



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### **Request for Information (RFI): Vaccines National Strategic Plan available for public comment**

**AGENCY:** Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) announces the draft Vaccines National Strategic Plan 2021-2025 (Vaccine Plan) available for public comment. The draft Vaccine Plan may be reviewed at [www.hhs.gov/oidp](http://www.hhs.gov/oidp).

**DATES:** All comments must be received by 5:00 p.m. ET on [INSERT DATE TEN CALENDAR DAYS FROM PUBLICATION] to be considered.

**ADDRESSES:** All comments must be submitted electronically to [NVP.RFI@hhs.gov](mailto:NVP.RFI@hhs.gov) to be considered.

**FOR FURTHER INFORMATION CONTACT:** David Kim, OIDP, [David.Kim@hhs.gov](mailto:David.Kim@hhs.gov), 202-795-7636.

### **SUPPLEMENTARY INFORMATION:**

The development of a National Vaccine Plan was mandated by Congress as a mechanism for the Director of the National Vaccine Program (as delegated by the Assistant Secretary for Health) to communicate priorities for achieving the Program's responsibilities of ensuring adequate supply of and access to vaccines and ensuring the effective and optimal use of vaccines. The most recent Plan, released in 2010, provided a comprehensive 10-year national strategy for enhancing all aspects of the plan, including vaccine research and development, supply, financing, distribution, and safety; informed decision-making by consumers and health care providers;

vaccine-preventable disease surveillance; vaccine effectiveness and use monitoring; and global cooperation ([http://www.hhs.gov/nvpo/vacc\\_plan/index.html](http://www.hhs.gov/nvpo/vacc_plan/index.html)). The 2010 Plan and the associated implementation plan ([https://www.hhs.gov/sites/default/files/nvpo/vacc\\_plan/2010-2015-Plan/implementationplan.pdf](https://www.hhs.gov/sites/default/files/nvpo/vacc_plan/2010-2015-Plan/implementationplan.pdf)) have played an important role in guiding strategies and allocations of resources with respect to vaccines and vaccination. However, since the publication of the 2010 Plan, there have been many changes in the vaccine landscape.

With U.S. vaccination rates above 90% for many childhood vaccines, most individuals have not witnessed firsthand the devastating illnesses against which vaccines offer protection, such as polio or diphtheria. According to a recent study, routine childhood immunizations among U.S. children born in 2009 will prevent 20 million cases of disease and 42,000 premature deaths, with a net savings of \$13.5 billion in direct costs and \$68.8 billion in total societal costs.<sup>1</sup> In contrast, adult vaccination coverage rates have remained persistently low, with only modest gains for certain populations in the past few years.<sup>2</sup> As a result, the standards for adult immunization practice were updated in 2014 to promote integration of vaccines into routine clinical care for adults.<sup>3</sup>

Despite the widespread availability of effective vaccines, vaccine-preventable diseases (VPDs) remain a significant public health challenge. In particular, rates of non-medical exemptions for childhood vaccines are increasing,<sup>4</sup> and there have been recent measles outbreaks in the U.S.<sup>5</sup> and globally, due to growing vaccine hesitancy and coverage levels below the threshold needed for herd immunity. With an estimated cost of \$20,000 per case of measles to the public sector in 2016,<sup>6</sup> the economic consequences of this and other VPDs, as well as the health consequences, are significant. Furthermore, few adults in any age group are fully vaccinated as recommended by the Advisory Committee on Immunization Practices.<sup>2</sup> Large disparities in vaccine coverage by race/ethnicity persist, with African Americans, Hispanics, and Asian Americans lagging behind whites in nearly all vaccination coverage rates.<sup>7</sup> VPDs such as pertussis and hepatitis B continue to take a heavy toll on public health,<sup>8</sup> with 18,975 cases of

pertussis and 3,409 (22,000 estimated) cases of hepatitis B infections reported in the United States in 2017.<sup>9,10</sup> In light of these challenges, strengthening the vaccine and immunization enterprise is a priority for HHS.

To respond to the public health challenges of VPDs, ODP in collaboration with other federal partners is leading the development of the Vaccines National Strategic Plan (Vaccine Plan). This updated plan will recommend vaccine strategies across the lifespan and guide priority actions for the period 2021–2025. While COVID-19 and coronavirus vaccine development are currently changing the landscape of the vaccine enterprise, the Vaccine Plan has a broad focus on the entire vaccine enterprise and is not focused specifically on any one vaccine or the pandemic response. HHS, through ODP, seeks input regarding the draft of the Vaccine Plan from subject matter experts and nonfederal partners and stakeholders such as health care providers, national professional organizations, health departments, school administrators, community-based and faith-based organizations, manufacturers, researchers, advocates, and persons affected by VPDs.

The following are the Vaccine Plan’s vision and goals. Vision: United States will be a place where vaccine-preventable diseases are eliminated through safe and effective vaccination over the lifespan. Goals:

1. Foster innovation in vaccine development and related technologies.
2. Maintain the highest possible levels of vaccine safety.
3. Increase knowledge of and confidence in routinely recommended.
4. Increase access to and use of all routinely recommended vaccines.
5. Protect the health of the American public by supporting global immunization efforts.

**Information Needs:**

The draft Vaccine Plan may be reviewed at [www.hhs.gov/oidp](http://www.hhs.gov/oidp).

ODP seeks to obtain feedback from external stakeholders on the following:

1. Do the draft Vaccine Plan’s goals, objectives, and strategies appropriately address the vaccine landscape?

2. Are there any critical gaps in the Vaccine Plan's goals, objectives, and strategies? If so, please specify the gaps.
3. Do any of the Vaccine Plan's goals, objectives and strategies cause concern? If so, please specify the goal, objective or strategy, and describe the concern regarding it.

Please be succinct and limit your comments to a maximum of seven pages.

Authority: 42 U.S.C. Section 300aa-3.

Dated: November 17, 2020.

B. Kaye Hayes,

Acting Director, Office of Infectious Disease and HIV/AIDS Policy.

#### **ENDNOTES:**

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<sup>1</sup> Zhou F et al. Economic evaluation of the routine childhood immunization program in the United States, 2009. *Pediatrics*. 2014; 133: 1–9

<sup>2</sup> <https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html>

<sup>3</sup> National Vaccine Advisory Committee. Recommendations from the National Vaccine Advisory Committee: standards for adult immunization practice. *Public Health Rep*. 2014;129:115–23.

<sup>4</sup> Omer, S. et al. Nonmedical exemptions to school immunization requirements: secular trends and association of state policies with pertussis incidence. *JAMA*. 2006;296(14):1757–1763.

<sup>5</sup> <https://www.cdc.gov/measles/cases-outbreaks.html>

<sup>6</sup> Lo NC, Hotez PJ. Public Health and Economic Consequences of Vaccine Hesitancy for Measles in the United States. *JAMA Pediatr*. 2017;171(9):887–892. doi:10.1001/jamapediatrics.2017.1695

<sup>7</sup> Lu PJ et al. Racial and Ethnic Disparities in Vaccination Coverage Among Adult Populations in the U.S. *Am J Prev Med*. 2015;49(6 Suppl 4):S412–S425. doi:10.1016/j.amepre.2015.03.005.

<sup>8</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf>

<sup>9</sup> <https://www.chop.edu/centers-programs/vaccine-education-center/global-immunization/diseases-and-vaccines-world-view>

<sup>10</sup> Schillie et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR*. 2018;67(1):1–31