Regulatory Outlook: Spring 2023 Unified Agenda

The Biden Administration recently released its <u>Spring 2023 Unified Agenda</u>, 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, social drivers of health, and cross-cutting topics, including behavioral health and drug pricing, among others.

• What it is. The Spring 2023 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 newly enacted laws, such as the Inflation Reduction Act of 2022; and regulations implementing Executive Orders and other priorities, such as regulatory proposals in the President's Budget. Most of the entries were included in the Fall 2022 edition and may have been updated with new timetables.

Each entry is organized by federal agency and its stage in the <u>rulemaking process</u> – 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 most agencies at the Department of Health and Human Services (HHS); Department of Labor's (DOL) Employee Benefits Security Administration (EBSA) and Occupational Safety and Health Administration (OSHA); Department of Treasury's Internal Revenue Service (IRS); Department of Agriculture's (USDA) Food and Nutrition Service (FNS); several agencies at the Department of Housing and Urban Development (HUD); Department of Justice's (DOJ) Drug Enforcement Administration (DEA); and the Federal Trade Commission (FTC).

Our regulatory outlook highlights federal regulatory actions by the following policy areas:

	A. Coverage and		B. Cross-Cutting		C. Public Health		D. Social Drivers
	Payment		Topics		and Safety		of Health
1.	Medicaid	1.	Behavioral Health	1.	Food and Drug	1.	Housing
2.	Medicare	2.	Drug Pricing		Administration	2.	Nutrition
3.	Private Insurance	3.	Health IT and	2.	Public Health	3.	Social Services
			Digital Health				
		4.	Mergers				
		5.	Nondiscrimination				
			Protections				



- 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 <u>EO 12866</u> meeting with the Office of Management and Budget (OMB) and/or submitting public comments. Projected dates for regulatory actions may shift, but they are helpful guides for advocacy planning.
- Next steps. Impact Health will flag 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, we note the lead Impact Health team member that can answer any questions or provide additional assistance.

Overview of Potential Regulatory Activity on Federal Policy Areas

A. Coverage and Payment

1. Medicaid

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Through an array of regulatory activities, the Administration will continue 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.

- Enrollment In and Maintenance Of Coverage: CMS plans to issue two final rules to simplify the
 processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP and the Basic
 Health Program. The first final rule expected in September 2023 will remove barriers and
 facilitate enrollment of new applicants, particularly those dually eligible for Medicare and
 Medicaid. The second final rule expected in February 2024 will implement changes to align
 enrollment and renewal requirements for most individuals in Medicaid and promote maintenance
 of coverage.
- Access to Services and Supports: CMS is also expected to issue 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. The unified agenda does not provide expected publication dates for the final rules, which may indicate that CMS is still contemplating a timeframe that strikes the correct balance between acting with urgency to strengthen Medicaid and minimizing administrative burden on states preoccupied with unwinding responsibilities. In the proposed rule, CMS sought feedback on an effective date of 60 days following publication of the final rules and separate compliance dates for various provisions.



• **Quality Measurement:** In August 2023, CMS plans to <u>finalize</u> requirements for mandatory annual state reporting on several quality measure sets for Medicaid and CHIP beneficiaries.

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 improving quality, ensuring access, and making the health care system more equitable. Notably, the Unified Agenda does not include a Request for Information (RFI) on an episode-based payment model that was received by the OMB for review in early June 2023.

Medicare Payment System Updates: CMS will finalize proposed fiscal year (FY) 2024 updates for Medicare payment in the <u>Inpatient Prospective Payment System</u>, the <u>Hospice Wage Index</u>, the <u>Inpatient Psychiatric payment system</u>, the <u>Inpatient Rehabilitative Facility payment system</u>, and the <u>Skilled Nursing Facility payment system</u> around August 2023.

CMS will also propose updates for Medicare payment in any remaining calendar year (CY)-based payment systems (the <u>Outpatient Prospective Payment System</u> (OPPS), the <u>Medicare Physician Fee Schedule</u>, the <u>End Stage Renal Disease (ESRD) payment system</u>, the <u>Home Health payment system</u>, and the <u>Durable Medical Equipment</u>, <u>Prosthetics</u>, <u>Orthotics and Supplies fee schedule</u>) before the end of July 2023 and finalize proposed updates around November 2023.

