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Regulatory Outlook: 2026 Unified Agenda

The Trump administration recently released its 2026 Unified Agenda, which outlines regulatory plans for federal agencies over the coming year. The Unified Agenda reflects the administration's priority on policies addressing health. In our regulatory outlook, we highlight rulemaking on coverage and payment, prescription drug prices, health IT, mental and behavioral health, workforce, public health, and more. The regulatory outlook also includes items advancing the administration's priorities on deregulation and fraud, waste, and abuse.

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Overview

- **What it is.** The 2026 Unified Agenda contains regulatory actions that federal agencies plan to undertake in the next 12 months. This includes annual regulatory updates (e.g., Medicare payment policies); regulations implementing recently enacted laws; and regulations implementing Executive Orders (EOs) and other priorities, such as regulatory proposals in the President's Budget.

  Each entry is organized by federal agency and its stage in the rulemaking process – prerule stage (e.g., Advanced Notices of Proposed Rulemaking), proposed rule stage (e.g., Notice of Proposed Rulemaking), final rule stage, long-term actions, and completed actions.

  We include entries from the following departments and agencies (linked to agency statements of regulatory priorities):

  - **Department of Health and Human Services (HHS)**
  - **Department of Labor (DOL)**
  - **Department of the Treasury**
  - **Department of Agriculture (USDA)**
  - **Department of Justice (DOJ)**
  - **Office of Management and Budget (OMB)** (no statement)

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The regulatory outlook notes items that are *NEW* (not published in a previous Unified Agenda) and *PENDING OMB REVIEW* (arrived at OMB for review).

- **Why it is important for you.** As a roadmap of the Trump administration's regulatory priorities, the Unified Agenda enables stakeholders to anticipate and prepare for rulemaking. Stakeholders can participate in the process by requesting an EO 12866 meeting with OMB and/or submitting public comments. The projected dates for regulatory actions may shift (likely later than scheduled), but they are helpful guides for advocacy planning.

- **Next steps**. Impact Health flags regulatory actions as they move through the process, specifically when they reach OMB for review and when regulatory review is completed. We include these updates in our Weekly sent on Mondays. For each policy area below, we note the lead Impact Health team members that can answer any questions or provide additional assistance.

Regulatory Activity by Policy Area

A. Coverage and Payment

1. Commercial Insurance

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The 2026 Unified Agenda includes new rulemaking actions on alternative coverage options (health reimbursement arrangements; association health plans; short-term, limited-duration insurance), mental health parity, Section 1332 state innovation waivers, and Section 1333 health care choice compacts that were not included in prior agendas.

HHS, Labor, and the Treasury (the "tri-agencies") also plan to complete rulemaking on transparency and initiate rulemaking on several delayed regulations implementing the No Surprises Act (NSA) (advanced explanation of benefits, provider discriminations, air ambulances, agents and brokers). Other items address Marketplace enrollment and electronic disclosures.

Lastly, the Unified Agenda does not include a timetable for the finalization of the tri-agency proposed rule allowing employers to provide standalone fertility benefits. It also does not include a proposed rule based on a request for information regarding the essential health benefits framework (comments due July 15, 2026).

- ***NEW*** **ICHRAs:** By July 2026, the tri-agencies plan to issue a proposed rule to clarify and streamline administrative requirements in order to expand the ability of employers to offer

health coverage through individual coverage health reimbursement arrangements (ICHRAs). Through ICHRAs, employers provide tax-advantaged dollars that employees can use to buy ACA-compliant individual health coverage on- or off-exchange. The first Trump administration created ICHRAs through regulations in 2019.

- **HRAs:** By July 2026, the IRS plans to issue a final rule regarding the application of the employer shared responsibility provisions to health reimbursement arrangements (HRAs) and other account-based group health plans. In 2019, the first Trump administration proposed but did not finalize regulations to clarify how the employer mandate interacts with HRAs and to provide certain safe harbors with respect to the application of the employer mandate to ICHRAs.

- ***NEW*** **Association Health Plan:** By November 2026, EBSA plans to issue a proposed rule to establish alternative criteria for determining when employers may join together in a group to be considered an "employer" under ERISA and sponsor an association health plan (AHP). In 2024, the Biden administration rescinded Trump-era regulations issued in 2018 that loosened the criteria for AHPs. A coalition of states challenged the 2018 AHP rule, resulting in the court vacating key provisions of the rule.

- ***NEW*** **Short-Term, Limited-Duration Insurance:** By August 2026, the tri-agencies plan to issue a proposed rule that is expected to allow premium tax credits to be used for short-term, limited-duration insurance. In the Unified Agenda, the tri-agencies note receiving feedback from stakeholders expressing concerns that current regulations have created barriers to affordable coverage options for consumers who do not qualify for premium tax credits.

- ***NEW*** **Mental Health Parity:** By December 2026, the tri-agencies plan to issue a proposed rule amending mental health parity regulations and implementing the nonquantitative treatment limitation (NQTL) comparative analyses requirement added by the Consolidated Appropriations Act, 2021. Earlier this year, the tri-agencies announced that they would pursue new rulemaking rather than defend the 2024 final rule challenged by The ERISA Industry Committee. The forthcoming proposed rule will make "significant revisions" to the provisions that were challenged in the lawsuit, which include the "meaningful benefits" requirement and the "material differences in access" standard.

- ***PENDING OMB REVIEW*** **ACA Marketplace Enrollment:** By July 2026, CMS plans to issue a proposed rule that will outline how Federal and State-based Exchanges will implement new requirements regarding eligibility verification for the premium tax credit. H.R. 1 requires states to establish a pre-enrollment verification process by August 1, 2027. For plan year 2028, subsidized enrollees will need to actively reverify their income and other eligibility information in order to receive an advance premium tax credit (APTC). This change effectively eliminates automatic re-enrollment. Additionally, H.R. 1 requires APTCs to be withheld until eligibility is fully verified. The proposed rule arrived at OMB for review on April 22, 2026.

- ***NEW*** **ACA Section 1332 and 1333 Waivers:** By July 2026, CMS plans to issue a proposed rule to update the regulations and policies governing Section 1332 State Innovation Waivers.

