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Analysis of Health Provisions in the Consolidated Appropriations Act, 2026

The bill can be accessed here.

The FY26 Labor-HHS-Ed Appropriations joint explanatory statement can be accessed here.

Overview

On January 22, the House passed H.R. 7148, the Consolidated Appropriations Act, 2026, in a 341–88 vote, which provides fiscal year (FY) 2026 appropriations for the Department of Health and Human Services, as well as the Departments of Labor, Education, Defense, Transportation, and Housing and Urban Development. The bill is expected to be combined with the Financial Services and General Government and National Security, Department of State, and Related Programs Appropriations Act, 2026, which passed the House on January 14. On January 22, the House separately passed a bill to fund the Department of Homeland with a 220–207 vote. The Senate is expected to take up the package next week in advance of the January 30 deadline, after which it will be sent to the President. The package will require 60 affirmative votes in the Senate in order to pass. The legislation must be passed and signed into law by midnight January 30 to avoid a second government shutdown in FY 2026.

Key Takeaways

- The bill does not implement the reorganization of HHS that was proposed in the President's FY 2026 budget request. As such, the bill provides funding for several agencies and programs that were proposed for elimination, including the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Health Resources and Services Administration (HRSA). Additionally, the bill does not include funding for an Administration for a Healthy America and requires HHS to publicly provide a detailed plan and justification prior to initiating the execution of any reorganization that would move functions currently carried out by CDC to another component of HHS.

- The bill also avoids making significant funding cuts proposed in the President's FY 2026 budget request. Instead, the FY 2026 Consolidated Appropriations Act provides $116.8 billion to HHS, which is an increase of $210 million over FY 2025. This includes the following amounts for key agencies:
    - $48.7 billion for NIH (+$415 million over FY 2025), including $1.5 billion for the Advanced Research Projects Agency for Health (ARPA-H) (level with FY 2025);
    - $8.9 billion for HRSA (+$929 million over FY 2025);
    - $9.2 billion for CDC (level with FY 2025); and
    - $3.7 billion for the Administration for Strategic Preparedness and Response (ASPR) (+$1 million over FY 2025), including $1 billion for Biomedical Advanced Research and Development Authority (BARDA) (+$35 million over FY 2025), $850 million for Project BioShield (+25 million over FY 2025); $76.9 million for the National Disaster Medical System, and $1 billion for the Strategic National Stockpile (+$20 million over FY 2025).
- In addition to discretionary appropriations for FY 2026, the bill extends mandatory funding for several public health programs, including community health centers, two special diabetes programs, and two health care workforce programs.
- The bill includes several provisions related to the practices of Pharmacy Benefit Managers (PBMs), including a provision requiring PBMs to delink their prices from those for Medicare Part D, a prohibition on spread pricing in Medicaid, and a provision directing HHS to publish a report every two years on related enforcement and oversight actions taken by the department.
- The Consolidated Appropriations Act, 2026, extends several Medicare programs and payment policies, including telehealth flexibilities and Acute Hospital Care At Home waiver authorities, and further delays Medicaid Disproportionate Share Hospital (DSH) cuts.
- Additionally, the legislation reauthorizes several programs related to preventing maternal deaths, sickle cell disease prevention and treatment, Lifespan Respite Care, preventing premature births (PREEMIE), and providers' mental health (Dr. Lorna Breen Health Care Provider Protection). The Mikaela Naylon Give Kids a Chance Act, which extends the rare pediatric disease priority voucher, is also included in the package.
- Congressionally directed spending or community projects are included under SAMHSA, ACF, ACL, and HRSA.

FY 2026 Appropriations

Health Resources and Services Administration (HRSA)

- The bill provides $8.95 billion in discretionary funding for HRSA, an increase of $929 million above the FY 2025 level, to support HIV/AIDS services, community health centers, health workforce initiatives, maternal and child health programs, health facility construction and renovation, family planning, and rural health. Specifically, the bill includes:
    - $2.57 billion for the **Ryan White HIV/AIDS Program** to support HIV/AIDS care and treatment (level with FY 2025 amounts).

