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The 2026 Childhood Immunization Schedule

SUMMARY

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Since 1995, the Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), has published an annual immunization schedule for children and adolescents (18 years of age and younger). Prior to 2026, the Advisory Committee on Immunization Practices (ACIP)—a committee of experts who advise on U.S. vaccine policy—led the annual process of updating the schedule in consultation with federal health officials and nonfederal health groups, such as medical associations.

In January 2026, the CDC Acting Director, forgoing the usual ACIP process, approved a new childhood immunization schedule developed solely by federal officials that included several changes to prior childhood vaccine recommendations. The schedule was supported by an assessment, developed by Food and Drug Administration (FDA) and other HHS officials, that outlined the rationale for the schedule's recommended changes. The assessment centered on three primary concerns: (1) how the U.S. vaccination schedule compares with those of other countries, (2) public trust in vaccines, and (3) vaccine safety. This assessment was prompted by a December 2025 presidential memorandum that directed HHS and CDC to review childhood vaccine recommendations. As of March 16, 2026, this schedule is currently stayed (i.e., suspended) by a U.S. district court; the federal government appealed the ruling on April 29, 2026. On May 29, 2026, Executive Order 14407 (E.O. 14407) stated that the assessment, and its proposed 2026 updates to the childhood immunization schedule, are a "guiding resource" for the federal government. E.O. 14407 directs CDC and ACIP to review the assessment and the latest clinical data and, to the extent permitted by law, take steps to update the child and adolescent immunization schedules.

The new schedule does not remove any vaccines from the previous childhood immunization schedule. The new schedule differs from the January 2025 schedule by

- incorporating prior 2025 ACIP-recommended changes to the COVID-19 and Hepatitis B vaccine recommendations;
- changing the recommendation type for three vaccines—Hepatitis A, Meningitis ACWY, and RSV—from a full recommendation for all children to risk-based and shared clinical decisionmaking recommendations, depending on a child's risk from the disease that the vaccine protects against;
- changing the recommendation type for two vaccines—rotavirus and influenza—from a full recommendation for all children to a shared clinical decisionmaking recommendation; and
- changing the number of recommended doses of the human papillomavirus (HPV) vaccine.

The process, timeline, and methods used to develop the revised schedule also deviated from those used in prior updates.

Many federal and state laws reference ACIP or CDC immunization recommendations, such as federal vaccine coverage requirements and certain state requirements on vaccine administration. CDC immunization recommendations also provide important guidance to clinicians in their practice. Following the January 2026 announcement, nonfederal professional medical society organizations have opposed the revised schedule and since published separate childhood vaccine schedules, which some states have adopted in their vaccine policy. These responses indicate the clinical and policy significance of the CDC immunization schedule and changes to the schedule, particularly if the 2026 revised schedule is allowed to go into effect. The specific potential federal policy implications of the 2026 schedule change are unclear at this time should the schedule go into effect.

This CRS report begins with a summary of the changes to the recommended childhood vaccine schedule. It also summarizes the rationale for the changes, as outlined in the HHS assessment, and provides a brief discussion of the justifications presented in the assessment. This report also describes how the process used to revise the 2026 childhood immunization schedule deviated from prior procedures. The report concludes by outlining potential clinical and federal policy implications of the 2026 childhood immunization schedule.

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Since 1995, the Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), has published an annually updated recommended immunization schedule for children and adolescents (18 years of age and younger).[1] The schedule provides a consolidated guide for clinicians and patients regarding who should receive which vaccine, at what age, and at what dosing schedule. The schedule was also historically designed in a way to effectively prevent and control vaccine-preventable diseases in the United States.[2]

CDC's publication of the schedule is not specifically directed by any statute. Rather, the practice developed over time to follow a process that, until recently, was led by the Advisory Committee on Immunization Practices (ACIP).[3] Prior to 2026, ACIP—a committee of experts who advise on U.S. vaccine policy—led the annual process of updating the schedule in consultation with federal health officials and nonfederal health groups, such as medical associations. ACIP voted annually, typically in the fall, to update the following year's immunization schedule. The CDC Director then determined whether to adopt the ACIP-recommended schedule.[4]

In January 2026, the CDC Acting Director, forgoing the usual ACIP process, approved a new 2026 childhood immunization schedule. This new schedule relied on an assessment developed by Food and Drug Administration (FDA) and other HHS officials and, compared to the childhood immunization schedule as of January 2025, included six changes to vaccine recommendations developed by federal health officials and two ACIP-recommended changes from June and September 2025 meetings. This 2026 schedule followed a December 2025 presidential memorandum that directed HHS and CDC to review the childhood vaccination recommendations.[5]

Prior to the schedule change, the HHS Secretary had terminated the appointments of all of the then-sitting ACIP members in June 2025, and the reconstituted ACIP subsequently changed several preexisting vaccine recommendations. For a summary of CDC vaccine recommendation changes in 2025 and 2026, see CRS Insight IN12684, *Changes to CDC Vaccine Recommendations in 2025 and 2026*.

[1] L. Reed Walton, Walter A. Orenstein, and Larry K. Pickering, "The History of the United States Advisory Committee on Immunization Practices (ACIP)," *Vaccine,* vol. 33 (2015), pp. 405-14.

The federal government's role in vaccine policy can be traced back to the early 1800s (2 Stat. 806). The federal government issued periodic vaccine recommendations prior to the establishment of the Advisory Committee on Immunization Practices in 1964. As discussed elsewhere in this report, ACIP began harmonizing its recommended childhood vaccine schedule with the American Academy of Pediatrics and other nonfederal health organizations in 1995. See the "Annual Updates of the Immunization Schedules" section of this report.

[2] See the "What Is an Immunization Schedule?" **text box** below.

[3] ACIP is authorized by Public Health Service Act (PHSA) Section 222 (42 U.S.C. §217a), a general authority that allows the HHS Secretary to appoint advisory committees. CDC also has general authority to publish research-based health information, for example, in PHSA Section 301(a) (42 U.S.C. § 241(a)) and to assist and advise states in public health matters in PHSA Section 311(a) (42 U.S.C. § 243(a)). For more information about ACIP, see CRS In Focus IF12317, *The Advisory Committee on Immunization Practices (ACIP)*.

[4] See the "Process Differences from Prior Schedule Updates" section of this report for more information on the updating process.

[5] Letter from Donald J. Trump, President of the United States, to Secretary of Health and Human Services; Director of the Centers for Disease Control and Prevention (CDC), December 5, 2025, https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/.

Ongoing litigation has sought to challenge multiple recent HHS vaccine policy actions, including the 2026 childhood immunization schedule revision.[6] On March 16, 2026, the U.S. District Court for the District of Massachusetts issued a stay that stops the CDC from implementing the 2026 childhood immunization schedule and reverts the schedule back to the version as of May 2025.[7] The court also stayed the appointments of 13 ACIP members appointed by HHS Secretary Robert F. Kennedy Jr. and their votes at prior ACIP meetings in 2025.[8] On April 29, 2026, the federal government appealed the ruling to the U.S. Court of Appeals for the First Circuit.[9] Although the specifics of these lawsuits are beyond the scope of this report, it remains to be seen how final legal decisions might affect the recommended childhood vaccine schedule moving forward.

In the meantime, on May 29, 2026, President Trump issued Executive Order 14407 (E.O. 14407) stating that the assessment that formed the basis of the 2026 childhood immunization schedule, and the assessment's proposed 2026 updates to the childhood immunization schedule, are "acknowledged as a guiding resource" for the federal government.[10] E.O. 14407 directs CDC and ACIP to review the assessment, alongside recent clinical data, and update the childhood and adolescent schedules to the extent permissible by law. Presently, because of the district court's stay order, it is unclear whether there are sufficient active members on ACIP to carry out E.O. 14407 14407 directive, but HHS filed a notice to reestablish ACIP on May 19, 2026, and the HHS Secretary may make further changes in ACIP's membership composition in the future to implement E.O. 14407.[11]

The ongoing legal challenges and other responses to the 2026 childhood immunization schedule highlight the clinical and policy significance of the CDC immunization schedule. Even though the publication of the immunization schedules is not itself governed by specific statute, many federal and state laws and regulations reference either ACIP vaccine recommendations or the CDC immunization schedule—for example, in the context of federal vaccine coverage requirements on most private health insurance plans, certain federal immunity protections for vaccine manufacturers, and certain state rules governing which providers (such as pharmacists) can administer certain vaccines.[12] In addition, the CDC immunization schedule may also affect providers' clinical practice and patients' understanding of the recommended vaccines. Changes to the CDC immunization schedule may therefore have significant policy implications.

This CRS report provides an overview of the changes in the 2026 childhood immunization schedule, discusses the primary rationale for the changes as provided by HHS, and offers a discussion of the claims made by HHS. The report concludes by outlining potential policy implications of the 2026 schedule change, though specific outcomes are unclear and remain subject to ongoing litigation.

[6] See Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass., filed July 7, 2025); Arizona v. Kennedy, No. 3:26-cv-1609 (N.D. Cal., filed Feb. 24, 2026).

[7] Am. Acad. of Pediatrics v. Kennedy,—F. Supp. 3d—, 2026 WL 733828, at *22 (D. Mass. Mar. 16, 2026).

[8] See Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass., filed July 7, 2025); Arizona v. Kennedy, No. 3:26-cv-1609 (N.D. Cal., filed Feb. 24, 2026).

[9] Notice of Appeal, Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass., filed Apr. 29, 2026), ECF No. 306.

[10] Executive Order 14407, "Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries," 91 *Federal Register* 106, May 29, 2026.

[11] CDC, "Advisory Committee on Immunization Practices (ACIP); Notice of Charter Re-Establishment," 91 *Federal Register* 29139, May 19, 2026.

[12] See the "Potential Implications of the Revised Schedule" section of this report for examples.

What Is an Immunization Schedule?

CDC, with consultation from ACIP, has maintained two main immunization schedules: one for children and adolescents (18 years of age and younger) and one for adults (19 years of age and older). Both schedules list all recommended vaccines for patients in the age groups. For each recommended vaccine, the schedule also includes information about the recommended age at which to administer each dose of the vaccine and under what circumstances—for example, to all people of that age (without medical contraindications) or to certain subgroups who are at high risk of the disease that the vaccine protects against. The immunization schedules essentially provide a visual representation of the detailed individual vaccine recommendations that are typically informed by ACIP and then published by CDC in the Morbidity and Mortality Weekly Report (MMWR).

CDC's immunization schedule has included three main categories of recommendations:

- **Universal.** The vaccine is recommended for all people in a certain age-based group (and for certain vaccines, also a sex-based group), except for those with medical contraindications. This is also considered a "full recommendation."
- **Risk-based.** The vaccine is recommended for certain groups at high risk of the disease that the vaccine protects against. In some cases, this is also considered a "full recommendation."
- **Shared clinical decisionmaking.** The decision to vaccinate should be individually based and informed by a decision process between a health care provider and the patient or the parent or guardian.

CDC's immunization schedules have also typically included detailed clinical notes about special situations, precautions and contraindications, and catch-up vaccination (i.e., for people who missed vaccine doses at the recommended ages). CDC has also published separate immunization schedules for certain patient populations. Typically, a separate schedule summarizes vaccine recommendations for people with certain health conditions or medical contraindications (e.g., immunocompromised individuals; people with diabetes). The schedules have typically excluded travel vaccines and vaccines used only in certain occupational and emergency situations (e.g., Ebola vaccines).

For more information, see CDC, "Healthcare Professionals: Immunization Schedules," https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html#cdc_listing_add_info-vaccination-resources.

The 2026 Childhood Immunization Schedule

In a December 2025 memorandum, President Donald J. Trump directed the HHS Secretary and CDC Director to review vaccination practices of peer, developed countries and in turn update childhood vaccine recommendations should the Secretary and Director determine that peer practices are "superior to the current domestic recommendations."[13] Presidential involvement in the updates to the immunization schedules is unusual; CRS did not identify any past instances of a President directing changes to the childhood immunization schedule.[14]

In response to the presidential memorandum, on January 5, 2026, the Acting CDC Director approved a decision memorandum sent by the Director of the National Institutes of Health (NIH), the Administrator of the Centers for Medicare & Medicaid Services (CMS), and the Commissioner of the U.S. Food and Drug Administration (FDA) that outlined a revised childhood and adolescent immunization schedule.[15] This new schedule was developed and recommended

[13] Letter from Donald J. Trump, President of the United States, to Secretary of Health and Human Services; Director of the Centers for Disease Control and Prevention, December 5, 2025, https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/.

[14] Based on CRS searches of presidential documents databases.

