

DEPARTMENT OF HEALTH & HUMAN SERVICES

Statement of Regulatory Priorities for Fiscal Year 2022

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 2022 delivers on the Biden-Harris Administration's commitment to tackle the COVID-19 pandemic, build, and expand access to affordable health care, address health disparities, increase health equity, and promote the wellbeing of children and families:

- This agenda expands access to quality, affordable health care for all Americans, with rules to provide evidence-based behavioral health treatment via telehealth and rules to streamline enrollment and improve access to care in Medicaid and the Children's Health Insurance Program (CHIP) to ensure that children and families eligible for these programs are able to maintain coverage and obtain needed care.
- As we work to expand access to affordable health care, we will simultaneously tackle disparities that persist in who gain access to care. Forthcoming rules—including one designed to prevent discrimination in accessing care and coverage—serve to protect every person's right to access the health care they need, no matter where they live or who they are.
- Building on recent rules requiring COVID-19 vaccinations for staff at most Medicare- and Medicaid-participating health care providers and in Head Start programs, our Regulatory Plan augments our fight against COVID-19 and future pandemics by including new rules that permit CDC to set vaccination requirements for airline passengers entering the U.S. and increase the resilience of HHS programs to deal with COVID-19 and future public health emergencies.

- Our work to promote the health and wellbeing of every person includes extending additional support and resources to children and families. Whether we are providing flexibility to ensure more children in foster care are placed in homes with their relatives or reimbursing state foster care agencies for the cost of providing independent legal representation for children and parents, we are working to support our next generation of leaders—and the people who help raise them.

In short, this agenda allows the Department to support government-wide efforts to build a healthy America by charting a course to Build Back Better with rules designed to help protect public health and improve the health and wellbeing of every person touched by our programs.

I. Building and Expanding Access to Affordable Health Care

Since its enactment, the Affordable Care Act (ACA) has dramatically reduced the number of uninsured Americans while strengthening consumer protections and improving our nation's health care system. Yet high uninsured rates and other barriers to care continue to persist, compounded by the health and economic challenges facing Americans nationwide due to the COVID-19 pandemic. From day one, the Biden-Harris Administration has been focused on closing these gaps in coverage and access. The American Rescue Plan (ARP) alongside the ACA and executive actions by the Biden-Harris Administration have already led to lower premiums for consumers and more opportunities to gain coverage, achieving record-high enrollment in ACA Marketplace and Medicaid coverage.

The Department plans to continue expanding access to affordable health care over the next year, including through its regulatory actions. Secretary Becerra's regulatory priorities in this area include: enhancing coverage and access for Americans in the ACA Marketplace, Medicaid, CHIP, and Medicare; expanding the accessibility and affordability of drugs and medical products; addressing behavioral health needs; and streamlining the secure exchange of health information.

Enhancing coverage and access in the ACA Marketplace, Medicaid, CHIP, and Medicare

The Department will take several regulatory actions in the next year building on the success of the ACA and improving access to care for Americans. In his Executive Order on Strengthening Medicaid and the Affordable Care Act (E.O. 14009), President Biden asked the Department to consider a range of actions, including actions that would protect and strengthen Medicaid. Following this regulatory review, the Department is issuing two rules. First, the Department will issue a proposed rule on Assuring Access to Medicaid and Children's Health Insurance Program (CHIP) Services. Together, Medicaid and CHIP cover nearly one in four Americans and provide for access to a broad array of health benefits and services critical to underserved populations, including low-income adults, children, pregnant women, elderly, and people with disabilities. This rule would empower the Department to assure and monitor equitable access to services in Medicaid and CHIP.

Additionally, the Department will issue a proposed rule on Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes. Although considerable progress has been made in these areas, gaps remain in states' ability to seamlessly process beneficiaries' eligibility and enrollment. This rule would streamline eligibility and enrollment processes for all Medicaid and CHIP populations and create new enrollment pathways to maximize enrollment and retention of eligible individuals. The first step to ensuring access to services is making certain that people can maintain a consistent source of high-quality coverage.

