

Audio conferencing will be available for the second day of the meeting.

DATES: The meeting will be held on February 5, 2009, from 8:30 a.m. to 6:30 p.m. and on February 6, 2009, from 8 a.m. to 3:30 p.m.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 800; 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Krull, National Vaccine Program Office, Department of Health and Human Services, Room 443-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Phone: (202) 690-5566; Fax: (202) 260-1165; e-mail: nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. Section 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program, on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

Topics to be discussed at the meeting on Thursday, February 5, 2009 include vaccine financing, vaccine safety, vaccine stockpile, seasonal influenza and related issues, vaccine development, and the National Vaccine Plan. Updates will be given by the NVAC Financing, Adult Immunization, and Safety working groups. The meeting on Friday, February 6, 2009 is a full day stakeholders' meeting to discuss the draft strategic National Vaccine Plan. The draft plan can be viewed at the following Web site: http://www.hhs.gov/nvpo/vacc_plan/. The meeting will begin with a plenary session to provide an overview of the day's agenda followed by break-out sessions for each of the five draft strategic National Vaccine Plan goals. Audio-conferencing will be available for the stakeholders' meeting on February 6, 2009 for the plenary as well as break-out sessions. Call-in numbers for the meeting are as follows: plenary sessions on February 6: (888) 390-3413 (passcode: 60302); goal 1: research (888) 469-1340 (passcode 27271); goal 2: safety (888) 989-4406 (passcode 41520); goal 3: communication (800) 779-6844 (passcode 19562); goal 4: supply (888)

994-8791 (passcode 37886); and goal 5: global health (888) 989-4717 (passcode 12377). Agendas for each day of the meeting will be posted on the NVAC Web site: www.hhs.gov/nvpo/nvac by January 21, 2009.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person at least one week prior to the meeting. Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to five minutes per speaker. Individuals who would like to submit written statements should e-mail or fax their comments to the National Vaccine Program Office at least five business days prior to the meeting. A separate **Federal Register** Notice will be issued with detailed instructions for submitting comments about the draft strategic National Vaccine Plan. Any members of the public who wish to have printed material distributed to NVAC members should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business January 30, 2009.

Dated: January 5, 2009.

Bruce Gellin,

*Deputy Assistant Secretary for Health,
Director, National Vaccine Program Office.*

[FR Doc. E9-498 Filed 1-13-09; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Decision To Evaluate a Petition To Designate a Class of Employees for the Piqua Organic Moderated Reactor Site, Piqua, Ohio, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees for the Piqua Organic Moderated Reactor site, Piqua, Ohio, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as

warranted by the evaluation, is as follows:

Facility: Piqua Organic Moderated Reactor site.

Location: Piqua, Ohio.

Job Titles and/or Job Duties: All employees associated with reactor activities who worked within and around the Reactor Dome.

Period of Employment: January 1, 1963 through December 31, 1966.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV.

Dated: January 6, 2009.

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. E9-571 Filed 1-13-09; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on Draft Strategic National Vaccine Plan

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: On behalf of the National Vaccine Advisory Committee (NVAC), the National Vaccine Program Office (NVPO) is soliciting public comment on the draft strategic National Vaccine Plan.

DATES: All comments on the draft strategic National Vaccine Plan should be received no later than 5 p.m. on January 30, 2009.

ADDRESSES: Electronic responses are preferred and may be addressed to NVPCComments@hhs.gov. Written responses should be addressed to National Vaccine Program Office, Department of Health and Human Services, 200 Independence Avenue, SW., Room 443-H, Washington, DC 20201, Attention: National Vaccine Plan RFI.

FOR FURTHER INFORMATION CONTACT: CAPT Raymond A. Strikas, M.D., National Vaccine Program Office, Department of Health and Human Services, 200 Independence Avenue, SW., Room 443-H, Washington, DC 20201; (202) 690-5566; fax 202-260-1165; e-mail nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The National Vaccine Program was established in 1986 to achieve optimal prevention of infectious diseases through immunization and optimal prevention of adverse reactions to vaccines. NVPO is located within the Office of Public Health and Science within the Office of the Secretary, HHS, and has responsibility for coordinating and ensuring collaboration among the many Federal agencies involved in vaccine and immunization activities as part of the National Vaccine Program. NVAC is a statutory Federal advisory committee that provides advice and makes recommendations to the Director of the National Vaccine Program on matters related to the Program. The purpose of the National Vaccine Plan is to promote achievement of the National Vaccine Program mission by providing strategic direction and promoting coordinated action by vaccine and immunization enterprise stakeholders.

