

DEPARTMENT OF HEALTH & HUMAN SERVICES
Statement of Regulatory Priorities for Fiscal Year 2023

As the federal agency with principal responsibility for protecting the health of all Americans and for 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) 2023 is focused on expanding access to health care, tackling disparities and advancing equity, increasing the nation's public health preparedness, and supporting the wellbeing of families and communities. To highlight a few of these regulatory priorities:

- **This Plan expands access to health care and strengthens behavioral health**, with rules that expand evidence-based behavioral health treatment via telehealth and streamline enrollment and improve access to care for children and families through the Medicaid program and the Children's Health Insurance Program (CHIP), among others.

- **The Department is also taking action to advance equity in health and social outcomes**, including through rules designed to prevent discrimination and protect every person's ability to equitably obtain health care and human services, regardless of where they live, who they are, or their background.

- **Forthcoming rules would also increase the nation's public health preparedness**, such as measures aimed at ensuring Americans are able to access safe produce and imported foods, and rules that would bolster the Department's ability to respond to the spread of COVID-19 and prevent future public health threats.

- **This Plan supports the wellbeing of families and communities** by including rules that would strengthen services for older Americans to allow them to live in their communities, as well as ensure that children and youth receive the care and support they need 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 help protect the public health and to improve the health and wellbeing of every person touched by HHS programs.

I. Building and Expanding Access to Affordable Health Care

The Biden-Harris Administration is committed to ensuring that high-quality health care is accessible and affordable for every American. The Inflation Reduction Act of 2022 (IRA), signed by President Biden in August, lowers costs for American families by continuing increased premium tax credits for plans under the Affordable Care Act (ACA), allowing the federal government to negotiate prices for certain drugs under Medicare, and more. The Bipartisan Safer Communities Act of 2022, signed by President Biden in June, expands capacity and advances access to behavioral health treatment, particularly for children and youth. Additionally, President Biden's Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage (EO 14070) calls on federal agencies—including the Department—to continue to expand the availability of health care coverage, improve its quality, strengthen benefits, and help more Americans enroll.

Charged with overseeing federal health programs such as Medicare, Medicaid, CHIP, and the ACA Marketplace, the Department plays a central role in the Administration's agenda to protect and strengthen access to health care. From day one of this Administration, the Department has worked closely with states to expand Medicaid to hundreds of thousands of newly eligible people and to allow Medicaid enrollees who are pregnant to keep their coverage for up to one year after pregnancy. The Department has also maximized opportunities to enroll a record number of people in ACA coverage and strengthened

policies related to coverage and benefits in the ACA Marketplace. These actions, alongside others, have contributed to an all-time low uninsured rate among Americans.

Over the next year, the Department will build upon its previous efforts by pursuing rules aimed at enhancing coverage and access to benefits in the ACA Marketplaces and the Medicaid, CHIP, and Medicare programs; expanding the accessibility and affordability of drugs and medical products; addressing behavioral health needs; and streamlining the secure exchange of health information.

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

The Department will take several regulatory actions in the next year to improve access to care for Americans in the ACA Marketplace, Medicaid, CHIP, and Medicare. For example, the Department expects to finalize a rule on eligibility and enrollment processes in Medicaid and CHIP that will streamline the application, eligibility determination, enrollment, and renewal processes for these programs and create new pathways to maximize enrollment and retention of eligible individuals.

Additional rules would promote access to care in Medicaid and CHIP and raise standards for hospitals, providers, and other entities participating in Medicare and Medicaid. For example, the Department plans to issue a proposed rule that would establish cultural competency and person-centered care requirements for all provider and supplier types that participate in the Medicare and Medicaid programs.

The HHS Regulatory Plan also includes regulations aimed at improving access to care for consumers in the ACA Marketplaces. For instance, the Department plans to propose a rule on provider nondiscrimination requirements for certain health plans and issuers. This rule would protect patients' access to care and promote competition by ensuring that plans do not engage in unlawful discrimination against health care providers. The Department will also work to ensure access to benefits and services afforded under the law. A critical part of this work will include amending regulations on contraceptive

coverage which guarantee cost-free coverage to the consumer under the ACA. Finally, the Department will propose to amend regulations on short-term limited duration plans to better ensure access to comprehensive coverage for Americans, especially those with pre-existing conditions.