The Department also plans to issue a proposed rule on Requirements for Rural Emergency Hospitals. This rule would establish health and safety requirements as Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) participating in Medicare or Medicaid, in accordance with Section 125 of the Consolidated Appropriations Act, 2021, and will establish payment policies and payment rates for REHs. This rule will aim to address barriers to health care, unmet social needs, and other health challenges and risks faced by rural communities.

Improving access to care for populations with ACA Marketplace coverage is also a regulatory priority of the Department. For instance, the Department will issue a proposed rule to protect patients' access to care and promote competition by ensuring that plans do not engage in unlawful discrimination against health care providers. While the ACA's provider nondiscrimination protections are currently set forth in guidance, the No Surprises Act directs the Department to implement these protections through regulation.

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. In addition to the actions described above, the Department's regulatory agenda includes several payment rules and notices issued annually by the Centers for Medicare & Medicaid Services (CMS) that affect Medicare, Medicaid, and the ACA Marketplace. These rules, though they are not included in the HHS Regulatory Plan, will include policies in service of the Secretary's priority of expanding access to affordable, high-quality health care.

Expanding the accessibility and affordability of drugs and medical products

The Department is committed to improving Americans' access to affordable drugs and medical products. Earlier this year, the Department issued a proposed rule entitled Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations. Consistent with President Biden's Executive Order on Promoting Competition in the American Economy (E.O. 14036), this rule proposes to establish a new category of over the counter of hearing aids. If finalized, the rule would allow hearing aids within this category to be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist. This action will address existing barriers on access to hearing aids, improve consumer choice, and have a direct impact on quality of life.

Over the next year, the Department will continue pursuing greater accessibility and affordability for Americans in need of drugs and medical products, consistent with the Department's Comprehensive Plan for Addressing High Drug Prices, released in September 2021. For example, the Department plans to

issue a proposed rule entitled Nonprescription Drug Product With an Additional Condition for Nonprescription Use. This rule would establish requirements for drug products that could be marketed as nonprescription drug products with an additional condition that a manufacturer must implement to ensure appropriate self-selection or appropriate actual use or both for consumers. The rule is expected to increase consumer access to drug products, which could translate into a reduction in under-treatment of certain diseases and conditions. The Department also plans to issue a proposed rule on Biologics Regulation Modernization, which would update Food and Drug Administration (FDA) biologics regulations to account for the existence of biosimilar and interchangeable biological products. This rule is intended to support competition and enhance consumer choice by preventing efforts to delay or block competition from biosimilars and interchangeable products.

In addition, the Department will issue a proposed rule entitled 340B Drug Pricing Program; Administrative Dispute Resolution. The 340B Drug Pricing Program, which requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net providers, is critical to the ability of safety net providers to stretch scarce federal resources and reach patients with low incomes or without insurance. The rule would establish new requirements and procedures for the Program's Administrative Dispute Resolution (ADR) process, making the process more equitable and accessible for participation by program participants. This is intended to replace the previous administration's rulemaking on the same subject, which was finalized in December 2020.

Addressing behavioral health needs

The COVID-19 pandemic has made clear that too many Americans have unmet behavioral health needs, which have seen an alarming rise during the pandemic due to illness, grief, job loss, food insecurity, and isolation. The Secretary is committed to addressing the behavioral health effects of the COVID-19 pandemic—including mental health conditions and substance use disorders—especially in underserved communities. This commitment informs the Department's regulatory priorities over the next year.

The Department is proposing two rules intended to extend telehealth flexibilities for substance use disorder treatments that were granted during the COVID-19 public health emergency. First, the Department will issue a proposed rule on Treatment of Opioid use Disorder With Extended Take Home Doses of Methadone. This rule would propose revisions to Substance Abuse and Mental Health Services Administration (SAMHSA) regulations to make permanent regulatory flexibilities for opioid treatment programs to provide extended take-home doses of methadone to patients when it is safe and appropriate to do so. Likewise, the Department also plans to issue a proposed rule on Treatment of Opioid Use Disorder with Buprenorphine Utilizing Telehealth. This rule would propose revisions to SAMHSA regulations to permanently allow opioid treatment programs and certain other providers to provide buprenorphine via telehealth. Both changes would allow more patients to receive comprehensive opioid use disorder treatment and could address barriers to treatment such as transportation, geographic proximity, employment, or other required activities of daily living.

