted products may be tested, depending on the response to this announcement and the results of screening tests. Each manufacturer that submits gowns that are tested will receive the test results from their gowns. Through submission of the gown samples, manufacturers will be making an important contribution to ASTM, International’s process to establish an important standard for evaluating the protection provided for health care workers by isolation gowns. Participating manufacturers will be recognized as contributing to the establishment of the performance standard. Manufacturers whose products are tested will also receive the results of all gowns tested in a blinded format.

Gown Criteria: Candidate gowns for inclusion in the research program must meet the following criteria: (1) The gowns must be identified (labeled) as “isolation gowns” and have full coverage in the back to provide protection for the health care worker and the patient; (2) A minimum of 100 units for each code (model) of disposable (single use) gown submitted; (3) A minimum of 200 “new” (unprocessed, unused, unwashed) reusable gowns for each model submitted. Reusable gown submissions must include a labeling recommendation for the maximum number of laundering cycles to be included in this study. Half of the gown samples will be tested after one laundering and drying cycle and half of the gown samples will be tested as laundered for the maximum number of cycles claimed by the manufacturer; and, (4) Samples should be provided in finished package format, with any claims that may not be noted on the packaging or labels provided by the manufacturer. NIOSH will not return any gowns submitted for this testing.

DATES: Submit letters of interest to provide gowns and participate in this research program prior to May 13, 2013.

ADDRESSES: Interested manufacturers should submit a letter of interest with information about their isolation gowns’ capabilities to: NIOSH, National Personal Protective Technology Laboratory, Attn: Selcen Kilinc, PO Box 16070, Pittsburgh, PA 15236, Email address: fqcp@cdc.gov

Background: It has been reported by user groups (e.g. Association of Perioperative Registered Nurses and Association for Professionals in Infection Control and Epidemiology) as well as U.S. Food and Drug Administration (FDA), that performance properties and levels of protection for isolation gowns are poorly understood and defined. NIOSH and FDA are currently working with the ASTM International Committee on Personal Protective Clothing and Equipment—Biological Subcommittee, to establish a standard that defines criteria for minimum levels of performance for isolation gowns. Development of a standard is expected
to improve users’ understanding of levels of protection to be provided. Product testing results will be provided to the ASTM Committee on Personal Protective Clothing and Equipment—Biological Subcommittee (a.k.a. ASTM Task Force), which will utilize the data as the scientific basis to develop a standard establishing minimum performance criteria for single-use and reusable isolation gowns. The research objective is to evaluate performance properties, such as strength and barrier properties, of isolation gowns to be provided to the ASTM Task Force as scientific input for establishing minimum performances for conformance to this standard.

In this study, all testing will be conducted blind. Results will be shared with the ASTM Task Force only in a blinded format. Results will be shared with the individual manufacturers for their gowns only. The final summary of the testing will be shared in a blinded format only with all manufacturers that participated.

Randomized samples will be tested by both NIOSH and Nelson Labs. The ASTM Task Force will review and analyze all test results. Establishment of the minimum requirement for each property will be the responsibility of the ASTM Task Force. NIOSH plans to conduct testing to measure the following properties: Fabric weight, breaking strength, tear strength, seam strength, water resistance (impact penetration and hydrostatic pressure), microbial/viral penetration resistance, air permeability, evaporative resistance, and thermal insulation.

Neither this announcement, nor product submittals in response to this announcement, obligates NIOSH to enter into a contractual agreement with any respondent. Inquiries should be sent to Selcen Kilinc at jcq8@cdc.gov. NIOSH reserves the right to establish a partnership based on scientific analysis and capabilities found by way of this announcement or other searches, if determined to be in the best interest of the government.

Dated: April 5, 2013.

John Howard,
Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

DEFENDANT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Maine State Plan Amendments (SPA) 12–010

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on May 23, 2013, at the CMS Boston Regional Office, JFK Federal Building, 15 N. Sudbury Street, Room 2050, Boston, Massachusetts 02203–0003 to reconsider CMS’ decision to disapprove Maine SPA 12–010.

DATES: Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by (15 days after publication).

FOR FURTHER INFORMATION CONTACT: Benjamin Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244. Telephone: (410) 786–3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS’ decision to disapprove Maine SPA 12–010 which was submitted on August 1, 2012, and disapproved on January 7, 2013. The SPA proposed changes to eligibility for parents, caretaker relatives, and children whose income is at or below 133 percent of the federal poverty level (FPL). The proposal would make eligibility standards, methods, and procedures more restrictive than those in effect on March 23, 2010.

CMS disapproved this SPA after consulting with the Secretary as required by 42 CFR 430.15(c)(2) because it appeared the proposal would have eliminated Medicaid eligibility for parents and caretaker relatives eligible under sections 1902(a)(10)(A)(i)(I) and 1931 whose incomes are between 100 percent and 133 percent of the FPL, and Medicaid eligibility of certain individuals considered “children” under Maine’s state Medicaid plan. Both proposals constituted more restrictive eligibility standards than those in effect in Maine as of March 23, 2010, that could not be excepted from the maintenance-of-effort (MOE) mandate that Maine is subject to under section 1902(a)(74) and (gg) of the Social Security Act (hereafter “the Act”). At issue in this appeal are the following issues:

While states generally have authority to modify Medicaid eligibility rules, sections 1902(a)(74) and (gg) of the Act require that states maintain eligibility standards, methodologies, and procedures that are no more restrictive than those in effect under a state’s plan as of the date of enactment of the Patient Protection and Affordable Care Act (March 23, 2010). This MOE requirement applies to adults until a state’s health insurance exchange is operational (January 1, 2014) and to children until October 1, 2019.

Section 1902(gg)(3) of the Act offers a partial non-application of the MOE requirement during the period between January 1, 2011, and December 31, 2013, when a state certifies to the Secretary that it has a budget deficit during the fiscal year for which it is seeking a non-application, or projects a budget deficit during the succeeding fiscal year. This provision limits the non-application to “nonpregnant, nondisabled adults who are eligible for medical assistance under the state plan or under a waiver of the plan at the option of the state and whose income exceeds 133 percent of the poverty line.”


Maine submitted SPA #12–010 on August 1, 2012, which proposed changes to its Medicaid eligibility rules for parents, caretaker relatives, children, and to Medicare savings programs (MSPs). Specifically, Maine proposed: Reducing the income eligibility limit from 150 percent of the FPL to 100 percent for parents and caretaker relatives who may qualify under section 1902(a)(10)(A)(i)(I) and 1931 of the Act; lowering the age limit of eligibility from 20 to 18 for children who meet the eligibility requirements for the aid to families with dependent children (AFDC) state plan but who would not have received AFDC based on age; and reducing income eligibility for the MSPs through the elimination of certain income disregards. Maine eventually split the SPA into two, with the proposal relating to families, caretaker relatives, and children identified as SPA #12–010, and the proposal relating to MSPs identified as SPA #12–010A. On January 7, 2013, CMS approved SPA #12–010A, but disapproved SPA #12–010. CMS determined that Maine’s SPAs as proposed eligibility rules more restrictive than Maine’s plan as of March 23, 2010. However, due to Maine’s FY 2013 budget deficit