

Regulatory Outlook: Spring 2024 Unified Agenda

The Biden Administration recently released its [Spring 2024 Unified Agenda](#), which outlines regulatory plans for federal agencies over the coming year. The Unified Agenda reflects the Biden Administration’s continued priority on policies addressing health. In our regulatory outlook, we highlight rulemaking on coverage and payment, public health and safety, mental and behavioral health, drug pricing, and health IT, and more.

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Overview

- **What it is.** The Spring 2024 edition of the semiannual unified agenda contains regulatory actions that federal agencies plan to undertake in the next 12 months. The Unified Agenda includes annual regulatory updates (e.g., Medicare payment policies); regulations implementing recently enacted laws, such as the Inflation Reduction Act of 2022 and the No Surprises Act; and regulations implementing Executive Orders and other priorities, such as regulatory proposals in the President's Budget. Many of the entries were included in the Fall 2023 edition (released on December 6, 2023) and may have been updated with new timetables.

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:

- **Department of Health and Human Services (HHS)** – Administration for Children and Families (ACF), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration, Health Resources and Services Administration (HRSA), Office for Civil Rights (OCR), Office of the Assistant Secretary for Health (OASH), Office of Inspector General (OIG), Office of the National Coordinator for Health Information Technology (ONC), Office of the Secretary (OS), and Substance Abuse and Mental Health Services Administration (SAMHSA)
 - **Department of Labor (DOL)** – Employee Benefits Security Administration (EBSA) and Occupational Safety and Health Administration (OSHA);
 - **Department of Treasury** – Community Development Financial Institutions Fund (CDFI Fund) and Internal Revenue Service (IRS);
 - **Department of Agriculture** – Food and Nutrition Service (FNS);
 - **Department of Housing and Urban Development (HUD)** – various agencies;
 - **Department of Justice (DOJ)** – Drug Enforcement Administration (DEA), Executive Office for Immigration Review (EOIR), and other agencies;
 - **Federal Trade Commission (FTC)**; and
 - **Office of Management and Budget (OMB).**
- **Why it is important for you.** As a roadmap of the Biden Administration's regulatory priorities, the Unified Agenda enables stakeholders to anticipate and prepare for rulemaking. Stakeholders can

participate by requesting an [EO 12866](#) meeting with OMB and/or submitting public comments. Projected dates for regulatory actions may shift, but they are helpful guides for advocacy planning.

- **Recent U.S. Supreme Court decisions ([IHPP memo](#)).** A series of recent Supreme Court decisions – including a ruling that overturned *Chevron* deference, i.e., judicial deference to agency interpretations of ambiguous statutes – has reshaped the regulatory landscape, further shifting power away from the executive and legislative branches to the judiciary branch. Because federal agencies have generally tried to minimize its reliance on *Chevron* deference and instead point to specific statutory authority (e.g., Social Security Act) to mitigate legal challenges to regulations, the extent to which the end of *Chevron* deference will alter rulemaking is unclear.

We anticipate that the regulatory process will slow down as agencies divert resources to prevent and defend against more frequent legal challenges and take time to ensure decisions are positioned as findings of fact rather than interpretations of law. Regulators are also likely to shy away from taking bold action or making dramatic shifts in policy and may instead issue non-binding guidance. Ultimately, more litigation means that some regulations may not take effect in a timely manner or ever, increasing uncertainty for stakeholders.

- **Presidential election.** The Biden Administration released the Spring 2024 Unified Agenda on July 2, 2024. Some regulations are forecasted for 2025, highlighting policy priorities for a potential second term. Another Democratic Administration, regardless of who the President is, will likely continue to pursue the same or a similar regulatory agenda. It is unlikely that the Biden Administration will accelerate timetables and promulgate these regulations in 2024. Instead, federal agencies will likely wind down their rulemaking (with the exception of statutorily mandated rulemaking) to limit political liability.
- **Congressional Review Act.** The [Congressional Review Act \(CRA\)](#) governs the federal rulemaking process and gives Congress the ability to overturn rules issued by federal agencies within a limited period following their finalization. The Congressional Research Service unofficially estimates that the [“lookback” period](#) will begin in August, meaning that rules submitted to the House or Senate on or after August 1, 2024 may be subject to CRA review in the first few months of the first session of the 119th Congress. Given that a President’s signature is required to enact any such action by Congress, this procedure is generally pursued when the same party controls Congress and the White House. If former President Donald Trump is reelected and Republicans win control of the House and Senate, then some Biden-era regulations might be vulnerable to CRA.
- **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 member that can answer any questions or provide additional assistance.

Regulatory Activity by Issue Area

A. Coverage and Payment

1. Medicaid

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Earlier this year, the Administration released numerous final rules to strengthen access to health care for Medicaid beneficiaries across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. These actions included the second of two [final rules](#) to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program. The agency also released two final rules to improve access to care and quality outcomes for Medicaid and CHIP beneficiaries enrolled in [fee-for-service systems](#) or [managed care delivery systems](#). CMS also [finalized](#) its updates to the regulatory requirements of the Disproportionate Share Hospital (DSH) program in response to the Consolidated Appropriations Act, 2021 (CAA) and made additional technical changes to the DSH program. Section 203 of the CAA changed the methodology for calculating the hospital-specific DSH limit to include only costs and payments associated with Medicaid-eligible individuals where Medicaid is the primary payer, with limited exceptions.

With the Administration having wrapped up its regulatory priorities for 2024, its focus will likely continue on securing access to coverage during the unwind of the continuous enrollment period. Currently, states still have the option to pursue additional Medicaid waivers and other flexibilities during the unwinding period and the flexibilities that they already put into place have been extended through June 2025. CMS outlines its recommended options [here](#). This includes section 1902(e)(14)(A) waivers, flexibilities that are availability to states without the need for waivers, and more. Tables illustrating the flexibilities that each state has adopted has available [here](#). Given Congressional attention to the millions of individuals who have lost Medicaid coverage nationwide for procedural reasons during the unwind, we could see additional administrative action encouraging states to take further action to reverse this trend.

Additionally, following criticism from Congress and State Medicaid Officials, CMS will also likely work to reduce the current backlog of 1115 demonstration waivers and amendments in need of review and approval. It is likely that additional waivers will be approved for continuous Medicaid enrollment for

children as well as for behavioral health services including increasing access to Medicaid for individuals transitioning out of incarceration.

2. Medicare

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In addition to fulfilling statutory requirements related to Medicare payment and care delivery, the Administration will continue to focus on accountability for quality and cost, ensuring access to care, and improving health equity.

- **Medicare Payment System Updates:** CMS will finalize proposed fiscal year (FY) 2025 updates for Medicare payment in the [Hospital Inpatient Prospective Payment System](#), the [Hospice Wage Index](#), the [Inpatient Psychiatric payment system](#), the [Inpatient Rehabilitative Facility payment system](#), and the [Skilled Nursing Facility payment system](#) around August 2024.