Federal involvement in civilian and military vaccination programs is longstanding, including in research and development, regulation, vaccine delivery and the evaluation of the impacts of immunizations. This draft strategic National Vaccine Plan builds on the many achievements of the vaccine and immunization enterprise prior to and since the establishment of the National Vaccine Program in 1986 and the completion of the first National Vaccine Plan in 1994. Both the draft strategic National Vaccine Plan and the 1994 National Vaccine Plan are available at http://www.hhs.gov/nvpo/vacc_plan/. New vaccines have been developed and licensed; many of these new vaccines are now recommended for children, adolescents and adults. These new vaccines have expanded the number of infections that can be prevented, and more effectively and safely prevent some diseases for which earlier generation vaccines already existed. Opportunities exist to improve protection against vaccine-preventable diseases by (1) developing improved vaccines based on new adjuvants and better understanding of the immune system, and (2) developing a variety of delivery systems for vaccines, such as intradermal, oral, and immunostimulant patches. In addition, federal immunization financing programs have reduced or eliminated many financial barriers to immunizations, particularly for children. The number of infections prevented by vaccination has decreased significantly while coverage for many vaccines has reached record levels. More robust systems have been developed to identify adverse events

following immunization and to assess potential associations of those events with vaccination. Globally, the United States has worked with multilateral and bilateral partners and non-governmental organizations in contributing to improvements in child health status and the prevention of hundreds of thousands of child deaths each year through improved vaccine coverage and introduction of new vaccines. Of the fourteen anticipated outcomes included in the 1994 National Vaccine Plan, most were substantially or fully realized.

Despite these successes, however, many of the challenges that stimulated establishment of the National Vaccine Program and the development of the 1994 National Vaccine Plan remain relevant today. Vaccine shortages have frequently been experienced for many routinely recommended vaccines. Despite improved vaccination coverage among children, the occurrence of several recent vaccine preventable disease outbreaks serves as a reminder that these diseases still occur. Among older adults both vaccination coverage and the effectiveness of some routinely recommended vaccines remain sub-optimal. As the number of vaccines has increased and vaccine preventable diseases have declined, vaccine safety concerns are expressed more prominently today and may be more widely shared. Enhancing the current vaccine safety system is important to keep pace with several factors influencing it: an increasing number of vaccines and vaccine combinations, expanding target populations, and a better understanding of human biology, especially the human immune system. As the cost of vaccination has increased, financial barriers to vaccination have emerged for health departments, health care providers, and the public. Significant scientific challenges remain in the development of safe and effective vaccines against existing global health threats, such as HIV, TB, malaria, and influenza (developing vaccines with broader protection). Vaccines that have been developed and are in use in industrialized countries have the potential to make major contributions to health in developing countries, but are underutilized. Additionally, emerging and pandemic infections and bioterrorist threats pose new challenges for vaccine development and manufacturing, vaccine delivery, regulation, and access in the U.S. and abroad.

The Plan is built around the achievement of five broad goals:

Goal 1: Develop new and improved vaccines.

Goal 2: Enhance the safety of vaccines and vaccination practices.

Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers.

Goal 4: Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States.

Goal 5: Increase global prevention of death and disease through safe and effective vaccination.

These goals will be achieved by pursuing objectives and strategies that address each of the key determinants of those outcomes. Success in achieving these goals will be assessed by tracking progress in achieving measurable outcomes (“indicators”) associated with each goal. Final definition of the indicators and the development of specific numeric targets will occur through further consultation with stakeholders and the IOM Committee.