[15] HHS, "Fact Sheet: CDC Childhood Immunization Recommendations," press release, January 5, 2026, https://web.archive.org/web/20260105195437/https://www.hhs.gov/press-room/fact-sheet-cdc-childhood-immunization-recommendations.html, and Jay Bhattacharya, Mehmet Oz, and Marty Makary, *Decision Requested - Adopting Revised Childhood and Adolescent Immunization*, HHS CDC, January 5, 2026, https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf.

based on an "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries" compiled by Dr. Tracy Beth Høeg, Acting Director for FDA's Center for Drug Evaluation and Research, and Dr. Martin Kulldorff, Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation (ASPE), with consultation from other federal health officials.[16]

As summarized in **Figure 1**, the new schedule differs from the 2025 childhood immunization schedule (in effect as of January 2025) by doing the following:

- Incorporating changes to the Coronavirus Disease 2019 (COVID-19) and Hepatitis B vaccines, as recommended by ACIP in September and December 2025, respectively.[17]
- Changing the type of recommendation for three vaccines—Hepatitis A, Meningitis ACWY, and RSV[18]—from a full recommendation for all children (without medical contradictions) to a targeted risk-based recommendation for children at high-risk of the disease.[19] For all children who are not at high-risk, the new schedule recommends that vaccination should be based on shared clinical decisionmaking (SCDM), where patients and providers discuss the benefits and risks of vaccination to determine whether to vaccinate.
    - The change in recommendation type for the RSV vaccine did not change the substance of the recommendation. The vaccine remains recommended for the same groups as before.[20]
- Changing the recommendations for two vaccines—rotavirus and influenza—from a full recommendation for all children to a SCDM recommendation.
- Changing the dosing for one vaccine, the human papillomavirus (HPV) vaccine, from a two- or three-dose regimen to a one-dose regimen.

[16] Tracy Beth Høeg and Martin Kulldorff, *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries*, HHS, January 2, 2026, https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf (hereinafter Høeg and Kulldorff, *Assessment*).

[17] For ACIP's recommended COVID-19 changes, see U.S. Department of Health and Human Services, "ACIP Recommends COVID-19 Immunization Based on Individual Decision-making," press release, September 19, 2025, https://www.hhs.gov/press-room/acip-recommends-covid19-vaccination-individual-decision-making.html. For ACIP's recommended Hepatitis B changes, see Centers for Disease Control and Prevention, "ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus," press release, December 5, 2025, https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html. Both recommendations were developed by ACIP after the HHS Secretary changed ACIP's members in June 2025.

[18] CDC previously categorized the recommendation to receive RSV immunization as a recommendation for "All Children" and specified that this recommendation is for infants (<8 months) unprotected by maternal vaccination. The CDC also recommended a second dose for "certain high-risk groups or populations." The 2026 change maintains both recommendations but recategorizes the first recommendation of "All Children" as a recommendation for "Certain High-Risk Groups or Populations." See CDC, *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years and Younger*, 2025, https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

[19] For Hepatitis A, vaccination is recommended for international travelers to areas with high or intermediate Hepatitis A endemicity. For Meningitis ACWY, vaccination is recommended for high-risk groups with certain medical conditions (e.g., anatomic or functional asplenia, or HIV infections) and during outbreaks. For RSV, see the previous footnote. See Høeg and Kulldorff, *Assessment*, p. 2.

[20] See footnote 18.

Nine recommendations remained unchanged from the prior schedule. No vaccines were removed from the childhood immunization schedule. The assessment did not consider the timing or order of vaccines, and discussed the number of doses only in relation to the HPV vaccine (see fourth bullet point above).[21] The new schedule also did not address use of certain combination vaccines (e.g., the measles, mumps, rubella, and varicella [MMRV] vaccine). The changes are summarized in **Figure 1**.

In May 2026, E.O. 14407 stated that the assessment and its proposed 2026 updates to the childhood immunization schedule are a "guiding resource" for the federal government.[22] E.O. 14407 directs CDC and ACIP to review the assessment, alongside recent clinical data, and take necessary steps to update the childhood and adolescent schedules to the extent permissible by law. E.O. 14407 further directs each executive department and agency to align immunization regulations, funding, and coverage with the ACIP-recommended schedule, among other actions.

[21] Høeg and Kulldorff, *Assessment*, p. 4.

[22] Executive Order 14407, "Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries," 91 *Federal Register* 106, May 29, 2026.

Figure 1. Comparison of 2025 and 2026 Childhood Immunization Recommendations

DISEASE / VACCINES	PREV. CDC/ACIP RECOMMENDATION	2026 CDC RECOMMENDATION
COVID-19*	All children	Shared Clinical Decision Making (SCDM)
Dengue	Certain High-Risk Groups or Populations	*Unchanged*
Diphtheria, tetanus, acellular pertussis (DTaP; Tdap)	All children	*Unchanged*
Haemophilus influenzae type b (Hib)	All children	*Unchanged*
Hepatitis A (HepA)	All children; Certain High-Risk Groups or Populations	Certain High-Risk Groups or Populations; SCDM for others
Hepatitis B (HepB)*	All children	Certain High-Risk Groups or Populations; SCDM for others
Human papillomavirus (HPV)	All children *Recommended 2 or 3 doses*	All children *Recommended doses reduced to 1*
Inactivated poliovirus (IPV)	All children	*Unchanged*
Influenza	All children	SCDM
Measles, mumps, rubella (MMR)	All children	*Unchanged*
Meningococcal B (MenB)	Certain High-Risk Groups or Populations; SCDM for others	*Unchanged*
Meningococcal ACWY (MenACWY)	All children; Certain High-Risk Groups or Populations	Certain High-Risk Groups or Populations; SCDM for others
Mpox	Certain High-Risk Groups or Populations	*Unchanged / Not addressed*
Pneumococcal (PCV)	All children	*Unchanged*
Respiratory syncytial virus (RSV-mAb)**	All children; Certain High-Risk Groups or Populations	Certain High-Risk Groups or Populations
Rotavirus (RV)	All children	SCDM
Varicella (VAR)	All children	*Unchanged*

Source: Figure developed by CRS. The "Prev. CDC/ACIP Recommendation" column reflects recommendations in effect as of January 2025 and presents information in CDC, *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years and Younger*, 2025, https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf. The 2025 COVID-19 vaccine recommendation is based on the recommendation for that vaccine as of the publication date of Anindita N. Issa, A. Patricia Wodi, Charlotte A.

Moser, et al., "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2025," *Mortality and Morbidity Weekly Report*, vol. 74, no. 2 (January 16, 2025), pp. 26-29. The "2026 CDC Recommendation" column presents information in U.S. Department of Health and Human Services, *Childhood Immunization Schedule by Recommended Group*, 2026, https://web.archive.org/web/20260105223912/https://www.hhs.gov/childhood-immunization-schedule/index.html.

Notes: Figure does not fully reflect all recommendations for special situations and populations with certain medical conditions. Based on source materials, figure does not reference combination vaccines, including the measles, mumps, rubella, and varicella (MMRV) combination vaccine.

*Changed by ACIP in 2025 and reaffirmed in the January 2026 recommendations; see bullet points above for more information.

**CDC previously categorized the recommendation to receive one dose of RSV immunization as a recommendation for "All Children" and specified that this recommendation is for infants (<8 months) unprotected by maternal vaccination. The CDC also recommended a second dose for "certain high-risk groups or populations." The 2026 change maintains both recommendations but recategorizes the first recommendation of "All Children" as a recommendation for "Certain High-Risk Groups or Populations."

HHS's Justification for Immunization Schedule Changes

The "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries" formed the primary basis of the decision memorandum approved by the CDC Director, and was published alongside the decision memorandum. The assessment stated that the main goals of the recommended schedule changes include "restor[ing] public confidence, provid[ing] much-needed clarity for parents of young children, and preserv[ing] the benefits of immunization programs."[23] In particular, the assessment centered around three primary concerns:

- comparison of the U.S. vaccination schedule with those of other countries,
- public trust in vaccines, and
- vaccine safety.

Comparison of the U.S. Vaccination Schedule with Those of Other Countries

Both the presidential directive and the assessment indicated that the United States has recommended more vaccine doses during childhood than other "peer, developed nations" (also referred to as "peer nations"). However, it is not clear how the directive or the assessment defined and identified "peer, developed nations" or "peer nations."[24] The assessment drew a distinction between "consensus" vaccines that 20 peer, developed nations also recommend and "non-consensus" vaccines that not all peer nations recommend.

The consensus vaccines include vaccines that protect against 10 diseases: measles, mumps, rubella, polio, pertussis, tetanus, diphtheria, Haemophilus influenzae type B (Hib), pneumococcal disease, and human papillomavirus (HPV). As described in the decision memorandum and assessment, the 2026 CDC childhood recommendations for these vaccines mostly remain as they were just prior to the January 2026 decision (see **Figure 1**), except for the number of HPV vaccine doses recommended.[25]

[23] Høeg and Kulldorff, *Assessment*, pp. 4-5.

[24] Peer nations included Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. See Høeg and Kulldorff, *Assessment*, pp. 14-15.

[25] Høeg and Kulldorff, *Assessment*, pp. 17, and HHS Decision Memorandum, PDF p. 4.

The 2026 schedule shifted all of the "non-consensus" vaccines to be either (1) recommended for only high-risk children with a shared clinical decisionmaking for all other children or (2) recategorized into "shared clinical decision-making" recommendations.[26] Some of these vaccines were already recommended only for high-risk children before 2026. For example, ACIP already recommended the dengue vaccine only for children with evidence of a prior dengue infection and who live in areas where dengue is endemic.[27] See the prior section and **Figure 1** for a summary of the vaccines with changed or unchanged recommendations.

Public Trust in Vaccines

The assessment pointed to a research study that showed declines in public trust in health care and linked this study to separate data displaying a decline in vaccination rates.[28] According to the assessment, shifting vaccine recommendations to risk-based and SCDM recommendations may improve public trust by increasing informed consent in vaccine decisionmaking.[29] The assessment also noted that states' vaccination requirements for school and day care attendance may decrease trust and long-term vaccination rates.[30] The assessment also stated that other countries, particularly Denmark, consider the impact on public trust when deciding to add vaccines to their schedule.[31]

Vaccine Safety

The assessment stated that before and after vaccine licensure (i.e., FDA approval), "manufacturers have inadequate incentives to study vaccine adverse effects."[32] The assessment stated that regulatory agencies have sometimes been slow to identify adverse effects in post-marketing studies and that "vaccine safety and risks are therefore often poorly characterized, quantified, or understood."[33] The assessment asserted that the United States ought to fund more "gold standard science" to assess health outcomes from vaccination, particularly more double-blind, placebo-controlled clinical trials on vaccines.[34] The assessment characterized the United States' postmarket surveillance systems for monitoring vaccine safety as "limited" and "underutilized."[35] The assessment also noted knowledge gaps in the safety of the entire U.S. vaccine schedule, pointing to a 2013 Institute of Medicine (IOM) report that recommended further HHS studies on the safety of the childhood immunization schedule, and a lack of related

[26] HHS Decision Memorandum, PDF pp. 5 and 6.

[27] Høeg and Kulldorff, *Assessment*, p. 10.

[28] Høeg and Kulldorff, *Assessment* p. 3.

[29] Høeg and Kulldorff, *Assessment* p. 3-4.

[30] Høeg and Kulldorff, *Assessment*, p. 4.

[31] Høeg and Kulldorff, *Assessment*, pp. 9-10.

[32] Gabriela Paz-Bailey, Laura Adams, Laura Adams, et al., "Dengue Vaccine: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021," *Morbidity and Mortality Weekly Report*, vol. 70, no. 6 (December 17, 2021), pp. 1-16.

[33] Høeg and Kulldorff, *Assessment*, p. 4.

[34] Høeg and Kulldorff, *Assessment* pp. 11-12.

[35] Høeg and Kulldorff, *Assessment*, p. 12.

research in the years following the 2013 report.[36] The assessment also encouraged more large, population-based studies on the safety of vaccines and potential linkages to chronic diseases.[37]

Discussion of HHS's Justifications

Comparison of the U.S. Vaccination Schedule with Those of Other Countries

An individual country's public health system may weigh a range of factors when determining and developing vaccine recommendations. These considerations for a specific vaccine recommendation commonly include sociodemographic characteristics and the size of a country's population, geographic factors, the prevalence and risk of contracting a vaccine-preventable disease, the morbidity or mortality associated with the vaccine-preventable disease, risks and benefits of the vaccine, and the nation's health care delivery system (e.g., vaccine supply and health care financing).[38] In the past, when making recommendations for the United States, ACIP considered data and evidence specific to the United States (see next section for more information on ACIP's prior recommendation process). The assessment for the new 2026 immunization schedule includes limited evidence and considerations specific to the United States with respect to the vaccines with changed recommendations. [39] In particular, in its analysis to inform the new recommendations, the assessment included almost no information about the specific health care context of the United States (e.g., health care access, financing) and limited information about the burden of vaccine-preventable diseases in the United States.

Other countries may emphasize different priorities than the United States when setting vaccination policy. For example, Denmark, Finland, Norway, and Sweden have made different rotavirus vaccination recommendations despite a similar pre-vaccine burden of the disease across those countries.[40] The rotavirus vaccine protects against rotavirus disease, a disease that can cause severe diarrhea and dehydration, which mostly affects children under five years of age.[41] According to the Danish Health Authority, the purpose of Denmark's childhood vaccination program is to protect children from diseases that can result in either death or long-term harm, using safe and effective vaccines. When developing its rotavirus vaccine recommendation, the Danish Health Authority found that while rotavirus led to over a thousand hospitalizations in the country annually, the children very rarely died from rotavirus when treated in their public health care system (rotavirus was estimated to cause about one death per five years in Denmark). Thus, the Danish Health Authority decided not to recommend rotavirus vaccines for its national immunization program. Conversely, Finland, Norway, and Sweden recommend universal

[36] Institute of Medicine, *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*, Washington, DC, 2013, https://www.ncbi.nlm.nih.gov/books/NBK206938/. Hereinafter, Institute of Medicine, *Childhood Immunization Schedule and Safety*.