CMS will also finalize proposed updates for Medicare payment in the calendar year (CY)-based payment systems (the [Hospital Outpatient Prospective Payment System](#), the [Medicare Physician Fee Schedule](#), the [End Stage Renal Disease payment system](#), and the [Home Health payment system](#)) around November 2024.

- **CMS Innovation Center:** CMS plans to issue a final rule for a new Medicare payment model called the [Increasing Organ Transplant Access \(IOTA\) Model](#), which is focused on accountability for quality and cost, access, and health equity. The rule includes general provisions for all models as well and is expected before the end of the year since the agency intends to launch the demonstration January 1, 2025.
- **Medicare Advantage Policies:** In December 2024, CMS is expected to release a [proposed rule](#) to codify long-established Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement. The CY 2026 Policy and Technical Changes to Medicare Advantage, Medicare Prescription Drug Benefit and Medicare Cost Plan Program [proposed rule](#) is expected to be released in September 2024.
- **Transitional Coverage for Breakthrough Devices:** By July, CMS intends on releasing the Transitional Coverage for Emerging Technologies (TCET) [final rule](#), which would provide medical devices with Breakthrough Designation Medicare coverage through the National Coverage Determination (NCD) process.

- **Organ Procurement:** In addition to the IOTA Model noted above, CMS plans to pursue other regulations on organ procurement. In October 2024, CMS is expected to issue a [proposed rule](#) implementing the HIV Organ Policy Equity Act. The proposed rule would remove clinical research and institutional review board (IRB) requirements for kidney and liver transplants of organs from people with human immunodeficiency virus (HIV). It would continue to require that the Organ Procurement and Transplantation (OPTN) adopt and use standards of quality with respect to kidneys and livers donated by persons with HIV, consistent with the National Organ Transplant Act of 1984 and in a way that ensures the use of kidneys and livers from people with HIV will not reduce the safety of organ transplantation. Additionally, in March 2025, CMS plans to [propose a rule](#) to change the standards used to evaluate and recertify organ procurement organizations as well as clarify the competition and decertification process for organ procurement organizations. Revisions would continue to hold OPOs responsible for improved performance.

3. Commercial Insurance

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The Administration will continue to use regulatory levers to protect and expand access to quality health insurance in the commercial market. The agenda includes rules that build on the Affordable Care Act (ACA), expand access to contraception, and implement surprise billing protections and transparency requirements.

- **ACA Marketplace:** In September 2024, CMS plans to release the [proposed](#) annual notice of benefit and payment parameters for 2026. The payment rule makes changes to regulations governing the Exchange and state-based marketplaces. In July 2024, IRS plans to issue a [final rule](#) on reporting requirements for issuers of catastrophic health care coverage in the Marketplace.
- **Reproductive Health Coverage:** In December 2024, CMS, EBSA, and IRS plan to issue a [final rule](#) that would expand access to contraceptive services. The [proposed rule](#) would allow the establishment of an “individual contraceptive arrangement” for individuals enrolled in private health plans that do not cover contraceptive services because of a religious objection.
- **Transparency:** In March 2025, CMS, EBSA, and IRS plan to issue a pair of long-awaited regulations required by the No Surprises Act to increase transparency, if President Biden is reelected. First, the departments plan to [finalize](#) requirements related to air ambulance services, agent and broker disclosures, and provider enforcement. The proposed rule would establish new data reporting requirements for providers of air ambulance service providers; enforcement action against potential violations by providers and facilities, including air ambulance providers; and disclosure and reporting requirements for agents and brokers regarding compensation for

enrollment in short-term, limited-duration insurance. Second, the departments plan to issue a long-awaited [proposed rule](#) to implement advanced explanation of benefits and good faith estimate requirements of the No Surprises Act. The departments issued a [request for information](#) in September 2022 to inform rulemaking.

- **Group Health Plan Reporting:** As part of a strategic project with the IRS and the Pension Benefit Guaranty Corporation, EBSA plans to issue a [proposed rule](#) in September 2024 to make information in the Form 5550 Annual Return/Report of Employee Benefit Plan more data mineable and to enhance the ability of EBSA and IRS to conduct compliance activities. House Education & Workforce Committee Ranking Member Bobby Scott (D-VA) and HELP Subcommittee Ranking Member Mark DeSaulnier (D-CA) recently sent a [letter](#) urging the Department of Labor to strengthen the Form 5500 to enhance data collection from group health plans. They are mainly concerned with the lack of transparency around benefit denials.
- **Surprise Medical Bills:** In November 2024, CMS, EBSA, and IRS plan to [finalize](#) a [proposed rule](#) on IDR operations.
- **Nondiscrimination Regarding Health Care Providers:** In August 2024, CMS, EBSA, and IRS plan to issue a [proposed rule](#), required by the No Surprises Act, that would codify protections established in the ACA against provider discrimination, which are currently implemented through sub-regulatory guidance. The provision prohibits a group health plan and a health insurance issuer offering group or individual health insurance coverage from discriminating against any health care provider who is acting within the scope of their license under state law.

B. Cross-Cutting Topics

1. Mental and Behavioral Health

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The Administration will use regulatory levers to help increase access to behavioral health care, specifically through advancing mental health parity and decreasing barriers to medications for opioid use disorder.

- **Mental Health Parity:** The Administration plans to issue a [final rule](#) to implement the mental health parity provisions included in the Consolidated Appropriations Act of 2021. In July 2023, the Administration released the [proposed rule](#) including new requirements for plans and issuers regarding the use and application of nonquantitative treatment limitations (NQTLs) – non-numerical limits on the scope or duration of benefits for treatments, such as preauthorization requirements. The final rule is expected to be released in July 2024.

- **Medication-Assisted Treatment (MAT)/Medication for Opioid Use Disorder (MOUD):** The Administration, largely through the Drug Enforcement Administration, is considering multiple rules regarding the delivery of treatment and medications for OUD. The DEA is expected to release a [final rule](#) by the end of the year that would clarify the use of electronic prescriptions to dispense controlled substances. The agency also plans to issue a [final rule](#) in September on whether it will make some of the COVID-19 telemedicine flexibilities permanent, including if providers can prescribe buprenorphine for opioid use disorder following an audio-only telemedicine encounter.

The DEA is also expected to release numerous regulations related to controlled substances and the treatment of substance use disorder. In April 2025, the DEA plans to issue a [final rule](#) implementing provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018. This rule would expand the number of eligible practitioners authorized to prescribe FDA-approved medications for treating OUD and adjust the governing provisions on the dispensing of controlled substances from a pharmacy to a practitioner. The agency is also expected to release a [final rule](#) by the end of the year to allow emergency medical services (EMS) registrants to transport controlled substances and provide additional guidance on the handling of those substances. 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. This proposed rule is expected to be released in November. In March of 2025, the DEA is expected to release a [final rule](#) that would require the use of online applications and related materials for the Controlled Substances Ordering System (CSOS).

