

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at <https://www.regulations.gov>, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: May 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-11641 Filed 5-30-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Human Papillomavirus Vaccination Implementation Work Group Draft Report and Draft Recommendations for Consideration by the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act. Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership and fosters collaboration

among the various federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in his capacity as the Director of the National Vaccine Program on matters related to vaccine program responsibilities.

The ASH charged the NVAC in February 2018 to establish a work group to produce a brief report by June 2018 on recommendations to strengthen the effectiveness of national, state, and local efforts to improve Human Papillomavirus (HPV) coverage rates. Through a series of conference calls, electronic communication, and public discussion at the May 3, 2018, NVAC public meeting, the work group identified a number of draft recommendations for consideration by the NVAC. The work group's draft report and recommendations will inform NVAC deliberations as it finalizes recommendations for transmittal to the ASH.

On behalf of NVAC, NVPO is soliciting public comment on the draft report and draft recommendations from a variety of stakeholders, including the general public, for consideration by the NVAC as they develop their final recommendations to the ASH. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented to the NVAC for adoption in June 2018 at the quarterly NVAC meeting.

DATES: Comments for consideration by the NVAC should be received no later than 5:00 p.m. EDT on June 15, 2018.

ADDRESSES:

(1) The draft report and draft recommendations are available on the web at <http://www.hhs.gov/nvpo/nvac/index.html>.

(2) Electronic responses may be sent to: nvac@hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Captain Angela Shen, Designated Federal Officer, National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: 202-690-5566; email nvac@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 9, 2015, the National Vaccine Advisory Committee (NVAC) issued a report "Overcoming Barriers to Low HPV Vaccine Uptake in the United States: Recommendations from the National Vaccine Advisory Committee."

This report provided recommendations to the ASH on how to increase Human Papillomavirus (HPV) vaccine uptake in young adolescents by reviewing the current state of HPV immunization, understanding the root cause(s) for the observed relatively low vaccine uptake (both initiation and series completion), and identifying existing best practices. Since the original NVAC HPV report, substantial progress led to policy and program changes and advances in research. To build on the substantial progress made toward increasing HPV vaccination coverage rates, the ASH charged the NVAC in February 2018 to establish a work group to produce a brief report by June 2018 on recommendations to "strengthen the effectiveness of national, state, and local efforts to improve HPV coverage rates." The ASH specifically requested the NVAC to consider the following:

(1) Many national organizations are currently supporting HPV efforts. Are there additional national organizations that might contribute to increasing HPV vaccination coverage?

(2) At the state level, many states have formed coalitions to support HPV vaccination efforts. Is there general guidance for states that do not yet have coalitions?

(3) Integrated health care delivery networks can successfully integrate comprehensive quality improvement approaches to increase vaccination coverage rates. How can state immunization programs and coalitions engage with health systems to work together on improving HPV vaccination coverage?

(4) Please specify recommendations on how to meet the needs of providers in rural areas.

The NVAC established the Human Papillomavirus Vaccination Implementation Work Group in February 2018, a work group tasked to engage with a wide-range of implementation partners from across all sectors (*e.g.*, government, industry, health systems, associations, academia, and non-profit) to inform NVAC's work and these recommendations.

The NVAC draft report highlights the progress made toward increasing HPV vaccination coverage rates, since the 2015 NVAC report. The recommendations detail how the ASH can support HHS activities to strengthen the effectiveness of national, state, and local efforts to improve HPV coverage rates.

II. Request for Comment

NVPO, on behalf of the NVAC HPV Vaccination Implementation Work Group, requests input on the draft report

and draft recommendations. Please limit your comments to three (3) pages.

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests U.S. vaccine and immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

- General public;
- advocacy groups, non-profit organizations, and public interest organizations;
- academics, professional societies, and healthcare organizations;
- public health officials and immunization program managers;
- physician and non-physician providers that administer immunization services, including pharmacists; and
- representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed three (3) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

Dated: May 24, 2018.

Roula Sweis,

Deputy Director, National Vaccine Program Office.

[FR Doc. 2018-11745 Filed 5-30-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the next meeting of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee) regarding the development of national health promotion and disease prevention objectives for 2030.

This meeting will be held online via webinar and is open to the public. The Committee will discuss the nation's health promotion and disease prevention objectives and will provide recommendations to improve health status and reduce health risks for the nation by the year 2030. The Committee will further develop recommendations regarding setting targets for the Healthy People 2030 objectives and recommendations regarding the role of law and policy, systems science, health literacy, health promotion, health and well-being, summary measures, and health equity in Healthy People 2030. Pursuant to the Committee's charter, the Committee's advice must assist the Secretary in reducing the number of objectives while ensuring that the selection criteria identifies the most critical public health issues that are high-impact priorities supported by current national data.

DATES: The Committee will meet on July 10, 2018, from 1:00 p.m. to 4:00 p.m. Eastern Time (ET).

ADDRESSES: The meeting will be held online via webinar. To register to attend the meeting, please visit the Healthy People website at <http://www.healthypeople.gov>.

FOR FURTHER INFORMATION CONTACT:

Emmeline Ochiai, Designated Federal Official, Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Room LL-100, Rockville, MD 20852, (240) 453-8255 (telephone), (240) 453-8281 (fax). Additional information is available on the Healthy People website at <http://www.healthypeople.gov>.

SUPPLEMENTARY INFORMATION: The names and biographies of the Committee members are available at <https://www.healthypeople.gov/2020/about/history-development/healthy-people-2030-advisory-committee>.

Purpose of Meeting: Through the Healthy People initiative, HHS leverages scientific insights and lessons from the past decade, along with new knowledge of current data, trends, and innovations, to develop the next iteration of national health promotion and disease prevention objectives. Healthy People provides science-based, 10-year national objectives for promoting health and preventing disease. Since 1979, Healthy People has set and monitored national health objectives that meet a broad range of health needs, encourage collaboration across sectors, guide

individuals toward making informed health decisions, and measure the impact of our prevention and health promotion activities. Healthy People 2030 health objectives will reflect assessments of major risks to health and wellness, changing public health priorities, and emerging technologies related to our nation's health preparedness and prevention.

Public Participation at Meeting:

Members of the public are invited to join the online Committee meeting. There will be no opportunity for oral public comments during this online Committee meeting. However, written comments are welcome throughout the entire development process of the national health promotion and disease prevention objectives for 2030 and may be emailed to HP2030@hhs.gov.

To join the Committee meeting, individuals must pre-register at the Healthy People website at <http://www.healthypeople.gov>. Participation in the meeting is limited. Registrations will be accepted until maximum webinar capacity is reached, and must be completed by 9:00 a.m. ET on July 10, 2018. A waiting list will be maintained should registrations exceed capacity, and those individuals will be contacted as additional space for the meeting becomes available. Registration questions may be directed to HealthyPeople@norc.org.

Authority: 42 U.S.C. 300u and 42 U.S.C. 217a. The Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C., App.) which sets forth standards for the formation and use of federal advisory committees.

Dated: May 24, 2018.

Don Wright,

Deputy Assistant Secretary for Health, (Disease Prevention and Health Promotion).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections