

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### *Statement of Regulatory Priorities for Fiscal Year 2026*

America faces an unprecedented healthcare crisis. With skyrocketing costs – nearing \$4.5 trillion annually – essential care has become unaffordable for millions of Americans.

To meet this generational challenge, the U.S. Department of Health and Human Services (HHS) will unlock innovation and apply “Make America Healthy Again” (MAHA) principles to improve the health and well-being of Americans, including with its regulatory agenda. The 2026 HHS regulatory plan prioritizes actions to promote health, manage chronic diseases; eliminate unnecessary administrative expenses and rent-seeking practices; combating fraud and abuse; protecting religious and individual liberties; supporting biological women, children, and families; and radical transparency. HHS is committed to fixing a system that rewards ineffective health care practices and delivers poor value.

This agenda highlights certain rulemakings that promote open government, reduce government transfers, and support small businesses, to ensure a transparent and efficient regulatory framework that promotes and protects public health.

#### I. Promoting Health and Managing Chronic Disease

Addressing chronic disease—the most pressing public health problem of our time—is the cornerstone of the MAHA agenda. In less than a year, under Secretary Kennedy’s leadership, HHS, CMS, and FDA have taken unprecedented steps to combat the obesity crisis and make

prescriptions more affordable to everyday Americans with Most-Favored-Nation pricing. And in the coming year, the Department will continue to take steps to make medicines affordable to address and manage chronic disease.

HHS will also explore ways to enhance our nation's response to this unprecedented challenge by critically examining its regulations. To better serve the American people through its programs, HHS will advance innovative care models and other regulatory actions to prevent and manage chronic diseases, for example:

- *Modernization of Coverage Pathways.* CMS will modernize coverage pathways for innovative technologies, streamlining implementation to ensure timely access to treatments. This rulemaking is expected to yield significant net benefits by improving health outcomes and reducing long-term costs.
- *Quality and Safety Measurements.* CMS will reduce the number of quality measures and shift from fee-for-service to value-based care, streamlining compliance burdens and creating reimbursement pathways for MAHA-based interventions. This action will promote fiscal responsibility by optimizing resource allocation.
- *Substances Generally Recognized as Safe.* This FDA rule proposes mandatory submission of GRAS notices, enhancing oversight of food substances to combat obesity-related risks. It promotes open government by ensuring transparent safety evaluations and is expected to yield large net benefits by reducing obesity-related health care costs.
- *Nutrient Content Claims for Added Sugars.* FDA will propose a rule to update definitions, terminology, and provisions related to nutrient content claims and added sugars to be consistent with terms related to and updates to requirements for the Nutrition Facts

label. The rule will define a new “low sugar” nutrient content claim that manufacturers could voluntarily use to communicate information about the level of added sugars in food products.

- *Nimble Powered Respirators*. This CDC rule will finalize performance standards allowing for the approval of PAPR100 class powered air-purifying particulate respirators. Although the current PAPR approval program has provided proven protections, these current requirements, as outlined in the interim final rule, will extend the same proven protection to smaller, lighter systems that may be more comfortable to wear.

## II. Eliminating Unnecessary Administrative Expenses and Rent-Seeking Practices

Unnecessary administrative expenses and rent-seeking practices contribute to inefficiency in health care. The Department is committed to advancing initiatives that reward innovation, value, and performance.

Across the Department, under Secretary Kennedy and Deputy Secretary O’Neill’s leadership, agencies are exploring, deploying, and integrating modern technology and AI to streamline internal operations of the Department and agencies. For example, HHS has launched internal tools to help employees leverage AI to streamline daily tasks; FDA has launched an AI tool to assist with scientific reviews; and CMS has launched an AI-assisted prior-authorization pilot.