Finally, the HHS Office of the Inspector General is expected to release a [proposed rule](#) that would establish a new safe harbor under the federal anti-kickback statute for certain behavioral health providers to allow for contingency management programs, an evidence-based practice to treat stimulant use disorder. This proposed rule is expected in November 2024.

2. Drug Pricing

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The Administration remains committed to addressing high prescription drug costs and plans to release final rules related to the Medicaid Drug Rebate Program, pharmacy standards, and prescription drug spending reporting by plans.

- **Medicaid Drug Rebate Program (MDRP):** In May 2023, CMS released a [proposed rule](#) that would establish new requirement under the MDRP, including a stacking of best prices and increased transparency requirements. This May, CMS [announced](#) that it would not be finalizing the best price stacking proposal after reviewing commenter feedback. CMS is expected to release the [final rule](#) in July 2024.
- **Pharmacy Standards:** By September 2024, CMS intends on releasing a [final rule](#) to require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10.
- **Prescription Drug Spending Reporting Requirements:** HHS, Labor, and Treasury plans on issuing two final rules ([here](#) and [here](#)) related to group health plan and health insurance issuer reporting on prescription drug spending in November 2024.

3. Long-Term Care

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In alignment with [President Biden's Executive Order](#) on increasing access to high-quality care and supporting caregivers, the Administration will continue to issue regulations focused on improving oversight of long-term care facilities (LTCFs).

- **Increased Oversight:** CMS intends to [propose](#) new federal reporting requirements for certain covered entities in LTCFs when there is “reasonable suspicion” that a crime has been committed against a resident or an individual receiving care. The rule, expected in April 2025, will include procedures for enforcement activities including civil money penalties.

4. Nondiscrimination Protections

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- **Disability:** In June 2025, HHS Office of Civil Rights plans to issue a [proposed rule](#) address discrimination on the basis of disability in programs and activities conducted by HHS. The proposed rule may address policies not covered in the recently [finalized rule](#). Covered topics may include nondiscrimination in medical treatment, accessible medical equipment, accessible communications, compliance procedures, coordination responsibilities, and other disability discrimination issues.

5. Health Care Competition

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In support of [President Biden's Executive Order](#) on promoting competition in the American economy, the Administration will continue to issue and implement regulations focused on addressing limits on worker mobility and improving oversight of proposed mergers, acquisitions, and joint ventures.

- **Worker Mobility:** The Federal Trade Commission (FTC) released its final [Non-Compete Clause Rule](#) in May 2024 but it is not set to take effect until September 2024. Whether or not the rule will ultimately be implemented is still unclear, as the FTC is facing multiple lawsuits regarding its authority to take such sweeping action.
- **Mergers:** The FTC plans to release [final rules](#) modifying the premerger notification form and regulations under the Hart-Scott-Rodino (HSR) Act to enhance the effectiveness and efficiency of the merger review process. The final rule on HSR form changes is expected in July 2024, while the final rule regarding the transition to an E-filing system is anticipated in October 2024.

6. Health IT and Digital Health

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The Administration plans to continue its work to improve the sharing of health information while promoting privacy and transparency.

- **Interoperability:** ONC's follow up to the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) [final rule](#), the [HTI-2 rule](#), was released in July but the Unified Agenda does not project a date for finalization. ONC incorporated feedback from a 2022 [request for information](#) on public support for electronic prior authorization processes and how to incorporate standards and certification criteria into the HTI-2 proposed rule. In November 2024, CMS plans to [finalize](#) the Administrative Simplification health care attachments [proposed rule](#) that enacts new standards for electronic claims and prior authorization. CMS plans to follow this rule with another Administrative Simplification [proposed rule](#) in December 2024 to adopt standards for electronic exchange under the Health Insurance Portability and Accountability Act (HIPAA). HHS also plans to issue a [proposed rule](#) in July 2024 to implement requirements for HHS to procure health information technology that meets ONC's standards and implementation specifications.

Additionally, in July 2024 ONC [finalized](#) a rule to establish disincentives for health care providers determined to have committed information blocking. The disincentives apply to the Promoting

Interoperability category of the Quality Payment Program, the Promoting Interoperability Program for hospitals, and participation in the Medicare Shared Savings Program.

7. Privacy

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The Administration intends to strengthen privacy protections by addressing commercial surveillance practices, improving children's online privacy rules, enhancing health breach notifications, and regulating bulk sensitive personal data transactions to mitigate national security risks.

- **Commercial Surveillance:** The FTC is currently reviewing comments on its [Advance Notice of Proposed Rulemaking](#) (ANPRM) initiated back in August 2022 on whether new rules are needed to protect people's privacy and information in the commercial surveillance economy. The Commission's intention is to limit privacy abuses, curb lax security practices, and ensure algorithmic decision-making does not result in unlawful discrimination against consumers. A [formal recommendation](#) to the Commission on whether it should issue rules to address commercial surveillance and data security practices is expected in July 2024.
- **Children's Online Privacy:** The FTC plans to issue a [final rule](#) to implement proposed changes to the Children's Online Privacy Protections Rule (COPPA). In January 2024, the Commission released the [proposed rule](#) including updated definitions, notice and parental consent requirements, exceptions to verifiable parental consent, and safe harbor provision. FTC staff is currently reviewing comments. However, an expected date of release for the final rule is not available.
- **Health Breach Notification:** In May 2024, the FTC released a [final rule](#) that strengthens and modernizes the Health Breach Notification Rule by clarifying its applicability to health apps and other similar technologies and expanding the information that covered entities must provide to consumers when notifying them of a breach of their health data. The rule goes into effect on July 29, 2024. Notably, the rule applies only to health information that is not secured through technologies specified by the Department of Health and Human Services (HHS). Also, the FTC's Rule does not apply to businesses or organizations covered by the Health Insurance Portability and Accountability Act (HIPAA).
- **Bulk Sensitive Personal Data:** The Department of Justice (DOJ) plans to issue a [proposed rule](#) directing the Attorney General to issue regulations that prohibit or otherwise restrict United States persons from engaging in any acquisition, holding, use, transfer, transportation, or exportation of, or dealing in, any property in which a foreign person has any interest, where the

transaction involves U.S. Government-related data or bulk U.S. sensitive personal data, or falls within a category of transactions that the Attorney General has determined pose an unacceptable national security risk of access by countries of concern. In March 2024, DOJ issued an [ANPRM](#) seeking public comment on various topics related to the implementation of the Order, including designating countries of concern and covered persons, and defining sensitive personal data. The proposed rule is expected in August 2024.

