

Memorandum

July 12, 2022



WHG REGULATORY OUTLOOK – SUMMER 2022 UPDATE

Recently, the Office of Management and Budget released the [Spring 2022 update](#) for its Unified Regulatory Agenda. This resource serves to outline the planned rulemaking the Administration intends to undertake and offers a base case on timing for when such regulations may be promulgated (though such timeframes are not binding). Though it is unclear when precisely the Administration will promulgate its planned rulemaking, the updated docket of regulatory actions provides insight into the Administration's current priority areas.

Overall, the Administration appears poised to continue moving forward on advancing its health priority areas through additional regulatory reform. Many of the planned changes are similar to those contemplated earlier under this Administration but have been delayed due to various reasons. For example, the Administration has signaled it continues to develop new regulations on the following issues:

- **Equity:** New proposed regulations to strengthen the nondiscrimination protections afforded under the Affordable Care Act (ACA) and previously weakened under the Trump Administration.
- **Payment Reform:** A mandatory alternative payment model under Medicare, though provides no detail on what this model would address specifically.
- **Mental health:** Extending flexibilities for patients seeking treatments for opioid use disorder. In addition, the White House remains interested in establishing new regulations to promote health insurer compliance with the federal mental health parity requirements.
- **Medicaid:** Reforms that would improve enrollment and access to Medicaid and CHIP.
- **Health Insurance:** Revising the definition of "short-term, limited-duration insurance."
- **Interoperability and Transparency:** Imposing stronger enforcements against information blocking; improving the electronic exchange of health information; and creating new requirements for electronic prior authorization processes (of note, many of these changes involve the Administrations' continued implementation of the 21st Century Cures Act and the No Surprises Act).

As for new regulatory actions announced by the White House, the Food and Drug Administration (FDA)'s proposed changes to tobacco – specifically, its plans to establish a maximum nicotine level for cigarettes – have garnered significant attention. On the equity front, new regulatory actions have appeared that would establish cultural competency requirements for Medicare and Medicaid providers, aligning with the Centers for Medicare & Medicaid Services (CMS)'s recently announced Health Equity Framework ([details](#)). Last, regarding payment reform, the Administration is planning to issue regulations that would update its mandatory Medicare demonstration model for radiation oncology (which was [delayed indefinitely](#) earlier this year).

A full set of anticipated regulatory changes – organized by topic area – is outlined below.

Equity

- **June 2022:** OCR plans to [propose a rule](#) to revise the 2020 final rule regarding section 1557 of the ACA, which repealed the 2016 definition of sex discrimination and weakened previously finalized nondiscrimination protections for transgender patients and women seeking abortions ([details](#)).

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- **June 2022:** OCR plans to [propose a rule](#) to determine which regulations are warranted to implement certain conscience protection laws in a manner that is consistent with the policies of the current Administration.
- **July 2022:** The Department of Justice (DOJ) intends to issue a [proposed rule](#) that would address how adjudicators within the Executive Office for Immigration Review (EOIR) determine whether a noncitizen is inadmissible to the United States on public charge grounds.
- **February 2023:** CMS will issue a [proposed rule](#) that would establish culturally competent and person-centered requirements for all provider and supplier types that participate in Medicare and Medicaid programs.

Mental Health and Substance Use Disorder

- **July 2022:** CMS is expected to issue a [proposed rule](#) that would clarify plans' and issuers' obligations under the Mental Health Parity and Addiction Equity Act, promote compliance with the law, and other related changes pursuant to the Consolidated Appropriations Act of 2021.
- **August 2022:** The HHS Office for Civil Rights (OCR) is slated to [propose a rule](#) to better harmonize the 42 CFR part 2 (part 2) confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act.
- **September 2022:** The Substance Abuse and Mental Health Services Administration (SAMHSA) is set to issue a [proposed rule](#) that would permanently extend the current COVID-19 flexibility that permits health care providers to prescribe buprenorphine for opioid use disorder via telehealth.
- **September 2022:** SAMHSA is expected to [propose a rule](#) to make permanent certain flexibilities for opioid treatment programs that provide extended take home doses of methadone.
- **December 2022:** The Drug Enforcement Agency (DEA) is planning to promulgate a [final rule](#) that would codify regulations clarifying the criteria by which DEA-registered practitioners may electronically issue controlled substance prescriptions and the criteria by which DEA-registered pharmacies may receive and archive these electronic prescriptions. As context, current flexibilities allowing providers to prescribe controlled substances via telehealth without an initial in-person visit have improved access to medication for those with mental health conditions.