[37] Høeg and Kulldorff, *Assessment*, pp. 12-13.

[38] Christoph A. Steffen, Louise Henaff, Antoine Durupt, et al., "Evidence-Informed Vaccination Decision-Making in Countries: Progress, Challenges, and Opportunities," *Vaccine*, vol. 39 (2021), pp. 2146-2152.

[39] Høeg and Kulldorff, *Assessment*, pp. 19-24.

[40] Gry St-Martin, Ann Lindstrand, Synne Sandbu, et al., "Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine into National Immunization Programs in Sweden, Norway, Finland, and Denmark," *Frontiers in Public Health*, vol. 6 (2018).

[41] CDC, "Clinical Overview of Rotavirus," April 2024, https://www.cdc.gov/rotavirus/hcp/clinical-overview/index.html.

rotavirus vaccination after taking into account different criteria, for example, based on the vaccine's effectiveness at reducing morbidity, primarily hospitalizations, from rotavirus.[42]

Throughout the assessment for the 2026 childhood immunization schedule, the authors referred to Denmark's vaccine recommendations to compare to those of the United States.[43] The United States has historically considered different factors from Denmark when formulating U.S. vaccine recommendations, taking into account U.S. specific data and health priorities.[44] With Denmark's population approximately 6 million and the U.S. population approximately 343 million, data between the two nations are not directly comparable.

An illustrative example surrounds rotavirus vaccine. In the United States, prior to the introduction of two rotavirus vaccines in 2006, rotavirus resulted in approximately 410,000 physician visits, 205,000-272,000 emergency department visits, 55,000-70,000 hospitalizations, and 20-60 deaths per year among U.S. children under five years of age.[45] At the time that CDC issued its recommendation for rotavirus vaccination, an analysis determined that U.S. rotavirus vaccination would result in 55,000 fewer physician visits, 137,000 fewer ED visits, 44,000 fewer hospitalizations, and 13 fewer deaths among children in a single U.S. birth cohort followed to age five years.[46] Therefore, in 2006, ACIP recommended routine vaccination with the rotavirus vaccine for all infants, based on evidence indicating that the vaccine was the best available prevention against severe rotavirus disease, even after accounting for new treatments and improved hygiene in the United States.[47] Over 10 years later, one meta-analysis found that by 2017, U.S. rotavirus vaccination led to a median 80% reduction in rotavirus disease hospitalizations and a 57% reduction in emergency department visits since the vaccine became recommended in 2006.[48] The rotavirus vaccine example illustrates how countries may weigh different values and factors when developing immunization policy, resulting in different country-specific decisions.

Public Trust in Vaccines

The assessment suggests that shifting universal vaccine recommendations to "risk-based" and "shared clinical decision-making" recommendations may increase vaccine uptake by improving public trust and strengthening informed consent in vaccine decisionmaking. The assessment cites data illustrating a decline in trust in health care generally, but it does not cite any studies or provide any evidence to directly support the claim that changing vaccine recommendations would increase uptake.[49] In the past, ACIP has considered prior evidence and stakeholder input when deciding whether to change a vaccine recommendation from a universal recommendation to risk-

[42] Gry St-Martin, Ann Lindstrand, Synne Sandbu, et al., "Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine into National Immunization Programs in Sweden, Norway, Finland, and Denmark," *Frontiers in Public Health*, vol. 6 (2018).

[43] Høeg and Kulldorff, *Assessment*.

[44] For recent U.S. practices in formulating vaccine recommendations, see the "Individual ACIP Vaccine Recommendations" section of this report.

[45] Umesh D. Parashar, James P. Alexander, and Roger I. Glass, "Prevention of Rotavirus Gastroenteritis Among Infants and Children," *Morbidity and Mortality Weekly Report*, vol. 55, no. RR12 (August 11, 2006), pp. 1-13.

[46] Umesh D. Parashar, James P. Alexander, and Roger I. Glass, "Prevention of Rotavirus Gastroenteritis Among Infants and Children," *Morbidity and Mortality Weekly Report*, vol. 55, no. RR12 (August 11, 2006), pp. 1-13.

[47] Umesh D. Parashar, James P. Alexander, and Roger I. Glass, "Prevention of Rotavirus Gastroenteritis Among Infants and Children," *Morbidity and Mortality Weekly Report*, vol. 55, no. RR12 (August 11, 2006), pp. 1-13.

[48] Talia Pindyck, Jacqueline E. Tate, and Umesh D. Parashar, "A Decade of Experience with Rotavirus Vaccination in the United States – Vaccine Uptake, Effectiveness, and Impact," *Expert Review of Vaccines*, no. 7, pp. 593-606.

[49] Høeg and Kulldorff, *Assessment*, p. 3, pp. 5-10.

based recommendation or vice versa. For example, in April 2025, when ACIP began considering changing the COVID-19 vaccine recommendation for children from a universal recommendation for all children to a risk-based recommendation, ACIP looked at past evidence on the changes in vaccine uptake when other vaccine recommendations shifted from universal to high-risk only, or vice versa. ACIP also considered feedback from medical societies, including concerns on how a risk-based vaccination recommendation might affect clinical practice.[50] The 2026 assessment does not incorporate similar evaluations of U.S. vaccine uptake after changes to previous vaccine recommendations or input from outside stakeholders. It is unclear whether a shift to risk-based or SCDM recommendations for certain vaccines would increase the uptake of those vaccines or improve public trust, should the 2026 childhood immunization schedule go into effect. (See the "Patient Information and Understanding" section of this report for additional discussion on the SCDM recommendation category.

Vaccine Safety

The assessment makes claims about the quality of vaccine safety review, both in clinical trials that study vaccines for safety and in other nonclinical trial assessments of vaccine safety, such as in vaccine safety surveillance systems and observational studies with patients. Typically, vaccines are tested in clinical trials before they are licensed (i.e., approved) by FDA based on a determination that the vaccine has met FDA's standards for safety and effectiveness. Once a vaccine is on the market, researchers continue to investigate the vaccine's safety through a variety of clinical trial and nonclinical trial approaches (see the **text box** below for information on study approaches).[51] In the past, federal vaccine recommendations have considered safety information in the context of the benefits of vaccination, seeking to balance the demonstrated benefits of a specific vaccine with any known or uncertain harms.[52]

For clinical trials, the assessment asserts that currently available vaccines need more "gold standard placebo-controlled randomized trials" to study their safety.[53] Clinical trials are research studies conducted with people that systematically test a health intervention (see the **text box** below).[54] According to FDA guidance, a "placebo" is a "dummy" treatment that physically appears as identical as possible to the treatment drug but does not contain the treatment drug.[55] FDA has recognized placebos as one type of scientifically valid control for clinical trials, among many other controls.[56] FDA has also noted that a placebo-controlled trial does not mean that the

[50] Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC National Center for Immunization and Respiratory Diseases, April 15, 2025, https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.

[51] CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*.

[52] Grace Lee, Wendy Carr, Art Reingold, et al., "Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report*, vol. 67, no. 45 (November 16, 2018), pp. 1271-1272, and CDC, *ACIP Evidence to Recommendation User's Guide*, October 1, 2020, https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf.

[53] Høeg and Kulldorff, *Assessment*, p. 11.

[54] NIH National Library of Medicine ClinicalTrials.gov, "Learn About Studies," last updated June 10, 2024, https://clinicaltrials.gov/study-basics/learn-about-studies#ClinicalTrials.

[55] U.S. Food and Drug Administration, *Guidance for Industry: Choice of Control Group and Related Issues in Clinical Trials*, May 2001, p. 14, https://www.fda.gov/media/71349/download.

[56] U.S. Food and Drug Administration, *Guidance for Industry: Choice of Control Group and Related Issues in Clinical Trials*, May 2001, https://www.fda.gov/media/71349/download.

control group does not receive another treatment, such as the current standard of care for the disease or condition.[57]

An Overview of Clinical Research Study Design

Clinical research is a type of scientific research that focuses on human health and disease. This report discusses two main types of clinical research:

Clinical Trials

Clinical trials, a type of experimental research, are conducted with people to systematically test outcomes from a health intervention (such as a vaccine), usually by assigning some research participants to receive the intervention ("treatment group") and others to receive a control ("control group") to compare outcomes between the treatment group and the control group. Controls can include placebos, but also can include the current standard of treatment for the disease, or other methods.

In many cases, the participant is to be *randomly* assigned to the intervention (i.e., in a randomized controlled trial, or RCT). Envisioned randomization may not always be ethical or practical. Clinical trials also often incorporate "blinding." In some cases, only the research team knows which treatment a participant receives (single-blinded clinical trials); in other cases, both the participant and the research team do not know which intervention a participant receives (double-blinded clinical trials). Conversely, in some clinical trials, it may be impossible to disguise which treatment a participant receives due to the nature of the treatment (unblinded clinical trials). When a randomized controlled trial can be conducted in full accord with federal regulations for the protection of human subjects, it can proceed.

In clinical trials, the control group, randomization, and blinding all serve to mitigate any factors aside from the study intervention that might influence health outcomes among the research participants. Well-designed clinical trials are generally able to draw robust scientific conclusions about health outcomes linked to the study intervention, though exact determinations can sometimes be challenging due to the complexity of human health.

In vaccine research, clinical trials may be used to investigate the safety and efficacy of new vaccines for which no vaccine previously existed, evaluate whether new vaccines are better than existing vaccines, or test whether two vaccines are equivalent to one another, among other scientific questions. FDA requires data from clinical trials in order to license (i.e., approve) new vaccines based on safety and efficacy before they are introduced on the market.

Observational Studies

Observational studies can also evaluate outcomes from medical interventions; however, unlike experimental studies, participants in observational studies are *not assigned* to the intervention. Rather, in observational studies, participants have chosen or have received the intervention of interest, often as part of their routine health care, and researchers collect and analyze data on differences in outcomes between participants receiving the intervention and those without. Some observational studies compare health outcomes in different time periods, for example, whether a certain adverse health effect is more likely to occur in a defined time period following vaccination compared with other time periods.

Observational studies can use a range of designs to compare data across different groups of people at different points in time. Observational studies may collect data over a long period of time (i.e., longitudinal studies) or summarize short-term findings in case reports or case studies. Since the research participants have chosen or received the intervention, the studies are not randomized. The differences in outcomes between intervention and control groups in observational studies, therefore, may be explained by factors other than the study intervention, due to other possible differences between the two groups. Researchers use a variety of study design and statistical methods to overcome this challenge and to try to measure outcomes linked to the intervention.

In vaccine research, observational studies may be used to examine rare, longer-term or related effects in vaccinated compared with unvaccinated populations, among other types of scientific questions. These types of studies are usually conducted after a vaccine has been licensed by FDA and introduced on the market. For vaccine safety studies, researchers can use data from federal postmarket vaccine safety surveillance systems (i.e., data monitoring systems) intended to track potential adverse health effects after vaccination, as discussed in this report. A major challenge with observational vaccine safety studies is that vaccinated populations often have different health and demographic characteristics than unvaccinated populations, making it difficult to determine whether any differences in health outcomes between the two groups are definitively linked to vaccination.

[57] U.S. Food and Drug Administration, *Guidance for Industry: Choice of Control Group and Related Issues in Clinical Trials*, May 2001, p. 5, https://www.fda.gov/media/71349/download.

For more information, see National Library of Medicine, *ClinicalTrials.gov*, Learn About Studies, https://clinicaltrials.gov/study-basics/learn-about-studies; Frank DeStefano, Paul A. Offit, and Allison Fisher, "Vaccine Safety," in *Plotkin's Vaccines*, ed. Stanley A. Plotkin, Walter A. Orenstein, and Paul A. Offit, 7th ed. (Elsevier, 2017), pp. 1589.

All of the vaccines that have been on CDC's childhood immunization schedule have been evaluated for safety and efficacy in clinical trials, including in some placebo-controlled clinical trials.[58] According to one analysis of vaccines licensed by FDA between January 2010 and June 2020, each vaccine was supported by a median of seven clinical trials, including two pivotal efficacy trials. Pivotal efficacy trials, typically Phase III clinical trials, are the large-scale studies that provide final evidence of a drug's safety and efficacy for FDA approvals.[59] Of the pivotal efficacy trials, 95% involved a placebo or active control group (e.g., another vaccine).[60] Aspects specific to each vaccine and disease inform clinical trial design, including the risk of infection, potential for adverse events linked to the vaccine or the disease, and the availability of existing vaccines against the disease. In many cases, it is considered unethical to use only a placebo control group in a clinical trial when there is an effective treatment available.[61] Many new vaccines are updates of previously available vaccines and are therefore often tested using the preexisting vaccines as a control in clinical trials.[62] FDA has already determined that the controlled clinical trials used for licensure of these approved vaccines have met its standards for safety.[63]

In many cases, the assessment uses the lack of placebo-controlled randomized trial data as part of the rationale for no longer recommending a vaccine for all children, despite the fact that such study design may not be methodologically appropriate or ethically sound, in the judgment of the attendant Institutional Review Board, to implement for some types of scientific questions.