In addition to the above, the Centers for Medicare & Medicaid Services (CMS) will issue several annual payment rules and notices over the next year that affect federal health programs, including Medicare and the ACA Marketplace. These rules, though they are not included in the HHS Regulatory Plan, 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

Over the next year, the Department will continue expanding the accessibility and affordability of drugs and other medical products for Americans. For example, the Department expects to issue a final rule to set requirements for nonprescription drug products with an additional condition to ensure appropriate self-selection or appropriate actual use (or both) for consumers. This rule is expected to increase consumer access to nonprescription drugs, which could mean a reduction in under-treatment of certain diseases and conditions. The Department also plans to propose updates to the Food and Drug Administration (FDA) biologics regulations to support competition and enhance consumer choice through changes that would prevent efforts to delay or block competition from biosimilars and interchangeable products.

The Department is also working to implement the IRA through policies aimed at reducing the high cost of prescription drugs for people with Medicare. Furthermore, the Department is committed to making sure Medicare beneficiaries are able to access emerging technologies and will initiate notice and comment rulemaking in the coming months to explore policy options that would create an accelerated approval pathway. This pathway would build on prior initiatives, including coverage with evidence development.

In addition, in November 2022, the Department issued a proposed rule on the Administrative Dispute Resolution (ADR) process used to settle certain disputes among covered entities and manufacturers

arising under the 340B Drug Pricing Program. This rule would establish new requirements and procedures for the Program's ADR process, making the process more equitable and accessible for participation by program participants, and supporting the Program's mission to expand access to health care for underserved communities.

c. Addressing behavioral health needs

The Secretary remains committed to expanding access to integrated and equitable behavioral health services, including by addressing the impacts of the COVID-19 pandemic on mental health and substance use, which have disproportionately affected young people and underserved communities. This commitment will guide the Department's planned regulatory activity for FY 2023, which includes several rules aimed at tackling mental health challenges and substance use disorders.

For example, the HHS Regulatory Plan includes a proposed rule that is intended to make permanent certain telehealth flexibilities for substance use disorder treatments that were granted during the COVID-19 public health emergency. This rule would allow certain providers to provide buprenorphine via telehealth, as well as provide extended take-home doses of methadone to patients, when it is safe and appropriate to do so. Both changes are intended to increase access to comprehensive opioid use disorder treatment and may address barriers to treatment such as transportation, geographic proximity, employment, or other required activities of daily living.

Working closely with the Departments of Labor and the Treasury, the Department will also issue a proposed rule to implement portions of the Mental Health Parity and Addiction Equity Act (MHPAEA) and the Consolidated Appropriations Act, 2021. The MHPAEA is a federal law that prevents group health plans and health insurance issuers that provide mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical and surgical benefits. This rule would clarify group health plans and health insurance issuers' obligations under the MHPAEA and promote compliance with MHPAEA, among other improvements.

In November 2022, the Department also announced a proposed rule on the confidentiality of substance use disorder patient records. Consistent with the CARES Act, this rule would align HHS regulations governing the disclosure and use of substance use disorder patient records (42 CFR Part 2) with aspects of the HIPAA Privacy, Breach Notification, and Enforcement Rules; strengthen protections against uses and disclosures of patients' substance use disorder records for civil, criminal, administrative, and legislative proceedings; and require that a HIPAA Notice of Privacy Practices address privacy practices with respect to Part 2 records.

d. 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.

To help ensure greater interoperability and transparency, the HHS Regulatory Plan includes rules focused on addressing and preventing information blocking, consistent with the 21st Century Cures Act (Cures Act). For instance, the Department plans to finalize a rule that would, among other things, empower the HHS Office of the Inspector General (OIG) to investigate claims of information blocking and impose civil monetary penalties on health IT developers and health information networks where appropriate. Another complementary proposed rule would implement the Secretary's authority under the Cures Act to establish appropriate disincentives for health care providers found to have committed information blocking. The Department is also proposing a rule on the Electronic Health Record (EHR) Reporting Program condition and maintenance of certification requirements under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program, which would include enhancements to support information sharing under the information blocking regulations.

The Department is also advancing interoperability policies in the context of the federal health programs it administers and oversees. For example, the Department will propose rules to improve the electronic exchange of health care data and streamline processes related to prior authorization for Medicare Advantage (MA) organizations, Medicaid managed care plans, CHIP managed care entities, state Medicaid and CHIP fee-for-service (FFS) programs, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchange (FFE). Similarly, the Department's upcoming proposed rule on strengthening and improving the Medicare Advantage and prescription drug programs will include provisions proposing to enhance interoperability within Medicare.

II. Tackling 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 tackling 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.

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 will issue 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. Topics that HHS may cover include nondiscrimination in medical treatment, child welfare programs and services, value assessment methodologies, accessible medical equipment, information and communication technology, and other relevant health and human services activities.

b. Strengthening health and safety standards for consumer products that 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.

