Statement of Regulatory Priorities for Fiscal Year 2020

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.

HHS Secretary Alex M. Azar II 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 2021 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 Trump 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 are increasingly out of reach for many Americans. HHS will continue to advance regulatory reforms to the individual market through the 2021 Notice of Benefit and Payment Parameters.

Fixing Health Care Financing through Making the ACA and Medicaid Fiscally Sustainable

The President's Fiscal Year (FY) 2019 and 2020 Medicaid administrative budgets include proposals to ensure that states fund their required portion of Medicaid expenditures and improve data collection for Medicaid supplemental payments. Centers for Medicare & Medicaid Services

(CMS) will finalize a rule to improve state accountability through additional state reporting, stronger financial definitions, and clearer federal guidance.

Separately, the Office for Civil Rights (OCR) has identified burdensome and costly regulations for revision and repeal. In accordance with the Executive Order (EO) "*Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal (PPACA)*," OCR published a proposed rule, and plans to issue a final rule, to revise and partly repeal burdensome regulations associated with the ACA's nondiscrimination requirements. These include costly notice and tagline paperwork requirements imposed on health care providers, health insurers, states, and small businesses, costs that are ultimately passed on to individuals, families, and patients. OCR plans to issue a final rule in FY 2020.

HHS will also finalize regulations to streamline requirements governing the relationship between states and Medicaid and CHIP Managed Care Organizations (MCOs). These regulations will provide states with greater flexibility in the management of their relationships with Medicaid MCOs and lessen the burden on states of federal program oversight.

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 that goal, the President signed an EO this June on "*Improving Price and Quality Transparency in American Healthcare to Put Patients First*." The implementation of the policy directives contained within the EO 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. The EO calls for the development of a tri-agency rule with the Departments of Labor and Treasury, increasing transparency in cost sharing information under the ACA.

Bringing Value to Health Care through Patient-centered Health IT

HHS has spearheaded efforts to rebuild our health care system into one that truly incentivizes effective and efficient patient care by paying for value. As such, a top priority of the Department is to bring value to health care through Patient-centered Health IT and increase patients' abilities to access their data. This priority encourages patients to be better informed, make better decisions and take control of their health care data. In furtherance of this goal, and in accordance with the 21st Century Cures Act, the National Coordinator for Health Information Technology (ONC) published the 21st Century Cures Act: Interoperability, Information Blocking and ONC Health IT Certification Program Proposed Rule in February of 2019. This rule proposed policies to implement certain provisions of the 21st Century Cures act and aims to provide patients the ability to retrieve their medical records through application programming interfaces (APIs) and other electronic means and ultimately access their records on their mobile device. In addition, CMS proposed the Interoperability and Patient Access Rule, which proposes to provide patients the ability to retrieve their health care claims data through APIs adopted by ONC. These rules, which ONC and CMS will soon finalize, are significant steps in solving the interoperability challenges that exist in health care and will create a new environment in which patients will be at the center of their health care, will have access to their health information, and will make informed health care decisions.

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

HHS launched the 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. Specifically, the regulatory sprint aims to encourage and improve:

- A patient's ability to understand treatment plans and make empowered decisions;
- Providers' alignment on end-to-end treatment (*i.e.*, coordination among providers along the patient's full care journey);
- Incentives for providers to coordinate, collaborate, and provide patients tools to be more involved in their own care; and
- Information sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting the confidentiality of patient information and patient access to their health information.

Reforming these regulations with these principles in mind 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) proposed rule will allow 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, would allow 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 is CMS's advance notice of proposed rulemaking for an International Pricing Index (IPI) Model for Medicare Part B drugs. Under a potential 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.

Bringing Value to Health Care through Accelerated Drug and Device Approval and Reimbursement

Advances in medical technology present opportunities to significantly improve patient health outcomes and care quality. A small number of medical technologies are given "Breakthrough" status by the FDA, meaning these technologies hold particular promise for advancing health outcomes or care quality. HHS is proposing a rule that modifies the Medicare coverage process to make these technologies more immediately available to Medicare beneficiaries.