8. Data Equity

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- **Public Trust in Data:** OMB plans to issue a [final rule](#) which requires each statistical agency to carry out the following four fundamental responsibilities: produce and disseminate relevant and timely statistical information, conduct credible and accurate statistical activities, conduct objective statistical activities, and ensure the confidentiality and exclusive statistical use of data collected for statistical purposes. OMB released the [proposed rule](#) in August 2023 seeking to provide direction to agencies in carrying out these responsibilities to promote public trust in the statistical agencies and units that produce Federal statistics. The final rule is expected in September 2024.

9. Oversight and Enforcement

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The Administration plans to update regulations regarding the HHS Office of Inspector General (OIG)'s authority to exclude individuals and entities from federally funded health care programs and regulations for civil monetary penalties.

- **HHS OIG's Exclusion Authorities:** In August 2024, HHS OIG plans to issue a [proposed rule](#) to modify regulations relating to its exclusions program. OIG has the authority to exclude individuals and entities from federally funded health care programs for a variety of reasons. HHS OIG plans to make the following changes: (1) Add manufacturers that misclassify outpatient drugs, fail to correct such misclassifications, or provide false information or data related to drug pricing or product information to the [List of Excluded Individuals/Entities](#) (LEIE); (2) Revise the section governing exclusion based on an individual's default on a health education loan or scholarship obligation; (3) Modify or eliminate various aggravating and mitigating factors used to set the length of an exclusion; (4) Modify the exclusion regulations that govern OIG's notice to the public and other agencies regarding exclusions, approval of reinstatement requests, and denial of reinstatement requests; and (5) Include clarifying changes and updates to the exclusion regulations based on OIG's recent experience related to exclusion actions.

- **Civil Monetary Penalties:** In July 2024, HHS plans to issue an [interim final rule](#) to update its regulations to reflect required annual inflation-related increases to the civil monetary penalties.

C. Public Health and Safety

1. Public Health

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In addition to policies to improve access to health care, the Administration is also focused on strengthening emergency preparedness and lowering the risk of preventable illnesses and injuries – particularly infectious diseases, smoking-related illnesses, heat illnesses, and workplace violence in health care.

- **Emergency Preparedness:** In July 2024, CMS plans to issue a [proposed rule](#) that would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to plan adequately for both natural and man-made disasters, including climate-related disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems based on lessons learned during the COVID-19 public health emergency and other recent events. OMB is currently reviewing the proposal. In November 2024, HRSA plans to issue a [proposed rule](#) to establish the COVID-19 Countermeasures Injury Table for the Countermeasures Injury Compensation Program (CICP), which will provide benefits to people who sustain serious physical injury or death as a direct result of the administration or use of covered countermeasures. OSHA plans to continue to advance an Emergency Response Standard (proposed rule comment deadline extended to July 22, 2024), but the Unified Agenda does not provide a timetable for the final rule.
- **Infection Prevention:** OSHA plans to issue a [final standard](#) intended to protect healthcare workers from COVID-19 ([emergency temporary standard](#)). Notably, the highly anticipated final standard, now scheduled for December 2024, has been at OMB for review since December 2022. The Unified Agenda further delays OSHA's [proposed standard](#) to protect workers from long-standing infectious disease hazards (e.g., tuberculosis), as well as new and emerging infectious disease threats (e.g., pandemic influenza, COVID-19). The proposed standard is expected in November 2024, though it was initially slated for September 2023. It would apply to a broader group of workplaces, including health care settings, correctional facilities, homeless shelters, drug treatment programs, and occupational settings where employees can be at increased risk of infection.

- **Tobacco Control:** As part of the Administration’s [Cancer Moonshot](#), the FDA is pursuing an array of rules to [reduce tobacco use](#). The Unified Agenda further delays their timetables, and it does not include several previously forecasted regulations – including a [final rule](#) to prohibit menthol as a characterizing flavor, a [final rule](#) to prohibit characterizing flavors in cigars, a [proposed rule](#) to establish a maximum nicotine level in cigarettes and certain other combusted tobacco products, and a [proposed rule](#) that would allow FDA to more effectively and efficiently identify e-cigarettes and other electronic nicotine delivery system products imported into the United States. First, FDA plans to issue a [final rule](#) in October 2024 that would increase the minimum age of sale for tobacco products from 18 to 21 years of age, as required by the Further Consolidated Appropriations Act, 2020 (P.L. 116-94). Second, FDA plans to [finalize new requirements](#) in April 2025 to assure the protection of public health related to the manufacturing, registration, advertising, and importation of tobacco products ([proposed rule](#)). Lastly, FDA plans to release several proposed rules related to importation of tobacco products. In July 2024, FDA plans to release a [proposed rule](#) to allow FDA to more effectively and efficiently determine the marketing authorization status of electronic nicotine delivery systems (ENDS) products (e.g., e-cigarettes) offered for import, and therefore enforce the premarket authorization requirements. In December 2024, FDA plans to release a [proposed rule](#) that would allow FDA to administratively detain tobacco products during inspections of manufacturers or other establishments that the FDA believes are adulterated or misbranded. In May 2025, FDA plans to issue a [proposed rule](#) on the establishment registration and tobacco product listings for both domestic and foreign manufacturers of tobacco products.
- **Heat Illness Prevention:** In July 2024, OSHA released a [proposed rule](#) to establish a heat injury and illness prevention standard. The Unified Agenda does not note the timing of the final rule. The proposal recognizes the impact of climate change and the risk that extreme heat poses on certain workers.
- **Workplace Violence Prevention in Health Care:** In December 2024, OSHA plans to issue a [proposed rule](#) to establish a standard preventing workplace violence in health care.
- **Gun and Firearm Violence Prevention:** The Department of Justice (DOJ) forecasts releasing at least five regulations related to gun and firearm violence prevention and could potentially release six. Of these, three are in the final rule state. The first, “[Carriage of Concealed Weapons Pursuant to the Law Enforcement Officers Safety Act of 2024](#),” is expected to be finalized in February 2025. It would authorize access to FBI-maintained criminal justice information systems to support performing background checks on current and retired law enforcement officers who would like to carry a concealed firearm under the Law Enforcement Officers Safety Act of 2004.

Two of the forthcoming final regulations pertain to residency requirements for acquiring firearms. The [first](#) is entitled, “Residency Requirement for Persons Acquiring Firearms,” is expected in March 2025 and would adopt interim final rules that require a firearm purchaser’s affirmative statement of his or her State of residence when acquiring a firearm from a Federal firearms licensee. The [second](#), “Residency Requirements for Noncitizens Acquiring Firearms” is also expected to be finalized in March 2025 and would remove the 90-day state residency requirement for noncitizens lawfully present in the U.S. to purchase or acquire a firearm. This is based on the Gun Control Act not permitting ATF to impose regulatory requirements that do not also apply to U.S. citizens.