These changes could include a revised interpretation of the statutory requirements related to coverage, affordability, comprehensiveness, and federal-deficit neutrality. The current interpretation of these requirements was established by the Biden administration in 2021 and replaced the Trump administration's interpretation in 2018, which established less restrictive standards for the statutory requirements. In the same proposed rule, CMS plans to establish procedural standards for health care choice compacts under Section 1333, which provides a framework allowing the sale of individual market qualified health plans (QHPs) across state lines. Prior to joining the administration as CCIIO Director, Peter Nelson argued in a report that 1333 compacts could provide a vehicle for states to make significant changes to the individual market. Additionally, the proposed rule will include proposals to update HHS's oversight and enforcement program for agents and brokers registered to sell QHPs through the Federal Exchange.

- **Transparency:** By July 2026, the tri-agencies plan to issue a final rule amending Transparency in Coverage (TiC) requirements. The proposed changes sought to improve the standardization, accuracy, and accessibility of the in-network rate and out-of-network allowed amount machine-readable files (IHPP summary). In June 2025, the tri-agencies published a request for information seeking input on ways to effectively implement or amend the prescription drug machine-readable file requirement, which is currently being enforced "on a case-by-case basis, as the facts and circumstances warrant." The 2026 Unified Agenda does not mention future rulemaking on prescription drug price transparency, which might signal that the tri-agencies may instead issue guidance.

- **Advanced Explanation of Benefits:** By September 2026, the tri-agencies plan to issue a proposed rule to implement the advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements. In CAA, 2021, Congress established requirements for providers and facilities to provide a GFE of the expected charges for scheduled items or services to plans and issuers. In turn, plans and issuers are required to provide enrollees with an AEOB that provides the contracted rate, the GFE of the amount the plan or coverage is responsible for paying, the cost-sharing amount based on the GFE received from the provider or facility, and other information. The Biden administration issued a request for information in 2022 but did not pursue rulemaking.

- **Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement:** By September 2026, the tri-agencies plan to issue a final rule to implement several NSA provisions. The proposed rule, issued in 2022 by the Biden administration, included: (1) transparency requirements for air ambulance service providers and payers to disclose information about air ambulance services; (2) transparency requirements for issuers offering individual health insurance coverage or short-term, limited-duration insurance to disclose to policyholders and to report any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage; and (3) changes to investigation and enforcement processes.

- **Provider Discrimination:** The tri-agencies plan to issue a proposed rule to implement provider nondiscrimination requirements for group health plans and health insurance issuers. The protections against provider discrimination were established in the ACA but there is no enforcement mechanism. In 2021, a group of Senate Democrats sent a letter to the Biden-appointed secretaries to provide clarity on their intention of the provision and the actions that they hope the agencies will take during rulemaking. The proposed rule is slated for December 2026 in IRS' Unified Agenda but is marked as a long-term action for EBSA and CMS.

- **Fertility Benefits:** The Unified Agenda does not mention a final rule for the tri-agency proposed rule allowing employers to provide standalone fertility benefits (excepted benefits) (IHPP summary). The comment period ended on July 13, 2026. It is unclear if the tri-agencies intend to finalize the proposal.

- ***PENDING OMB REVIEW*** **Electric Disclosures:** By July 2026, EBSA plans to issue a proposed rule that is expected to allow e-delivery of group health plan disclosures required under ERISA, as a default. This option became available to ERISA pension plans in 2020 through regulations. The proposed rule arrived at OMB for review on May 13, 2026.

2. Medicaid

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Over the course of the next year, CMS will continue to release sub-regulatory guidance, proposed rules and final regulations to implement H.R. 1 including proposed rules on provider taxes and the budget neutrality requirements for 1115 demonstration waivers. The agency also intends to issue a new proposed rule related to the administration's efforts to secure Medicaid and CHIP program integrity that will revise/rescind certain Biden administration regulations and enhance oversight of provider enrollment.

- ***NEW*** **Provider Taxes:** In July 2026, CMS plans to release another proposed rule implementing the changes to provider taxes found in H.R. 1, adding that the proposed rule will revise regulations to reflect the new hold harmless limits as well as set requirements that will allow the agency to implement the statutory changes in an accurate and effective manner.

- ***NEW*** **Medicaid and CHIP Program Integrity:** In July 2026, CMS plans to release a proposed rule implementing a variety of changes designed to address fiscal and program integrity in Medicaid and CHIP. First, the agency intends to revise and rescind Biden Era rulemaking from 2024, which includes the Medicaid and Children's Health Insurance Program Managed Care Access, Finance and Quality Final Rule (IHPP summary) and the Ensuring Access to Medicaid Services Final Rule (IHPP summary). CMS also intends to issue new proposals to enhance oversight of states managed care plans and provider enrollment such as (1) revising various overpayment, disallowance, and other administrative action authorities, (2) adding new grounds for state Medicaid agencies (SMA) to use to terminate/deny the enrollment of bad actor

providers, and (3) giving SMAs greater authority to conduct on-site visits of providers to verify compliance with state Medicaid requirements. The rule will also detail proposals affecting managed care and access intended to reduce administrative costs and burden for both states and the federal government.

- ***NEW*** **Section 1115 Demonstrations and Budget Neutrality:** In January 2027, CMS plans to issue a proposed rule entitled "Strengthening the Integrity of Medicaid and CHIP Eligibility, Managed Care, Financing and Section 1115 Demonstrations" in January 2027 that would implement section 1115 demonstration budget neutrality codified in statute under section 71118 of H.R.1. CMS previously released a letter to states previewing the changes expected in this regulation (IHPP summary).

3. Medicare

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In addition to fulfilling annual statutory requirements related to Medicare payment and care delivery, the administration is expected to use the Innovation Center to advance broader priorities related to lowering health care costs, reducing administrative burden, and accelerating the transition to value-based care. While CMS has not disclosed details, future mandatory payment models are expected to reflect the administration's emphasis on payment innovation, fiscal responsibility, and improving health outcomes.