II. Promoting Health and Protecting Life

Addressing Impactable Health Challenges: Kidney Health

In July, the President signed an EO "*Advancing American Kidney Health*." To address the EO's direction to propose a regulation to remove financial barriers to living organ donation, the Health Resources and Services Administration will issue a proposed rule to amend the Organ Procurement and Transplantation Network regulations to further remove financial barriers to living organ donation by expanding reimbursement to nonmedical expenses typically incurred in the donation process. Additionally, CMS is proposing a rule that would change the standards used to evaluate Organ Procurement Organizations and ensure that proper data on available organs and transplants is collected.

Addressing Impactable Health Challenges: Combatting the Opioid Crisis

The opioid crisis is one of the most pressing public health problems of our time. It has steadily grown over the past several decades and is affecting communities across the country. In addition to providing unprecedented levels of support for states, local governments, and community organizations working to combat this crisis, HHS is exploring ways to enhance our nation's response through critically examining its regulations. This July, the Centers for Disease Control and Prevention's National Center for Health Statistics reported a 5.1 percent decline in provisional counts of total drug overdose deaths in the United States from 2017 to 2018. Defeating this epidemic requires identifying all possible ways to treat and manage chronic pain, including non-pharmacological treatment options. This summer, CMS proposed a National Coverage Determination to cover acupuncture for Medicare patients with chronic low back pain who are enrolled participants in either National Institutes of Health (NIH)-sponsored clinical

trials or CMS-approved studies. This proposal will provide patients with new pain management options and could help reduce reliance on prescription opioids.

Furthermore, the Substance Abuse and Mental Health Services Administration is proposing broad changes to Confidentiality of Alcohol and Drug Abuse Patient Records, also known as 42 CFR part 2. This proposal would remove barriers to coordinated care and permit additional sharing of information among providers and part 2 programs assisting patients with substance use disorders, which would foster further alignment with HIPAA. Due to a lack of common understanding among covered entities regarding HIPAA Privacy Rule disclosures, OCR plans to clarify and strengthen the ability of HIPAA-covered entities to disclose— to family members, friends, and others— protected health information with respect to individuals suffering from opioid use disorder or serious mental illness and to enable such persons to help these individuals, while appropriately respecting individual privacy. OCR's proposed deregulatory reforms of the HIPAA Privacy Rule also include removing barriers to coordinated care, empowering individual engagement, and reducing costs associated with recordkeeping, business associate agreements, and compliance with the minimum necessary standard.

Protecting Conscience and Life at All Stages

Religious and faith-based organizations and individuals have historically played an important role in providing needed health care and human services in the United States. However, in recent years, regulatory and other burdens on religious freedom and conscience that discourage such organizations and individuals from participating in HHS programs have been overlooked. HHS continues to work to ensure that the Department's programs respect religious liberty and

conscience and to relieve regulatory and other burdens imposed on the exercise of religion and conscience with HHS programs and activities. The Center for Faith and Opportunity Initiatives will propose regulations to ensure equal treatment for faith-based organizations by removing barriers to full and active engagement by the faith-based community in all HHS programs and initiatives. Through implementation of the EO on the "*Establishment of a White House Faith and Opportunity Initiative*" signed in May 2018, the rule will ensure the ability of faith-based organizations to participate in HHS programs and activities, while protecting their free exercise of religion, consistent with federal law.

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 November 2018, CMS issued the Exchange Program Integrity proposed rule. Consistent with the requirements of the ACA, the proposed rule requires issuers of Qualified Health Plans to issue and transmit to consumers two separate premium invoices: one for coverage of non-Hyde abortions and a second for the remainder of the coverage premium. HHS and CMS plan to issue the final Exchange Program Integrity Rule in CY 2019.