The assessment also discusses limitations with nonclinical trial assessments of vaccine safety, including those that involve data from vaccine safety surveillance systems (i.e., data monitoring systems for vaccine safety) and other observational studies (see the **text box** above for explanation). Observational studies have been used to assess vaccine safety after vaccines are licensed and introduced to the market. In recent years, the federal government has commissioned independent reviews of all the available evidence on the safety of recommended vaccines, including from clinical trials, observational studies, and other relevant evidence. These reviews, first published in 2011 and updated in 2024 and 2021, have found evidence of some very rare

[58] See information on clinical trials that supported each vaccine in the package inserts for each vaccine linked from FDA, "Vaccines Licensed for Use in the United States," https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

[59] Craig A. Umscheid, David J. Margolis, Craig E. Grossman, et al., "Key Concepts of Clinical Trials: A Narrative Review," *Postgraduate Medicine*, vol. 123 (September 2011). See also CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*.

[60] Jeremy Puthumana, Alexander C. Egilman, Audrey D. Zhang et al., "Speed, Evidence, and Safety Characteristics of Vaccine Approvals by the U.S. Food and Drug Administration," *Journal of the American Medical Association- Internal Medicine*, November 10, 2020.

[61] U.S. Food and Drug Administration, *Guidance for Industry: Choice of Control Group and Related Issues in Clinical Trials*, p. 15, May 2001, https://www.fda.gov/media/71349/download.

[62] Annette Rid, Abha Saxena, Abdhullah H. Baqui, et al., "Placebo Use in Vaccine Trials: Recommendations of a WHO Expert Panel," *Vaccine*, vol. 32, no. 37 (August 2014), p. 4708-4712.

[63] FDA, "Vaccines Licensed for Use in the United States," https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

safety issues linked with certain vaccines.[64] For example, the 2014 review concluded, "There is evidence that some vaccines are associated with serious adverse events; however, these events are extremely rare and must be weighed against the protective benefits that vaccines provide."[65] The reviews have also noted that there are cases where there is insufficient evidence to determine whether certain rare adverse health events are linked to vaccines.[66] Studying rare health effects of vaccines can be methodologically difficult, as studies may need to have very large study populations to accurately estimate how often a rare adverse health event occurs after vaccination, and it can be difficult to conclusively rule out other possible causes of the rare adverse health event.[67] Some vaccine scientists have called for further research to address evidence gaps on rare safety issues linked to vaccines and their underlying biological mechanisms as a means to improve trust in the safety of vaccines.[68]

In particular, the assessment posits a lack of studies on chronic health conditions that might be linked to vaccines. Yet, some relationships between chronic health conditions and certain vaccines are well-studied. For example, studies have explored a potential relationship between measles, mumps, and rubella (MMR) vaccine and autism, and have found no association.[69] Independent reviews of this scientific evidence have also rejected any causal relationship between MMR vaccination and autism.[70]

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[64] Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality*, 2012, https://www.nationalacademies.org/projects/PHPH-H-08-17-A/publication/13164 (hereinafter, IOM, *Adverse Effects of Vaccines: Evidence and Causality.*; Maglione MA, Gidengil C, Das L, et al., *Safety of Vaccines Used for Routine Immunization in the United States*, Evidence Report/Technology Assessment No. 215 (prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2007-10062-I), AHRQ Publication No. 14-E002-EF, Rockville, MD: Agency for Healthcare Research and Quality, July 2014, http://www.effectivehealthcare.ahrq.gov/reports/final.cfm; DOI: https:// doi.org/10.23970/AHRQEPCERTA215; and Courtney Gidengil, Matthew Bidwell Goetz, Margaret Maglione, et al., *Safety of Vaccines Used for Routine Immunization in the United States: An Update, Comparative Effectiveness Review*, AHRQ, AHRQ Publication No. 21-EHC024, May 2021, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-244-safety-vaccines.pdf.

[65] Maglione MA, Gidengil C, Das L, et al., *Safety of Vaccines Used for Routine Immunization in the United States*, Evidence Report/Technology Assessment No. 215 (prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2007-10062-I), AHRQ Publication No. 14-E002-EF, Rockville, MD: Agency for Healthcare Research and Quality, July 2014, http://www.effectivehealthcare.ahrq.gov/reports/final.cfm.

[66] Courtney Gidengil, Matthew Bidwell Goetz, and Margaret Maglione, et al., *Safety of Vaccines Used for Routine Immunization in the United States: An Update, Comparative Effectiveness Review*, AHRQ, AHRQ Publication No. 21-EHC024, May 2021, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-244-safety-vaccines.pdf.

[67] Frank DeStefano, Paul A. Offit, and Allison Fisher, "Vaccine Safety," in *Plotkin's Vaccines*, ed. Stanley A. Plotkin, Walter A. Orenstein, and Paul A. Offit, 7th ed. (Elsevier, 2017), pp. 1589.

[68] Daniel A. Salmon, Walter A. Orenstein, Stanley A. Plotkin, et al., "Funding Postauthorization Vaccine-Safety Science," *New England Journal of Medicine*, vol. 391 (2024), pp. 102-105.

[69] Frank DeStefano and Tom T. Shimabukuro, "The MMR Vaccine and Autism," *Annual Review of Virology*, vol. 6 (2019), pp. 585-600; Carlo Di Pietrantonj, Alessandro Rivetti, Pasquale Marchione, et al., "Vaccines for Measles, Mumps, Rubella, and Varicella in Children," *Cochrane Database of Systematic Reviews*, no. 11 (May 13, 2021); and Courtney Gidengil, Matthew Bidwell Goetz, Margaret Maglione, et al., *Safety of Vaccines Used for Routine Immunization in the United States: An Update, Comparative Effectiveness Review*, AHRQ, AHRQ Publication No. 21-EHC024, May 2021, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-244-safety-vaccines.pdf.

[70] IOM, *Adverse Effects of Vaccines: Evidence and Causality*; Maglione MA, Gidengil C, Das L, et al., *Safety of Vaccines Used for Routine Immunization in the United States*, Evidence Report/Technology Assessment No. 215 (prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2007-10062-I), AHRQ Publication No. 14-E002-EF. Rockville, MD: Agency for Healthcare Research and Quality; July 2014, http://www.effectivehealthcare.ahrq.gov/reports/final.cfm. DOI: https:// doi.org/10.23970/AHRQEPCERTA215; and Courtney Gidengil, Matthew Bidwell Goetz, Margaret Maglione, et al., *Safety of Vaccines Used for Routine Immunization in the United States: An Update, Comparative Effectiveness Review*, AHRQ, AHRQ Publication No. 21-EHC024, May 2021, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-244-safety-vaccines.pdf.

In other cases, there are fewer studies on the link between certain vaccines and certain adverse health outcomes, and independent, nonfederal reviews of this limited evidence have not identified any adequate studies that explore associations between certain vaccines and certain adverse health effects.[71] It can be analytically challenging to assess direct causes of chronic diseases because many diseases are driven by a combination of different factors.[72] For example, as the assessment notes, one study found an association between cumulative exposure to aluminum in childhood vaccines and asthma.[73] Aluminum is an ingredient in several recommended childhood vaccines used as an *adjuvant* to help enhance immune responses.[74] However, the cited study did not fully control for other possible contributors to asthma risk among the vaccinated children, such as family history of asthma, socioeconomic backgrounds, or health care-seeking behavior. Children are also exposed to aluminum through their diet, in addition to vaccines, and therefore studies should take into account the different sources of aluminum exposure in order to assess health outcomes linked to vaccines specifically. One February 2026 analysis published in the *Journal of the American Medical Association* concluded that given an understanding of how aluminum is processed and relative levels of aluminum exposures from diets versus vaccines, "the evidence is reassuring that aluminum exposure from vaccines based on the January 2025 immunization schedule does not cause untoward health effects during the first few years of life or later."[75] This example illustrates the complexity of studying chronic health conditions linked to vaccines or vaccine ingredients.

The assessment also calls for further studies on the safety of the entire immunization schedule. The assessment acknowledges that some important studies have been conducted, but that progress has been slow and some gaps remain.[76] The cited 2013 IOM report clarified that although each new vaccine is evaluated in the context of the overall immunization schedule at the time of clinical trials conduct for approval, certain elements of the vaccine schedule are not systematically reevaluated once a new vaccine is added.[77] The assessment called for some large placebo-controlled clinical trials on combinations of vaccines and vaccination schedules as needed.[78] There are practical constraints to studying safety of the entire immunization schedule; for instance, there are logistical and financial challenges (for both researchers and participants) associated with large, multiyear clinical trials. There are also ethical concerns with a clinical trial

[71] IOM, *Adverse Effects of Vaccines: Evidence and Causality*; Maglione MA, Gidengil C, Das L, et al., *Safety of Vaccines Used for Routine Immunization in the United States*, Evidence Report/Technology Assessment No. 215 (prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2007-10062-I), AHRQ Publication No. 14-E002-EF, Rockville, MD: Agency for Healthcare Research and Quality; July 2014, http://www.effectivehealthcare.ahrq.gov/reports/final.cfm. DOI: https:// doi.org/10.23970/AHRQEPCERTA215; and Courtney Gidengil, Matthew Bidwell Goetz, Margaret Maglione, et al., *Safety of Vaccines Used for Routine Immunization in the United States: An Update, Comparative Effectiveness Review*, AHRQ, AHRQ Publication No. 21-EHC024, May 2021, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-244-safety-vaccines.pdf.

[72] National Academy of Medicine, *Health Basics: Chronic Disease*, September 24, 2025, https://nam.edu/product/health-basics-chronic-disease/. William C. Cockerham, Bryant W. Hamby, and Gabriela R. Oates, "The Social Determinants of Chronic Disease," *American Journal of Preventive Medicine*, vol. 52, no. 1 (January 2017), pp. S5-S12.

[73] Høeg and Kulldorff, *Assessment*, p. 12. For the study, see Daley, Matthew F., Liza M. Reifler, Jason M. Glanz, et al. 2023, "Association Between Aluminum Exposure From Vaccines Before Age 24 Months and Persistent Asthma at Age 24 to 59 Months," *Academic Pediatrics* 23 (1): 37–46, https://doi.org/10.1016/j.acap.2022.08.006.

[74] CDC, "Adjuvants and Vaccines," December 20, 2024, https://www.cdc.gov/vaccine-safety/about/adjuvants.html.

[75] Moser, Charlotte A., and Paul A. Offit, "Aluminum Exposure From Vaccines and Diet," *JAMA*, ahead of print, February 9, 2006, https://doi.org/10.1001/jama.2026.0056.

[76] Høeg and Kulldorff, *Assessment*, pp. 12-13.

[77] Institute of Medicine, *Childhood Immunization Schedule and Safety*, p. 130.

[78] Høeg and Kulldorff, *Assessment*, p. 4.

that would assign some children to receive all of the vaccines on the immunization schedule while others receive none of the vaccines or are delayed in taking certain vaccines.[79]As mentioned in the IOM report, the IOM committee deemed this type of study design as one that would "needlessly endanger" children.[80]

The assessment pointed to another option to study the schedule—conduct of observational studies (see the "An Overview of Clinical Research Study Design" **text box** above).[81] For instance, in 2016, CDC issued a white paper on potential approaches and challenges in conducting observational studies through its Vaccine Safety Datalink (VSD) in order to examine the safety of the entire immunization schedule.[82] VSD is an ongoing data collaboration between CDC, health care organizations, and academic institutions to study vaccine safety.[83] Since the white paper was published, researchers have published some studies based on VSD analyses to examine questions relevant to the safety of the entire U.S. childhood immunization schedule.[84] Some of these studies have found no association between the childhood immunization schedule and certain health outcomes (e.g., type 1 diabetes), while others have found some evidence of an association of vaccines on the schedule and certain health outcomes (e.g., cumulative exposure of aluminum from vaccines and asthma, as discussed in further detail two paragraphs above).[85] The assessment calls for more of such studies.[86]

In the past, federal vaccine recommendations have considered safety research and data on a particular vaccine in context, weighing the known benefits of vaccination against any known or uncertain harms of the vaccine, as well as the known harms of the disease that the vaccine protects against.[87] The assessment does not provide a detailed analysis of potential harms resulting from increased rates of the diseases that the recommended vaccines protect against, aside from some incidence data on hospitalizations and death from certain diseases. Nor does the assessment provide an overview of benefits or harms associated with certain vaccines with changed recommendations, aside from limited discussion on the influenza vaccine. Rather, the assessment mostly focuses on the comparative annual incidence of a disease or annual mortality rates linked to the diseases that the vaccines protect against.[88] See **Table 1** for an example of an outline of benefits and harm linked to a particular vaccine, in this case, rotavirus vaccine.

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[79] Institute of Medicine, *Childhood Immunization Schedule and Safety*, pp. 106-107.

[80] Institute of Medicine, *Childhood Immunization Schedule and Safety*, pp. 106-107.

[81] Høeg and Kulldorff, *Assessment*, p. 13.

[82] CDC Immunization Safety Office, White Paper on Studying the Safety of the Childhood Immunization Schedule For the Vaccine Safety Datalink, 2016, https://stacks.cdc.gov/view/cdc/57885.

[83] CDC, "About the Vaccine Safety Datalink," https://www.cdc.gov/vaccine-safety-systems/vsd/index.html.