Over the next year, 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 have the potential to 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 tobacco is disproportionately marketed to underserved communities and vulnerable populations—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 by the Department 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. The World Trade Center (WTC) Health Program is a limited federal health program that provides no-cost medical monitoring and treatment for certified WTC-related health conditions to those directly affected by the 9/11 attacks. The Department plans to issue a proposed rule to add uterine cancer to the List of WTC-Related Health Conditions. Permitting the Program to pay for medically necessary treatment, this rule would advance health equity for those WTC Health Program members who are found to have WTC-related uterine cancer.

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, including COVID-19. 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 handle COVID-19 and future public health threats and improve Americans' access to safe and nutritious food.

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

The Department continues to play a central role in the Biden-Harris Administration's whole-of-government response to the COVID-19 pandemic. From ensuring access to COVID-19 testing, treatment, and vaccines, to bolstering the capacity of the health care system in a public health emergency, Secretary Becerra has leveraged the Department's full resources to pursue a comprehensive strategy to combat COVID-19.

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, on an interim basis, 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 this regulation in FY 2023. This would allow 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.

In addition to strengthening the public health system, the Department is continuing to address the need for flexibility in HHS programs to minimize disruptions and alleviate burdens that may be caused by

COVID-19 or future emergencies. To that end, the Department also plans to finalize its rule allowing current grantees under the Administration for Native Americans (ANA) to request an emergency waiver for the non-federal share match. This update to ANA's regulation would provide a new provision for recipients to request an emergency waiver in the event of a natural or man-made emergency such as a public health pandemic.

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. It also supports the goals of the White House Conference on Hunger, Nutrition, and Health, by advancing work to improve consumers' ability to access nutritious food to prevent disease and protect public health.

For example, the Department will 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. Moreover, the Department is proposing a rule that would require importers of certain foods to certify, or otherwise provide appropriate assurances, that these imported foods comply with U.S. safety requirements. This rule would help prevent potentially harmful imported foods from reaching consumers and thereby improve the safety of the U.S. food supply. In November 2022, the Department finalized its rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods identified on the Food Traceability List (FTL). This rule is intended to make it easier to rapidly and effectively track the movement of a food to prevent or mitigate a foodborne illness outbreak.

In addition, the Department seeks to improve dietary patterns in the United States to help reduce the burden of diet-related chronic diseases. One 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.

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 the COVID-19 pandemic and its economic consequences, 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 propose regulations for Adult Protective Services (APS) programs that will strengthen services for older adults and adults with disabilities that experience adult maltreatment. Additionally, the Department will propose changes to its Older Americans Act (OAA) regulations to support long-term care services, nutrition, caregiver supports, and more, for older adults. In both rulemakings, the Department

plans to incorporate applicable elements EO 13985 and ensure access to services for individuals with the greatest social and economic need.

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, in the next year, the Department plans to issue proposed rules that are intended to institute minimum staffing standards in nursing homes, protect residents, and prevent fraud, waste, and abuse.

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 COVID-19 pandemic and its economic consequences, 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 2023 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 will propose changes to the Adoption and Foster Care Analysis and Reporting System (AFCARS) regulations that would help the Department to administer foster care and adoption assistance programs more effectively and better serve children and families. This rule would require title IV-E agencies to collect and report for AFCARS additional information related to the Indian Child Welfare Act of 1978 and the sexual orientation of youth in the reporting population and their foster parents, adoptive parents, and legal guardians. The Department will also propose a rule allowing licensing standards for relative or kinship foster family homes that are different from non-relative or non-kinship homes. The proposed change would address barriers to licensing 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 will issue 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.

Moreover, the Department's commitment to children and youth includes rules intended to ensure the highest level of services and care for unaccompanied children in the Department's custody. For instance, the Department will propose a new rule to strengthen and codify protections and service provisions for children cared for by the Office of Refugee Resettlement's (ORR's) Unaccompanied Children Program. Furthermore, the Department will issue a proposed rule that would provide new regulations governing the federal licensing of ORR facilities, which may be used in certain situations when state governments do not provide state licensing for such facilities.

Finally, the Department is taking action to protect the sustainability of tribal child support programs. The Department's forthcoming proposed rule on tribal child support programs would modify the non-federal share of the program expenditures requirement, including 90/10 and 80/20 cost sharing rates.

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 issue a proposed rule to reform the TANF program to strengthen the safety net and work preparation program for families and individuals with the lowest income, change allowable uses of TANF funds to refocus on the intended purposes of TANF,

improve work program effectiveness, and reduce administration burden. These changes are intended to improve the overall wellbeing of families while addressing inequities in program services and policies.