

**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
**Statement of Regulatory Priorities for Fiscal Year 2025**

As the Federal agency with principal responsibility for protecting the health of all Americans and providing essential human services, the Department of Health and Human Services (HHS or the Department) implements programs that strengthen the health care system; advance scientific knowledge and innovation; and improve the health, safety, and wellbeing of the American people.

The Department's Regulatory Plan for Fiscal Year (FY) 2025 focuses on lowering costs and expanding coverage, reducing disparities, and advancing equity, increasing public health preparedness, and supporting the wellbeing of families and communities. Highlights from the FY2025 Regulatory Plan include:

- Policies to expand access to affordable care and protect health coverage following the end of the COVID-19 public health emergency.
- Advancing health and safety across the health care delivery system through policies and programs that promote health equity.
- Bolstering the Department's ability to identify and prevent future public health threats.
- Improving the Department's ability to identify foodborne illnesses and advancing work to improve consumers' ability to access nutritious food to prevent disease and protect public health.

In short, the Department's Regulatory Plan reflects the Biden-Harris Administration's commitment to continue building a better, healthier America, through rules designed to protect and enhance the lives of every person touched by HHS programs.

## I. Lowering health care costs and expanding access to coverage

The Biden-Harris Administration has worked to expand and strengthen coverage for millions of Americans enrolled in Medicare, Medicaid, or ACA Marketplace plans. In implementing key provisions of the Inflation Reduction Act, HHS rules will help lower the cost of prescription drugs in Medicare. HHS has prioritized efforts to protect health coverage following the end of the COVID-19 public health emergency, working with State partners to make it easier for beneficiaries and consumers to stay covered.

### a. Enhancing coverage and access in the ACA Marketplaces, Medicaid, CHIP, and Medicare

Rulemaking related to Medicare, Medicaid, and the ACA Marketplaces will strengthen coverage under these programs and help make it easier for Americans to stay covered. HHS will propose a rule to streamline processes for the prior authorization of certain drugs so that patients have timely access to the medications they need as part of their health care. The proposed rule would serve to further address obstacles and process-related challenges associated with the prior authorization of drugs, which continues to be a significant source of provider burden and directly affect patient care. The proposed rule will also include updates to the technical standards to support implementation of CMS interoperability policies, and requirements to report certain metrics to CMS.

In addition, CMS will issue annual payment rules and notices over the next year that affect federal health programs, including Medicare and the ACA Marketplace. Though they are not included in the HHS Regulatory Plan, these rules will include policies that further the Secretary's priority of expanding access to affordable, high-quality health care.

b. Expanding the accessibility and affordability of drugs and medical products

Under the Inflation Reduction Act (IRA), HHS policy allows Medicare to negotiate the cost of some drugs and provide coverage without cost sharing for recommended vaccines in the Medicare program. The IRA requires rebates if the cost of some Medicare Part B physician-administered drugs rise faster than the rate of inflation—reducing costs and increasing peace of mind for millions of older Americans and those with disabilities.

In FY2025, HHS will propose a rule amending the regulations regarding coverage of preventive services under the Public Health Service Act, to ensure all plans allow patients to receive coverage without cost-sharing requirements for recommended, medically necessary preventive services, as determined by their health care provider. This proposed rule would also expand preventive services coverage to recommended over-the-counter drugs, including contraceptives, without cost-sharing.

c. Streamlining the secure exchange of health information

The secure exchange of health information and interoperability among health care providers and other entities improves patient care, promotes competition, reduces costs, and provides more accurate public health data. Considering increasing cyberattacks targeting critical infrastructure, upcoming HHS rulemaking will propose modifications to the HIPAA Security Rule to improve cybersecurity in the health care sector by strengthening requirements for HIPAA regulated entities to safeguard individuals' electronic protected health information to prevent, detect, contain, mitigate, and recover from cybersecurity threats.

## II. Reducing Disparities and Advancing Equity

Equity is the focus of over a dozen Executive Orders issued by President Biden, and it remains a cornerstone of the Biden-Harris Administration's agenda. The Department recognizes that people of color; people with disabilities; lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) people; and other underserved groups in the U.S. have been systematically denied a full and fair opportunity to participate in economic, social, and civic life. Among its other manifestations, this history of inequality shows up as persistent disparities in health and social outcomes and in access to care.

As the Federal agency responsible for ensuring the health and wellbeing of Americans, the Department, under Secretary Becerra's leadership, is committed to tackling these entrenched inequities and their root causes throughout its programs and policies. The Department's regulatory priority of reducing disparities and advancing equity includes rules aimed at preventing and remedying discrimination, strengthening health and safety standards for consumer products that impact underserved communities, and promoting equity in federally supported health care services.

### a. Preventing and remedying discrimination

The HHS Regulatory Plan includes actions to eliminate discrimination as a barrier for historically marginalized communities seeking access to HHS programs and activities. For instance, the Department has issued a proposed rule addressing discrimination on the basis of disability in health and human services programs or activities. This rule would revise regulations under section 504 of the Rehabilitation Act of 1973 to address unlawful discrimination on the

basis of disability in HHS-funded health and human services programs. The proposed rule includes new requirements prohibiting discrimination in the areas of medical treatment; the use of value assessments; web, mobile, and kiosk accessibility; and requirements for accessible medical equipment, so that persons with disabilities have an opportunity to participate in or benefit from health care programs and activities that is equal to the opportunity afforded others. It also adds a section on child welfare to expand on and clarify the obligation to provide nondiscriminatory child welfare services. The proposed rule would also update the definition of disability and other provisions to ensure consistency with statutory amendments to the Rehabilitation Act, enactment of the Americans with Disabilities Act and the Americans with Disabilities Amendments Act of 2008, the Affordable Care Act, as well as Supreme Court and other significant court cases. It also further clarifies the obligation to provide services in the most integrated setting.