- CMS Innovation Center: CMS pushed out the timeline for a proposed new mandatory Medicare payment model from September 2023 to May 2024. Though it does not specify what the model would entail, it could be one of the models announced in response to an Executive Order on Lowering Prescription Drug Costs for Americans. The Innovation Center is also considering a model that will enable participating states to manage the total cost of care in the state as well as a model aimed at dementia care.
- drugs billed by hospitals under the OPPS were unlawful and directed CMS to remedy affected hospitals for cost years 2018-2022. CMS has indicated that it will do so through notice and comment rulemaking, which is scheduled for June 2023 and could be issued alongside the CY 2024 OPPS proposed rule. A final rule revising the program's Administrative Dispute Resolution (ADR) is also anticipated before the end of the year. It will establish new requirements and procedures for 340B covered entities and manufacturers to file claims for specific compliance areas outlined in statute after good faith efforts have been exhausted.

- Medicare Disproportionate Share Hospital (DSH) Payments: Between August 2023 and March 2024, CMS will issue a series of final rules further detailing DSH payment methodology. This includes treatment of Medicare Part C Days, counting of certain days associated with Section 1115 demonstrations in the Medicaid fraction, and Medicaid shortfall and third-party payments.
- Increased Oversight of Long-Term Care: In alignment with President Biden's EO on increasing access to high-quality care and supporting caregivers. CMS plans to propose a rule to establish minimum staffing standards for long-term care facilities (LTCFs) in June 2023. Relatedly, CMS will seek to improve oversight of accrediting organizations (AOs), prevent AO conflicts of interest, and improve transparency around quality and safety issues through a proposed rule also expected in June. Finally, CMS will 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 early 2024, will also propose procedures for enforcement activities including civil money penalties.
- Operational Changes: In June 2023, CMS will propose culturally competent and person-centered requirements for providers and suppliers that participate in Medicare and Medicaid which will revise the Conditions of Participation/Conditions for Coverage across a range of areas. Additional requirements will be included for transplant programs, Organ Procurement Organizations (OPOs), and ESRD facilities to advance equity and reduce disparities in organ transplantation and donation. Towards the end of the year, CMS plans to issue proposed revisions to emergency preparedness requirements for providers and suppliers in Medicare and Medicaid. The proposals will include updates to requirements for climate-related disasters and integrate lessons learned from the COVID-19 public health emergency and other recent events. CMS will also propose amendments to the rules governing OPOs in December. The proposed changes, which will reflect responses received from a RFI issued in late 2021, will adjust evaluation and recertification standards as well as clarify the competition and decertification process among other changes.

3. Private 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) and reverse Trump-era measures weakening consumer protections, as well as rules implementing surprise billing protections and requirements. Notably, the Unified Agenda does not include dates for final rules to expand access to reproductive health coverage or to make recipients of the Deferred Action for Childhood Arrival Programs (DACA) eligible for coverage on the Exchange, Medicaid, and Basic Health Program. Still, we anticipate the Administration will finalize these proposals, because they are top priorities for the President.



- ACA Marketplace: In November 2023, CMS plans to <u>propose</u> the annual notice of benefit and payment parameters for 2025. The payment rule makes changes to regulations governing the Exchange and state-based marketplaces. The final rule will likely be released in spring 2024. In November 2023, the IRS plans <u>finalize</u> rules regarding reporting requirements for issuers of catastrophic health care coverage in the Marketplace.
- Alternative Coverage: CMS and EBSA plan to issue two proposed rules expected to reverse Trump-era regulations that expanded the availability of plans without protections for preexisting conditions specifically, short-term limited duration insurance (proposed rule in June 2023), and association health plan (proposed rule in August 2023). In December 2023, 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.
- Reproductive Health Coverage: The Unified Agenda states that CMS is reviewing public comments on a proposed rule that would expand access to contraceptive services but does not include an anticipated date for a final rule. 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. The Administration recently highlighted this measure in an Executive Order on Strengthening Access to Contraception.
- DACA Recipients: As part of the <u>Administration's efforts</u> to provide DACA recipients the opportunities and the support they need, CMS issued a <u>proposed rule</u> to revise the definition of "lawfully present" in order to expand eligibility for health insurance coverage through the Exchange (including premium tax credits), Medicaid, and Basic Health Program to DACA recipients. The Unified Agenda does not include an <u>anticipated date</u> for a final rule.
- 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 March 2024 to make information in the Form 550 Annual Return/Report of Employee Benefit Plan more data mineable and to enhance the ability of EBSA and IRS to conduct compliance activities.
- No Surprises Act: CMS and EBSA will issue a slate of regulatory measures implementing the No Surprises Act, including a proposed rule in June 2023 that would amend requirements for the independent dispute resolution process; a proposed rule in August 2023 that would implement protections against provider discrimination; a <u>final rule</u> in August 2023 that would establish requirements related to air ambulance services; and a <u>proposed rule</u> in March 2024 that would establish new requirements for private health plans to send patients an "Advanced Explanation of Benefits."