[84] Sophia R. Newcomer, Matthew F. Daley, Komal J. Narwaney, et al., "Order of Live and Inactivated Vaccines and Risk of Non-vaccine-targeted Infections in US Children 11-23 Months of Age," *The Pediatric Infectious Disease Journal*, vol. 39, no. 3 (March 2020), pp. 247-253; Jason M. Glanz, Christina L. Clarke, Matthew F. Daley, et al., "The Childhood Vaccination Schedule and the Lack of Association with Type 1 Diabetes," *Pediatrics*, vol. 148, no. 6 (December 1, 2021); and Matthew F. Daley, Liza M. Reifler, Jason M. Glanz, et al., "Association Between Aluminum Exposure From Vaccines Before Age 24 Months and Persistent Asthma at Age 24 to 59 Months," *Academic Pediatrics*, vol. 23, no. 1 (September 2022), pp. 37-46.

[85] See footnote 79.

[86] Høeg and Kulldorff, *Assessment*, p. 13.

[87] Grace Lee, Wendy Carr, Art Reingold, et al., "Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report*, vol. 67, no. 45 (November 16, 2018), pp. 1271-1272, and CDC, *ACIP Evidence to Recommendation User's Guide*, October 1, 2020, https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf.

[88] Høeg and Kulldorff, *Assessment*, pp. 18-24.

Table 1. Benefits and Harms of a Vaccine Example: Rotavirus Vaccine

Harms of Rotavirus Disease	Benefits of Vaccination	Harms of Vaccination	Summary of Benefits and Harms
Rotavirus can cause gastrointestinal disease in children under age five that can involve severe dehydration, diarrhea, and vomiting. In rare cases, rotavirus disease may lead to intussusception, an obstructed bowel syndrome. [a] Prior to the introduction of rotavirus vaccines in the United States in 2006, rotavirus disease caused annually among children under five years of age:[b] • 410,000 physician visits, • 205,000-272,000 emergency department visits, • 55,000-70,000 hospitalizations, • 20-60 deaths.[b]	There are two types of rotavirus vaccines approved for use in infants in the United States:[c] • RotaTeq (RV5): In clinical trials, RotaTeq demonstrated 98% protection against severe rotavirus disease and 74% effectiveness against rotavirus disease of any severity. Infants were 96% less likely to be hospitalized with rotavirus disease in the first two years after vaccination.[c] • Rotarix (RV1): In clinical trials, Rotarix was found 85-96% effective against severe disease. One study found the vaccine 96% effective in reducing hospitalizations.[c] Over 10 years after both vaccines were recommended by ACIP in 2006, one meta-analysis found that by 2017, U.S. rotavirus vaccination led to: • A median 80% reduction in rotavirus disease hospitalizations and • A 57% reduction in emergency department visits. [d] During much of that period, around 70% of U.S. children ages 19 to 35 months had received a rotavirus vaccine each year.[d]	Rotavirus vaccination is associated with some mild side effects such as irritability, mild diarrhea, and vomiting.[e] Intussusception is a rare, but serious side effect of rotavirus vaccination. Estimated risks range from about 1 in 20,000 to 1 in 100,000 US infants who get the rotavirus vaccine. Intussusception is typically treated in the hospital with non-surgical interventions, though in some cases surgery is required. In rare cases, intussusception can be fatal or cause long-term complications, especially if left untreated.[f]	Rotavirus infection may cause intussusception, though it is unclear exactly how often this occurs. Some researchers argue that there may be no difference in intussusception risk with vaccination compared to infection.[g] Some studies estimate that for every intussusception hospitalization caused by the rotavirus vaccine, hundreds of rotavirus disease hospitalizations are prevented by the rotavirus vaccine (128-1,142; varies by study).[h] Risk-benefit analyses have concluded that even if intussusception rates are higher following vaccination than infection, the benefit of preventing hundreds of rotavirus disease hospitalizations and averting multiple deaths as a result of the rotavirus vaccine outweigh the risks (or harms) of a hospitalization due to intussusception.[h]

Source: See sources below.

Notes: This table is meant to illustrate the benefits and harms of a specific vaccine. While CRS aims to be thorough, this outline is not a result of a comprehensive and systematic literature review.

a. Corinne Williame, Brigitte Cheuvart, Emmanuel Aris, et al., "Association between Rotavirus Gastroenteritis and Intussusception: Suggested Evidence from a Retrospective Study in Claims Databases in the United States," *Human Vaccines and Immunotherapeutics*, vol. 17, no. 1 (2021), pp. 269-277.

b. Umesh D. Parashar, James P. Alexander, and Roger I. Glass, "Prevention of Rotavirus Gastroenteritis Among Infants and Children," *Morbidity and Mortality Weekly Report*, vol. 55, no. RR12 (August 11, 2006), pp. 1-13.

c. CDC, "Rotavirus Vaccination: Information for Health Care Providers," https://www.cdc.gov/vaccines/hcp/by-disease/rotavirus.html.

d. Talia Pindyck, Jacqueline E. Tate, and Umesh D. Parashar, "A Decade of Experience with Rotavirus Vaccination in the United States – Vaccine Uptake, Effectiveness, and Impact," *Expert Review of Vaccines*, no. 7, pp. 593-606.

e. CDC, "Vaccine Information Statement: Rotavirus Vaccine,"https://www.cdc.gov/vaccines/hcp/current-vis/downloads/rotavirus.pdf.

f. CDC, "Questions & Answers about Intussusception and Rotavirus Vaccine," https://www.cdc.gov/vaccines/vpd/rotavirus/about-intussusception.html.

g. Robert Cohen, Federico Martinón-Torres, Inga Posiuniene, et al., "The Value of Rotavirus Vaccination in Europe: A Call for Action," *Infectious Diseases and Therapy*, vol. 12 (2023), pp. 9-29.

h. Adnane Lamrani, Pascale Tubert-Bitter, Catherine Hill, et al., "A Benefit–Risk Analysis of Rotavirus Vaccination, France, 2015," *Eurosurveillance*, vol. 22, no. 50 (December 14, 2017), and Rishi Desai, Umesh D Parashar, Benjamin Lopman, et al., "Potential Intussusception Risk Versus Health Benefits from Rotavirus Vaccination in Latin America," *Clinical Infectious Diseases*, vol. 54, no. 10 (March 19, 2012), pp. 1397-1405.

Process Differences from Prior Schedule Updates

To recap the process leading to the 2026 childhood immunization schedule: in January 2025, CDC published a 2025 childhood and adolescent immunization schedule that ACIP had recommended in October 2024.[89] After HHS Secretary Kennedy was sworn into office in February 2025, HHS changed several vaccine recommendations throughout 2025, including recommendations adopted following 2025 ACIP meetings, that differed from the recommendations in the January 2025 immunization schedule (or added new recommendations).[90] In December 2025, a presidential memorandum directed the HHS Secretary and CDC Director to determine whether to change childhood vaccine recommendations based on practices from "peer, developed nations."[91] In response to the presidential memorandum, on January 5, 2026, the Acting CDC Director approved a decision memorandum outlining a 2026 immunization schedule developed by federal health officials—based on their evaluation of the scientific assessment discussed above—that included several changed vaccine recommendations from the January 2025 schedule. The changes are summarized in **Figure 1**.[92]

[89] Anindita N, Issa. A. Patricia Wodi, Charlotte A. Moser, et al., "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2025," *Mortality and Morbidity Weekly Report*, vol. 74, no. 2 (January 16, 2025), pp. 26-29.

[90] For a summary, see CRS Insight IN12684, *Changes to CDC Vaccine Recommendations in 2025 and 2026*, by Kavya Sekar and Alexandria K. Mickler.

[91] Letter from Donald J. Trump, President of the United States, to Secretary of Health and Human Services; Director of the Centers for Disease Control and Prevention, December 5, 2025, https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/.

[92] HHS, "Fact Sheet: CDC Childhood Immunization Recommendations," press release, January 5, 2026, https://web.archive.org/web/20260105195437/https://www.hhs.gov/press-room/fact-sheet-cdc-childhood-immunization-recommendations.html, and Jay Bhattacharya, Mehmet Oz, and Marty Makary, *Decision Requested - Adopting Revised Childhood and Adolescent Immunization*, HHS CDC, January 5, 2026, https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf.

The process leading to the 2026 childhood schedule was unusual. CRS did not identify any past instances of a President directing a review of, or changes to, the childhood immunization schedule.[93] The process was also unusual because federal health officials developed, published, and adopted the schedule in January 2026 without consulting ACIP, a change from the process followed in typical years as explained in this section. Following litigation that resulted in a district order that stayed the 2026 childhood immunization schedule, President Trump, on May 29, 2026, issued E.O. 14407 referencing the assessment and its proposed 2026 updates to the childhood immunization schedule as a "a guiding resource" for the federal government.[94] E.O. 14407 directs ACIP and CDC to review the assessment and proposed childhood immunization schedule revision and take steps to update the immunization schedule to the extent permitted by law. E.O. 14407 appears to direct ACIP and CDC to revisit the update of the immunization schedule by following the typical ACIP-led process. At the same time, E.O. 14407 is unusual in directing ACIP and CDC (and other federal agencies) to consider the assessment, with its proposed updates to the childhood immunization schedule, as "a guiding resource."

As mentioned, in prior years, ACIP has led the process of updating federal vaccine recommendations.[95] ACIP is established under a general authority that allows the HHS Secretary to appoint advisory committees, and the updating and publication of the childhood immunization schedule is not governed by any specific law.[96]ACIP has operated pursuant to a committee charter that outlines the committee's general objectives and duties, which was mostly recently renewed on May 19, 2026.[97] Prior to 2026,he updated childhood immunization schedules each year reflected two different processes: (1) ACIP's process of considering and voting on individual vaccine recommendations and (2) ACIP's process of updating the entire schedule. ACIP typically met to vote on new or updated recommendations three times per year.[98] In the past, ACIP usually voted on changes to the full schedules once per year in its fall meeting.

Individual ACIP Vaccine Recommendations

Since its first meeting in 1964, ACIP has considered and voted on new vaccine recommendations.[99] Oftentimes ACIP has voted on recommendations after FDA licensed a new

[93] Based on CRS searches of presidential documents databases.

[94] Executive Order 14407, "Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries," 91 *Federal Register* 106, May 29, 2026.

[95] HHS, "HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP," press release, June 9, 2025, https://www.hhs.gov/press-room/hhs-restore-public-trust-vaccines-acip.html. For changed recommendations, see, for example, HHS, "ACIP Recommends COVID-19 Immunization Based on Individual Decision-making," press release, September 19, 2025, https://www.hhs.gov/press-room/acip-recommends-covid19-vaccination-individual-decision-making.html. For ACIP's recommended Hepatitis B changes, see CDC, "ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus," press release, December 5, 2025, https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html.

[96] ACIP is established pursuant to authority provided by Public Health Service Act (PHSA) Section 222 (42 U.S.C. §217a), a general authority that allows the HHS Secretary to appoint advisory committees. CDC also has general authority to publish research-based health information, for example, in PHSA Section 301(a) (42 U.S.C. § 241(a)) and to assist and advise states in public health matters in PHSA Section 311(a) (42 U.S.C. § 243(a)). For more information about ACIP, see CRS In Focus IF12317, *The Advisory Committee on Immunization Practices (ACIP)*.

[97] CDC, "Advisory Committee on Immunization Practices (ACIP); Notice of Charter Re-Establishment," 91 *Federal Register* 29139, May 19, 2026.

[98] CDC, *Advisory Committee on Immunization Practices Policies and Procedures*, June 2022, p. 7, https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf.

[99] L. Reed Walton, Walter A. Orenstein, and Larry K. Pickering, "The History of the United States Advisory Committee on Immunization Practices (ACIP)," *Vaccine*, vol. 33 (2015), pp. 405-14.

vaccine (or an existing vaccine for a new indication), as required by statute.[100] ACIP has also revisited prior vaccine recommendations based on new evidence or new circumstances, such as disease outbreaks, vaccine shortages, or new safety issues that have emerged after a vaccine was introduced.[101] According to committee policy, ACIP has sought to revisit existing vaccine recommendations at least once every seven years to determine if updates or changes are warranted.[102]

ACIP's process of developing, considering, and voting upon a new vaccine recommendation has typically taken at least several months, except in instances when the process was expedited, such as in response to an emergency situation.[103] When there was potential to develop a new vaccine recommendation—for example, if new evidence emerged that might change an existing recommendation—ACIP formed a work group specific to that vaccine.[104] An example timeline for this type of vaccine recommendation update is presented in **Figure 2**. ACIP work groups typically consisted of two or more voting ACIP members, CDC staff members (providing administrative and scientific support), and sometimes included other federal staff or nonvoting representatives from nonfederal health organizations.[105] Work groups typically met about once a month throughout the evidence review and recommendation development process.[106] The work group would first systemically gather evidence and then present summaries of the evidence to the full ACIP in a public meeting. As of 2018, ACIP has used a structured "Evidence to Recommendation" (EtR) framework to develop vaccine recommendations by systemically weighing the strength of evidence associated with the benefits, harms, and considerations with different vaccination approaches.[107] After reviewing and presenting the evidence, the work group

[100] 21st Century Cures Act (P.L. 114-255; §3091) and 21 U.S.C. § 360bbb–4 note.