Payment and Delivery Reform

- **December 2022:** CMS is expected to [propose](#) a new mandatory Medicare payment model to test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.
- **March 2023:** OCR is expected to [finalize](#) a rule that would strengthen individuals' rights to access their own protected health information and improve information sharing for care coordination, as well as increase family and caregiver involvement, among other changes.
- **April 2025:** CMS indicates it plans to [finalize](#) updates to the mandatory Radiation Oncology model, which has been indefinitely delayed per recent rulemaking.

Interoperability, Transparency, and Payment Integrity

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- **June 2022:** CMS is planning to issue a [proposed rule](#) to implement provisions related to the independent dispute resolution process pursuant to sections 103 and 105 of the No Surprises Act.
- **September 2022:** The HHS Office of Inspector General (OIG) is expected to [finalize a rule](#) that would: (1) impose civil monetary penalties, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements; (2) authorize OIG to investigate claims of information blocking and provide HHS the authority to impose CMPs for information blocking; and (3) increase the penalty amounts of CMPs.
- **September 2022:** CMS is expected to issue a [proposed rule](#) that would place new requirements on Medicare Advantage plans, Medicaid managed care plans, CHIP managed care entities, Medicaid and CHIP fee-for-service entities, and Qualified Health Plans to improve electronic exchange of health care data and implement electronic prior authorization programs. As a reminder, the Trump Administration proposed a similar regulation in 2020 that did not include MA and was ultimately withdrawn.
- **October 2022:** The Office of the National Coordinator of Health IT (ONC) is planning to issue a [proposed rule](#) that would implement certain provisions of the 21st Century Cures Act regarding the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rule would also include proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program.
- **December 2022:** CMS is expected to [propose a rule](#) that would promote payment accuracy and efficiency and help CMS identify and deter fraud, waste, and abuse in a timely, effective manner.
- **January 2023:** CMS is slated to [propose a rule](#) to implement section 111 of the No Surprises Act, which would impose new requirements on health plans to send patients “Advanced Explanations of Benefits” prior to scheduled care or upon request by patients seeking more information prior to scheduling.

340B & DSH

- **June 2022:** The Health Resources and Services Administration (HRSA) is expected to issue a [proposed rule](#) to replace the Administrative Dispute Resolution (ADR) rule currently in place with new requirements and procedures for the 340B Program’s ADR process.
- **December 2022:** The Centers for Medicare and Medicaid Services (CMS) is expected to issue a [proposed rule](#) updating certain Consolidated Appropriations Act of 2021 (CAA) provisions related to Medicaid shortfall and third-party payments. The proposed rule would also make additional technical changes to the disproportionate share hospitals (DSH) program.

Drug Manufacturing

- **October 2022:** The Food and Drug Administration (FDA) is expected issue a [proposed rule](#) that would amend FDA medication guide regulation to require a new form of regulation and an additional [proposed rule](#) that would require investigational new drug applications (INDs) to submit an FDA developed safety update report.

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- **March 2023:** The FDA is expected to issue a [NPRM](#) which will update biologics regulation to clarify existing requirements and promote the agency's implementation of the abbreviated licensure pathway.
- **May 2023:** The FDA is expected to issue a [final rule](#) on amending regulations on direct-to-consumer (DTC) advertisement of prescription drugs.