B. Cross-Cutting Topics

1. Behavioral Health

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The Administration will use regulatory levers to help alleviate the overdose and mental health crisis by increasing access to care. This will largely consist of increasing compliance with mental health parity requirements and reducing provider barriers in prescribing medications for opioid use disorder including in the use of telemedicine.

- **Mental Health Parity:** The Administration plans to issue a <u>proposed rule</u> to implement the mental health parity provisions included in the Consolidated Appropriations Act of 2021. The expected release date was December 2022.
- Medication-Assisted Treatment (MAT)/Medication for Opioid Use Disorder (MOUD): In November 2023, SAMHSA and the DEA plan to issue their final rules (SAMHSA, DEA, DEA) on making some of the COVID-19 telemedicine flexibilities permanent for the prescription of controlled medications including buprenorphine. The DEA also plans to issue a final rule in July 2023 to increase the number of practitioners able to prescribe MOUDs and a final rule that was expected in June 2023 to increase the availability of narcotic medications for individuals experiencing acute withdrawal symptoms while awaiting subsequent long-term treatment.

2. Drug Pricing

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The Administration remains committed to addressing high prescription drug costs and may release a new Center for Medicare and Medicaid Innovation (CMMI) model for drug pricing in Medicare or Medicaid.

- CMMI Drug Pricing Model: In February 2023, CMMI released three models for addressing drug
 pricing incentives, including a Medicare high-value drug list model, a cell and gene therapy model
 in Medicaid, and an accelerating clinical evidence model in Medicare. CMS is expected to release
 a proposed rule in May 2024 for a mandatory alternative model, which may feature one of the
 models described earlier this year.
- Part D Redesign: The CY 2025 Policy and Technical Changes to Medicare Advantage and Part D plan proposed rule will fully implement the Part D redesign, pursuant to the Inflation Reduction Act. Changes to the Part D benefit beginning in 2025 include the \$2000 annual out-of-pocket cap, elimination of the coverage gap, a smoothing option, and increased liability for manufacturers and insurers. The rule is expected to be released in October 2023.



• **340B:** In December 2023, the Health Resources and Services Administration (HRSA) is expected to release the <u>final rule</u> to revise the 340B Drug Pricing Program Administrative Dispute Resolution (ADR) process. In the <u>proposed rule</u> released in November 2022, HRSA seeks to recognize resource constraints of covered entities and make the process less burdensome.

3. Health IT and Digital Health

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The Administration plans to continue its work on improving the sharing of health information while promoting privacy and transparency. Notably, the Unified Agenda does not include a plan to finalize the Advancing Interoperability and Improving Prior Authorization <u>proposed rule</u> that was published in December 2022.

- **Information Blocking:** In September 2023, the Office of the National Coordinator for Health Information Technology (ONC) plans to release a <u>proposed rule</u> to establish disincentives for providers that are determined to have committed information blocking.
- Interoperability: In April 2024, CMS plans to <u>finalize</u> the Administrative Simplification health care attachments <u>proposed rule</u> that enacts new standards for electronic claims and prior authorization. ONC will also follow the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) <u>proposed rule</u> with a HTI-2 <u>proposed rule</u> focused on public health and interoperability in November 2023.
- Privacy: The Administration will continue its efforts to improve the privacy and security of health data through the Federal Trade Commission (FTC), although there are not currently any specific rules planned. The FTC expects to use input from stakeholders to develop unspecified action on the Health Breach Notification Rule, initially anticipated by June 2023. The FTC will also review and analyze public comments on potential updates to the Children's Online Privacy Protection Rule. This review may inform future rulemaking.

4. Mergers

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FTC seeks to modify the premerger notification form and rules under the Hart-Scott-Rodino (HSR) Act to address potential competition concerns in a more prompt and effective manner. FTC anticipates a <u>final rule</u> by September 2023 to update the HSR Form and Instructions to the new cloud-based, e-filing system, which eliminate paper filings; by September 2023, followed by a recommendation for a proposed Rule on substantive HSR form changes by December 2023.