A proposed rule is expected to be released in August 2024 for the “[Bipartisan Safer Communities Act of 2022 – Criteria for National Instant Criminal Background Check System \(NICS\) Background Checks on Firearms Handlers](#).” The Bipartisan Safer Communities Act authorized federal firearms licensees (FFL) to use the NICS to voluntarily conduct background checks and are a current or prospective employee of the FFL. Use of the NICS for this purpose will be known as Firearm Handler Background Checks (FHC). The regulation will authorize FHCs to be used for people who are or will be responsible for transferring or handling firearms on behalf of the FFL.

Last, final action on “[Commerce in Firearms and Ammunition \(Omnibus Consolidated Appropriations Act of 1997\)](#)” is technically pending but no estimated timeframe is included. It has not been finalized since the comment period ended in 1998.

2. Drug Development and Safety

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The FDA intends on finalizing proposals related to National Drug Code format and nonprescription drugs, while releasing proposed rules to address product recall regulations, adverse drug experiences, and commercial importers.

- **Nonprescription Drug Product with Additional Condition for Nonprescription Use:** By October 2024, the agency is expected to release the [final rule](#) addressing requirements for nonprescription drug products with an additional condition for nonprescription use (ACNU). The June 2022 [proposed rule](#) asserted that such regulations would allow consumers to appropriately self-select or use nonprescription drug products without the supervision of a healthcare practitioner.
- **Product Recalls:** The FDA intends on releasing an [advanced notice of proposed rulemaking](#) to seek comments, research, information, data, and responses from stakeholders to inform the modernization of product recall regulations by December 2024. The FDA will also issue a [proposed rule](#) to amend the regulation regarding the list of drug products that were withdrawn

or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective and may not be compounded under the exemptions provided by section 503A. This is expected by December 2024.

- **Adverse Drug Experiences:** By July 2024, the FDA intends to [propose](#) to amend the Adverse Event Reporting regulations for marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application.
- **National Drug Code Format:** The FDA is expected to issue a [final rule](#) by October 2024, to standardize the format of all National Drug Codes (NDCs), which would include NDCs being 12-digits in length with three distinct segments: labeler code, product code, and package code.
- **Commercial Importer Regulations:** By October 2024, the FDA intends on releasing a [proposed rule](#) to establish registration and good importing practice requirements for commercial importers of drugs.

3. Nutrition

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The Administration plans to promulgate several regulations to improve the integrity, security, and quality of federal nutrition programs while also continuing to focus on equity.

- **SNAP Work Requirements:** A [final rule](#) is anticipated to be released in November 2024 regarding SNAP work requirements for able bodied adults without dependents, pursuant to the Fiscal Responsibility Act of 2023. FNS also plans to [finalize](#) an interim final rule with comment period from 2016 to implement reporting requirements for Employment and Training programs from the Agricultural Act of 2014. A second interim final rule from 2016 is scheduled to be [finalized](#) in November to require states to verify applicant wage data through the National Directory of New Hires for SNAP eligibility and benefits at the time of certification and recertification.
- **SNAP Benefits and Energy Assistance:** A [proposed rule](#) that would standardize State Heating and Cooling Utility Allowances is also expected to be finalized in December 2024. It will be combined with a [proposed rule](#) finalizing a proposal from 2016 to establish a minimum standard utility allowance for states that use a utility allowance in SNAP determinations. A [proposed rule](#) in November 2024 would also update the price of food adjustment used for SNAP benefits in Hawaii to be based on the full state rather than Honolulu.

- **Child Nutrition:** In September 2025, [FNS](#) plans to [finalize](#) a proposed rule from 2012 to codify statutory requirements for elementary schools participating in the Fresh Fruit and Vegetable program.
- **Equity:** A [proposed rule](#) is projected to be finalized in September 2024 with a focus on improving access and parity within a range of food distribution programs including the Commodity Supplemental Food Program, Food Distribution Program on Indian Reservations, and The Emergency Food Program. The rule was informed by stakeholder feedback and experience during the COVID-19 pandemic. FNS also expects to release a [proposed rule](#) in December 2024 to require that SNAP applications contain a nondiscrimination statement.
- **Program Integrity:** In December 2024, USDA plans to [finalize](#) an interim final rule from 2022 to implement a provision of the 2018 Farm Bill to establish an interstate National Accuracy Clearinghouse for states to prevent issuances of SNAP benefits to an individual by more than one state.
- **Quality Control:** FNS plans to continue to advance multiple rules to help ensure quality in nutrition programs. This includes a [proposed rule](#) to strengthen SNAP's quality control system that is anticipated to be [finalized](#) in October 2024. A second [final rule](#) slated for January 2025 seeks to ensure quality in the Child and Adult Care Food Program and Summer Food Service Program. A [proposed rule](#) in November 2024 would formally incorporate the FNS quality control reviewer handbook into SNAP regulations.
- **WIC Modernization:** USDA plans to release a [final rule](#) in February 2025 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).
- **Replacing Stolen SNAP Benefits and Increasing Security to Protect Them:** An [interim final rule](#) is expected in March 2025 that will establish regulations requiring states to replace SNAP benefits that are stolen through various fraudulent means. Additionally, a [proposed rule](#) is expected by October 2024 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.

D. Social Determinants of Health

1. Housing

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The Department of Housing and Urban Development (HUD) plans to issue more than 20 housing-related regulations in support of the [Administration's policy agenda](#) to lower housing costs and expand access to affordable rent and home ownership. HUD's forthcoming regulations range from a proposed rule that would ensure that HUD housing programs are in compliance with the Violence Against Women Reauthorization Act of 2022 to final rules that would ensure adequate time and tenant communication related to non-payment of rent.

- **Housing Protections & Violence Against Women:** A [proposed rule](#) from HUD is expected in September 2024 that will implement the Violence Against Women Reauthorization Act of 2022 within federal housing programs.
- **Reducing Evictions:** Two regulations that would help reduce evictions are expected to be finalized in late 2024. The first, entitled "[30-Day Notification Requirements Prior to Termination of Lease for Nonpayment of Rent](#)," is projected to be finalized in November 2024 and would create a 30-day notification requirement before a lease is terminated. The second, entitled "[Extension of Time and Required Disclosures for Notification of Nonpayment of Rent](#)," is expected to be finalized in December 2024 and would shape the minimum amount of time that tenants must have to receive emergency rent relief during public health emergencies when they are facing eviction in public housing and properties. The intention is to prevent unnecessary evictions.
- **Affordable Housing:** In October 2024, a [proposed rule](#) is expected to be released that would reduce regulatory complexities in Section 8 project-based rental assistance programs that provide Housing Assistance Payments (HAP) by standardizing regulations and contracts. A [final rule](#) is forecasted to be released in December 2024 that would streamline project requirements in HUD's HOME Investment Partnership Program to improve the production and maintenance of affordable housing for both home ownership and rental housing.
- **Making Housing Counseling Services More Accessible:** A [rule](#) is expected to be finalized in July 2024 that will modernize the housing counseling services funded through HUD to expand the options available to clients including virtual and/or telephone meetings rather than solely in person.

