*Statement of Regulatory Priorities for Fiscal Year 2021*

The Department of Health and Human Services (HHS or the Department) carries out a wide array of activities in order to fulfill its mission to "*enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.*" HHS influences the health and well-being of Americans in a number of diverse and important ways. This impact is felt through HHS's support for cutting-edge research and disease surveillance, the regulation of medical products and facilities, and the delivery of health care and social services to America's elderly and most economically vulnerable. The breadth of the HHS regulatory footprint makes it imperative that it be a prudent regulator and deregulator. HHS will continue to explore opportunities to reduce or limit its regulatory impact without jeopardizing the integrity of its programs and the health and wellness of the American people.

In FY 2021, the Department anticipates sustaining its key role in the whole-of-government fight to end the COVID-19 pandemic and aid American recovery. The Department is taking direct action to both respond to the pandemic and institutionalize lessons learned from the response.

## Pandemic-Related Regulatory and Deregulatory Actions

*Protecting the Nation*

On January 31, 2020, Secretary Azar declared COVID-19 a Public Health Emergency (PHE), which has continued over the course of the year. Among the many key responses made by the Department for the protection of the American public, the Centers for Disease Control (CDC) has strictly limited the flow of international travelers to prevent the spread of disease, under a

variety of existing authorities. Going forward, and based on lessons learned, HHS will propose to revise, modernize, and strengthen Departmental authorities in this area by amending its Foreign Quarantine Regulations, issuing a Notice of Proposed Rulemaking (NPRM) on *Suspension of the Right to Introduce and Prohibition of Introduction of U.S. Citizens and Lawful Permanent Residents into United States from Designated Foreign Countries or Places for Public Health Purposes*. This rule proposes a procedure for the CDC Director to suspend the right to introduce and prohibit introduction, in whole or in part, of American citizens and lawful permanent residents as the Director shall designate in order to avert the danger of the introduction of a quarantinable communicable disease into the United States, and for such period of time as the Director may deem necessary.

*Creating and Maintaining Regulatory Flexibility for the Public*

The Department has also issued a large number of regulatory and subregulatory flexibilities in response to the pandemic, in order to rapidly mitigate the regulatory burden on the public in the often restrictive circumstances of the pandemic. Under Executive Order 13924, issued by the President on May 19, 2020, all agencies are asked to seek additional regulatory flexibilities and examine flexibilities already issued on a temporary basis to determine those that should be made permanent in order to aid in American economic recovery. HHS is committed to the EO 13924 process and anticipates a robust response in FY 2021, identifying many burden-reducing guidance and regulatory policies that can be beneficially retained.

In the Unified Agenda, HHS notes particularly the Centers for Medicare and Medicaid Services's (CMS) *Continuing CfC/CoP Flexibilities for Providers and Suppliers –Omnibus Proposed Rule*.

In an effort to help health care providers and suppliers effectively respond to the COVID-19 PHE, CMS issued an unprecedented number of regulatory waivers and other flexibilities. The intent of these waivers was to temporarily waive certain requirements, while expanding healthcare system capacity and maintaining public and patient safety. CMS has identified some of these waivers as further opportunities to meet the Administration's goal of eliminating burden by permanently revising the requirements, placing them in this rule.

Also responding to COVID-19, the Office of the National Coordinator issued an interim rule *Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency*. The interim final rule with comment period gives health IT developers and health care providers flexibilities to effectively respond to the public health threats posed by the spread of COVID-19. The rule extends certain applicability and compliance dates and timeframes in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), including compliance dates for the information blocking provisions, certain 2015 Edition health IT certification criteria, and Conditions and Maintenance of Certification requirements under the ONC Health IT Certification Program.

**Strategic Regulation and Deregulation**

HHS Secretary Azar has organized the Department's focus around the achievement of three broad strategies: I) facilitating patient-centered markets; II) promoting health and protecting life; and III) promoting independence. These strategies have the potential to deliver lasting change across America's health care system.

## *I. Facilitating Patient-Centered Markets*

The United States has achieved remarkable success at improving health care coverage through the development of market segments and the establishment of targeted programs that address the coverage needs of each constituent group. These include the individual insurance market, the employer-sponsored market, and Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The financial models for each of these markets and programs are unique, but all rely on effective regulatory (or deregulatory) stewardship to work effectively for their constituents. HHS will pursue regulatory strategies and policies to strengthen the degree to which these programs are responsive to patient and consumer needs and interests, consistent with preserving consumer choice and market competition.

*Fixing Health Care Financing through Protecting Private Insurance and Medicare*

HHS's policies will continue to favor and support the development of patient-centered private insurance markets and will pursue actions that increase consumer options within the Medicare program while increasing its financial viability. As such, the 2022 Medicare Advantage / Part D rule will propose additional flexibilities for Medicare Advantage plans who wish to customize benefit designs to the targeted needs of their members.