Nondiscrimination Protections

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By September 2024, HHS plan to issue a final rule to reinstate and strengthen protections from discrimination in health programs and activities in Section 1557 regulations. Notably, the Biden Administration's proposal strengthens protections against discrimination on the basis of sex, including discrimination on the basis of pregnancy or related conditions (including abortion) and discrimination on the basis of sexual orientation and gender identity, overed entities of the proposed rule are recipients of federal financial assistance, HHS, and group health insurance issuers offering group or individual health insurance coverage that receive financial support.

C. Public Health and Safety

1. Food and Drug Administration

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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 regulation of laboratory developed tests and product recall regulations.

- Laboratory Developed Tests (LDTs): The FDA is expected to issue a proposed rule in August 2023 to make explicit that LDTs are devices under the Food, Drug, and Cosmetic Act that are subject to FDA regulation. This rule may address proposals that were included in the <u>Verifying</u> Accurate Leading-edge IVCT Development (VALID) Act from last Congress.
- Nonprescription Drug Product with Additional Condition for Nonprescription Use: By April 2024, the agency is expected to release the <u>final rule</u> addressing requirements for nonprescription drug products with an additional condition for nonprescription use (ACNU). The June 2022 <u>proposed rule</u> asserted that such regulations would allow consumers to appropriately self-select or use nonprescription drug products without the supervision of a healthcare practitioner.
- National Drug Code Format: The FDA is expected to issue a <u>final rule</u> by January 2024, to standardize the format of all National Drug Codes (NDCs), which would include NDCs being 12digits in length with three distinct segments: labeler code, product code, and package code.
- **Product Recalls:** The FDA intends on releasing an <u>advanced notice of proposed rulemaking</u> to seek comments, research, information, data, and responses from stakeholders to inform the modernization of product recall regulations. The expected release date was June 2023.



2. Public Health

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In addition to policies to improve access to health care, the Administration is also focused on lowering the risk of preventable diseases – particularly infectious diseases and smoking-related illnesses.

- Infection Prevention: OSHA plans to issue a <u>final standard</u> intended to protect healthcare workers from COVID-19 hazards. Notably, the final standard scheduled for June 2023 has been at OMB for review since December 2022. The Unified Agenda further delays OSHA's <u>proposed standard</u> 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 March 2024, rather than 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. First, FDA plans to issue a final rule in April 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 issue product standards (1) to prohibit menthol as a characterizing flavor in cigarettes (final rule in August 2023); (2) to prohibit characterizing flavors in cigars (final rule in August 2023); and (3) to establish a maximum nicotine level in cigarettes and certain other combusted tobacco products (proposed rule in December 2023). Lastly, FDA is proposing new rules intended to assure the protection of public health related to the manufacturing, registration, advertising, and importation of tobacco products.

D. Social Drivers of Health

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1. Housing

The Department of Housing and Urban Development (HUD) plans to issue an array of proposed rules in support of the <u>Administration's policy agenda</u> to lower housing costs and expand access to affordable rent and home ownership.

• Affirmatively Furthering Fair Housing: The Affirmatively Furthering Fair Housing rule is expected to be finalized in December 2023. Comments were accepted this spring.



- Housing Protections & Violence Against Women: A proposed rule from HUD is expected in October 2023 that will implement the Violence Against Women Act within federal housing programs.
- Equity, Housing & Criminal Justice: A proposed rule from HUD is expected in August that will expand access to public housing and rental assistance for individuals who have criminal histories but do not pose a threat to other residents. Housing helps individuals with criminal justice system involvement successfully integrate back into society.
- 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 <u>first rule</u> is
 expected in October 2023 and would expand lead safety protections to include zero bedroom
 dwellings built before 1978. The <u>second rule</u> pertains to the same protections and is also
 expected in October.
- Homelessness: HUD expects to propose two rules that will help address homelessness and to
 finalize a third. The first of the proposed rules would shape the Continuum of Care Program; the
 second proposed rule would alter the Emergency Solution Grants Program. Both are expected in
 September. HUD expects to finalize a third rule, by March 2024 that addresses the use of federal
 properties to help homeless individuals.
- Climate: HUD anticipates publishing a proposed rule by May 2024 that will update HUD
 requirements to comply with the National Environmental Policy Act and other environmental
 laws.

2. Nutrition

The USDA's Food and Nutrition Services (FNS) plans to use regulatory channels to advance equity in an array of nutrition programs including making more students eligible for free school meals, finalizing nutrition standards to increase the quality of meals served, removing stigmatizing terminology, improving program integrity in the Supplemental Nutrition Assistance Program (SNAP), implementing previously enacted laws to ensure ongoing access to baby formula in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and more. The Administration is also advancing regulations through the FDA to support nutrition.

