

DEPARTMENT OF HEALTH & HUMAN SERVICES

Statement of Regulatory Priorities for Fiscal Year 2024

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) 2024 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 FY2024 Regulatory Plan include:

- Policies to expand access to affordable care and protect health coverage following the end of the COVID-19 public health emergency.
- Policies to strengthen Federal early care and education programs that enhance quality of services to children and families, lower child care costs for working families, and provide needed support to early educators.
- Advancing health and safety across the health care delivery system through policies and programs that promote health equity.
- Expanding access to the full continuum of mental health and substance use prevention, treatment, and recovery.
- 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.
- Strengthening services for older Americans to allow them to remain in their communities.
- Ensuring that children and youth receive safe and appropriate care and support in order to thrive.

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. In response to the President's Executive Orders to strengthen Medicaid and the ACA, HHS rules will simplify the enrollment process to help maintain continuous coverage for vulnerable populations and reduce administrative burdens for States, while improving access to care, quality, and health outcomes across delivery systems. HHS rules will set a minimum access standard in Medicaid and CHIP programs, advancing access to care for adult and pediatric populations in primary care, behavioral health, home and community-based services and maternal health.

In collaboration with the Departments of Labor and Treasury, HHS has issued proposed rules to improve the comprehensiveness of coverage and protect consumers from low-quality coverage. These rules will help to expand access to mental health and substance use care and preventive services as well as

ensure that consumers protected from buying coverage through Short-Term, Limited-Duration Insurance (STLDI) that provide little to no coverage and can discriminate against those with pre-existing conditions.

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 will allow Medicare to negotiate the cost of some drugs and provide coverage without cost sharing for recommended vaccines in the Medicare program. The IRA will require 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.

Consistent with the President's drug pricing priorities, revisions to the 340B Drug Pricing Program's (340B Program) Administrative Dispute Resolution (ADR) rule would establish new requirements and procedures for the Program's ADR process, making the process more equitable and accessible for participation, while supporting the Program's mission to expand access to health care for underserved communities.

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. Upcoming HHS rulemaking will implement provisions of the 21st Century Cures Act to set out disincentives for health care providers who engage in information blocking, ensuring effective health

information exchange and patient access to quality care. HHS will also issue proposed 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.

In addition to the specific rulemakings identified in this section, HHS is committed to advancing equity in all aspects of the Department's work. Consistent with President Biden's Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (EO 13985), the Department's efforts in this area include an ongoing assessment of whether underserved communities face barriers in accessing benefits and opportunities in HHS programs and whether policy changes are necessary to advance equity. This process continues to inform the Department's broader regulatory agenda.

Further, HHS continues to seek out meaningful and equitable opportunities for public input by a range of interested or affected individuals and communities, including underserved communities, to inform our regulatory actions consistent with Executive Order 14094, Modernizing Regulatory Review.

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 plans to finalize its rule on nondiscrimination in health programs and activities, which would amend the existing regulations implementing Section 1557 of the ACA, ensuring that the regulations reflect the proper scope of the statute's protections. Because discrimination in the U.S. health care system is a driver of health disparities, the Section 1557 regulations present a key opportunity for the Department to promote equity and ensure protection of health care as a right.

Additionally, 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.

Further, the Department plans to finalize two rules that prohibit menthol as a characterizing flavor in cigarettes and prohibit all characterizing flavors (other than tobacco) in cigars. These and other potential future regulatory actions would significantly reduce disease and death from combusted tobacco product use, the leading cause of preventable death in the United States.

The regulations are also expected to promote better health outcomes across population groups. Evidence shows that menthol cigarettes are disproportionately marketed to specific communities —such as disproportionate storefront and outdoor marketing, as well as point-of-sale marketing, in Black, Hispanic, and low-income communities. The disparities in tobacco marketing and use shape disparities in tobacco-related disease and death. These planned regulatory actions on tobacco are expected not only to benefit the population as a whole, but in doing so, also substantially decrease tobacco-related health disparities.

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 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.

Currently, the Centers for Disease Control and Prevention (CDC) is authorized to require airlines to collect certain data regarding passengers and crew arriving from foreign countries for the purposes of health education, treatment, prophylaxis, or other appropriate public health interventions, including contact tracing and travel restrictions. The Department intends to finalize a rulemaking in FY 2024 that allows the Department to continue to receive data in a timely manner and more effectively provide critical public health services in response to COVID-19 and other communicable diseases that may put Americans' health at risk.