- ***NEW*** **New Models:** CMS is expected to propose two new mandatory payment models in July and October 2026, although the agency has not released details. Based on recent statements and Innovation Center activities, one model is likely to focus on prescription drug payment and affordability, potentially building on the administration's Most Favored Nation pricing initiative or other drug pricing reforms. The second could test new payment approaches in areas such as Medicare Advantage or other Medicare payment reforms that advance the administration's goals of improving health outcomes, reducing administrative burden, and lowering Medicare spending.

4. Medicare Advantage

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CMS is expected to issue a third final rule from contract year (CY) 2026 proposals, as well as routine rulemaking for contract year (CY) 2028.

- **Medicare Advantage Policies:** In December 2027, CMS expected to release a third final rule from the CY 2026 proposals. CMS will also issue the CY 2028 Policy and Technical Changes proposed rule to strengthen and improve the MA and Part D programs, which is expected to be released in September 2026.

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B. Medical Products

1. Laboratory

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- ***NEW*** **CLIA Modernization:** CMS plans to issue a proposed rule to modernize clinical labs in the following areas: 1) virtual access implementation, 2) gynecologic cytology PT, and 3) personnel qualification requirements, by September 2026

2. Medical Devices

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- ***NEW*** **Electronic Medical Device Labeling:** By November 2026, the FDA is expected to issue a proposed rule to clarify that the "adequate directions for use" requirement in section 502(f) of the Federal Food, Drug, and Cosmetic Act could be satisfied when labeling is provided solely by electronic means for certain types of devices in certain circumstances. The FDA states that this would help modernize the way required labeling is provided to consumers of medical devices.

3. Prescription Drugs

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Related to prescription drug transparency and pricing, the DOL/EBSA will look to finalize a rule to increase transparency of pharmacy benefit manger (PBM) compensation and fees, while CMMI will finalize the GLOBE and GUARD models. On the affordability front, CMS will issue a proposed rule to address copay accumulator programs, in light of the first Trump administration's policy to allow such programs being struck down by the courts.

- **PBM Fee Disclosure:** DOL/EBSA is expected to release the final rule which requires pharmacy benefit managers (PBMs) to disclose information on fees and compensation arrangements to group health plans subject to Employee Retirement Income Security Act (ERISA) by September 2026. This action is pursuant to President Trump's executive order on *Lowering Drug Prices by Once Again Putting Americans First*, which requires the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by PBMs.

- ***PENDING OMB REVIEW*** **GLOBE and GUARD Models:** By December 2028, CMS is expected to release the final rules for the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model. Each would test the calculation of inflation rebates using international pricing data and were expected to launch by October 2026 and January 2027. Given the expected long-term timeframe, the pending rules may be notices to delay the implementation of the models.

- **Copay Accumulator Programs:** By July 2027, the tri-agencies are expected to issue a proposed rule to applicability of drug manufacturer support to the annual limitation on cost sharing for group and individual coverage address. This is in response to the 2023 court ruling that struck down the 2021 Notice of Benefit and Payment Parameters policy that allowed insurers to utilize copay accumulator programs that exclude manufacturer copay assistance from patients' cost-sharing calculations.

The Unified Agenda also features several Food and Drug administration (FDA) rules that increase transparency across several areas, including requiring full risk information in direct-to-consumer advertising, mandating reporting manufacturing information, and a new patient labeling requirement, among other proposals.

- ***NEW*** **Direct-to-Consumer Advertisements:** By December 2026, the FDA will release a proposed rule that would eliminate the option for manufacturers to disclose risk, contraindication, and other safety information in another source beyond the radio or television advertisement itself. With this option removed, manufacturers would be required to disclose all relevant risk and safety information to consumers within the confines of the ad itself rather than referring consumers to an external source where they can request the full FDA-approved labeling.

- ***NEW*** **Drug Supply Chain Transparency:** By July 2026, the FDA is expected to issue a proposed rule to require brand and generic pharmaceutical manufacturers to improve transparency of pharmaceutical manufacturing information in an effort to enhance FDA oversight of the drug supply chain.

- ***NEW*** **Expedited Investigational New Drug (IND) Applications:** The FDA plans to release a proposed rule by July 2026, that would make changes to the IND process and content, as well as sponsor responsibilities, to modernize and streamline the application process for Phase 1 clinical trials.

- **Drug Labeling:** The FDA is expected to finalize FDA medication guide regulations to require a new form of patient labeling, known as the Patient Medication Information, by December 2026.

- **Pediatric Drugs:** The FDA intends to release a proposed rule by November 2026 to amend its existing regulations and add new regulations pertaining to submission of required initial pediatric study plans (iPSPs) under the Federal Food, Drug, and Cosmetic Act.

4. Organ Procurement

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HHS continues its work to strengthen oversight of organ procurement and implement the IOTA model.

- ***NEW*** **OPTN:** A Health Resources and Services administration (HRSA) proposed rule listed for December 2025 would update oversight of the Organ Procurement and Transplantation Network (OPTN) by making certain authorities enforceable rather than voluntary and align with the Securing the U.S. Organ Procurement and Transplantation Act from 2023.

- **OPOs:** CMS plans to issue a final rule in January 2029 to revise the Conditions for Coverage for Organ Procurement Organizations (OPOs) based on the proposed rule issued in January 2026.

- **IOTA:** CMS plans to issue a final rule in December 2028 to revise the Increasing Organ Transplant Access (IOTA) model for performance year two.

C. Health Services

1. Mental and Behavioral Health

Contact: Lena Marceno; lena@impacthealthpolicy.com

- ***NEW*** **Mental Health Parity:** By December 2026, the tri-agencies plan to issue a proposed rule amending mental health parity regulations and implementing the nonquantitative treatment limitation (NQTL) comparative analyses requirement added by the Consolidated Appropriations Act, 2021. Earlier this year, the tri-agencies announced that they would pursue new rulemaking rather than defend the 2024 final rule challenged by The ERISA Industry Committee. The forthcoming proposed rule will make "significant revisions" to the provisions that were challenged in the lawsuit, which include the "meaningful benefits" requirement and the "material differences in access" standard.