- **Access for Persons with Disabilities:** A [notice of proposed rulemaking](#) is expected in September 2024 that will seek public comments on whether HUD should adopt a national accessibility standard to ensure that multifamily housing is designed and constructed in a manner that is accessible for individuals with disabilities as required by the Fair Housing Act.
- **Non-Discrimination:** HUD anticipates releasing a [proposed rule](#) in October 2024 to update its regulations that ensure nondiscrimination on the basis of disability in all programs and activities receiving federal financial assistance. The regulations have not been updated since 1988. The proposed changes could account for advances in accessible design, information and communication technology, and assistive technologies.
- **Safe Lead-Free Housing:** Two proposed rules pertain to HUD's efforts to protect young children from lead-based paint which is known to have long term negative health impacts. The [first rule](#) is expected in February 2025 and would primarily do two things: (1) streamline reporting processes, and (2) expand lead safety protections to include zero bedroom dwellings built before 1978. The [second rule](#) pertains to the same protections and is also expected in February.
- **Homelessness:** HUD expects to finalize one rule and propose a second to help address homelessness. The agency expects to finalize a the "*Use of Federal Properties to Assist the Homeless*" [rule](#) by September 2024. By December 2024, HUD anticipates releasing a [proposed rule](#) that would shape the [Continuum of Care Program](#).
- **Financing:** Multiple regulations pertain to financing to make housing more accessible. This includes a [proposed rule](#) that is expected to be released in October 2024 that would allow the financing of the purchase of a cooperative manufactured home community under the National Housing Act. Currently, only refinancing is allowed; purchasing it not. The National Housing Act, however, authorizes FHA mortgage insurance for existing multifamily housing projects and the proposed rule would align HUD's regulations with this statutory authority. A separate [proposed rule](#) that is expected to be released in July 2024 aims to improve the financing available for insured affordable multifamily project loans.
- **Equity, Housing & Criminal Justice:** HUD is expected to finalize a [rule](#) in December 2024 that would amend HUD's existing regulations for public housing and project-based rental assistance for individuals with a criminal history. Housing helps reintegrate individuals with criminal justice involvement back into society. The final rule would require Public Housing Authorities and project-based rental assistance providers to revise practices that unnecessarily prevent such individuals from participating in HUD programs so long as they do not pose a risk to the health and safety of other residents or property employees/agents.

2. Immigration

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The Administration plans to pursue rulemaking intended to support immigrants, people seeking asylum, and refugees and unaccompanied children.

- **Public Charge:** DOJ's Executive Office for Immigration Review (EOIR) plans to issue a [proposed rule](#) in March 2025 to establish consistent substantive standards for addressing the public charge ground of inadmissibility irrespective of the agency handling a particular noncitizen's case. DOJ initially [planned](#) to issue the proposed rule in May 2024.
- **Asylum:** DOJ's EOIR intends to address several immigration issues in 2024. DOJ plans to issue a [proposed rule](#) expected in October 2024 to amend asylum eligibility regulations to clarify the burden of proof and address issues related to the persecutor bar, such as duress and lack of knowledge. EOIR also plans to issue a [proposed rule](#) expected in July 2024, which would modify or withdraw DOJ's [December 2020 rule](#) on asylum eligibility. Specifically, the 2020 rule, scheduled to take effect on December 31, 2024, would bar covered asylum seekers from refugee protection in the United States if they have transited through or come from a country with a communicable disease or exhibit symptoms "consistent with" such disease. The Biden Administration has repeatedly paused implementation of the rule.

Additionally, the Department of Homeland Security (DHS) and DOJ plan to issue a [proposed rule](#) expected in February 2025 to amend asylum eligibility regulations, focusing on definitions and interpretations related to membership in a particular social group and other critical elements. These changes align with [Executive Order 14010](#), which directs the creation of joint regulations to clarify when a person should be considered part of a particular social group.

Furthermore, DOJ's EOIR plans to issue a [proposed rule](#) expected in January 2025 revising regulations for adjudicating asylum and related protection applications, combining two separate rulemakings into one to ensure immigration judges conduct evidentiary hearings before making decisions. DOJ and DHS also plan to issue a [final rule](#) expected in November 2024 to finalize amendments to procedures for handling protection claims and expedited removal for individuals with credible fear of persecution or torture. The Departments issued an [interim final rule](#) in March 2022 establishing timelines for asylum application reviews and streamlining removal proceedings for denied applications, and plan to consider additional feedback in the final rule. Lastly, on June 3, 2024, President Biden signed a [Proclamation](#) to limit the entry of certain noncitizens at the southern border due to emergency circumstances. In response, DHS and DOJ issued an [interim final rule](#) (IFR) making certain individuals who cross the southern border ineligible for asylum

unless they can prove exceptionally compelling circumstances. The comment period on the IFR ended on July 8, 2024, and [final action](#) is yet to be determined.

- **Refugees & Unaccompanied Children:** ACF plans to issue a [proposed rule](#) expected in August 2024 to update the Refugee Resettlement Program and the Cuban/Haitian Entrant Program by expanding eligibility for benefits and services, adding new support services, and regulating administrative structures. It also removes outdated references and requirements, including those related to the State Legalization Impact Assistance Grants Program. ACF also plans to issue a proposed rule expected in September 2024 that would establish a regulatory framework for the federal licensing of shelter care providers for unaccompanied children when state governments do not provide licensing. A new office within ACF will manage child welfare procedures related to this federal licensing, separate from the Office of Refugee Resettlement.

Additionally, ACF plans to issue a [proposed rule](#) expected in December 2024 to update the 2014 interim final rule on preventing, detecting, and responding to sexual abuse and harassment involving unaccompanied children, incorporating public feedback and aligning practices with the Office of Refugee Resettlement's operational realities. The proposed rule would fulfill requirements from the Violence Against Women Reauthorization Act of 2013 to adopt national standards for custodial facilities and assess compliance regularly.

Lastly, ACF plans to issue an [Interim Final Rule](#) (IFR) expected in August 2024 that will outline how the Office of Refugee Resettlement (ORR) will investigate and substantiate allegations of child abuse or neglect in certain ORR care facilities, including maintaining a registry of perpetrators when state agencies do not conduct these investigations. It will also detail the responsibilities of care provider facilities during such investigations.