Furthermore, the Department, working closely with the Department of Labor, will issue a proposed rule on 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.

Finally, the Department also plans to issue a proposed rule on the Confidentiality of Substance Use Disorder Patient Records. Section 3221 of the CARES Act modifies the statute that establishes protections for the confidentiality of substance use disorder treatment records and directs the Department to work with other federal agencies to update the regulations at 42 CFR part 2 (part 2). As required by the CARES Act, this rule would align certain provisions of part 2 with aspects of the HIPAA Privacy, Breach Notification, and Enforcement Rules; strengthen part 2 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.

Streamlining the secure exchange of health information

The secure exchange of health information among health care providers and other entities improves patient care, reduces costs, and provides more accurate public health data. The 21st Century Cures Act (Cures Act) included important provisions related to improving the interoperability and transparency of health information.

Two of the Department's planned rulemakings directly address and implement these statutory provisions. First, the Department plans to finalize the implementation of the Cures Act provision that authorizes the Department to impose civil monetary penalties, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements. It would also implement Cures Act provisions on information blocking, which authorize the Office of Inspector General (OIG) to investigate claims of information blocking and grant the Department the power to impose civil monetary penalties (CMPs) for information blocking. The Department's regulations would also be updated to include the increased civil monetary penalties provided in the Bipartisan Budget Act of 2018.

Additionally, the Department will issue a proposed rule entitled Health Information Technology: Updates to the ONC Health IT Certification Program, Establishment of the Trusted Exchange Framework and Common Agreement Attestation Process, and Enhancements to Support Information Sharing. This rule would implement certain provisions of the Cures Act, including the Electronic Health Record (EHR) Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program (Certification Program); a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to the agreed upon

interoperable data exchange; and enhancements to support information sharing under the information blocking regulations.

II. Addressing Health Disparities and Promoting 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, and queer (LGBTQ+) 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 outcomes and 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. This regulatory priority includes promoting equity in health care, strengthening health and safety standards for consumer products that impact underserved communities, preventing and combatting discrimination, and ensuring the equitable administration of HHS programs. The Department is also systematically reviewing existing regulations to make certain they adequately address the needs of those most vulnerable to climate change related impacts.

Promoting equity in health care

The Department is taking action to promote equity in health care programs and delivery. Earlier this year, the Department finalized a rule on Ensuring Access to Equitable, Affordable, Client-centered, Quality Family Planning Services. This rule revoked the previous administration's harmful restrictions on the use of Title X family planning funds, which had a disproportionate impact on low-income clients and caused substantial decreases in utilization among clients of color. Revoking the previous rule will allow the Title X service network to expand in size and capacity to provide quality family planning services to more clients.

In addition, the rule updates the Title X regulations to ensure access to equitable, affordable, client-centered, quality family planning services.

The Department is also committed to improving the effectiveness of federal health programs that constitute an important source of care for underserved communities. For instance, the Department plans to issue a proposed rule on the Catastrophic Health Emergency Fund (CHEF). CHEF was established to reimburse tribally operated Indian Health Service (IHS) Purchased/Referred Care programs, which serve American Indian/Alaska Native patients, for medical expenses related to high-cost illnesses and events after a threshold cost has been met. This rule would establish regulations governing CHEF, set the threshold cost that must be reached before CHEF reimbursement can be paid, and establish the procedures for reimbursement under the program.

Strengthening health and safety standards for consumer products that impact underserved communities

The Department recognizes that people of color, LGBTQ+ people, people with disabilities, people with low incomes, and other underserved populations experience longstanding disparities in leading public health indicators—including obesity and the use of certain tobacco products. To protect the public health and advance equity, the Department is pursuing regulatory action with respect to consumer products that have a disproportionate impact on the health of underserved groups.