- ***NEW*** **Medication-Assisted Treatment (MAT)/Medication for Opioid Use Disorder (MOUD):** As in previous years, the DEA is expended to release numerous regulations related to controlled substances and the treatment of substance use disorder. New this year, the DEA plans to revisit a 2010 interim final rule that established the requirements for electronic prescriptions of controlled substances and instead issue a notice of proposed rulemaking to add additional safeguards to prevent bad actors from generating and filling fraudulent prescriptions. The timing of the NPRM is currently unknown. The DEA is also planning to issue a proposed rule on the role of pharmacies in dispensing controlled substances and establishing if pharmacists/pharmacy technicians are permitted to adjust prescriptions for schedule II-V

controlled substances after the prescription is signed off on by a DEA registered provider. The proposed rule is expected in July 2026.

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was enacted to prevent the illegal online distribution of controlled substances by requiring an in-person medical evaluation before prescribing, with certain exceptions for telemedicine. The DEA has been working since 2023 to propose and implement a special registration process for telemedicine practitioners. This final rule is expected in November 2026.

2. Reproductive Health

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- **Title X.** By July 2026, HHS's Office of the Assistant Secretary for Health (OASH) plans to issue a proposed rule revising Title X family planning program regulations to align them more closely with statutory program integrity requirements under 42 CFR Part 59. Although the scope of the proposed changes has not yet been specified, the rule is expected to modify compliance obligations for Title X grant recipients, including requirements related to program administration, oversight, and the separation of Title X-funded services from other activities. The administration is expected to consider reinstating elements of the 2019 Title X regulations, which prohibited Title X-funded entities from referring patients for abortion services and required physical separation between Title X-funded family planning services and abortion-related activities.

D. Technology & Data

1. Health IT

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The administration plans to further its work on digital health, most notably with long-term work on the use of AI in clinical care.

- **HHS Acquisition:** HHS also plans to issue a final rule in February 2027 to implement requirements for HHS to procure health information technology that meets ONC's standards and implementation specifications.

- **HITECH Act:** The HHS Office of Civil Rights (OCR) includes a proposed rule for November 2027 with a methodology to distribute civil monetary penalties and monetary settlements to those harmed by an offense under HIPAA relating to privacy or security.

- **Artificial Intelligence in Clinical Care:** HHS's Office of the National Coordinator for Health Information Technology (ONC) continues to identify as a long-term action its initiative to accelerate the adoption and use of artificial intelligence (AI) in clinical care. Following the Request for Information (RFI) issued in December 2025, ONC is seeking public feedback on

actions HHS can take to establish a forward-looking, industry-supportive approach to promote the safe and effective integration of AI into clinical care. The Unified Agenda does not identify a subsequent regulatory action or timeline.

2. Interoperability

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The administration plans to further its work on improving interoperability and the flow of health information, including through deregulation.

- ***NEW*** **APIs and Information Blocking:** ONC will propose a rule in November 2026 with proposals for standards adoption, certification of application programming interfaces (APIs), and enhancements to conditions of certification, along with updated information sharing requirements.

- **Deregulation:** In August 2026, the Office of the National Coordinator for health IT (ONC) plans to finalize the Health Data, Technology, and Interoperability: Deregulatory Actions to Unleash Prosperity (HTI-5) rule related to Certified Programs for Health IT and information blocking, with the goal of reducing burden and supporting innovation.

- **Care Coordination and Public Health:** ONC plans to finalize the remaining parts of the Health Data, Technology, and Interoperability (HTI-2) proposed rule related to care coordination and management. In the HTI-5 proposed rule related to deregulation, ONC proposed to withdraw the non-finalized portions of the HTI-2 proposed rule which may now be revisited in this projected final rule.

- **Standards for Data Exchange**: The administration for Children and Families (ACF) is planning to update data exchange standards for certain categories of information shared for agencies operating TANF, child support services, child welfare services, and foster care and adoption assistance. The standards will be identified through a working group and stakeholder input. The action was targeted for May 2026.

3. Privacy

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The administration plans to modernize and strengthen privacy protections across health care, cybersecurity, federal data systems, and broader data management practices. These efforts focus on improving cybersecurity, expanding individuals' access to their health information, updating HIPAA transaction standards, ensuring timely access to federal data assets, and modernizing longstanding privacy regulations.

- **HIPAA Electronic Transaction Standards Modernization:** CMS plans to issue a proposed rule by December 2026 to update the Health Insurance Portability and Accountability Act of 1996 (HIPAA) electronic transaction standards governing health care claims and electronic remittance advice. The proposal would adopt newer X12 standards to improve interoperability and reduce administrative burden for providers and health plans.

- ***NEW*** **HIPAA Right of Access:** By November 2026, HHS plans to issue a proposed rule to improve individuals' timely access to their protected health information under the HIPAA Privacy Rule. The proposal would focus on reducing the amount of time covered entities have to respond to requests for protected health information.

- ***PENDING OMB REVIEW*** **HIPAA Privacy Rule Enhancements:** HHS plans to issue a final rule by August 2026 to strengthen individuals' rights to access their protected health information, improve information sharing for care coordination and case management, facilitate greater family and caregiver involvement during emergencies, expand disclosures for national security readiness among uniformed services, support accessibility through telecommunications relay services, and reduce administrative burdens on providers while maintaining privacy protections. HHS initially proposed these updates in January 2021.

- **HIPAA Security Rule Updates:** HHS now expects to issue a final rule by July 2027 to strengthen the HIPAA Security Rule and improve the health care sector's ability to prevent, detect, respond to, and recover from cybersecurity threats involving electronic protected health information. HHS issued the proposed rule in January 2025.

- **Updated Privacy Act Regulations:** HHS plans to issue a proposed rule by July 2026 to modernize the Department's implementation of the Privacy Act of 1974 by updating outdated regulations, reflecting statutory and organizational changes, simplifying individuals' access to records, and eliminating duplicative FDA Privacy Act regulations.

- **HITECH Act:** The HHS Office of Civil Rights (OCR) includes a proposed rule for November 2027 with a methodology to distribute civil monetary penalties and monetary settlements to those harmed by an offense under HIPAA relating to privacy or security.