  - $1.86 billion for **Community Health Centers**, including $157.3 million for Ending the HIV Epidemic (level with FY 2025 amounts) and $55 million for School-Based Health Centers.
  - $45.6 million for the **Office for the Advancement of Telehealth** (+$3.5 million over FY 2025).
  - $27.85 million for Poison Control Centers.
  - $1.41 billion for **health workforce programs**, including the National Health Service Corps, nurse training programs, and primary care training.
  - $1.18 billion for **maternal and child health programs** (+$10 million over FY 2025), including $818.7 million for the Title V Maternal and Child Health Block Grant, along with funding for Healthy Start, newborn hearing screening, and maternal mortality prevention.
  - $417.9 million for rural health programs.
  - $15 million for grants to community-based organizations to develop produce prescription interventions for maternal populations at risk of poor health outcomes due to nutrition insecurity and other health-related factors.
  - $15.2 million for necessary administrative expenses for the **Vaccine Injury Compensation Program** and "such sums as may be necessary" for claims associated with vaccine-related injuries.
- The Joint Explanatory Statement (report) also includes funding for HRSA's **sickle cell disease** program. Appropriators note in the report language that there is concern regarding HRSA's proposed **340B Rebate Model Pilot Program** and require HRSA to provide a briefing to the committees within 30 days about the impact of the pilot program on patients.

National Institutes of Health (NIH)

- This bill funds **NIH** at $48.7 billion in FY 2026, an increase of $415 million above the FY 2025 level, to support biomedical research, scientific discovery, and innovation.
  - The bill includes $47.2 billion for NIH institutes and centers (ICs) and $1.5 billion for the **Advanced Research Projects Agency for Health (ARPA-H)**.
  - Funding is sustained across all 27 NIH Institutes and Centers, including approximately **$7.35 billion for the National Cancer Institute**, $**6.59 billion for the National Institute of Allergy and Infectious Diseases (NIAID)**, and $3.99 billion for the **National Health, Lung, and Blood Institute (NHLBI)**.
  - The bill includes a $100 million increase for **Alzheimer's disease research**, a $10 million increase each for **diabetes** and **rare disease research**, and continued support for the **BRAIN Initiative** through both base and 21st Century Cures Act funding, with a $4 million increase.
  - The bill also allocates funding for childhood cancer initiatives, antimicrobial resistance research, women's health research through the Office of Research on Women's Health, and minority health initiatives through the National Institute for Minority Health and Health Disparities.
- The report language continues to prevent HHS from making changes to the indirect costs rates that were in effect in the third quarter of FY 2017.
- It also requires NIH to brief the appropriations committees on a quarterly basis about efforts to fill IC director vacancies.

- The report language directs ICs that receive funding increases in FY 2026 to support new and competing research grants. This language relates to NIH's proposal to reserve funding to fully fund out year grant commitments, as some groups were concerned that implementing the proposed policy would significantly reduce the number of new grants awarded.

Centers for Disease Control and Prevention (CDC)

- The bill provides $9.2 billion in funding for CDC, including $7.7 billion in discretionary budget authority and $1.4 billion in transfers from the Prevention and Public Health Fund (PPHF). The bill and report provide funding for each of CDC's existing centers, including centers related to chronic disease prevention and health promotion, environmental health, and occupational health, which were significantly impacted by reduction-in-force (RIFs) actions in 2025.
    - Funding is maintained for **HIV/AIDS** ($1.01 billion), **Public Health Infrastructure and Capacity** ($360 million), **Tobacco Prevention and Control** ($247 million), **Data Modernization** ($185 million), and **Preventive Health and Health Services Block Grant** ($160 million PPHF transfer).
    - The bill funds the **Section 317 Immunization Program** at $681.9 million, maintaining the FY 2025 funding level to support vaccine access and immunization coverage nationwide.
    - The report language also includes $231 million for **influenza planning and response** and nearly $69 million for the **Racial and Ethnic Approaches to Community Health (REACH)** program.
    - **Opioid overdose prevention and surveillance programs** are maintained, including continued funding for the Overdose Data to Action initiative and research into emerging public health threats.
    - Under **emerging and zoonotic infectious diseases**, the agreement funds Lyme Disease activities at $27 million, Vector-Borne Diseases at $64.6 million, Emerging Infectious Diseases at $224 million, Food Safety at $74 million, and Epidemiology and Lab Capacity at $40 million (PPHF transfer).
    - Funding is also provided for **diabetes prevention** and control efforts, including initiatives focused on Native Americans, alongside continued funding for heart disease, stroke, cancer prevention, and injury prevention programs.
    - $6 million is included for the **Sickle Cell Disease Data Collection** program.