*Fixing Health Care Financing through Reforming the Individual Market*

The Administration has taken a number of regulatory steps to address the failings of the Affordable Care Act (ACA) and its impact on the individual insurance market. Collectively, the Administration's actions brought premium stability to the Exchange, albeit at premiums

that remain increasingly out of reach for many Americans. HHS will continue to advance regulatory reforms to the individual market through the 2022 Notice of Benefit and Payment Parameters.

*Bringing Value to Health Care through Price and Quality Transparency*

A top goal of the Department is to improve private insurance programs. In furtherance of Executive Order 13877, *Improving Price and Quality Transparency in American Healthcare to Put Patients*, issued by the President in June 2019, the Department will begin enforcement of its CMS *Price Transparency Requirements for Hospitals to Make Standard Charges Public* in January 2021. The implementation of the policy directives contained within EO 13877 through this final rule will provide patients with timely and relevant information about the price and quality of health care services, including "shoppable" services. Increasing health care price and quality transparency will provide individuals with the information they need to take become more active participants in deciding where, and from whom to receive health care. As patients become more engaged consumers, suppliers of health care services will be rewarded for their ability to meet consumer needs and expectations.

*Bringing Value to Health Care through Deregulation, Especially for Coordinated Care*

In FY 2021, HHS intends to implement additional major components of its Regulatory Sprint to Coordinated Care to remove potential regulatory barriers to care coordination and value-based care created by four key health care laws and associated regulations: (I) the physician self-referral law; (II) the federal anti-kickback statute; (III) the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and (IV) rules under 42 CFR Part 2 related to substance use disorder treatment records. Changes in FY 2021 to 42 CFR Part 2, *Confidentiality of*

*Substance Use Disorder Patient Records-CARES Act Implementation,* will build on reforms already put in place by a Substance Abuse and Mental Health Services Administration (SAMHSA) Final Rule in July 2020, extending care coordination and aligning 42 CFR Part 2 requirements with HIPAA standards under new legislative authorities given by section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in March 2020. Reform of these regulations occurs under the broad principle that providers should have incentives to coordinate with each other and with informed and empowered patients. When complete these changes will allow patients to be more engaged in their care, allow providers to better coordinate care for patients, and move the health care system closer to one that pays for value.

*Bringing Value to Health Care through Tackling the High Cost of Prescription Drugs*

In May 2018, Secretary Azar unveiled the President's comprehensive strategy to tackle the high cost of prescription drugs: *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint).* Since then, HHS has aggressively worked to implement the recommendations laid out in the Blueprint, finalizing a number of regulations to improve the Medicare Part D program and improve the transparency of list prices for patients.

The Blueprint identifies foreign free-riding as one of the major problems with prescription drug pricing. The Food and Drug Administration's (FDA) rule allows the importation of prescription drugs from Canada, potentially giving Americans access to lower priced drugs. This rulemaking, grounded in the authority in Food, Drug, and Cosmetic Act (FDCA) section 804(b) to allow importation of drugs from Canada, allows safe importation of certain prescription drugs with the goal of reducing prescription drug costs for the American consumer, consistent with requirements of the FDCA.

Also in line with the policies discussed in the Blueprint was CMS's previously issued advance notice of proposed rulemaking for an International Pricing Index (IPI) Model for Medicare Part B drugs. Under a IPI model, Medicare's payments for select physician- administered drugs would shift to a level more closely aligned with prices in other countries, which could lead to savings for American taxpayers and patients. Pursuant to the President's Executive Order of September 13, 2020, on *Lowering Drug Prices by Putting America First,* HHS intends to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than an international price, as specified in the Executive Order. The model would test whether, for patients who require pharmaceutical treatment, paying no more than this price would mitigate poor clinical outcomes and increased expenditures associated with what would otherwise be high pharmaceutical costs affecting patient access.

To further enable struggling Americans by leveraging market power, the Health Resources and Services Administration (HRSA) will introduce a new rule on *Access to Affordable Life-saving Medications.* Many Americans rely on insulin and injectable epinephrine to treat diabetes and severe allergic reactions, yet many low-income Americans struggle to afford these life-saving medications. In order to provide low-income Americans with access to these medications, the President signed Executive Order 13937, *Access to Affordable Life-saving Medications*, on July 24, 2020. This Executive Order calls for patients at Federally Qualified Health Centers (FQHCs) to access insulin and injectable epinephrine at the discounted price paid by the FQHC grantee or sub-grantee under the 340B Drug Pricing Program. To implement the policy described in this Executive Order, HRSA is finalizing a rule to ensure all future grants available under section 330(e) of the Public Health Service Act, as amended, 42 U.S.C.

254b(e), are conditioned upon FQHCs having established practices to make insulin and injectable epinephrine available at or below the discounted 340B price. This final rule complies with the Executive Order's support for improved access to these life-saving medications.

## *II. Promoting Health and Protecting Life*

The Department's agile regulatory posture in response to the COVID-19 pandemic, and its forward-looking approach to facilitating the marketplaces for healthcare, are both ultimately tied to producing higher value patient and public health outcomes. The Department remains committed, in addition, to promoting health and protecting life in other priority areas.