- **Cyber Incident Reporting Requirements:** DHS's Cybersecurity and Infrastructure Security Agency (CISA) plans to issue a final rule by September 2026 implementing the Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA). The rule will establish reporting requirements for covered entities to notify CISA of significant cyber incidents and ransomware payments while seeking to reduce reporting burden and better align with other federal cybersecurity reporting requirements. CISA issued the proposed rule in April 2024.

- **Presumption of Accessibility:** OMB plans to issue a proposed rule by August 2026 to require the timely provision of federal data assets, identify statutory exemptions, establish Privacy Act compliance standards, and create a transparent process for handling requests for access to federal data.

- **Expanding Secure Access to Statistical Data:** OMB continues to plan a proposed rule to establish standards for assessing the sensitivity of data assets under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), modifying data to improve secure access, and requiring statistical agencies to conduct transparent risk assessments. The proposed rule is now scheduled for August 2026.

E. Workforce

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1. Graduate Medical Education

The administration is expected to pursue regulatory changes to graduate medical education (GME) that support its broader workforce and health policy priorities. Beyond expanding physician training capacity and modernizing accreditation, the rule could reflect aspects of the Make America Healthy Again (MAHA) agenda by encouraging physician training that places greater emphasis on prevention, nutrition, chronic disease, and primary care.

- **Graduate Medical Education:** A proposed rule is expected in February 2027 to update regulations governing HHS GME funding and new accrediting bodies. While the scope of the proposal remains uncertain, it could expand physician training capacity, reduce barriers to establishing residency programs, and align federal GME policy with evolving accreditation standards and broader MAHA priorities related to prevention, nutrition, and chronic disease. The rule may also build on HHS's recent initiative under which a number of accrediting and certification organizations voluntarily committed to strengthen nutrition education and competency requirements across medical education and residency training (IHPP summary).

2. Long-term Care Staffing

CMS is expected to complete rulemaking to implement statutory changes affecting federal nursing home staffing requirements. The agency must finalize regulations repealing the minimum staffing standards that Congress prohibited CMS from implementing, administering, or enforcing until September 30, 2034.

- **Repeal of Minimum Staffing Standards for Long-Term Care Facilities:** CMS has until December 2028 to issue a rule finalizing the December 3, 2025 interim final rule with comment period that repealed provisions of the "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting" final rule (IHPP summary). The interim final rule was issued in response to changes made by the One Big Beautiful Bill Act of 2025, which precluded HHS from implementing, administering, or enforcing certain provisions of the final rule until September 30, 2034.

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F. Federal Oversight

1. Deregulation

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The Unified Agenda includes efforts to advance the President Trump's deregulatory agenda, with plans to eliminate or reform regulations governing Conditions of Participation in Medicare and Medicaid and possibly rollback the process to petition for rulemaking.

- ***NEW*** **Conditions of Participation:** By August 2026, CMS plans to issue a proposed rule to revise the Conditions of Participation, Conditions for Coverage, and Requirements for Medicare- and Medicaid-participating providers and suppliers, reducing burden and increasing flexibility to deliver high quality care. CMS intends to eliminate or reform regulations that it considers "obsolete, outdated, and excessively burdensome" in order to enhance direct patient care.

- ***NEW*** **Petition for Rulemaking:** By July 2026, HHS plans to issue an interim final rule to establish new procedures for the submission, processing, and review of petition to amend or repeal a rule and for regulatory review. HHS notes that the changes are intended to lessen the burden on both the public and agency to respond to rulemaking petitions and to enhance transparency and public trust in the rulemaking process. In 2025, HHS issued a policy statement empowering HHS to promulgate or rescind certain rules relating to "agency management or personnel or to public property, loans, grants, benefits or contracts" without a period of notice and comment rulemaking. The interim final rule could also serve as another way for HHS to limit public engagement in the rulemaking process. Under the Administrative Procedures Act, the public may petition HHS to issue, modify, or withdraw a rule.

2. Federal Funding

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The administration continues efforts to modernize federal financial assistance policies by updating government-wide grant management requirements and aligning agency-specific regulations with revisions to OMB's Uniform Guidance. These actions are intended to improve transparency, accountability, oversight, and consistency across federal grant programs while reducing administrative burden.

- **OMB Federal Financial Assistance Regulations:** The Unified Agenda does not mention a final rule for OMB's proposed revisions to the government-wide Uniform Guidance governing federal financial assistance. The comment period for the proposed rule is scheduled to close on July 13, 2026. Although the 2026 Unified Agenda lists only the proposed rule, OMB indicated in the

proposed rule that it intends to issue a final rule effective October 1, 2026, so that a single set of government-wide requirements applies to federal awards made during fiscal year 2027.

- ***NEW*** **Agency Companion Rules:** By July 2026, multiple federal agencies, including HHS, DOJ, SBA, and others, plan to issue companion proposed rules revising their agency-specific federal financial assistance regulations to align with OMB's updated Uniform Guidance. Consistent with OMB's revisions, these proposals are intended to improve transparency, accountability, and oversight of federal awards, revise indirect cost policies, reduce administrative burden, and convert existing guidance into regulation while maintaining government-wide consistency.

- ***NEW*** **501(c)(3) Organizations:** By August 2026, IRS plans to issue a proposed rule to revise the Form 990 as part of the Treasury's initiative to strengthen oversight of fiscal sponsorship arrangements. In April 2026, Treasury announced their plans to increase reporting requirements to help the IRS and the public better understand how nonprofit organizations use funds, the projects that are funded, and who controls project funds. The proposed rule may seek to address concerns about "non-profit sponsorships of left-wing radicals" raised by congressional Republicans. Rep. Morgan (R-TX) and Sen. Cruz (R-TX) introduced legislation to hold 501(c)(3) liable for the conduct of the projects they sponsor.

3. Fraud, Waste, and Abuse

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The Unified Agenda includes several items that advance the Trump administration's anti-fraud agenda. These efforts may be informed by the President Trump's Task Force to Eliminate Fraud.

- ***NEW*** **Program Integrity:** By October 2026, CMS plans to issue a proposed rule aimed at strengthening CMS's ability to crush fraud, enhance program integrity efforts across Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), and maximize legislative authorities to address inappropriate payments. It will include proposals related to provider enrollment, medical review, investigations, and other program integrity oversight provisions. The proposed rule will be informed by feedback collected in the CRUSH request for information.