HHS will also propose rulemaking that incorporates learnings from the 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 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. For example, the Department intends to finalize a rule intended to improve the safety of produce by requiring farms to conduct comprehensive assessments of pre-harvest agricultural water that would help farms identify and mitigate hazards in water used to grow produce.

The HHS Regulatory Plan also 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. Another way HHS is working towards creating a healthier food supply is by proposing a rule that would permit use of salt substitutes, rather than salt, to help reduce the amount of sodium in standardized foods. Moreover, proposed rulemaking that would standardize food package labeling and finalization of a rule updating the definition of the term "healthy" would 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 strengthening high-quality services for older adults, expanding opportunities for children and youth to thrive, and providing pathways to economic success.

a. [Strengthening high-quality services for older adults](#)

The HHS Regulatory Plan includes rules aimed at enhancing the ability of Administration for Community Living (ACL) programs to protect the rights and wellbeing of older adults. For instance, the Department plans to finalize regulations for Adult Protective Services (APS) programs that will strengthen services for older adults and adults with disabilities that may experience elder abuse.

Furthermore, consistent with the Biden-Harris Administration's Nursing Home Reform Action Plan, the Department's Regulatory Plan includes efforts to improve the safety and quality of care in the nation's nursing homes. For example, the Department plans to finalize rules that institute minimum staffing standards in nursing homes, protect residents, and prevent fraud, waste, and abuse, and mandate transparency of ownership, management, and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities. These efforts complement the Department's ongoing efforts to also strengthen long term services and supports delivered to older adults and people with disabilities in their homes and communities.

Notably, consistent with the Administration's commitment to maximize transparency and public engagement, and to allow communities greater opportunities to provide input in the regulatory process, HHS sought the expertise of colleagues in the Office of Management and Budget, the General Services Administration, and the Consumer Financial Protection Bureau to inform an alternative approach to public comments for the proposed nursing home minimum staffing rule. The Department ultimately established

and disseminated in public materials a direct web link to allow a more accessible comment submission path to the public, lowering the barriers to participation for the nursing home residents, families, and facility staff who will be directly impacted by this regulation.

b. [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 2024 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.

As part of its focus on the foster care and the child welfare system, the Department plans to clarify requirements for title IV-E/IV-B agencies to effectively serve LGBTQI+ children and families by ensuring safe and appropriate foster care placements and ensure a process that is responsive to children's concerns. The Department recently issued a final rule allowing licensing standards for relative or kinship foster family homes that are different from non-relative or non-kinship homes. These changes reduce barriers to licensing for relatives and kin who can provide continuity and a safe and loving home for children when they cannot be with their parents. Additionally, the Department recently issued a proposed rule to facilitate the provision of independent legal representation to a child who is a candidate for foster care, or in foster care, and to a parent preparing for participation in foster care legal proceedings. Improving access to independent legal representation may help prevent the removal of a child from the home or, for a child in foster care, achieve permanence faster.

The Department will also finalize a rule to amend the Child Care and Development Fund (CCDF) regulations with changes that will lower child care costs for families, increase parent's child care options,

reduce barriers to receiving child care assistance, increase payments to providers, support higher program quality, and improve child care stability.

Moreover, the Department will propose a rule that aims to improve the quality, stability, and continuity of comprehensive Head Start services for thousands of children and their families by adding provisions to the Head Start Program Performance standards to better support the Head Start workforce.

The Department also plans to finalize a rule to strengthen services and protections for unaccompanied children in its care.

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

In administering the Temporary Assistance for Needy Families (TANF) program, the Department works with States, territories, and tribes to help children and families achieve economic success. The COVID-19 pandemic highlighted the importance of using Federal investments and existing program flexibilities strategically to reduce family poverty and alleviate economic crises, especially for families of color and underserved communities. In the next year, the Department plans to finalize a rule to reform the TANF program to strengthen its role as a safety net and for families and individuals with the lowest incomes. The proposed rule would strengthen TANF's role in supporting family well-being and work, as well as creating additional accountability for States to ensure TANF funds serve their intended purpose, while maintaining State flexibility. These changes are intended to improve the overall wellbeing of families while addressing inequities in program services and policies.

Additionally, the Department is proposing 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.