[101] As an example of a vaccine for which the recommendation changed in response to a safety issue, in 1999, ACIP withdrew its recommendation for the RotaShield vaccine, a first-generation vaccine against rotavirus, after "a review of scientific data from several sources, concluded that intussusception occurs with significantly increased frequency in the first 1-2 weeks after vaccination with RRV-TV, particularly following the first dose." See CDC, "Withdrawal of Rotavirus Vaccine Recommendation," *Mortality and Morbidity Weekly Report* 48 (43) (1999), p. 1007,https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm.

[102] CDC, *Advisory Committee on Immunization Practices Policies and Procedures*, June 2022, p. 5, https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf.

[103] For example, in December 2020, ACIP issued a recommendation for the Pfizer-BioNTech COVID-19 vaccine. ACIP held nine public meetings on the vaccine between June 2020 and December 2020. FDA issued an Emergency Use Authorization (EUA) for the vaccine on December 11, 2020, and on December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged 16 years and older for the prevention of COVID-19. See Sara E. Oliver, MD, PhD Julia W. Gargano, MD Mona Marin, et al., "The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine—United States, December 2020," *MMWR. Morbidity and Mortality Weekly Report* 69 (50) (2025), pp. 1922-1924, https://doi.org/10.15585/mmwr.mm6950e2.

[104] CDC, *Advisory Committee on Immunization Practices Policies and Procedures*, June 2022, p. 5, https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf, and CDC Advisory Committee on Immunization Practices Secretariat, *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures*, August 2018, p. 3, https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

[105] CDC, *Advisory Committee on Immunization Practices Policies and Procedures*, June 2022, p. 4, https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf, and CDC Advisory Committee on Immunization Practices Secretariat, *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures*, August 2018, p. 4, https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

[106] CDC Advisory Committee on Immunization Practices Secretariat, *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures*, August 2018, p. 8, https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

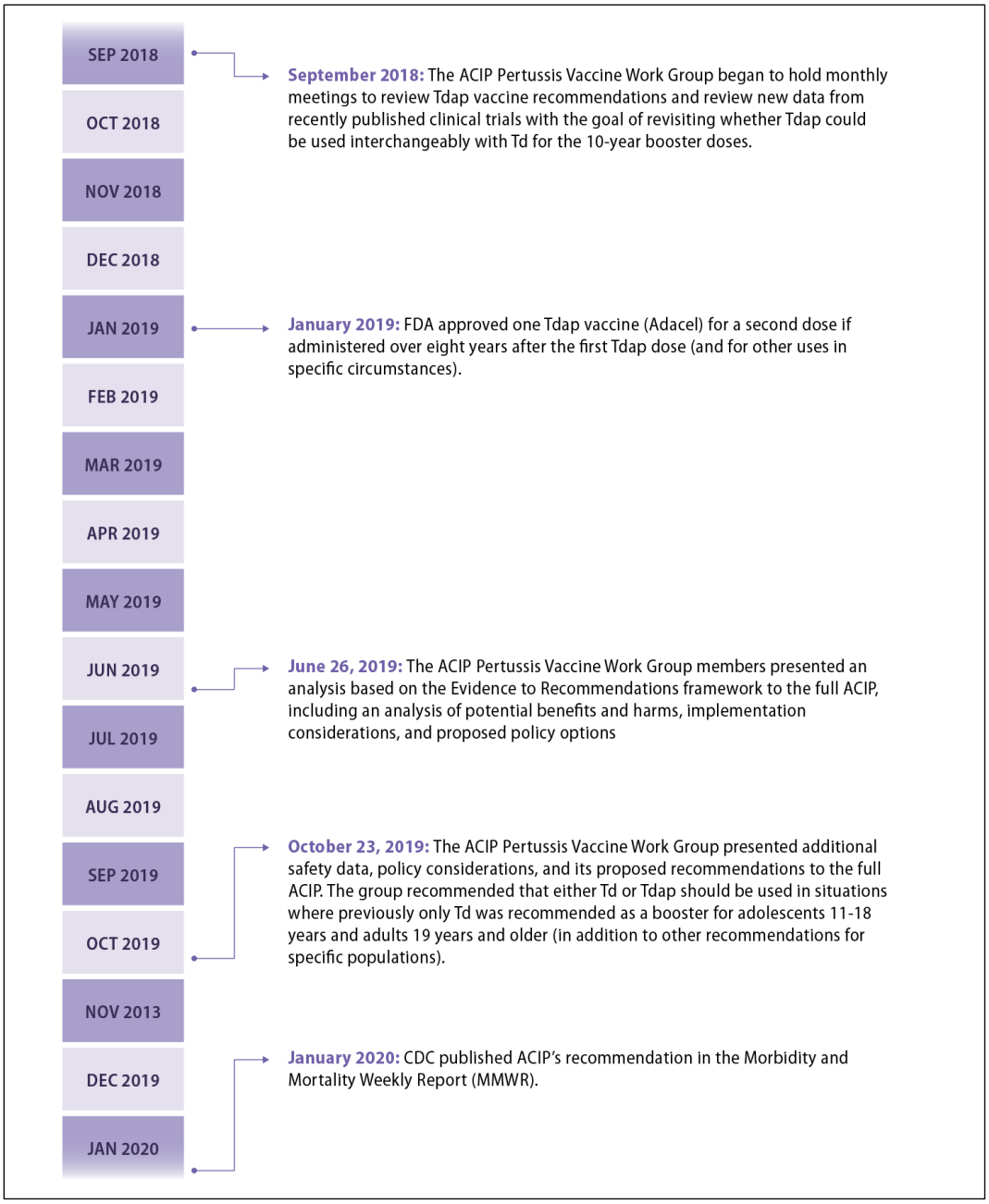
[107] Grace Lee, Wendy Carr, Art Reingold, et al., "Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report*, (continued...)

would usually then develop an analysis based on the EtR framework and solicit feedback. After presenting the initial EtR analysis, the work group would typically draft a recommendation and present a final EtR analysis for a full committee vote. If the majority of committee members voted to adopt the recommendation, then the CDC Director would decide whether to adopt that recommendation as an official federal recommendation. Prior to 2025, the CDC Director formally adopted the majority of ACIP recommendations.[108]

vol. 67, no. 45 (November 16, 2018), pp. 1271-1272, and CDC, *ACIP Evidence to Recommendation User's Guide*, October 1, 2020, https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf.

[108] CRS has identified two instances when the CDC Director did not adopt a recommendation that received a majority ACIP vote. First, in 2021, CDC Director Rochelle Walensky did not adopt part of ACIP's proposed criteria for who should receive COVID-19 booster shots; see CDC, "CDC Statement on ACIP Booster Recommendations," press release, September 24, 2021, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html. Second, in 2003, CDC Director Julie Gerberding recommended that the federal government continue with a smallpox vaccination campaign after ACIP had voted to recommend against it; see "CDC Backs Smallpox Vaccination Program Expansion Despite Panel's Advice," *California Healthline*, June 27, 2003, https://californiahealthline.org/morning-breakout/cdc-backs-smallpox-vaccination-program-expansion-despite-panels-advice/.

Figure 2. Example ACIP Vaccine Review Process: Tdap Vaccine Update



Source: Figure developed by CRS using information available at CDC, *ACIP Recommendations: Diphtheria, Tetanus and Pertussis (DTaP/Tdap/Td) Vaccines*, https://www.cdc.gov/acip-recs/hcp/vaccine-specific/dtap-tdap-td.html.

Annual Updates of the Immunization Schedules

In recent years, ACIP has voted on the entire child and adult immunization schedules once per year.[109] These annual updates reflected all individual recommendations ACIP made that year

[109] See, for example, A. Patricia Wodi, Anindita N. Issa, Charlotte A. Moser, et al., "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older—United States, (continued...)

regarding specific routinely recommended vaccines. The updated schedules generally did not include new recommendations apart from the individual vaccine recommendations that ACIP had already approved that year.[110] The schedules also typically did not include vaccines that are not routinely offered to patients, such as travel vaccines.

ACIP has had permanent work groups for updating the child/adolescent and adult immunization schedules.[111] These work groups have focused on changing the formatting and clinical notes of the schedules, mostly to reflect the changed individual vaccine recommendations for each year.[112] From 1995 until 2024, through its annual update, ACIP/CDC harmonized its childhood immunization schedule with nonfederal health groups such as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians, which meant that these nonfederal health organizations formally endorsed the ACIP/CDC childhood immunization schedule.[113] Beginning in 2025, physician groups such as AAP have published a separate childhood immunization schedule from CDC, as discussed further in the next section.[114] As AAP stated, its recommended childhood immunization schedule "differs from recent recommendations of the Advisory Committee on Immunization Practices of the CDC, which was overhauled this year and replaced with individuals who have a history of spreading vaccine misinformation."[115]

2025," *Morbidity and Mortality Weekly Report*, vol. 74, no. 2 (January 16, 2025), pp. 30-33, and Anindita N. Issa. A. Patricia Wodi, Charlotte A. Moser, et al., "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2025," *Mortality and Morbidity Weekly Report*, vol. 74, no. 2 (January 16, 2025), pp. 26-29.

[110] ACIP October 24 meeting minutes, p. 77, https://www.cdc.gov/acip/downloads/minutes/summary-2024-10-23-24-508.pdf.

[111] CDC Advisory Committee on Immunization Practices Secretariat, *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures*, August 2018, p. 8, https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

[112] ACIP October 24 meeting minutes, p. 77, https://www.cdc.gov/acip/downloads/minutes/summary-2024-10-23-24-508.pdf.

[113] For 2025, see Anindita N. Issa. A. Patricia Wodi, Charlotte A. Moser, et al., "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2025," *Mortality and Morbidity Weekly Report*, vol. 74, no. 2 (January 16, 2025), pp. 26-29.

and for 1995 see CDC, "Recommended Childhood Immunization Schedule—United States, 1995," *Mortality and Morbidity Weekly Report*, vol. 44, no. RR-5 (1995).

[114] American Academy of Pediatrics, *The American Academy of Pediatrics Releases Its Own Evidence-Based Immunization Schedule*, August 19, 2025, https://www.aap.org/en/news-room/news-releases/aap/2025/the-american-academy-of-pediatrics-releases-its-own-evidence-based-immunization-schedule/.

[115] American Academy of Pediatrics, *The American Academy of Pediatrics Releases Its Own Evidence-Based Immunization Schedule*, August 19, 2025, https://www.aap.org/en/news-room/news-releases/aap/2025/the-american-academy-of-pediatrics-releases-its-own-evidence-based-immunization-schedule/.

Potential Implications of the Revised Schedule

As mentioned at the beginning of this report, a federal district court stayed the 2026 revised childhood immunization schedule in *American Academy of Pediatrics v. Kennedy*, meaning that the effective date of the revised schedule is postponed while the court considers the case.[116] The district court also stayed the appointments of the 13 ACIP members appointed by Secretary Kennedy and all votes from the now stayed ACIP.[117] This decision stops the CDC from implementing the new schedule and reverts the recommended CDC immunization schedules back to the version recommended as of May 2025.

E.O. 14407, issued after the district court's decision, states that the assessment, with its proposed updates to the childhood vaccine schedule, is a "guiding resource" for the federal government, and directs CDC and ACIP to review the assessment and proposed childhood immunization schedule revision and take necessary steps to update the immunization schedule to the extent permitted by law. Presently, because of the district court stay, it is unclear whether there are a sufficient number of ACIP members to carry out the E.O. 14407 directive. HHS filed a notice to reestablish ACIP on May 19, 2026, and the HHS Secretary may make further changes to ACIP's composition to implement E.O. 14407[118]

Still, the CDC's issuance of the revised immunization schedule has already prompted certain responses from relevant stakeholders. The following sections discuss some of those responses and potential implications of the revised schedule, should it go into effect. Ultimately, these changes in clinical practice and patient information and understanding may affect uptake of vaccines and therefore may lead to changes in rates of certain vaccine preventable diseases.

Clinical Practice

As mentioned above, ACIP historically harmonized its immunization schedules with health professional organizations, such as the AAP. Following the January 2026 announcement, the AAP opposed the revised CDC schedule and has since published a separate 2026 schedule that was formally endorsed by 12 other medical and health professional groups.[119] Some medical and academic groups have created an independent vaccine evidence review process, the Vaccine Integrity Project, that will parallel HHS's process and potentially inform future nonfederal

[116] Order, Am. Acad. of Pediatrics v. Kennedy, -No. 25-11916, 2026 WL 733828, at *21–22 (D. Mass. Mar. 16, 2026) (staying the 2026 revised immunization schedule pursuant to 5 U.S.C. § 705): 5 U.S.C. § 705 (authorizing courts to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings").

As previously mentioned, the federal government appealed the ruling to the U.S. Court of Appeals for the First Circuit on April 29th, 2026. Notice of Appeal, Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass., filed Apr. 29, 2026), ECF No. 306.

[117] Order, Am. Academy of Pediatrics v. Kennedy, No. 25-11916, 2026 WL 733828 (D. Mass. March 16, 2026).

[118] CDC, "Advisory Committee on Immunization Practices (ACIP); Notice of Charter Re-Establishment," 91 *Federal Register* 29139, May 19, 2026.