- ***NEW*** **Medicaid and CHIP Program Integrity:** In July 2026, CMS plans to release a proposed rule implementing a variety of changes designed to address fiscal and program integrity in Medicaid and CHIP. First, the agency intends to revise and rescind Biden Era rulemaking from 2024, which includes the Medicaid and Children's Health Insurance Program Managed Care Access, Finance and Quality Final Rule (IHPP summary) and the Ensuring Access to Medicaid Services Final Rule (IHPP summary). CMS also intends to issue new proposals to enhance oversight of states managed care plans and provider enrollment such as (1) revising various overpayment, disallowance, and other administrative action authorities, (2) adding new grounds for state Medicaid agencies (SMA) to use to terminate/deny the enrollment of bad actor providers, and (3) giving SMAs greater authority to conduct on-site visits of providers to verify compliance with state Medicaid requirements. The rule will also detail proposals affecting

managed care and access intended to reduce administrative costs and burden for both states and the federal government.

- **Exclusions Program:** By July 2027, CMS plans to issue a final rule to modify the authority of the HHS Office of Inspector General (OIG) to exclude individuals and entities from federally funded health care programs. This proposed rule adds exclusion authorities related to misclassification and false information about outpatient drugs, and updates and clarifies OIG's procedures for excluding individuals and entities from participation in federal health care programs.

- **Crimes in Long-Term Care Facilities:** CMS plans to issue a proposed rule to implement federal requirements requiring specific covered individuals in long-term care facilities to report to the Secretary and law enforcement entities any reasonable suspicion that a crime has been committed against a resident of or an individual who is receiving care from such facility. It would also implement requirements of these long-term care facilities to notify such covered individuals of their reporting obligations, as well as their rights under this reporting requirement, and prohibit retaliation for making such reports. Additionally, the proposed rule would establish enforcement procedures (civil penalties, exclusions, hearings, and appeals). The Unified Agenda does not provide a timetable.

G. Health Equity & Civil Rights

1. Gender Identity

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The administration is advancing a regulatory agenda to limit federal support for and access to gender-affirming care, particularly for minors, consistent with several executive orders, including *EO 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*; *EO 14173, Ending Radical and Wasteful Government DEI Programs and Preferencing*; and *EO 14187, Protecting Children From Chemical and Surgical Mutilation*.

- ***NEW*** **Biological Sex on ATF Forms:** By July 2026, the Department of Justice's Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) plans to issue a proposed rule requiring applicants completing federal firearms and explosives forms to report their biological sex rather than their gender identity. If finalized, the proposal would align ATF forms with the administration's broader federal policy on sex classification and could require transgender and some intersex individuals to provide information that differs from their gender identity.

- ***NEW*** **Condition of Participation:** By December 2028, CMS plans to release a final rule that would make hospitals ineligible to participate in Medicare and Medicaid if they provide what the administration defines as "sex-rejecting procedures" to individuals under age 18. If finalized, the

rule would establish compliance with this prohibition as a Medicare and Medicaid Condition of Participation, substantially expanding federal oversight of hospital policies governing gender-affirming care for minors. The proposed rule was originally released in December 2025 (IHPP summary).

- ***NEW* *PENDING OMB REVIEW* Federal Financial Participation:** By September 2026, CMS is expected to release the much-anticipated final rule that would prohibit federal Medicaid matching funds (FFP) for what the administration defines as "sex-rejecting procedures" provided to individuals under age 18. The rule would also prohibit the use of federal Children's Health Insurance Program (CHIP) funds for such services for individuals under age 19. If finalized, the rule would significantly restrict federal financing for gender-affirming care for minors under Medicaid and CHIP. The proposed rule was originally released in December 2025 (IHPP summary).

2. Nondiscrimination Protections

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The administration's nondiscrimination agenda focuses on two primary objectives: (1) revising disability and civil rights regulations to align more closely with President Trump's Executive Orders and the administration's regulatory reform priorities; and (2) expanding federal protections for conscience, religious exercise, and faith-based participation consistent with President Trump's Executive Orders.

- ***NEW* Section 1557 of the Affordable Care Act**: By February 2027, HHS' Office for Civil Rights (OCR) is expected to release a proposed rule amending portions of its regulations implementing Section 1557, the ACA's primary health care nondiscrimination provision. According to the Unified Agenda, the rule is intended to align the regulations more closely with President Trump's *EO 14219 Directing the Repeal of Unlawful Regulations*, *EO 14168 Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, *EO 14192 Unleashing Prosperity Through Deregulation*, and the administration's regulatory reform objectives. Although the scope of the proposal has not yet been released, the rule could significantly modify existing nondiscrimination requirements affecting health care providers, insurers, and other covered entities.

- ***NEW* Faith-Based Organizations:** By November 2026, the HHS Office of the Secretary plans to issue a proposed rule implementing *Executive Order 14205*, which established the White House Faith and Opportunity Initiative. The rule would amend HHS regulations governing participation by faith-based organizations in HHS-funded programs and activities by clarifying their rights and aligning program administration with the First Amendment and the Religious Freedom Restoration Act (RFRA).

- ***NEW* *PENDING OMB REVIEW* Rescinding Portions of HHS Title VI Regulations:** By July 2026, HHS OCR plans to issue a direct final rule rescinding portion of its Title VI regulations that the department believes exceed the statutory requirements of the Civil Rights Act of 1964.

According to the Unified Agenda, the proposal would align HHS regulations more closely with the statutory text and implement *EO 14281 Restoring Equality of Opportunity and Meritocracy*. The rule was submitted to OMB for review on April 24, 2026.

- ***NEW* *PENDING OMB REVIEW* Rescission of Vocational Education Nondiscrimination Guidelines:** By July 2026, HHS OCR is expected to finalize a rule rescinding Appendix B to 45 CFR Part 80, which contains guidance addressing discrimination in vocational education programs based on race, color, national origin, sex, and disability. The rule would also remove related references to these guidelines in regulations implementing Section 504 and Title IX. The rule was submitted to OMB for review on June 4, 2026.