Substance Abuse and Mental Health Services Administration (SAMHSA)

- The bill provides $7.4 billion in discretionary funding for SAMHSA to address mental health and substance use disorders (+$65 million over FY 2025). The bill and report language reflect continued programs for which HHS recently terminated and then reinstated grant awards, including suicide prevention, Minority Fellowship, Medication Assisted Treatment, and Pregnant and Postpartum Women programs. The bill provides:
    - $4.1 billion for **substance abuse treatment**, including $1.6 billion for **State Opioid Response grants (+$20 million over FY 2025)**.

- $2.8 billion for **mental health services**, including $1.01 billion for the **Mental Health Block Grant** (MHBG) (+$5 million over FY 2025), $535 million for the 988 Suicide and Crisis Lifeline, $132 million for Programs for Children with Serious Emotional Disturbances, and $101 million for the National Child Traumatic Stress Network.
- $240.9 million for substance abuse prevention programs, including Drug-Free Communities and youth prevention initiatives.
- $203 million is provided for health surveillance and program support, including $54.3 million for community project funding and $31.4 million for national surveys and public awareness campaigns.

Administration for Community Living (ACL)

- The bill provides $2.5 billion for ACL, which includes $2.45 billion in discretionary funding for aging and disability services programs (-$50 million from FY 2025), along with a $55 million transfer from the Medicare Trust Funds.
  - The bill maintains more than $1 billion in funding for **Older Americans Act nutrition, caregiver, and supportive services**, including congregate and home-delivered meals, home- and community-based services, and health promotion.
  - The bill maintains $21.9 million for the Long-Term Care Ombudsman Program and continues funding for Adult Protective Services and Elder Justice programs, including the Senior Medicare Patrol.
  - Assistive Technology Act programs, Independent Living Centers, traumatic brain injury coordination, Aging and Disability Resource Centers, and Care Corps activities continue at previously enacted levels, with Care Corps funded at $5.5 million.

Administration for Children and Families (ACF)

- The bill provides $33 billion in discretionary funding for ACF to support early childhood education, childcare, welfare services, and refugee assistance. The package provides:
  - $14.9 billion for Children and Families Services Programs, including child welfare services, Child Abuse Prevention and Treatment Act (CAPTA) grants, child support enforcement, Temporary Assistance for Needy Families (TANF) contingency funding, and $75 million for adoption and guardianship incentives.
  - $12.4 billion for Head Start, a $85 million increase over FY 2025.
  - $8.8 billion for the Child Care and Development Block Grant (+$85 million increase over FY 2025) and requires that not less than 5 percent of such funds be reserved for payments to Indian Tribes and Tribal organizations.
  - $5.2 billion for Refugee and Entrant Assistance, including $5.1 billion available through FY 2028 for refugee services and unaccompanied children, with contingency funding for high referral levels and expanded transfer authority.
  - $4.05 billion for the Low-Income Home Energy Assistance Program.
  - $810.4 million for Community Services Block Grant Act programs, with authority for carryover of unexpended funds.

- $2 million for medical legal partnerships.