The current draft strategic National Vaccine Plan is based largely on input received from Federal Departments and agencies. Recognizing that success can best be achieved through a national plan that includes coordinated action by public and private sector stakeholders in pursuit of the Plan’s goals, extensive outreach and consultation will be implemented as the Plan is finalized. A committee empaneled by the National Academy of Sciences’ Institute of Medicine (IOM) reviewed the 1994 National Vaccine Plan and provided guidance on the development of the updated Plan (see <http://www.iom.edu/CMS/3793/55143.aspx>). The IOM committee is also holding a series of national meetings focused around each of the goals in which perspectives from many of the stakeholders will be obtained. Following these meetings, the IOM committee will prepare a report that includes conclusions and recommendations about priority actions within major components of the Plan. The National Vaccine Advisory Committee (NVAC), a Federal advisory committee that includes representatives from many of the key vaccine and immunization enterprise stakeholders, is also implementing a process to obtain input from a wide range of stakeholder groups. This input will include comments on this draft Plan and additional strategies that they can contribute to achieve Plan goals. The NVAC will devote its meeting on February 6, 2009 to stakeholder and public comments on the draft Plan. In addition, input from the public will also be solicited to identify priority areas from their perspective in a series of meetings planned for later in 2009,

locations to be determined. This draft Plan will serve as the basis for the development of the updated National Vaccine Plan and based on this range of input, indicators of measurable outcomes will be determined and priorities will be presented. In addition, an implementation plan will be drafted that identifies specific actions that will be undertaken by government and other vaccine and immunization enterprise stakeholders to achieve the objectives and strategies in the plan and milestones will be established that will allow progress to be measured. The draft Plan has a ten-year horizon, and thereby balances a strategic vision, which requires development and implementation of new initiatives, with the recognition that changing circumstances and new opportunities and challenges will occur over the next decade. The ten-year horizon also allows incorporation of the HealthyPeople 2020 objectives once those are established by the Department of Health and Human Services (see <http://www.healthypeople.gov>). Annual monitoring of progress and a mid-course review will promote both accountability and flexibility. The updated National Vaccine Plan is expected to be completed by early 2010.

Through this Request for Information, HHS is seeking broad comment from stakeholders and the general public. Comments received will be available for public viewing and will be summarized in an open meeting on February 6, 2009, to the NVAC in Washington, DC. If you wish to attend the meeting in person or by audioconference, please reply to nvpo@hhs.gov, or to 202-690-5566.

II. Information Request

NVPO, on behalf of the NVAC requests information in four broad areas. Responders may address one or more of the areas below.

(1) *Comments on priorities for the National Vaccine Plan for a ten-year period:* What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you? [Provide up to 3 pages for an answer to these questions].

(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded

or revised? Which ones, and why? [Provide up to 3 pages for an answer to these questions].

(3) *Comments on the indicators for the National Vaccine Plan for a ten-year period:* Please comment on the existing indicators in the draft Plan, and suggest target estimates for them. Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft strategic Plan that should be discarded or revised? Which ones, and why? [Provide up to 3 pages for an answer to these questions].

(4) *Comments on stakeholders' roles in the National Vaccine Plan:* Please identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan. [Provide up to 3 pages for an answer to these questions].

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in vaccines and the immunization enterprise. Some examples of these organizations include, but are not limited to, the following:

- General public.
- Advocacy groups and public interest organizations.
- State, local, and tribal governments and public health agencies.
- State and local public health departments.
- Vaccine manufacturing industry, distributors, investors, and other businesses.
- Health care professional societies and organizations.
- Academic researchers and groups.
- Health care payers and plans.
- International organizations.
- Non-governmental organizations.
- Philanthropic organizations.
- Travel industry.

The submission of written materials in response to the RFI should not exceed 12 pages (3 pages for each of the four broad topics), not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses. Any information you submit will be made public. Consequently, do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public. Information and comments will not be considered nor made publicly available, if it is not

signed by, or attributed to, an individual, or an individual representing an organization.

Public Access: Responses to this RFI will be available to the public on the NVPO Web site at http://www.hhs.gov/nvpo/vacc_plan/. You may access public comments received from this RFI by going to the above Web site.

Dated: January 7, 2009.

Bruce Gellin,

Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, U.S. Department of Health and Human Services.

[FR Doc. E9-495 Filed 1-13-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10161, CMS-1882, CMS-437A and B, CMS-1557 and CMS-10036]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* New Freedom Initiative—Web-based Reporting System for Grantees; *Use:* CMS currently awards competitive grants to States and other eligible entities for the purpose of designing and implementing effective and enduring improvements in community-based long-term services