- **Conscience and Religious Exercise:** By July 2026, HHS OCR is expected to release a proposed rule amending the 2024 Biden-era Conscience Rule governing federal health care conscience and religious protections. The proposal would make technical revisions and clarify OCR's interpretation and enforcement of existing federal conscience and religious freedom statutes consistent with President Trump's *EO 14202, Eradicating Anti-Christian Bias*, and *EO 14188, Additional Measures to Combat Anti-Semitism*.

- **Disability Nondiscrimination for Recipients of Federal Financial Assistance:** HHS and the Department of the Treasury are expected to update regulations governing Section 504 obligations for recipients of federal financial assistance. By September 2026, HHS OCR is expected to release a final rule clarifying that gender dysphoria is not recognized as a disability under Section 504, reversing the Biden administration's interpretation. The proposed rule was published on December 19, 2025, with the reopened comment period closing on February 20, 2026. Separately, by July 2026, the Department of the Treasury plans to issue a second proposed rule establishing agency-specific Section 504 regulations for recipients of Treasury financial assistance. Unlike the HHS proposal, Treasury's rule is primarily administrative and would establish the department's framework for implementing and enforcing Section 504 requirements. Treasury previously issued a proposed rule in 2017 that was not finalized.

- **Disability Nondiscrimination in Federally Conducted Programs:** HHS and the Department of the Treasury are expected to update Section 504 regulations governing programs operated directly by each agency. By November 2027, HHS OCR plans to issue a proposed rule establishing disability nondiscrimination standards for HHS-operated programs, aligning them with standards already applicable to recipients of HHS financial assistance, including requirements related to medical treatment, accessible medical equipment, communications, and compliance procedures. Separately, by July 2026, the Department of the Treasury plans to issue a proposed rule revising 31 CFR Part 17 to clarify its approach to implementing and enforcing Section 504 requirements in Treasury-conducted programs and activities.

- **ADA Website Accessibility:** By July 2026, DOJ plans to issue an interim final rule extending implementation deadlines for its April 2024 final rule establishing technical standards for state and local governments to make websites and mobile applications accessible to individuals with disabilities under Title II of the ADA. DOJ is also considering a subsequent notice of proposed

rulemaking to evaluate whether certain provisions of the rule should be revised to reduce regulatory burden while maintaining existing ADA obligations.

- **ADA Regulatory Reviews:** DOJ plans to issue proposed rules conducting the required 10-year (Section 610) reviews of its ADA regulations. The Title II review will examine regulations governing nondiscrimination in state and local government services, while the Title III review will evaluate accessibility requirements for public accommodations and commercial facilities. Both reviews will assess whether regulatory changes can reduce burden while continuing to implement the ADA's statutory requirements.

H. Population Health and Prevention

1. Nutrition

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The administration plans to promulgate regulations implementing provisions of H.R. 1 and to reduce fraud, waste, and abuse.

- ***NEW, PENDING OMB REVIEW*** **Work Requirements:** USDA plans to issue a proposed rule in July 2026 to codify the provisions of H.R. 1 that expand the scope of individuals subject to the community engagement requirement to waive the time limit for able-bodied adults without dependents (ABAWDs) and changes to the requirements for states seeking waivers to these time limits.
- ***NEW*** **State Cost Sharing:** A proposed rule is scheduled for December 2026 to implement the requirement in H.R. 1 for states to share a portion of the cost of SNAP benefits based on their payment accuracy rate.
- ***NEW*** **Immigrant Eligibility:** By July 2026, USDA plans to issue a proposed rule to conform SNAP regulations with the restriction limiting SNAP eligibility to U.S. citizens and certain lawfully present aliens from H.R. 1.
- **SNAP Utility Allowances:** A proposed rule is scheduled for August 2026 to implement changes to the requirements for standard utility allowances and treatment of energy assistance payments, including a restriction on including internet costs and limiting which households may use a standard utility allowance for determining household income and SNAP eligibility.
- ***PENDING OMB REVIEW*** **SNAP Eligibility:** A proposed rule scheduled for November 2026 would limit categorical eligibility for SNAP based on Temporary Assistance for Needy Families (TANF) to households that receive cash or “substantial” TANF assistance. UDSA says that the proposal would create a clearer nationwide policy and ensure categorical eligibility is used only for households that qualify for ongoing and substantial TANF benefits.

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- **SNAP Retailers**: USDA plans to issue a proposed rule in October 2026 implement provisions of the 2018 Farm Bill to deter retailer fraud, abuse, and non-compliance in SNAP. Additionally, a final rule in July 2026 would increase requirements for retailers to stock items in staple food categories.

- **SNAP Foods:** USDA plans to issue a proposed rule in December 2026 to amend the definition of "eligible foods" to align with the Make America Healthy Again (MAHA) agenda. USDA is currently in a lawsuit challenging the agency's solicitation and approval of state SNAP waivers to prohibit purchase of "junk foods" like candy and soda.

- **SNAP Benefit Security**: Additionally, a proposed rule is expected by September 2026 that will require state agencies to implement new card security measures to protect against card skimming, card cloning, and other fraudulent efforts to steal SNAP benefits.

- ***PENDING OMB REVIEW*** **WIC Modernization:** USDA plans to release a final rule in July 2026 to change the provisions that prevent online ordering in the WIC program and to modernize WIC vendor regulations to facilitate the transition to Electronic Benefit Transfer (EBT). Additionally, USDA plans to release a proposed rule also in July to increase program flexibility to adapt to a changing retail marketplace, amend outdated regulations, and ensure that EBT and other electronic solutions are considered holistically between WIC and Farmers' Market Nutrition programs.

- ***NEW*** **WIC Program Integrity:** A proposed rule is planned for September 2026 to modernize vendor integrity requirements to reflect nationwide implementation of electronic benefits transfer (EBT), advance security requirements to protect WIC participants' personal information and taxpayers, and enhance requirements for state agency vendor selection criteria and investigation techniques.

- **Child Nutrition Programs**: USDA plans to issue a proposed rule in the September 2026 to adjust meal pattern and monitoring requirements in child nutrition programs with the goal of increasing operational flexibility and reducing food waste. The Biden administration increased meal pattern requirements in alignment with the Dietary Guidelines for Americans to reduce added sugars and sodium, increase protein options, and ensure access to traditional Indigenous foods.