Administration for Strategic Preparedness and Response (ASPR)

- The bill provides $3.7 billion in discretionary funding for ASPR, an increase of $58 million above the FY 2025 level, to strengthen public health emergency preparedness and medical countermeasure development. The bill provides:
  - $3.2 billion for Research, Development, and Procurement, including $1.05 billion for **BARDA** and $850 million in funding for Project BioShield.
  - $1 billion in continued funding for the **Strategic National Stockpile**, and the package directs HHS to brief Congress on state-level stockpile guidance.
  - $484.6 million for operations, preparedness, and emergency response, supporting the National Disaster Medical System, Hospital Preparedness Program, emergency operations, and response teams.
- The report language also notes that the committees recognize the "challenges of developing single MCMs to address a wide range of known and unknown threats and supports efforts by ASPR to develop and validate biotechnology platform technologies that may be capable of addressing a variety of health security threats."
- The report language also notes support for investments to accelerate advanced development of investigational vaccines, therapeutics and diagnostics, as well as efforts to increase domestic manufacturing capacity of critical medicines or their active pharmaceutical ingredients.

Office of the Secretary

- The bill provides $509 million for General Departmental Management in the Office of the Secretary, a decrease of $201 million from FY 2025, and $87 million for the **Office of Inspector General**, level with FY 2025.
- Additionally, under the Office of the Secretary, the bill includes $69 million for the **Office of the National Coordinator (ONC)**, level with FY 2025, including $3 million to develop patient matching standards that prioritize interoperability, patient safety, and patient privacy.
  - The bill provides $5 million for ONC to support interoperability and information sharing efforts related to Fast Healthcare Interoperability Resources (FHIR) standards or associated implementation standards.
- Of note, the report language notes that "grant terminations can significantly and negatively impact the implementation of programs" and directs HHS to consult with the appropriations Committees prior to terminating grants, and specifically requires HHS notify the appropriations committees "no less than three days prior to announcing or providing notice of a grant termination."
- The bill also requires HHS to "support staffing levels necessary to fulfill its statutory responsibilities including carrying out programs, projects, and activities funded" in the bill in a "timely manner." HHS is also required to provide detailed plan and justification prior to initiating the execution of any reorganization moving functions that are carried by CDC to another component of HHS.

Centers for Medicare & Medicaid Services (CMS)

- The bill provides a total of $3.7 billion for CMS administrative expenses, equal to the 2025 level.
- This bill provides $508.15 billion for Grants to States for Medicaid in FY 2026, representing the estimated federal share of Medicaid benefit costs.
- The bill includes an advance appropriation of $316.5 billion for the first quarter of FY 2027 to ensure continuity of Medicaid payments.
- $699.1 million is designated for CMS program integrity activities to prevent fraud, waste, and abuse, and $108.7 million is provided for HHS Inspector General oversight of Medicare.
- The bill also provides $42 million through December 31, 2026, for implementation of the No Surprises Act.

Agency for Healthcare Research and Quality (AHRQ)

- The bill provides $345 million for AHRQ, a decrease of $24 million from FY 2025. This includes $214.1 million for research on health costs, quality, and outcomes, of which $11.5 million is intended for the U.S. Preventive Services Task Force.

Additional Provisions

Medicaid and CHIP Provisions

- The legislation **delays Medicaid disproportionate share hospital (DSH)** cuts set to begin on January 31, 2026, until FY 2028, and extends Tennessee's DSH allotments through FY 2027 (Sec. 6105). The legislation also changes the definition of the Medicaid shortfall component of the Medicaid DSH cap to include costs and payments for patients whose primary source of coverage is Medicaid and for patients who are dually eligible for Medicare and Medicaid. DSH caps determine the maximum amount of federal Medicaid DSH funding a hospital can receive (Sec. 6106).
- The legislation includes several additional changes to Medicaid. Specifically:
    - Sec. 6101 directs states to adopt and implement a process to allow eligible out-of-state providers to treat Medicaid and CHIP enrollees under the age of 21 without the imposition of additional screening or enrollment requirements. The provision notes that the state in which the provider is located must be determined to have a limited risk of waste fraud and abuse in their provider screening as determined by the Secretary or the State agency administering the plan. The provisions are effective for three years following enactment of the legislation.
    - Sec. 6102 removes the current age restrictions on the Medicaid Ticket to Work, in which people with disabilities may pay a premium to obtain Medicaid coverage, even if their earnings exceed the threshold. The section removes the upper age limit on the program, allowing adults over 65 to participate. States participating in the program must comply by January 1, 2028.