The Department’s regulatory priorities further reflect its commitment to eliminating unnecessary administrative burdens. In the upcoming year, HHS will take deregulatory actions to reduce common and/or significant regulatory burdens, such as:

- *Updating the Common Rule.* The Department is considering revising 45 CFR part 46 to modernize and simplify subpart A, known as the Common Rule, to uphold protections for human subjects while reducing burden and ambiguity for investigators, institutional review boards, and research institutions. Examples of changes include clarifying terminology, expanding exemptions for certain low-risk research activities, and enabling flexibilities for regulatory review of de minimis protocol changes.
- *Amending Regulations that Require Multiple Copies to Single Submission.* FDA will replace paper-based, multiple-copy submissions with single, electronic submissions. This rule reduces paperwork burdens, saving time and costs for submitters. This action aligns with public RFI feedback calling for simplified submission processes.
- *Electronic Labeling for Medical Devices.* FDA will propose a rule to clarify the “adequate directions for use” requirement in the Federal Food, Drug, and Cosmetic Act can be satisfied when labeling is provided solely by electronic means for certain types of devices in certain circumstances.
- *Ending Accreditation Monopolies.* CMS will work toward reforming accreditation processes to eliminate monopolies, reduce unjustified costs, and align accreditation with principles that will make Americans healthy again. This deregulatory action promotes competition and fiscal responsibility.
- *Innovative Payment Models for Affordable Drugs.* This CMS initiative will streamline drug pricing models, reducing government transfers and promoting fiscal responsibility, and is expected to yield large net benefits by lowering costs for patients.
- *Reducing Bureaucracy and Burden in the Child Care and Development Fund.* This ACF proposed rule would modify Child Care and Development Fund (CCDF) regulations to

improve child care access and choice for families, reduce administrative burdens for states, territories, and Tribes, and provide additional flexibilities by removing outdated provisions, changing requirements for Tribal CCDF programs, and streamlining complicated and burdensome requirements for states and territories.

- *Modernizing the Head Start Program by Reducing Requirements and Enhancing Alignment with State and Local Systems.* This ACF proposed rule will reduce and streamline Head Start regulatory requirements to align standards with state and local systems and reduce burden on Head Start programs. The proposed rule would also make regulatory changes to ensure children and families have access to healthy food and comprehensive nutrition services and that programs are supporting improved early literacy outcomes for children.

### III. Combatting Waste, Fraud, and Abuse

Waste, fraud, and abuse are the antithesis of efficient health care. Improved technology such as AI will not only help the Department make processes more efficient, but will help root out fraud, waste, and abuse. For example, CMS's WISer Model will assess whether new technologies like AI can expedite the prior authorization processes for select items and services that have been identified as particularly vulnerable to fraud, waste, and abuse, or inappropriate use.

In the coming year, HHS will strengthen oversight and eligibility standards with its regulatory agenda to combat fraud and reduce government transfers.

- *Strengthening the Integrity of Medicaid and CHIP Eligibility, Managed Care, Financing, and Section 1115 Demonstrations.* By streamlining implementation through

clarifying payment and access requirements, this CMS rule enhances oversight of state enrollment processes and establishes budget neutrality for Section 1115 demonstrations, reducing fraudulent transfers and ensuring fiscal responsibility.

- *Administrative Detention of Tobacco Products.* By allowing FDA to detain adulterated or misbranded tobacco products during inspections, this rule strengthens oversight, protecting public health and reducing risks of costly recalls.
- *Zero-Based Regulation.* The goal of this ACF proposed rule is to take the ZBR approach to ACF's regulations and remove any regulations identified as outdated or unnecessary in a cross-cutting package. This proposal seeks to trim the nearly 1,500 sections of regulations associated with ACF, some of which have not been updated since the '60s.
- *Eliminating Bureaucratic Waste in Federal Reporting and Assessments.* This rulemaking seeks to restructure the way in which Child and Family Services Reviews are conducted by the states to comply with federal requirements. The current system is both ineffective and costly. Regulatory changes will allow for streamlined reporting and better outcomes.
- *Strengthening Regulatory Oversight of the Organ Procurement and Transplantation Network to Ensure Patient Safety.* HRSA will make the policies of the Organ Procurement and Transplantation Network (OPTN), which are currently voluntary, legally enforceable.