3. Economic Opportunity

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The Administration plans to pursue rulemaking to promote economic opportunities for individuals and families.

- **504 Loan Program:** SBA has released multiple rules to expand the [504 Loan Program](#). An [interim final rule](#) was released by SBA in June 2022 which implemented the expanded authority granted to Accredited Lenders Program CDCs under section 328(b) of the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act to make loans of not more than \$500,000 in the 504 Loan Program. A [proposed rule](#) is expected in August 2024. A [direct final rule](#) is expected in July

2024 to broaden eligibility and increase access to capital for small business borrowers. This will include debt refinancing with and without expansion as well as economic development objectives.

- **Bad Debt:** A [final rule](#) is expected in December 2024 that will guide when a loan held by a financial institution will be conclusively presumed to be worthless for purposes of section 166 of the Internal Revenue Code.
- **Business Development Program:** In January 2021, the U.S. Small Business Administration (SBA) issued an [interim final rule](#) that included amendments to the regulations governing the 8(a) Business Development (BD) program. These changes were made in response to a provision in the Consolidated Appropriations Act, of 2021, which authorized eligible 8(a) Participants to extend their participation in the program by one year. The interim final rule aims to implement these legislative changes by revising the 8(a) BD program regulations accordingly. A final rule is expected in November 2024.
- **Child Support Services:** Multiple agencies have released rules aiming to bolster child support services for families. A [proposed rule](#) from the Department of Treasury is expected in July 2024 that aims to clarify the definition of temporary absence due to incarceration for various provisions, as well as to specify criteria for determining when a qualifying child placed in foster care is temporarily absent from the principal place of abode, specifically for the residency test. A proposed rule comment period ends in July 2024 and a [final action](#) is expected in December 2024 from ACP for a rule that aims to make the child support program more effective and to increase regular child support payments, while the Office of Child Support Services will propose to allow child support agencies to strengthen supportive services for noncustodial parents. Another [proposed rule](#) is expected in December 2024 that would support a name change of the Office of Child Support Enforcement to the Office of Child Support Services. ACF is expected to release another [proposed rule](#) in July 2024 that would amend the Child Care and Development Fund (CCDF) regulations to allow all Indian Tribes and Tribal Organizations operating CCDF programs, at their discretion, to establish and use family eligibility criteria regardless of family income.
- **Data Exchange:** A [proposed rule](#) is expected in December 2024 from the ACF that would designate data exchange standards for certain categories of information required to be shared under applicable Federal law for agencies operating the Temporary Assistance for Needy Families (TANF), child support services, child welfare services, and foster care and adoption assistance programs.
- **Disaster Assistance:** SBA has released several rules to assist individuals in times of disaster. SBA is expected to publish a [proposed rule](#) in July 2024 to increase the unsecured loan amounts for disaster survivors. A [final rule](#), expected in October 2024, implements changes to the Disaster

Loan Program regulations, specifically for COVID-19 Economic Injury Disaster Loans (EIDL). It includes adjustments to the definition of affiliation, expands eligible uses of loan proceeds, modifies how size standards are applied to severely affected eligible entities, and sets a maximum loan limit for borrowers within a single corporate group. A [direct final rule](#) is expected in October 2024 that implements regulatory changes mandated by recent amendments to the Small Business Act through three laws: the [Disaster Assistance for Rural Communities Act](#), the [Coronavirus Aid, Relief, and Economic Security Act](#), and the [National Defense Authorization Act for Fiscal Year 2020](#). These amendments provide two new types of disaster declaration authority.

- **Education Tax Credits:** A [final rule](#) is expected in July 2024 that would revise reporting rules for qualified tuition and related expenses on Form 1098-T. It aligns with the regulations introduced by the [Protecting Americans from Tax Hikes Act of 2015](#). Additionally, the proposed regulations aim to amend guidelines for education tax credits under section 25A, incorporating amendments from the Trade Preferences Extension Act of 2015 and the Protecting Americans from Tax Hikes Act of 2015.
- **Export Loan Program:** An [advance notice of proposed rulemaking](#) was released in September 2019 to receive feedback on BA's Export Loan Programs. SBA received a sizable number of comments on potential changes to the Export Loan Programs to increase the volume of export loans made to small businesses. Based on feedback SBA is expected to release a [proposed rule](#) in September 2024 to revise 13 CFR 120.340 to 120.349, which govern the Export Working Capital Program and the International Trade Loan Program. SBA will also propose regulation changes to refine the definition of export transactions, modernize collateral requirements for asset-based lending, and clarify collateral requirements for standby letters of credit.
- **Export Programs:** SBA has released multiple rules for export and express loans. In a [proposed rule](#), expected November 2024, SBA plans to codify specific guidance on the SBA Express loan program and the Export Express Program as well as the CARES Act authorization to permanently increase the maximum loan amount from \$350,000 to \$500,000 for SBA Express, which is effective October 1, 2021. SBA will publish a [proposed rule](#) in September 2024 to enhance the Export Working Capital Program (EWCP). The revisions concern (1) increasing the maximum maturity on an EWCP loan from 3 years to 5 years; (2) changing the regulations to allow EWCP loan proceeds to be used to finance export transactions or support companies who engage in export transactions by providing working capital against their accounts receivable and inventory; (3) allowing the use of proceeds for asset-based working capital secured by inventory and accounts receivable; (4) including a de minimis amount of domestic accounts receivable (not to exceed 30%) for EWCP loans used as an asset-based line of credit; (5) allow applicants to submit projections to support the need for facilities supporting pre-shipment working capital; (6) revise the unique requirements for the EWCP to align with industry standards for asset-based lending.

- **Head Start:** ACF has multiple rules that aim to support the Head Start Program. In November 2023, ACF released a [proposed rule](#) that proposes changes to the Head Start Program Performance Standards to support the Head Start workforce better and to maintain the quality of comprehensive Head Start services, final action is expected in July 2024. A [direct final rule](#) is expected in September 2024 that describes how the Office of Head Start officially delays the compliance date for programs to meet the new competitive threshold for the Instructional Support domain of the Classroom Assessment Scoring System (CLASS®) used to determine whether a Head Start agency will be subject to an open competition under the Designation Renewal System.
- **HUBZone Program:** A [proposed rule](#) is expected to be released in July 2024 to amend SBA regulations governing the Historically Underutilized Business Zone (HUBZone) Program to clarify certain policies. This proposed rule is intended to clarify and improve policies surrounding some of those changes. In particular, the rule proposes to require any certified HUBZone small business to be eligible as of the date of offer for any HUBZone contract.
- **Loan Liquidation and Litigation:** An [advanced notice of proposed rulemaking](#) is expected to be released in December 2024 by the Small Business Administration (SBA). SBA will propose amendments to the regulations governing the Agency's loan liquidation and litigation procedures and requirements. This rule will address payment of legal fees, procedures for approval of liquidation and litigation plans, including maximum amounts for routine litigation, and occupancy requirements during the liquidation phase.
- **Low-Income Housing Credit:** A [final rule](#) is expected in December 2024 that addresses recordkeeping and reporting requirements related to the average income test for the low-income housing credit. Compliance with this test allows residential rental projects to qualify for low-income housing credits. The regulations will impact owners of low-income housing projects and state or local housing credit agencies responsible for monitoring compliance.
- **Low-Income Taxpayer Clinics:** A [proposed rule](#) is expected in December 2024 to propose regulations that guide organizations applying for, or receiving, a low-income taxpayer clinic grant under IRC 7526.
- **Multiple Award Contract:** A [proposed rule](#) is expected to be released in September 2024 that would increase the use of small businesses in the placement of orders and on multiple-award contracts.