- Sec. 6103 provides that, for the purposes of Medicaid home and community-based services, active-duty members of the military and their dependents are treated as residents in the state in which they are stationed. This provision also allows members to retain their place on the waiting list for HCBS services in their state.
- Sec. 6104 requires that within 30 months of enactment and every five years after, each state must conduct, and submit to HHS, a study on the costs of providing maternity, labor, and delivery services in hospitals that are rural, receive predominantly Medicaid reimbursement for labor and delivery services, or furnish services for less than 300 births per year. $10 million is appropriated in FY 2026 for the purpose of providing grants and technical assistance to support hospitals in compiling the reports. An additional $3 million is appropriated to HHS in FY 2026 to support states with implementation.

Medicare Provisions

- The Consolidated Appropriations Act, 2026, extends several Medicare programs and payment policies. Specifically:
  - Sec. 6201 extends the increased inpatient hospital payment adjustment for certain **low-volume hospitals** through December 31, 2026.
  - Sec. 6202 extends the Medicare-dependent Hospital program through December 31, 2026.
  - Sec. 6203 extends add-on payments for ambulance services through December 31, 2027.
  - Sec. 6204 extends incentive payments for participation in eligible alternative payment models through payment year 2028 (for performance year 2026) and applies an adjustment amount of 3.1 percent for 2028.
  - Sec. 6205 provides $13.3 million in funding for quality measure endorsement, input, and selection for FY 2026, and $15.1 million for FY 2027.
  - Sec. 6206 provides $30 million for State Health Insurance Assistance Programs, $30 million for Area Agencies on Aging, $10 million for Aging and Disability Resource Centers, and $30 million to inform older Americans about benefits available under Federal and state programs. The funding extends these activities through December 31, 2027.
  - Sec. 6207 provides $4.4 million in funding for Medicare Hospice Surveys through December 31, 2026, or until expended.
  - Sec. 6208 extends the 1.0 work geographic practice cost index floor used in the calculation of payments under the Medicare physician fee schedule through December 31, 2026.
  - Sec. 6209 extends **telehealth flexibilities**, including removing geographic requirements, through December 31, 2027.
  - Sec. 6210 extends the Acute Hospital Care at Home initiative through September 30, 2030, and directs HHS to conduct and submit to Congress a study of the initiative by September 30, 2029.
  - Sec. 6217 extends Medicare Part D coverage of certain oral antiviral drugs through December 31, 2026.
  - Sec. 6218 extends the adjustment to calculation of the hospice cap amount through FY 2035 (previously through FY 2033).

- The legislation also:
  - Provides for cardiopulmonary rehabilitation to be furnished through telehealth between January 31, 2026, and January 1, 2028 (Sec. 6211).
  - Expands HHS oversight measures related to billing for DME items for which a substantial number of claims are ordered by a physician who has not previously furnished to the individual any items or service (Sec. 6212).
  - Directs HHS to issue guidance on best practices for furnishing telehealth services for individuals with limited English proficiency as well as improving the accessibility of digital patient portals and communications within a year of enactment (Sec. 6213).
  - Expands participation in the Medicare Diabetes Prevent Program (MDPP) to MDPP suppliers offering only distance learn or online delivery modalities for the period beginning January 1, 2026, to December 31, 2029 (Sec. 6214).
  - Directs HHS to provide education and outreach to Medicare physicians and other practitioners on screening for medication induced movement disorders associated with mental health treatment (Sec. 6215).
  - Directs GAO to report on "the capabilities and limitations of wearable medical devices used to support clinical decision-making," to include discussion of their capabilities to prescribe treatments, the use of AI to augment these devices, and related policy options (Sec. 6216).
  - Prohibits cost sharing for generic drugs for Part D beneficiaries who are eligible for the low-income subsidy (Sec. 6219).
  - Requires Medicare Advantage Organizations (MAO) to maintain on a public facing website an accurate provider directory. MAOs will be required to remove a provider from the directory within five business days if the organization determines that the provider is no longer in network, beginning with plan year 2028 (Sec 6220).
  - Adds multi-cancer early detection screening tests as a covered benefit beginning in 2029 (Sec. 6221).
  - Permits coverage of external infusion pumps and non-self-administrable home infusion drugs for use in the home. This provision also directs HHS to ensure that patients are notified of the cost sharing for selecting home infusion therapy compared to other care settings (Sec. 6222).
  - Requires hospitals to have unique national provider identifiers for off campus departments effective January 1, 2028. The legislation directs CMS to, through notice and comment rulemaking, establish a process for each provider with an off-campus outpatient department of a provider to submit attestation regarding their compliance with the provisions (Sec. 6225).
  - Delays scheduled payment reductions to the Medicare Clinical Laboratory Fee Schedule through 2026 (Sec. 6226).
  - Extends mandatory Medicare payment reductions of 2 percent under sequestration for an additional three months beginning in FY 2033 (Sec. 6227).