[119] American Academy of Pediatrics, "AAP Opposes Federal Health Officials' Unprecedented Move to Remove Universal Childhood Immunization Recommendations," press release, January 5, 2026, https://www.aap.org/en/news-room/news-releases/aap/2025/aap-opposes-federal-health-officials-unprecedented-move-to-remove-universal-childhood-immunization-recommendations/. American Academy of Pediatrics, *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years and Younger*, United States 2026, February 5, 2026, https://publications.aap.org/redbook/resources/15585/AAP-Immunization-Schedule.

vaccine recommendations.[120] Providers and patients therefore face navigating a patchwork of clinical guidance and vaccine recommendations from federal and nonfederal groups.

Prior immunization schedules also contained extensive clinical notes, such as those that detail certain contraindications or precautions.[121] The revised CDC schedule lacks these notes, potentially limiting its usefulness for clinical practice.[122] Moreover, CDC has in the past published specific guidance for vaccines recommended for shared clinical decisionmaking to inform health care provider conversations about the vaccines.[123] No such guidance has been published thus far for the vaccines with recommendations changed to shared clinical decisionmaking recommendations in the 2026 schedule. Prior to the district court decision, CDC's websites for its immunization schedules were still being revised to reflect the changes; it is possible that, should the 2026 schedule go into effect, these revised websites would include more clinical guidance in the future.[124]

State law and policy informs vaccine uptake and access, including vaccines required for school and day care attendance, as well as health care provider "scope-of-practice," or the types of providers that are authorized to administer vaccines and under what circumstance.[125] Some of these laws reference or have referenced ACIP recommendations.[126] As of January 20, 2026, 28 states (including Washington, DC) and several multistate health alliances have announced they plan to follow AAP's vaccine guidance; other states have announced plans to partially adopt some aspects of the new CDC vaccine schedule, though some states have introduced measures to require health providers to follow the new CDC guidance.[127] These changes may affect clinical

[120] American Medical Association, "AMA, Vaccine Integrity Project Launch Vaccine Review for Next Respiratory Season," press release, February 10, 2026, https://www.ama-assn.org/press-center/ama-press-releases/ama-vaccine-integrity-project-launch-vaccine-review-next.

[121] See, for example, Patricia Wodi, Charlotte A. Moser, et al., "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2025," *Mortality and Morbidity Weekly Report*, vol. 74, no. 2 (January 16, 2025), pp. 26-29.

[122] Jay Bhattacharya, Mehmet Oz, and Marty Makary, *Decision Requested - Adopting Revised Childhood and Adolescent Immunization*, HHS CDC, January 5, 2026, https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf, and Tracy Beth Høeg, and Martin Kulldorff, *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries*, HHS, January 2, 2026, https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf.

[123] See, for example, CDC, "Shared Clinical Decision-Making Meningococcal B Vaccination," 2024, http://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.htmlwww.cdc.gov/vaccines/hcp/imz-schedules/adult-age.htmlwww.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html.

[124] CDC, "Healthcare Professionals: Immunization Schedules," https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html.

[125] National Conference of State Legislatures, *State Non-Medical Exemptions From School Immunization Requirements*, January 22, 2026, https://www.ncsl.org/health/state-non-medical-exemptions-from-school-immunization-requirements, and Alexandra M. Stewart, Megan C. Lindley, and Marisa A. Cox, "State Law and Standing Orders for Immunization Services," *American Journal of Preventive Medicine*, vol. 50, no. 5 (May 2016), pp. e133-e142.

[126] Association of State and Territorial Health Officials (ASTHO), *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, June 23, 2025, https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/.

[127] Jennifer Kates and Clea Bell, *State Recommendations for Routine Childhood Vaccines: Increasing Departure from Federal Guidelines*, KFF, January 22, 2026, https://www.kff.org/state-health-policy-data/state-recommendations-for-routine-childhood-vaccines-increasing-departure-from-federal-guidelines/, and ASTHO, *States Seek Policy Guidance Beyond ACIP Vaccine Recommendations*, October 24, 2025, https://www.astho.org/communications/blog/2025/states-seek-policy-guidance-beyond-acip-vaccine-recommendations/. For multistate alliances, see, for example, the West Coast Health Alliance's announcement at Oregon Health Authority, "OHA statement: West Coast Health Alliance (continued...)

practice throughout the country, potentially leading to differences in the vaccines available to or required for children in different states, or the types of providers that can administer them.

Patient Information and Understanding

The approach of "shared clinical decision-making" (SCDM) has been used in medical practice as a collaborative approach in which clinicians and patients discuss medical treatments or interventions, weigh the risks and benefits, communicate preferences, and select the best course of action.[128] The use of this approach in federal vaccine recommendations is not unique to the 2026 updated childhood immunization schedule; ACIP first introduced the SCDM category for some adult vaccines in 2019 (see the "What Is an Immunization Schedule?" **text box** above).[129] The 2026 assessment asserted that SCDM can help "restore trust in public health recommendations made by CDC."[130]

Recent surveys of the general public suggest that respondents have an incomplete or incorrect understanding of what SCDM means. For example, about one-quarter of respondents interpreted SCDM to mean that they should consult family about vaccine decisions; nearly half incorrectly stated that SCDM means it is up to an individual whether or not to consult with a health care provider about a vaccine.[131] Neither of these interpretations aligns with the ACIP-developed definition of SCDM, which states the recommendation is "individually based and informed by a decision process between the health care provider and the patient or parent/guardian."[132]

There is also debate on how SCDM should be implemented. Some experts assert that SCDM is appropriate only in situations where medical guidance does not clearly recommend one option or other (e.g., when two different antibiotics are effective or, conversely, when no effective treatment is available and similar therapeutic approaches are the only available options).[133] These observers contend that SCDM is not an appropriate approach for vaccines with demonstrated effectiveness against serious illness or death.[134]

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continues to endorse AAP-recommended child, adolescent immunization schedules," press release, January 5, 2026, https://www.oregon.gov/oha/ERD/Pages/OHA-statement-West-Coast-Health-Alliance-continues-to-endorse-AAP-recommended-child-adolescent-immunization-schedules.aspx.

[128] Victor M. Montori, Merel M. Ruissen, Ian G. Hargraves, et al., "Shared decision-making as a method of care," *BMJ Evidence-Based Medicine*, vol. 28, no. 4 (August 2023).

[129] Michael D. Hogue, Stephan Foster, and Mitchel C. Rothholz, "Shared Clinical Decision Making on Vaccines: Nothing Has Really Changed for Pharmacists," *Journal of the American Pharmacists Association*, 2020, pp. 1-4.

[130] Høeg and Kulldorff, *Assessment*, p. 4.

[131] Annenberg Public Policy Center, University of Pennsylvania, *CDC Urges "Shared Decision-Making" on Some Childhood Vaccines; Many Unclear About What That Means*, January 5, 2026, https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/. Michael D. Hogue, Stephan Foster, and Mitchel C. Rothholz, "Shared clinical decision making on vaccines: Nothing has really changed for pharmacists," *Journal of the American Pharmacists Association*, vol. 60, no. 6 (November-December 2020).

[132] CDC, *ACIP Shared Clinical Decision-Making Recommendations*, https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.

[133] Eric Boodman, "Is 'shared decision-making' being hijacked by U.S. health officials to sow doubt about vaccines?," *Stat*, January 20, 2026.

[134] Rita Rubin, "Hundreds of Medical Groups Challenge Childhood Immunization Schedule Changes—Here's What to Know," *Journal of the American Medical Association (JAMA)*, vol. 335, no. 6 (February 9, 2026).

Selected Federal Policy Implications

While the revised 2026 childhood immunization schedule published in January 2026 is not currently in effect due to the district court order and thus it has no immediate implications for other federal policies (e.g., coverage requirements) that rely on the schedule for implementation, that status of the revised schedule may change depending on further court action. Moreover, depending on actions taken (including by ACIP, CDC, and/or the HHS Secretary) to implement E.O. 14407, a newly adopted schedule could be similar to the revised childhood immunization schedule.

Accordingly, the following summarizes key areas in which the revised schedule may have federal policy implications, depending in part on how it may go into effect: the Vaccines for Children program, private health insurance coverage requirements, and the Vaccine Injury Compensation Program (VICP).

Coverage

Because the majority of young children in the United States are eligible for vaccine coverage through the Vaccines for Children (VFC) program or private health insurance,[135] this section focuses on potential implications of the revised childhood immunization schedule for these coverage programs. There may also be implications for other coverage programs, not discussed in this report.

Vaccines for Children

The VFC program is a Medicaid-financed and CDC-administered program to provide recommended childhood vaccines at no cost to eligible children, which includes those who are (1) Medicaid eligible, (2) not insured, (3) without adequate insurance and who are receiving a vaccine at a federally qualified health center or a rural health clinic, and (4) American Indian or Alaska Native.[136] The VFC statute requires the HHS Secretary to use "the list established (and periodically reviewed and as appropriate revised) by [ACIP]" to determine the vaccines to be purchased, delivered, and administered under the program.[137] ACIP has implemented this statutory directive through VFC-ACIP Vaccine Resolutions, which are adopted through a process separate from ACIP's annual vaccine recommendations summarized above.[138] The 2026 childhood immunization schedule was not accompanied by any changes to these VFC-ACIP Vaccine Resolutions, and therefore it does not appear that the revised schedule would affect the vaccines covered under VFC should it go into effect as part of ongoing litigation.[139]

[135] Madeleine R. Valier, David Yankey, Laurie D. Elam-Evans, et al., "Vital Signs: Trends and Disparities in Childhood Vaccination Coverage by Vaccines for Children Program Eligibility—National Immunization Survey-Child, United States, 2012–2022," *Morbidity and Mortality Weekly Report (MMWR)*, vol. 73, no. 33 (August 22, 2024), pp. 722-730. According to CRS analysis of Table 1 health insurance status subtotals, 93% of U.S. children were either VFC eligible or covered by private health insurance (children aged 19-35 months born between 2011 and 2022). The rest of the children were covered by other programs, such as CHIP or the military health program.

[136] As defined in the Indian Health Care Improvement Act (25 U.S.C. §1603), Social Security Act (SSA) Section 1928, and CDC, "VFC Eligibility Criteria," https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html.

[137] Social Security Act §1928(e); 42 U.S.C. §1396s(e).

[138] These resolutions are separate from other ACIP recommendations. See CDC, "VFC-ACIP Vaccine Resolutions," https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html.

[139] CDC, "VFC-ACIP Vaccine Resolutions," https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html.

E.O. 14407 expressly states that all immunizations in any category on any revised schedule recommended by ACIP and adopted by CDC pursuant to the E.O. 14407's directive should continue to be covered without cost-sharing by VFC.[140]

Private Health Insurance

Under federal law on private health insurance coverage of certain preventive services, most private health insurance plans must cover (without cost-sharing) "immunizations that have in effect a recommendation from [ACIP] of the [CDC] with respect to the individual involved."[141] Under regulations implementing the preventive services coverage requirement, this includes immunizations with a recommendation in effect by ACIP for routine use for a given individual.[142] For purpose of these regulations, an ACIP recommendation is considered "in effect" if it is adopted by the CDC Director; an immunization is considered recommended "for routine use" if it is listed on the CDC immunization schedules.

Of the 17 recommended vaccines on the 2026 CDC childhood immunization schedule

- nine recommendations are unchanged from the schedule recommended by ACIP in 2024 and published on CDC's childhood immunization schedule in January 2025;
- two vaccine recommendations incorporated ACIP recommendations made in September and December 2025 (COVID-19 and Hepatitis B);[143] and
- ACIP was not involved in some or all aspects of the recommendation changes for the remaining six changed recommendations (regarding Hepatitis A, HPV, Influenza, Meningococcal ACWY, RSV, and Rotavirus).[144]

Both the decision memorandum and the underlying assessment issued in conjunction with the revised 2026 childhood immunization schedule stated that "broad-based insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the vaccine schedule."[145] However, if the 2026 schedule goes into effect (as part of ongoing litigation) without further ACIP or agency action, it is unclear whether the new schedule provides

[140] See Section 2(c) of Executive Order 14407, "Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries," 91 *Federal Register* 106, May 29, 2026.

[141] PHSA §2713(a)(2), codified at 42 U.S.C. §300gg-13(a)(2). This requirement also addresses private health insurance coverage of other preventive services such as recommended screenings. For more information, see CRS In Focus IF13010, *The ACA Preventive Services Coverage Requirement*.

[142] 45 C.F.R. §147.130(a)(1)(ii).

[143] For ACIP's recommended COVID-19 changes, see HHS, "ACIP Recommends COVID-19 Immunization Based on Individual Decision-making," press release, September 19, 2025, https://www.hhs.gov/press-room/acip-recommends-covid19-vaccination-individual-decision-making.html. For ACIP's recommended Hepatitis B changes, see CDC, "ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus," press release, December 5, 2025, https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html. Both recommendations were developed by ACIP after the HHS Secretary changed all of ACIP's members in June 2025.

[144] As mentioned in "The 2026 Childhood Immunization Schedule" section above and in the notes of **Figure 1**, the 2026 immunization schedule changed the category of recommendation for the RSV vaccine but did not change the substance of that recommendation, meaning the populations for which vaccination is recommended remains the same as in the 2025 schedule and the June 2025 ACIP recommendation.