- ***NEW*** **Summer Meals Program Integrity**: A proposed rule is scheduled for July 2026 to implement provisions of the Consolidated Appropriations Act, 2023 authorizing a rural non-congregate meal option in the Summer Food Service Program (SFSP)and enhance program integrity for non-congregate meals in SFSP and the National School Lunch Seamless Summer Option.

- ***NEW*** **Fraud in CACFP and SFSP**: USDA plans to issue a proposed rule in July 2026 to minimize false and fraudulent claims in the Child and Adult Care Food Program (CACFP) and SFSP by giving state agencies and sponsors additional tools, applying reciprocal disqualification

procedures to school meal programs, CACFP, and SFSP, and changing the monitoring of day care homes and recordkeeping requirements.

- **Food Labels**: FDA plans to issue a final rule in December 2026 to require the front of food labels to display certain nutrition information to help consumers make informed dietary choices, based on feedback received on a January 2025 proposed rule.
- **SNAP Interstate Data Matching:** USDA targets December 2027 to issue a final action the SNAP National Accuracy Clearinghouse data matching system, following an interim final rule from 2022.

2. Public Health

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The Unified Agenda identifies several key public health priorities, including tobacco product regulation, workplace health and safety, infection prevention, heat injury prevention, and federal data governance. Expected rulemaking from FDA, OSHA, and OMB that would establish new requirements for tobacco product manufacturers and importers, strengthen workplace health and safety standards, and update policies governing access to confidential federal data.

- ***NEW*** **Electronic Nicotine Delivery System (ENDS) Product Standards:** By July 2026, the FDA plans to issue a proposed rule establishing product standards for electronic nicotine delivery systems (ENDS) under the Federal Food, Drug, and Cosmetic Act. The rule would establish standards that manufacturers must meet as part of the FDA's premarket review process, providing greater clarity and predictability regarding product requirements for ENDS applications seeking marketing authorization.
- ***PENDING OMB REVIEW*** **Administrative Detention of Tobacco Products:** By July 2026, the FDA plans to issue a proposed rule establishing procedures for the administrative detention of tobacco products suspected of being adulterated or misbranded. The rule would allow the FDA to temporarily detain tobacco products identified during inspections of manufacturers, vape shops, and other tobacco-related establishments while the agency evaluates whether additional enforcement actions, such as seizure or other legal remedies, are warranted. If finalized, the rule would provide the FDA with an additional enforcement tool to restrict potentially unlawful tobacco products from entering or remaining in commerce.
- **Tobacco Product Establishment Registration and Product Listing:** By July 2026, the FDA plans to issue a proposed rule establishing requirements for tobacco product establishment registration and product listing under the Federal Food, Drug, and Cosmetic Act. The rule would define submission requirements, including the format, content, and procedures for providing establishment and product information to the FDA. The proposal would expand existing registration and listing requirements beyond certain domestic manufacturers to include foreign establishments and additional categories of domestic tobacco product manufacturers.

- **ENDS Safety Standards, Including Standards for Toxicants and Impurities in E-Liquids:** By July 2026, the FDA plans to issue a proposed rule establishing tobacco product standards for ENDS, including requirements addressing the purity and allowable levels of toxicants and impurities in nicotine, propylene glycol, and vegetable glycerin used in e-liquids. FDA states that toxicants and impurities in these components may pose risks of adverse health effects and that the proposed standards are intended to limit exposure to harmful substances and establish requirements appropriate for the protection of public health.

- **FDA Import Data Requirements for Tobacco Products:** By September 2026, the FDA plans to finalize a rule requiring import filers to submit FDA premarket application numbers through the Automated Commercial Environment (ACE) system for imported ENDS products. The requirement would allow the FDA to more efficiently verify whether imported products have received the required marketing authorization and strengthen the enforcement of premarket authorization requirements for electronic nicotine delivery systems, including e-cigarettes and vaping products.

- **Tobacco Product Manufacturing Practices:** By July 2027, the FDA plans to finalize a rule establishing Tobacco Product Manufacturing Practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. The rule would establish manufacturing standards that address pre-production design validation, production controls, packaging, and storage requirements to help prevent contaminated, adulterated, or otherwise nonconforming tobacco products from entering the market.

- **Heat Injury and Illness Prevention in Outdoor and Indoor Work Settings:** By December 2026, OSHA plans to issue a supplemental proposed rule addressing heat injury and illness prevention in outdoor and indoor workplaces, with a final rule anticipated in October 2027. The rule would establish a federal workplace heat standard applicable to employers in OSHA-covered industries, including general industry, construction, maritime, and agriculture.

- **Removal of COVID-19 Healthcare Emergency Temporary Standard:** By July 2026, OSHA plans to finalize a rule removing 29 CFR 1910 Subpart U, the agency's COVID-19 Emergency Temporary Standard (ETS) for healthcare settings, from OSHA's workplace safety regulations. OSHA issued the ETS in June 2021 in response to the COVID-19 pandemic, but later that year discontinued enforcement of most provisions after determining that a permanent standard could not be completed within the timeframe contemplated by the Occupational Safety and Health Act. OSHA terminated the related rulemaking in January 2025 and subsequently proposed removing the remaining provisions of Subpart U in July 2025.

- **Expanding Secure Access to CIPSEA Data Assets:** By August 2026, OMB plans to issue a proposed rule establishing standards for evaluating the sensitivity of data protected under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), determining appropriate access levels, and improving access to protected statistical data assets. The

proposal would also require statistical agencies to conduct transparent risk assessments when managing access to confidential information.

- **Workplace Violence in Health Care and Social Assistance:** OSHA is continuing long-term rulemaking efforts to establish a workplace violence prevention standard for the health care and social assistance sectors. The potential rule would address risks of violence against health care and social service workers and could establish employer requirements related to workplace violence prevention plans, hazard assessments, employee training, incident reporting, and protective measures. OSHA has not yet issued a proposed rule, and the scope and timing of any future requirements remain uncertain.