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. Accordingly, in FY 2020, HHS plans to engage in rulemaking to amend its Human Research Subjects Protection Regulations (45 CFR Part 46, Subpart B, Additional Protections for Pregnant Women, Human Fetuses, and Neonates) and its grants regulations (45 CFR Part 75) to provide additional safeguards concerning the use of such

tissue in HHS-funded research (including strengthened informed consent requirements and implementation of the ban on the provision of valuable consideration for human fetal tissue).

Reducing the Disease and Death Associated with Tobacco Use

FDA plans to continue work on needed regulations for its tobacco programs. FDA will propose establishing tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products. This proposal will help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products.

Further, the FDA is proposing to issue a modified risk tobacco product (MRTP) applications rule that would set forth content and format requirements to ensure that MRTP applications contain sufficient information for FDA to determine whether it should permit the marketing of a modified risk tobacco product. The MRTP provisions of the FD&C Act are valuable tools in the effort to promote public health by reducing the disease and death associated with tobacco use, particularly if companies take advantage of these provisions by making bold, innovative product changes that substantially reduce or eliminate the toxicity and/or addictiveness of tobacco products.

III. Promoting Independence

Returning TANF to Promoting Work, Marriage and Family

One of the hallmarks of welfare reform and the establishment of the Temporary Assistance for Needy Families (TANF) program in 1996 was its focus on ending the dependence of needy parents on government benefits by promoting job preparation, work, and marriage, and on

encouraging the formation and maintenance of two-parent families. Under TANF, states are required to meet certain work participation rates. However, the current TANF regulations permit states to artificially lower their work participation rate goals. The Administration for Children and Families (ACF) will issue a notice of proposed rulemaking to address common practices used by states to lower work target thresholds, enhancing the program's focus on promoting job preparation and work as the primary means to end family dependence on government assistance and to promote family independence and self-sufficiency.

Supporting Adoption

The Department recognizes the burden that requirements for many of its programs place on states, territories, tribes, local governments, industry, providers and facilities, caseworkers, grant recipients, and individuals. HHS plans to actively engage stakeholders in transparent, deliberative processes to ensure that the Department reduces burden while continuing to administer high-quality programs. One example is the Adoption and Foster Care Analysis and Reporting System (AFCARS) regulation, which was finalized in December 2016 and increased the required reported information by states and tribes from the current AFCARS requirements that were in place prior to the December 2016 final rule. In April 2019, ACF issued a proposed rule to streamline AFCARS reporting requirements; it will finalize the rule in May 2020. Streamlining the required reported information to AFCARS would eliminate the undue burden related to reporting imposed on states and tribes.

Empowering Americans to Improve Their Nutrition

FDA is committed to finding new ways to reduce the burden of chronic disease through improved nutrition, and has established a Nutrition Innovation Strategy to take a fresh look at

actions that can reduce preventable death and disease related to poor nutrition. To support the Department's public health goal, FDA will propose updating the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. The rule will revise the requirements as to when the claim "healthy" can be voluntarily used in the labeling of human food products to ensure that the claim reflects current science and dietary guidelines and helps consumers maintain healthy dietary practices.

Promoting Flexibility for States, Grantees, and Regulated Entities

The Department recognizes that, when it comes to the implementation of its programs, one size does not fit all. As such, the Department is committed to regulatory changes to provide flexibility to states, grantees, and other regulated entities in implementing HHS programs so that they can best meet the needs of the people they serve. One example of this commitment to flexibility is in the Head Start program. The Office of Head Start currently requires that, by August 1, 2021, Head Start programs operate 100 percent of their preschool center-based slots for 1,020 annual hours, which would substantially increase the minimum amount of time preschool children must receive Head Start services. That requirement would reduce grant recipients' flexibility to meet the needs of the communities they serve and would be costly for grantees to meet, likely resulting in a reduction in the number of children served by Head Start. ACF has proposed to remove the 100-percent service duration requirement from the Head Start Program Performance Standards (as well as to make certain technical changes to their Program Structure regulations) to provide flexibility to Head Start grantees to best address the needs of the children and families they serve.

IV. 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.