#### IV. Protecting Religious and Individual Liberty and Standing Up for Biological Women, Children, and Families

Good health care policy begins with protecting life, liberty, and immutable, biologically rooted truths. HHS will amend regulations consistent with this policy, such as:

- *Making Technical Changes and Clarifying How OCR Addresses Conscience Authorities in Health Care; Delegation of Authority.* This deregulatory rule clarifies federal conscience authorities, reducing ambiguity for providers and aligning with public feedback emphasizing religious liberty protections.
- *Restoring Flexibility to the Child Care and Development Fund.* This ACF deregulatory rule increases parental choice and reduces administrative burdens in the CCDF program, streamlining implementation and supporting families. It is of particular interest to small businesses, such as childcare providers, by simplifying compliance.
- *Medicare; Hospital Condition of Participation: Prohibiting Sex Trait Modifications.* By prohibiting specified sex trait modification procedures on children, this CMS rule enhances oversight and aligns with evidence-based care, yielding large net benefits by safeguarding child health.
- *Clarifying Statutory Limitation on Disability as it Applies to Gender Identity and Dysphoria in Nondiscrimination:* This OCR deregulatory rule clarifies that gender identity disorders do not qualify as disabilities under Section 504, reducing unjustified burdens on providers and ensuring fiscal responsibility.
- *Modification of Certain Terminology in Title 21.* FDA will modify certain terminology in Title 21 of the Code of Federal Regulations (CFR) to comply with Executive Order EO 14168, “Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,” issued on January 20, 2025. Specifically, this proposed rule will propose removing the term “gender” wherever it appears and

either replace it with the term “sex,” or delete reference to gender as applicable, along with other editorial changes to improve readability.

- *HIPAA Privacy Rule to Promote Individuals' Timely Access to their Protected Health Information.* OCR will solicit comment on proposals to modify the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). The proposals would address the amount of time that covered entities have to respond to requests for protected health information (PHI) made pursuant to the right of access.

## V. Radical Transparency

Radical transparency—making information, decisions, processes, and even failures publicly visible—is a force multiplier for the MAHA agenda. Radical transparency exposes impropriety, accelerates evidence-based policies, system self-correction, and ensures merit prevails in a free market. Most important, radical transparency builds trust and gives patients and care-providers the tools to make informed choices that are best for them, as opposed to having to rely on government bureaucrats. Numerous HHS agencies have already taken steps to promote radical transparency, such as FDA’s release of Complete Response Letters (CRLs).

In the coming year, the Department will take other novel and unprecedented actions to promote radical transparency, including streamlining operational issues with public disclosure statutes.

New regulatory actions relevant to increased transparency include:

- *Proactive Disclosure of Complete Response Letters.* This rule will clarify and expand the FDA Commissioner’s discretion to release CRLs and not approvable letters and eliminate the longstanding presumption that the mere existence of a marketing application constitutes confidential commercial information to enable proactive disclosure of information maintaining appropriate redactions for trade secrets and personal private information.
- *Transparency in Direct-to-Consumer Advertising.* This rule will revise 21 CFR 202.1 to eliminate the option for prescription drug advertisements broadcast through media such as radio or television to fulfill the statutory “brief summary” requirement of the Federal Food, Drug, and Cosmetic Act by disclosing risk, contraindications, and other safety information in another source beyond the advertisement itself.
- *Updating Privacy Act Regulations.* This rule will update Department regulations at 45 CFR part 5b and remove duplicative Food and Drug Administration (FDA) Privacy Act regulations at 21 CFR part 21.
- *Health Data, Technology, and Interoperability: Application Programming Interfaces and Information Blocking Advancements.* ASTP will propose a rule to advance interoperability through API certification and updated information blocking regulations, promoting open government by enhancing data sharing and improved patient outcomes.
- *Reforming the HHS Petition Process.* HHS will put forward new streamlined procedures for handling rulemaking petitions, including a process to review existing regulations.

## VI. Conclusion

In the coming year, HHS will take regulatory actions to further the MAHA agenda and reduce burdens and costs while maximizing benefits and transparency. To fully realize the potential of these efforts, HHS seeks to collaborate with stakeholders and the public to ensure concerns are given due consideration and properly and transparently addressed. By working with stakeholders and the public, the Department hopes to Make America Healthy Again, ensure regulations better serve the needs of the American people, and restore confidence in our public health agencies.