For instance, the Department plans to propose two rules on tobacco product standards. First, the Department will issue a proposed rule on Tobacco Product Standard for Menthol in Cigarettes, which would ban menthol as a characterizing flavor in cigarettes. Menthol cigarettes are marketed to and disproportionately used by Black smokers and increase the appeal of smoking for youth and young adults. This standard would reduce the availability of menthol cigarettes. By likely decreasing consumption and increasing the likelihood of cessation, the standard would likely improve the health of current menthol cigarette smokers. Similarly, the Department plans to issue a proposed rule on Tobacco Product Standard for Characterizing Flavors in Cigars. This rule is a tobacco product standard that would

ban characterizing flavors—such as strawberry, grape, orange, and cocoa—in all cigars. As with menthol cigarettes, flavored cigars appeal to youth and disproportionately affect underserved communities. This product standard would likely reduce the appeal of cigars, particularly to youth and young adults, and is intended to decrease the likelihood of experimentation, progression to regular use, and the potential for addiction to nicotine.

Furthermore, the Department will issue a proposed rule entitled Nutrient Content Claims, Definition of Term: Healthy. This rule would update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. This would ensure that foods labeled "healthy" can help consumers build more healthful diets to help reduce their risk of diet-related chronic disease. This action is necessary to improve the public health and reduce disparities in health outcomes, particularly among people of color and people with low incomes in the U.S., who are disproportionately affected by obesity and diet-related chronic illness.

Preventing and remedying discrimination

The Department is taking actions to eliminate discrimination as a barrier for historically marginalized communities seeking access to HHS programs and activities. This includes two proposed rules in the Department's Regulatory Plan for the coming year. First, the Department will issue a proposed rule on Nondiscrimination in Health Programs and Activities, which would make changes to the previous administration's final rule implementing the nondiscrimination provisions in section 1557 of the ACA. The current section 1557 regulations significantly narrow the scope of section 1557'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 entitled Rulemaking on Discrimination on the Basis of Disability in Critical 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 certain vital HHS-funded health and human services programs. Covered topics

include nondiscrimination in life-sustaining care, organ transplantation, suicide prevention services, child welfare programs and services, health care value assessment methodologies, accessible medical equipment, auxiliary aids and services, Crisis Standards of Care and other relevant health and human services activities.

Ensuring the equitable administration of HHS programs

Consistent with President Biden's Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (EO 13985), the Department is working to embed equity throughout HHS programs and policies, including in the awarding of grants, loans, and procurement contracts.

For instance, the Department plans to issue a proposed rule on the National Institute for Disability, Independent Living, and Rehabilitation Research (NIDILRR), which would propose revisions to the NIDILRR regulations to advance equity in the peer review criteria used to evaluate disability research applications across all of its research programs, in addition to making other changes. The Department will also issue a proposed rule on the Native Hawaiian Revolving Loan Fund (NHRLF). The Native Hawaiian Revolving Loan Fund (NHRLF) was established to provide loans and loan guarantees to Native Hawaiians who are unable to obtain loans from private sources on reasonable terms and conditions for the purpose of promoting economic development in Hawaii. This rule proposes to reduce the required Native Hawaiian ownership or control for an eligible applicant to NHRLF program from 100 percent, as the 100 percent Native Hawaiian ownership requirement prevents many Native Hawaiian family-owned businesses and families from obtaining a loan. Additionally, the Department plans to issue a proposed rule entitled Acquisition Regulations; Buy Indian Act; Procedures for Contracting. This rule would establish regulations guiding implementation of the Buy Indian Act, which allows the Department to set aside procurement contracts for Indian-owned and controlled businesses. This would promote the growth and development of Indian industries and in turn, foster economic development and sustainability in Indian Country.