Drug Pricing Provisions

- The legislation includes several provisions (Secs. 6223, 6224 and 6701–6703) related to **Pharmacy Benefit Managers (PBMs)** that are nearly identical to the PBM package proposed for inclusion in the failed December 2024 appropriations bill. Specifically, the legislation:
    - Prohibits PBMs and their affiliates from deriving remuneration for covered Part D drugs based on the price of a drug.
    - Requires PBMs to define and apply drug and drug pricing terms in contracts with Part D plan sponsors transparently and consistently.
    - Creates annual requirements for PBMs to report on drug price and other information to Part D plan sponsor clients.
    - Provides Part D plan sponsors with new audit rights with respect to PBMs.
    - Requires group health plans and plan issuers to only contract with PBMs that agree to disclose certain information on drug pricing to the plans at least semi-annually, within 30 months of enactment.
    - Requires PBMs to pass through 100 percent of drugs rebates to the employer or health plans regulated under the Employee Retirement Income Security Act of 1974 (ERISA) for new contracts, extensions, or renewals entered into for plan years beginning 30 months after the date of enactment.
    - Codifies requirements that Medicare plan sponsors contract with any willing pharmacy that meets their standard contract terms and conditions.

Public Health Provisions

- The bill extends mandatory funding for the following public health programs:
    - $4.6 billion for **Community Health Centers** for FY 2026 and $1.16 billion for the period from October 1, 2026, to December 31, 2026.
    - $350 million for **National Health Service Corps** for FY 2026 and $88 million for the period from October 1, 2026, to December 31, 2026.
    - $225 million for the **Teaching Health Center Graduate Medical Education** program for FY 2026, $250 million for FY 2027, $275 million for FY 2028, and $300 million for FY 2029.
    - $200 million for the **Special Diabetes Program for Type I Diabetes** for FY 2026 and $50 million for the period beginning on October 1, 2026, and ending on December 31, 2026, to remain available until expended.
    - $200 million for FY 2026 and $50 million for the period on October 1, 2026, and ending on December 31, 2026, for the **Special Diabetes Program for Indians**.
- The bill also extends several key HHS **authorities related to national health security** through December 31, 2026 (Sec. 6403). These include:
    - The Assistant Secretary for Preparedness and Response's direct hire authority for the National Disaster Medical System;
    - The ability for states and Tribes to request temporary reassignment of federally-funded personnel;