[145] Decision memo, p. 4; Høeg and Kulldorff, *Assessment*, p. 16. As indicated earlier in this report, the assessment drew a distinction between "consensus" vaccines that 20 peer, developed nations also recommend and "non-consensus" vaccines that not all peer nations recommend.

a recommendation "in effect" by ACIP for the last six vaccines listed above, and thus whether they will be subject to the federal provision on private health insurance coverage.[146]

Another coverage-related question raised by the updated 2026 immunization schedule concerns the change in the number of recommended doses—from two to one—for the HPV vaccine. Unlike the other revised recommendations that changed the *type* of recommendation made regarding a vaccine (e.g., from all children to SCDM), the change in HPV vaccines' recommended doses arguably rescinds the prior recommendation with respect to the second dose. If so, there may no longer be an applicable recommendation "in effect" for the second dose of the HPV vaccine for purposes of the coverage requirement.

If, pursuant to E.O. 14407, ACIP makes new recommendations (in keeping with the 2026 childhood immunization schedule released in January 2026 or otherwise), and the CDC updates the childhood schedule accordingly, that process may eliminate the coverage-related questions about whether certain vaccines have ACIP recommendations "in effect." E.O. 14407 also directs each executive department and agency to align immunization regulations, funding, and coverage with the ACIP-recommended schedule, among other actions. The agencies with jurisdiction over private health insurance requirements could provide guidance following any new ACIP and CDC actions, or in the meantime, addressing any outstanding questions about the coverage requirements.[147]

Separately, 10 of the 17 vaccines on the 2026 childhood schedule (across the three bullets above and **Figure 1**) are recommended only for certain high-risk groups and populations, and/or are based on shared clinical decisionmaking (SCDM). This includes three recommendations based solely on SCDM.[148] On the 2025 childhood schedule, three of the 17 vaccines were recommended only for high risk and/or SCDM, and none were SCDM only.[149] Prior agency guidance on the vaccine coverage requirements has indicated that plans must cover vaccines recommended by ACIP "for certain individuals rather than an entire population," when a health care provider prescribes the vaccine for an individual, consistent with the ACIP recommendations.[150] However, that guidance did not use the terms "shared clinical decision making" or SCDM, and in recent

[146] In staying the 2026 revised immunization schedule, the district court in *American Academy of Pediatrics v. Kennedy*, concluded that the plaintiffs were likely to succeed on the claim that CDC's issuance of the revised schedule without ACIP was contrary to law, including contrary to this coverage requirement.—F. Supp. 3d—, 2026 WL 733828, at *8–9, 11 (D. Mass. Mar. 16, 2026); see also Arizona v. Kennedy, No. 3:26-cv-1609 (N.D. Cal., filed Feb. 24, 2026), Complaint ¶¶354-355 (alleging that "Congress has specifically designated ACIP—not the CDC—as the body that establishes the immunization schedules triggering federal obligations in a number of federal health statutes" and that "[t]his was a deliberate choice that forecloses CDC-only action").

[147] Given the shared jurisdiction of the Departments of HHS, Labor, and the Treasury over different types of private health insurance plans, the three Departments have jointly issued numerous FAQs providing subregulatory guidance on federal requirements on private health insurance plans. See, for example, Centers for Medicare & Medicaid Services (CMS), "Fact Sheets & Frequently Asked Questions (FAQs), https://www.cms.gov/marketplace/resources/fact-sheets-faqs.

[148] See **Figure 1**. On the 2026 schedule: seven of 17 vaccines are recommended for all children; three for certain high-risk groups or populations; four for high risk and/or SCDM populations; and three are recommended as SCDM.

[149] On the prior schedule: 14 of 17 vaccines were recommended for all children, some with additional recommendations for certain high-risk groups or populations; two for high-risk groups or populations only; and one vaccine was high risk and/or SCDM. No vaccines were SCDM only. See **Figure 1**.

[150] Departments of HHS, Labor, and the Treasury, Question 8, "Affordable Care Act Implementation FAQs – Set 12," February 20, 2013, https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/aca_implementation_faqs12.

years, there have been some indications that health insurers have not consistently covered SCDM vaccines per the federal preventive services coverage requirement.[151]

As of January 2025, a CDC webpage indicated that private health insurance plans are required to cover SCDM recommendations that are listed on CDC's immunization schedules, but the CDC does not have oversight of private health insurance coverage requirements.[152] E.O. 14407 states that "all the immunizations that are in any category on the schedule recommended by the ACIP and adopted by the CDC should continue to be covered without cost sharing by private insurance."[153] This directive may reflect the executive branch's interpretation that a SCDM recommendation is a relevant recommendation under the preventive service coverage requirements. If there is also any new agency guidance specific to private health insurance vaccine coverage requirements, pursuant to E.O. 14407, coverage based on SCDM recommendations could be further addressed.

Finally, to the extent the 2026 immunization schedule goes into effect (as currently published or subject to any new ACIP recommendations and CDC adoption), there is a question of the timing of any private health insurance coverage changes. Regulations provide that if an existing recommendation is removed, plans must generally still provide coverage of the preventive service through the end of the plan year, unless it is determined to pose a safety risk as specified.[154] Many but not all private health insurance plan years align with the calendar year. Thus, even if the January 2026 schedule is allowed to go into effect in 2026, and regardless of the other questions above, such plans may still be federally required to cover vaccines according to the 2025 schedule for the remainder of 2026.[155] If ACIP adds or otherwise changes a recommendation, and it is adopted by the CDC, plans generally must provide new coverage as of the plan year that begins one year after the recommendation.

While there may be questions about the federal requirement on plans' vaccine coverage, another consideration is that states may impose their own coverage requirements on the private health insurance plans they regulate.[156] As of September 2025, four states have recently imposed new requirements on coverage without cost-sharing of all vaccines recommended by the state, and another nine states have done this for COVID-19 vaccines only. Nine states have identified nonfederal entities as the source of all of their vaccine recommendations, and another 13 states have done this for COVID-19 vaccines only. Overall, at least these 23 states have recently imposed these new requirements on coverage, recommendation source, or both.[157]

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[151] Richard Hughes IV, Reed Maxim, and Alessandra Fix, "Vague Vaccine Recommendations May Be Leading To Lack Of Provider Clarity, Confusion Over Coverage," *Health Affairs*, May 7, 2019.

[152] CDC, *ACIP Shared Clinical Decision-Making Recommendations*, January 7, 2025, https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.

[153] See Section 2(c) of Executive Order 14407, "Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries," 91 *Federal Register* 106, May 29, 2026.

[154] 45 C.F.R. 147.130(b).

[155] As the 2026 childhood immunization schedule was announced in January 2026, calendar year plans may still be required to provide coverage according to the 2025 immunization schedule through December 2026. Other plans that began before issuance of the new immunization schedule would also have to provide such coverage through their plan year (for example, a plan that began July 2025 and ends June 2026).

[156] In general, states may regulate fully insured group plans and nongroup plans, but not self-insured group plans. For discussion of plan types and state and federal regulation, see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*.

[157] CRS summary of Table 1 data in KFF, "Tracking State Actions on Vaccine Policy and Access, September 24, 2025, https://www.kff.org/state-health-policy-data/tracking-state-actions-on-vaccine-policy-and-access/. KFF indicates that this analysis includes only "actions that were taken in anticipation of or in response to changes in federal vaccine policy (continued...)

In addition, private health insurers may voluntarily provide coverage of vaccines. For example, in September 2025, a stakeholder group representing a number of insurers, America's Health Insurance Plans, or AHIP, announced that its member health plans will continue to cover all vaccines recommended by ACIP as of September 1, 2025, through the end of 2026.[158] At a congressional committee hearing in late January 2026, all five testifying health insurance executives confirmed that their companies would continue providing comprehensive vaccine coverage.[159] In May 2026, AHIP updated its September 2025 announcement to indicate that its member plans would continue to cover "all ACIP-recommended immunizations with no cost-sharing through the end of 2027." This statement does not specify a particular date of ACIP recommendations on which coverage will be based, as the last AHIP statement did.[160]

More than 60% of the individuals with private health insurance in the U.S. are in a self-insured plan provided by their (or a family member's) employer.[161] State health insurance requirements do not apply to such plans, and insurance companies' voluntary coverage commitments do not necessarily apply to such plans. The federal requirement on preventive services coverage does apply to these and most other types of private plans.

In sum, if the 2026 childhood immunization schedule goes into effect, there may be questions about its implications for private health insurance coverage for certain vaccines. However, vaccine coverage is unlikely to be affected in 2026, and some of the current questions about coverage could be addressed by ACIP, CDC, and other agency actions pursuant to E.O. 14407. If future changes in coverage are allowable per the federal requirements, certain plans may still be subject to state requirements on vaccine coverage, and plans may also continue providing coverage voluntarily.

Vaccine Injury Compensation

The Vaccine Injury Compensation Program is a no-fault compensation program for deaths and injuries allegedly caused by certain vaccines. From 2006 to 2024, 14,501 petitions for alleged vaccine injuries were adjudicated by VICP and 10,732 received compensation. During this same time period, over 5 billion doses of vaccines covered by the VICP were distributed in the United States. The Health Resources and Services Administration (HRSA, the HHS agency that administers VICP) has stated, "This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated." Most petitions are resolved through a negotiated settlement, though compensation can be achieved through other means (i.e., court

under the Trump administration." There may be more states that have previously existing requirements on vaccine coverage or recommendations.

[158] America's Health Insurance Plans (AHIP), "AHIP Statement on Vaccine Coverage," press release, September 16, 2025, archived at https://web.archive.org/web/20250917104217/https://www.ahip.org/news/press-releases/ahip-statement-on-vaccine-coverage.

[159] Modern Healthcare, "Insurance CEO hearings: Execs endure criticism on costs, business practices," January 22, 2026, https://www.modernhealthcare.com/politics-regulation/mh-health-insurance-ceo-hearings-live-updates/. See also, CQ, *House Ways and Means Committee Holds Hearing on Health Care Affordability*, CQ Congressional Transcripts, January 22, 2026.

[160] AHIP, "AHIP Statement on Vaccine Coverage," press release, updated May 2026, https://www.ahip.org/news/press-releases/ahip-statement-on-vaccine-coverage.

[161] As of December 2023, 196 million U.S. individuals were enrolled in a private health insurance plan, including approximately 121 million (62%) in a self-insured plan, per CRS analysis of National Supplemental Health Care Exhibit (SHCE) and California Department of Managed Health Care (DMHC) data, accessed August 2025. SHCE data accessed from Mark Farrah Associates, "Health Coverage Portal" (CRS subscription), https://www.markfarrah.com/. DMHC data accessed from California Health Care Foundation, "California Health Insurers, Enrollment Almanac – 2025 Edition," https://www.chcf.org/resource/california-health-insurers-enrollment-almanac/.

decision, concession) or the case may be dismissed.[162] According to the HRSA, 60% of all compensation awarded by VICP occurs through a negotiated settlement in which HHS has not "concluded, based on a review of the evidence, that the alleged vaccine(s) caused the alleged injury."[163]

To be entitled to VICP compensation, an injured party must first show that they have suffered a "vaccine related injury or death," which is defined in statute as an injury or death that is associated with a vaccine listed on the Vaccine Injury Table.[164] To be listed on the Vaccine Injury Table, a vaccine must be

- recommended by the CDC for routine administration to children or pregnant women,[165]
- added to the table by the HHS Secretary via rulemaking[166] or have been listed in the initial Vaccine Injury Table enacted into statute when the VICP program was signed into law,[167] and
- subject to an excise tax that funds the Vaccine Injury Compensation Trust Fund from which compensation is paid.[168]

Several of the vaccines with changed recommendations listed in the 2026 schedule released by CDC are vaccines currently listed in the Vaccine Injury Table. If the new schedule were to take effect, it would be legally unclear whether the vaccines whose recommendations were changed from being recommended for administration to all children to being recommended only for certain high-risk populations, or to being recommended for shared clinical decisionmaking, are still considered to be recommended for "routine administration" to children, in accordance with the VICP statute. The VICP statute and accompanying regulations do not define what it means for a vaccine to be recommended for routine administration to children. For more information, see CRS Legal Sidebar LSB11427, *CDC's Updated Childhood Vaccine Schedule: Litigation and Potential Implications for Vaccine Injury Compensation Program*, and CRS Report R46982, *Compensation for COVID-19 Vaccine Injuries*.

[162] HRSA, *Data and Statistics*, May 1, 2026, p. 4, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-05-01-26.pdf, and CRS Report R46982, *Compensation for COVID-19 Vaccine Injuries*.

[163] For additional information on VICP adjudication categories by vaccine from 2006 through 2024, see HRSA, *Data and Statistics*, May 1, 2026, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-05-01-26.pdf.

[164] PHSA Section 2133(5); 42 U.S.C. § 300aa-33(5).

[165] PHSA Section 2115(e); 42 U.S.C. §300aa–14(e).

[166] PHSA Section 2115; 42 U.S.C. §300aa–14.

[167] 1986 National Childhood Vaccine Injury Act (P.L. 99-660) Section 2114.

[168] 26 U.S.C. §§4132, 9510.

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