- **Native Americans:** The ACF has released rules to support Native Americans. A [proposed rule](#) is expected in December 2024 from the ACF that would update Native Employment Works (NEW) regulations to avoid inconsistencies and reflect the changes that have been made to the new statute and Administration for Children and Families (ACF) grant policy and procedures since the existing regulation's publication on February 18, 2000. A [proposed rule](#) is expected in November 2024 that would remove the 20 percent non-federal contribution requirement for all grant awards under the Native American Programs Act (NAPA).
- **Paycheck Protection Program:** SBA has proposed multiple final actions to codify guidance for the Paycheck Protection Program, the rules will be finalized and codified as part of a single [consolidated rule](#). In April 2020, the SBA issued several interim final rules implementing the Paycheck Protection Program ([PPP](#)). The PPP program was established through sections 1102 and 1106 of the Coronavirus Aid, Relief, and Economic Security Act ([CARES Act](#)). Section 1102 of the Act temporarily adds a new product, titled the Paycheck Protection Program, to the U.S. Small Business Administration's (SBA's) 7(a) Loan Program. Section 1106 of the Act provides for forgiveness of up to the full principal amount of qualifying loans guaranteed under the Paycheck Protection Program. The Paycheck Protection Program and loan forgiveness were intended to provide economic relief to small businesses nationwide adversely impacted by the Coronavirus Disease (COVID-19) Emergency Declaration (COVID-19 Emergency Declaration) issued on March 13, 2020. The final consolidated rule is expected in May 2025.
- **Prevailing Wage and Registered Apprenticeship:** The Department of Treasury released a [proposed rule](#) in August 2023 that outlines rules for increased tax credits or deductions under the Inflation Reduction Act of 2022 (IRA) for taxpayers meeting prevailing wage and registered apprenticeship (PWA) requirements. The comment period ended October 2023 and the Department is reviewing comments through July 2024. The DOL is planning to release [final action](#) in August 2024 that would revise regulations to strengthen, expand, modernize, and diversify the National Apprenticeship System by enhancing worker protections and equity, improving the quality of registered apprenticeships, revising the state governance provisions, and more clearly establishing critical pipelines to registered apprenticeships such as pre-apprenticeships so that the National Apprenticeship System is more responsive to current worker and employer needs.
- **Remote Workers:** The Department of Labor is expected to release a [proposed rule](#) in April 2024 that would clarify the application of a single site of employment as it relates to remote workers under the Worker Adjustment and Retraining Notification (WARN) Act.
- **SCORE Program:** SBA is considering multiple rules to update the SCORE Program. A [proposed rule](#) is expected in August 2024 that proposes various program requirements and procedures for SCORE as outlined in the statute including the use of Federal funds; standards for effectively

carrying out program duties and responsibilities; use of client data as stipulated in statute; and requirements for reporting on financial and programmatic performance. Another [proposed rule](#) is expected in August 2024 to update existing and issue new regulations concerning the SCORE program to align with the Agency's performance and evaluation framework, including the proposal of regulations concerning the collection of programmatic performance data, review, reporting requirements, and other client data-based activities.

- **Small Business Investment Company:** A [proposed rule](#) expected in July 2024 aims to advance reforms based on comments received during and after the close of the comment period for the Direct Final Rulemaking that clarified and provided technical updates to the Small Business Investment Company Investment Diversification and Growth final rule implemented on August 17, 2023. Reforms in the rule will be to enhance the compatibility and alignment of SBIC program regulations with other Federal financial regulatory agencies and industry practices to reduce potential burdens on program applicants and participants.
- **Small Business Procurement Programs:** A [proposed rule](#) is expected to be released in September 2024 where SBA is issuing conforming revisions to its affiliation rules that govern all of the small-business procurement programs. These revisions will ensure consistent requirements for ownership and control across SBA's procurement programs.
- **Small Business Size:** SBA plans to release two proposed rules, in these SBA will evaluate all industries with employee-based size standards and make necessary adjustments to their size standards. One rule focuses on [employee-based industry](#) standards and the other is [monetary-based](#) industry size standards.
- **TANF:** ACF has multiple rules that bolster TANF. A [proposed rule](#) is expected in November 2024 that will propose changes to how Temporary Assistance for Needy Families (TANF) regulations describe the federal work participation rate (WPR) calculation. ACF released a [proposed rule](#) in October 2023, and final action is expected in December 2024 that would improve the effectiveness and integrity of the TANF program as a safety net program by clarifying allowable uses of TANF funds and reducing administrative burden. An [interim final rule](#) is expected in July 2024 that would implement the statutory changes enacted by section 304 of the Fiscal Responsibility Act of 2023 related to the reporting of work outcomes under the TANF program.
- **Unemployment:** The Department of Labor is expected to release a [proposed rule](#) in May 2025 that would include comprehensive updates to the unemployment compensation program.
- **Veterans Business Outreach Center Program:** A [proposed rule](#) is expected in July 2024 that proposes to update existing and issue new regulations concerning the Veterans Business

Outreach Center program and other veteran-focused grant programs to align with the Agency's performance and evaluation framework, including the proposal of regulations concerning the collection of programmatic performance data, review, reporting requirements, and other client data-based activities.

- **Women in Business:** SBA has released multiple rules to assist women in business. A [proposed rule](#) is expected in September 2024 that will propose to update the Women Business Center program regulations to align with the agency's performance and evaluation framework, including the proposal of new regulations concerning the collection of programmatic performance data, review, reporting requirements, and other client data-based activities. A [final rule](#) is expected in October 2024 will update SBA regulations to incorporate policy changes and integrate feedback received since the publication of a [May 2020 final rule](#) that established certification requirements for the [Women-Owned Small Business Program](#). Another [final rule](#) is expected in August 2024 that contains amendments to the Women-Owned Small Business Program.