In FY 2021, among other actions, the Food and Drug Administration (FDA) intends to help ensure that the United States has the safest food system in the world. The FDA will help prevent outbreaks of foodborne illness by revising and streamlining the *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption Relating to Agricultural Water*. These new rules will represent a more modern approach to food safety, including a refined approach to testing requirements for pre-harvest agricultural water. As part of the implementation of the Food Safety Modernization Act, FDA previously published the Produce Safety Rule (November 2015), which included requirements in subpart E related to agricultural water. FDA received feedback from stakeholders regarding the practical challenges of implementing those requirements in light of the diversity of farming operations, water sources, and water uses that are affected. Since then, FDA has evaluated how to address these concerns, further reduce regulatory burdens, and continue to maintain public health benefits. FDA is

proposing to modify the current requirements for pre-harvest agricultural water for most covered produce and to offer a more flexible, modern approach.

The FDA also intends to take action in FY 2021 to help protect the health of American women by providing an update to its regulations under the *Mammography Quality Standards Act* (MQSA) in order to modernize mammography services and improve their quality. The MQSA was designed to ensure quality mammography for early breast cancer detection. FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published more than 20 years ago. By recognizing new technologies, making improvements in facility processes, and updating reporting requirements, these changes will improve the delivery of mammography services and expand the information mammography facilities must provide to women and their health care providers, empowering their medical decision-making with more information.

*Protecting Life at All Stages*

In HHS's strategic plan, HHS recognizes its special role in serving and protecting Americans at every stage of life, from conception to natural death. In June 2019, the Administration announced its policy with respect to the use of human fetal tissue from elective abortions in HHS-conducted or -funded research. That announcement included a commitment to undertake changes to HHS regulations and to NIH's grants policy to adopt or strengthen safeguards and program integrity requirements applicable to extramural research involving human fetal tissue Consistent with that announcement and the strategic plan, the Department will propose changes in FY 2021 under the heading, *Establishment of Safeguards and Program Integrity Requirements for HHS-Funded Extramural Research Involving Human*

*Fetal Tissue.* This rulemaking will revise human subject protection regulations and its grants regulations in order to adopt and strengthen safeguards and program integrity requirements applicable to extramural research involving the use of human fetal tissue.

## *III. **Promoting Independence***

The Department continues to support personal autonomy and family self-sufficiency for all Americans. The Office for Civil Rights will assist disabled citizens achieve independence and have fuller access to opportunities through its *Rulemakings on Disability Discrimination in the Denial of Vital Health and Human Services*. These proposed rules would revise regulations under laws including section 504 of the Rehabilitation Act of 1973 and the Emergency Medical Treatment and Labor Act to robustly address unlawful discrimination in certain vital HHS-funded health and human services programs. The Administration for Children and Families (ACF), in new rules that are expected to increase the availability of childcare for lower-income Americans, will revise the *Provisional Employment Requirement for Prospective Child Care Staff Members*. The current requirements of the Child Care and Development Fund (CCDF) include non-statutory mandates of continual supervision for provisional employees. This deregulatory action would remove that requirement, which otherwise threatens the CCDF funding for the majority of states, currently out of compliance with the existing rule and potentially subject to penalty. Maintaining full CCDF funding, and removing unnecessary barriers to hiring child care employees, will help increase the supply of a critical job support for low-income parents, enabling more of them to return to work.

## Reforming the Regulatory Process

In addition to advancing its key substantive priorities, the Department will also be making systemic reforms to how it conducts regulatory policy and develop mechanisms for continuous improvement. HHS proposes to issue regulation *Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication*. These rules put in place procedural safeguards to ensure that guidance documents are used appropriately in administrative enforcement actions, and protect the due process rights of individuals and regulated entities. These regulations will help to ensure that the agency, where feasible, fosters greater private-sector cooperation in enforcement and promotes information sharing with the private sector. HHS will also create new procedures *Securing Updated Necessary Statutory Evaluations Timely*, for the periodic review of the Department's regulations. The Regulatory Flexibility Act requires agencies to publish plans to conduct periodic reviews of their regulations. This will help implement multiple executive orders also require agencies to submit plans for periodic reviews of regulations, including E.O. 13563, *Improving Regulation and Regulatory Review*. To further facilitate and accelerate the retrospective review process, HHS will pioneer in FY 2021 the use of artificial intelligence to assist agency personnel in identifying candidates for regulatory improvement, deploying natural language processing to detect errors and outdated provisions within regulatory text, as part of its *Regulatory Clean-Up Initiative*.

## Summary

In the coming fiscal year, HHS plans to consider a number of deregulatory actions and regulatory changes intended to make its processes more flexible, efficient, and transparent. In

order to fully realize the potential of these efforts, HHS recognizes the need for a collaborative rulemaking process where the concerns of patients, providers, states, tribes, faith-based and community organizations, and other stakeholders are appropriately considered. By working with its partners in bringing better health care and human services to the American people, and understanding the challenges that they face under HHS's current regulatory structures, the Department will continue to modernize its role in this critical sector of the national economy, assuring its vitality and the increased well-being of those it serves.