  - Three national advisory committees related to preparedness and response, which are focused on individuals with disabilities, seniors, and children in disasters;
  - Authority related to limited antitrust exemptions for medical countermeasure meetings and consultations; and
  - Nondisclosure of certain national security-related information.
- The legislation reauthorizes and makes changes to several public health programs, including:
  - The **World Trade Center Health Program**: The legislation requires HHS to report on the program's budgetary needs, projected budget authority, and expenditures on a per-fiscal year basis through FY 2090 (Sec. 6411).
  - **Preventing Maternal Deaths**: The bill directs HHS to identify and disseminate best practices for preventing maternal morbidity and mortality to health care providers and professional societies at least once per fiscal year. The legislation also increases the authorization of appropriations for maternal mortality review committees and related maternal health programs to $100 million for each of FYs 2026 through 2030 (Sec. 6501).
  - **Organ Procurement and Transplantation Network**: The legislation grants the Secretary temporary authority (expiring three years after the enactment of the Consolidated Appropriations Act of 2026) to collect registration fees from OPTN members for each transplant candidate placed on the waiting list to support Network operations. This bill also prohibits grant administrators from considering the income of the organ recipient when providing reimbursement to a donating individual (Sec. 6502).
  - **Sickle cell disease prevention and treatment**: The bill reauthorizes HHS programs related to sickle cell prevention and treatment, increasing authorization amounts to $8.2 million for each of FYs 2026 through 2030. The bill also modified program language to focus explicitly on the "treatment of sickle cell disease and the prevention and treatment of complications" of the disease, rather than general prevention and treatment (Sec. 6505).
  - **Lifespan respite care**: This provision broadens the definition of "family caregiver" by replacing "unpaid adult" with "unpaid individual." Additionally, it reauthorizes the program's funding for FYs 2026 through 2030 (Sec. 6506).
  - **PREEMIE**: The legislation reauthorizes funding for research relating to preterm labor and the care of preterm infants for FYs 2026 through 2030 and mandates that the Secretary of HHS establish an interagency working group within 18 months of enactment. It also directs the Secretary to arrange for the National Academies of Science, Engineering, and Medicine to convene an expert committee within 30 days to study premature births. This committee must submit a report within 24 months containing raw data, an assessment of the financial costs to society and families including NICU and post-discharge costs, an analysis of factors impacting preterm birth rates, opportunities for early detection, and targeted research strategies for effective interventions and precision medicine (Sec. 6507).
  - **Dr. Lorna Breen health care provider protection**: The legislation expands eligibility for grants promoting mental health among the workforce to include entities that focus on reducing administrative burden on health care workers. The legislation also reauthorizes funding for these programs for FYs 2026 through 2030 (Sec. 6508).

- **Pediatric therapeutic studies**: The legislation reauthorizes $25 million for each of FYs 2026 through 2028 for NIH activities related to safety and efficacy studies of medication in pediatric populations (Sec. 6504).

Food and Drug Administration Provisions

- The legislation includes the **Mikaela Naylon Give Kids a Chance Act** to:
  - Modify requirements relating to pediatric cancer research to permit research of new drugs in combination with active ingredients that currently meet certain standards.
  - Require FDA to issue guidance within one year of enactment on the implementation of the requirements, and to issue final guidance within one year of the end of the comment period, and to provide a report to Congress within six years of enactment on the program's implementation.
  - Permit FDA to take enforcement action against drug sponsors that fail to comply with pediatric study requirements should they have been determined by FDA to have lacked due diligence in satisfying the requirements.
  - Require FDA to conduct an evaluation of compliance with the Pediatric Research Equity Act.
  - Reauthorize the pediatric priority review voucher program for products intended for pediatric rare diseases through FY 2029.
  - Require GAO to conduct and submit a report to Congress on the effectiveness of the program within five years of enactment.
  - Direct GAO to conduct a study of the effectiveness of requiring investigations in the develop of drugs for pediatric cancer indications and submit to congress ten years after enactment.
- The legislation also:
  - Requires FDA to inform **generic drug applicants** of whether the generic drug is quantitively or qualitatively the same as the listed drug, and if so, to provide specific information regarding the ingredients that cause the drug to be quantitative or qualitatively different and the amount of deviation. FDA is required to issue draft guidance or update existing guidance detailing this process within one year of enactment, and final guidance within one year of the close of the comment period on the draft guidance.
  - Clarifies that the **exclusivity period for orphan drugs** in the Orphan Drug Act is limited to the approved indication of the drug.
  - Requires FDA to create **Abraham Accords Offices** to provide technical assistance to regulatory partners in Abraham Accords countries on regulatory oversight, and support conformity with FDA regulatory requirements in these countries (Sec. 6611).