• Summer EBT Program: A proposed interim final rule that is part of establishing a permanent Summer EBT Program and codifying flexibilities for rural areas is anticipated by December 15, 2023. The program was created as a temporary program during the COVID-19 pandemic and made permanent by the Consolidated Appropriations Act at the end of December 2022.

- Expanding Access to Universal School Meals: In April 2024, FNS anticipates finalizing a <u>rule</u> to lower the threshold for the Community Eligibility Provision (CEP) from 40 percent to 25 percent.
 Under the rule, more schools will be eligible to offer free universal school meals with federal financial support.
- Child Nutrition Standards: FNS anticipates publishing a <u>final rule</u> in April 2024 to make school meals more nutritious. The rule will finalize long-term school nutrition standards based on Dietary Guidelines and stakeholder feedback.
- Front-of-Package Nutrition Labeling: A proposed rule from the FDA is expected in December 2023 that would require certain nutrition information to be displayed on the front of food labels. The rule is intended to help address the obesity epidemic by helping consumers quickly and easily identify healthy foods. It is also intended to encourage the food industry to produce healthier foods. Similar labeling approaches are used in other parts of the world.
- Clarifying What "Healthy" Means: A <u>second FDA rule</u> will be finalized by April 2024 updating the definition of "healthy" so that it aligns with current nutrition science and federal dietary guidelines. This rule is intended to help consumers make healthier, more-informed food choices. Comments on the rule were accepted until February 2023.
- Equity: In January 2024, FNS anticipates publishing a proposed rule to modernize SNAP terminology to make it more inclusive and equitable by removing stigmatizing terminology and utilizing person-first language instead. This proposed rule aligns with a January 2021 Executive Order on Advancing Racial Equity and Support for Undeserved Communities Through the Federal Government. A separate proposed rule is projected to be published in July 2023 with a focus on improving access and parity within a range of nutrition programs including SNAP.
- Race & Ethnicity Data Collection: USDA expects to finalize a <u>rule</u> in October 2023 preventing states from using visual observation to collect rate and ethnicity data from SNAP program applicants who choose not to provide this information. The final rule will align SNAP regulations with current federal policy.
- Quality Control: FNS plans to release multiple rules to help ensure quality in nutrition programs.
 This includes a proposed rule to strengthen SNAP's quality control system and another proposed rule related to the Child and Adult Care Food Program as well as the Summer Food Service Program. A third rule related to Child Nutrition Program integrity is expected to be finalized in July 2023.

- Replacing Stolen SNAP Benefits: A <u>final rule</u> is expected in December 2023 that will lay out regulations requiring states to replace SNAP benefits that are stolen through various fraudulent means.
- WIC & Baby Formula: A <u>rule</u> codifying the Access to Baby Formula Act of 2022 is expected in December 2023. The rule will add requirements to state infant cost containment contracts, establish waiver authority for the Secretary of Agriculture to use in emergencies, disasters, and supply chain disruptions that impact WIC, and require WIC state agencies to have disaster plans to ensure WIC access to baby formula. Other changes to WIC program regulations might also be made.

3. Social Services

The Administration plans to pursue regulatory actions to support other federal programs serving underserved communities.

- Refugees & Unaccompanied Children: A proposed rule from the Administration for Children and Families (ACF) is anticipated in October 2023 that will update the Refugee Resettlement Program including removing outdated provisions in the unaccompanied refugee minors program and refugee medical and cash assistance program. A separate proposed rule is anticipated in August 2023 and would establish and regulatory framework for the Unaccompanied Children Program with the intention of codifying protections and service delivery. A final rule that is expected by May 2024 will implement part of the Violence Against Women Reauthorization Act to apply to facilities that house unaccompanied immigrant children.
- Temporary Assistance for Needy Families (TANF): A proposed rule that ACF anticipates releasing in August 2023 aims to strengthen the TANF program in alignment with President Biden's Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.
- Childcare: Multiple rules seek to improve childcare including access, affordability, quality, and workforce. One proposed rule that ACF anticipates releasing in July 2023 would update the Child Care and Development Fund (CCDF) regulations to increase access to quality childcare for families using subsidies. The rule will address enrollment, provider payment rates, and more. Another proposed rule focuses on supporting the Head Start workforce, plus the program more broadly. It too is expected in July.