b. [Strengthening health and safety standards for consumer products, including those that disproportionately impact underserved communities](#)

To protect the public health and advance equity, the Department continues to pursue regulatory action with respect to consumer products that harm the health of underserved groups. For example, HHS will propose a rule to require the labeling of fragrance allergens on cosmetic products, providing information that will help consumers to avoid products containing fragrance ingredients to which they may be allergic, and the significant health impacts associated with sensitizing reactions. We will also propose rulemaking to establish good manufacturing practices for cosmetic product facilities, employing a quality management system approach to help ensure the safety of cosmetic products by minimizing or preventing the distribution of cosmetic products that are unsafe due to contamination,

c. Promoting equity in federally supported health care services

The Department continues to seek out opportunities to embed equity throughout HHS programs and policies, including in federally supported health care services, and through upcoming rulemaking aimed at identifying appropriate culturally competent and person-centered care requirements for Medicare and Medicaid participating providers. The Department will continue to provide comprehensive, culturally appropriate and quality personal and public health services to American Indian and Alaskan Native people through the Indian Health Service (IHS).

III. Increasing Public Health Preparedness

Protecting the nation's public health is a primary responsibility of the Department. This responsibility includes ensuring that the right protections and infrastructure are in place to help the nation to respond to public health threats and outbreaks quickly and effectively. It also includes ensuring healthy and safe food for every American through protections against foodborne illness in the food supply chain.

In service of this regulatory priority, over the next year, the Department is pursuing rules that would bolster the nation's resilience to better manage the long-term effects of COVID-19 and to identify and prepare for future public health threats and improve Americans' access to safe and nutritious food.

a. Bolstering the nation's resilience to manage COVID-19 and future public health threats

In the context of COVID-19 and other disease outbreaks, it is crucial for public health authorities to be able to identify and evaluate persons who may have been exposed to a communicable disease.

HHS will propose rulemaking that incorporates learnings from the COVID-19 public health emergency into updates to national emergency preparedness requirements for participating Medicare and Medicaid providers, to assure adequate planning for natural and man-made disasters, including climate-related disasters, and seamless coordination with official emergency preparedness systems.

b. [Improving access to safe and nutritious food](#)

To help ensure healthy and safe food for every American, the HHS Regulatory Plan includes rules that improve the Department's ability to identify foodborne illnesses, prevent them from reoccurring, and remove unsafe products from the market.

The HHS Regulatory Plan supports the goals of the White House Conference and Strategy on Hunger, Nutrition, and Health, by advancing work to improve consumers' ability to access nutritious food to prevent disease and protect public health. The Department seeks to improve dietary patterns in the United States to help reduce the burden of diet-related chronic diseases. As such, proposed rulemaking that would standardize food package labeling will help consumers more easily identify nutritious foods and maintain healthy diets.

IV. [Supporting the Wellbeing of Families and Communities](#)

The Department strives to support the wellbeing of Americans by funding and providing access to a range of critical social services. Millions of people benefit from HHS programs that help older adults and people with disabilities participate fully in their communities, promote opportunity and economic security for families, help refugees and other eligible newcomers integrate and thrive, and provide care for unaccompanied children. The Secretary recognizes that

these programs and forms of assistance are more important than ever due to ongoing consequences of the pandemic, which have had an outsized impact on people of color and other underserved communities.

To sustain and strengthen these essential benefits and services, the Department is prioritizing regulations that would improve their quality and accessibility while reducing burdens and increasing the efficiency of service delivery. The Secretary's regulatory priority in this area includes rules aimed at, expanding opportunities for children and youth to thrive, and providing pathways to economic success.

a. [Expanding opportunities for children and youth to thrive](#)

The Department's mission to provide effective human services includes a focus on protecting the wellbeing of children and youth. This focus has special significance given the ongoing consequences of the pandemic, which have deeply affected the lives of children and youth—particularly Black, Latino, Indigenous, Native American, and other underserved youth with disproportionate involvement in the child welfare system. Several rules planned for FY 2025 are aimed at enhancing programs and protections for youth and families experiencing foster care, unaccompanied children in the Department's care, and individuals entitled to child support.

Building on its recently finalized Unaccompanied Children Program Foundational Rule, the Department continues to strengthen services and protections for unaccompanied children in its care and will finalize policy in FY2025 satisfying a court order allowing the Office of Refugee Resettlement to terminate the Flores Settlement Agreement.



Additionally, a new proposed rule would update the Tribal Child Support Program to promote Tribal self-determination by allowing tribes to privatize particular child support services (which states are currently able to do), such as locating noncustodial parents, establishing paternity, or collecting support owed; ensure timely access to federal funding by extending the period for review and approval of tribal budget submissions; and lessen program reporting burdens. This regulation demonstrates the federal child support program's commitment to promoting equity and ensuring federal funding for tribes and tribal organizations is accessible, flexible, and equitable.

b. [Providing pathways to economic success](#)

The Department will finalize its rule to allow Federal support for employment and training services for non- custodial parents as a supplement to traditional enforcement tools, to make the child support program more effective and help noncustodial parents find and sustain work to be able to support their children.

Additionally, the Department will propose changes to the Runaway and Homeless Youth Program that will increase access for youth and young adults and build the capacity of community-based organizations to provide high-quality services that meet the diverse needs of youth and young adults seeking services through the RHY program, to support a successful transition to adulthood and build a pathway to self-sufficient.