III. Tackling the COVID-19 Pandemic

As the federal agency charged with protecting the health of all Americans, the Department plays 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, to addressing the effects of the pandemic on the behavioral health of Americans, Secretary Becerra has leveraged the Department's full resources to pursue a comprehensive strategy to combat COVID-19. Over the last several months, the Secretary has pursued this regulatory priority by issuing a number of critical rules requiring COVID-19 vaccinations to keep schools, workplaces, and communities safe and increasing regulatory oversight of SARS-CoV-2 laboratory experimentation. Over the next year, the Department plans to continue its work to address COVID-19 through new regulations.

Building on COVID-19 vaccine requirements to keep schools, workplaces, and communities safe

Despite tremendous gains over the course of 2021, tens of millions of people remain unvaccinated against COVID-19. Reaching this population is an essential component of the Biden-Harris Administration's strategy to accelerate our nation's path out of the pandemic. For this reason, vaccine requirements are one of the Department's most impactful regulatory options in combatting COVID-19.

Accordingly, the Department has recently issued rules expanding COVID-19 vaccine requirements. For example, the Department issued an interim final rule requiring COVID-19 vaccinations for staff at most Medicare- and Medicaid-participating providers and suppliers.

Additionally, the Department issued an interim final rule with comment period to add new provisions to the Head Start Program Performance Standards to mitigate the spread of the COVID-19 in Head Start programs through COVID-19 vaccine requirements.

Building on these accomplishments, in the coming months, the Department plans to issue an interim final rule that will provide CDC with authority to require individuals entering the U.S. at any port of entry to present proof of vaccination or other proof of immunity against any quarantinable communicable diseases for which the Centers for Disease Control and Prevention (CDC) determines that a public health need exists. This rule will provide CDC with authority to require travelers to be fully vaccinated upon arrival and will reduce the number of international travelers arriving while infected.

Increasing the resilience of HHS programs to deal with COVID-19 and future public health emergencies

The Department is planning to introduce new flexibilities in HHS programs to minimize disruptions and alleviate burdens that may be caused by COVID-19 or future emergencies. For example, the Department issued a final rule on Flexibility for Head Start Designation Renewals in Certain Emergencies. This rule adds a new provision to the Head Start Program Performance Standards to establish parameters by which the Administration for Children and Families (ACF) may make designation renewal determinations during widespread disasters or emergencies and in the absence of all normally required data.

The Department also plans to issue a proposed rule on Administration for Native Americans (ANA) Non-federal Share Emergency Waivers. The rule will propose the ability for current grantees 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.

Additionally, the Department issued a proposed rule on Paternity Establishment Percentage Performance Relief. This rule proposes to modify the Paternity Establishment Percentage performance requirements in child support regulations to provide relief from financial penalties to states impacted by the COVID-19 pandemic. Without regulatory relief, 20 out of the 54 child support programs may be subject to financial penalties associated with their failure to achieve performance for the Paternity Establishment Percentage (PEP). PEP-related financial penalties, which are imposed as reductions in the state's Temporary Assistance for Needy Families (TANF) program funding, place an undue burden on state budgets and threaten funding that supports the very families who are most in need during this time of crisis.

IV. Boosting the Wellbeing of Children and Families

The Department's mission to provide effective human services to Americans includes a focus on protecting the wellbeing of children and families. This focus has special significance given the COVID-19 pandemic and its economic consequences, which have deeply affected the lives of children and youth, especially those who are in foster care or otherwise involved in the child welfare system. Secretary Becerra has therefore prioritized children and youth that are in, or candidates for, foster care in the HHS Regulatory Plan.

In support of this priority, the Department will issue a proposed rule to allow Licensing Standards for Relative or Kinship Foster Family Homes that are different from non-relative homes. Currently, in order to claim Title IV-E funding, federal regulations require that all foster family homes meet the same licensing standards, regardless of whether the foster family home is a relative or non-relative placement. 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.

The Department will also issue a proposed rule to reimburse agencies for Title IV-E Administrative Expenditures for Independent Legal Representation in Foster Care and other Related Civil Legal Issues. This rule would make it easier for Title IV-E agencies 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.