Tobacco

- **June 2022:** The FDA is soon expected to propose a [final rule](#) that would reflect the increased minimum age of sale for tobacco products from 18 to 21 years of age, increase the minimum age for verification from under the age of 27 to under the age of 30; and increase the minimum age for facilities that maintain vending machines or self-service displays that sell tobacco products from 18 years to 21 years of age.
- **July 2022:** The FDA is expected to [propose a rule](#) that would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product, and would thereby help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products.
- **October 2022:** The FDA anticipates [proposing a rule](#) that would establish content and format requirements to ensure that modified risk tobacco product applications contain sufficient information for FDA to determine whether it should permit the marketing of a modified risk tobacco product.
- **December 2022:** The FDA plans to [propose a rule](#) to establish requirements for the administrative detention of tobacco products, which would allow FDA to administratively detain tobacco products encountered during inspections of manufacturers or other establishments that manufacture, process, pack, or hold tobacco products that an authorized FDA representative conducting the inspection has reason to believe are adulterated or misbranded.
- **May 2023:** The FDA is expected to issue a [proposed rule](#) implementing a tobacco standard that would establish a maximum nicotine level in cigarettes and certain finished tobacco products. The FDA says in addition that this product standard would also help to prevent experimenters (mainly youth) from initiating regular use, and, therefore, from becoming regular smokers (WHG summary with additional details [here](#)).

Workforce

- **February 2023:** The National Institutes of Health is expected to issue a [final rule](#) to reflect the changes in NIH loan repayment programs (LRPs) that resulted from enactment of the 21st Century Cures Act. Specifically, this entails consolidating the NIH LRPs into two programs and increasing the annual loan repayment amount, among other changes.

Long-term Care

- **September 2022:** CMS is slated to [propose](#) a rule that would implement federal requirements requiring specific covered individuals in long-term care facilities to report to the Secretary and law enforcement entities any reasonable suspicion that a crime has been committed against a resident of or an individual who is receiving care from such facility.
- **May 2023:** CMS is expected to issue a [proposed rule](#) that would revise the infection control requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs.

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Medicaid

- **July 2022:** CMS will [propose a rule](#) to require the mandatory reporting of the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set), the behavioral health measures on Adult Health Care Quality Measures for Medicaid (Adult Core Set) and the Core Set of Health Care Quality Measures for Medicaid Health Home Programs (Health Home Core Set).
- **August 2022:** CMS intends to [propose a rule](#) that would streamline eligibility and enrollment processes for all Medicaid and CHIP populations and create new enrollment pathways to maximize enrollment and retention of eligible individuals.
- **October 2022:** CMS plans to issue a proposed rule that would implement new requirements related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it will propose new beneficiary protections, as well as MDRP program integrity and administration changes.
- **February 2023:** CMS plans to [propose a rule](#) to better ensure comprehensive access to Medicaid and CHIP.
- **February 2023:** CMS is slated to [propose a rule](#) to ensure the efficient operation of state managed care delivery systems and enhance access to care for Medicaid managed care enrollees. Specifically, CMS may do so by including additional parameters on states' use of In Lieu of Services or Settings (ILOS) and state directed payments under Medicaid managed care contracts.

Organs

- **December 2022:** CMS is slated to issue a [proposed rule](#) that would modify the standards used to evaluate and recertify organ procurement organizations.

Insurance Coverage

- **June 2022:** CMS plans to issue a [proposed rule](#) that would clarify existing Medicare Secondary Payer (MSP) obligations associated with future medical items services related to liability insurance (including self-insurance), no fault insurance, and worker's compensation settlements, judgments, awards, or other payments.
- **August 2022:** CMS is expected to [propose](#) amendments to the definition of "short-term, limited-duration insurance" in such a way that protects enrollees with pre-existing conditions.
- **August 2022:** CMS is planning to [propose](#) amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under the Affordable Care Act.
- **September 2022:** : CMS is planning to issue a [proposed rule](#) pursuant to section 108 of the No Surprises Act, which prohibits a group health plan and a health insurance issuer offering group or individual health insurance coverage from discriminating with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law.

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- **December 2022:** CMS intends to [propose](#) a rule that would codify long-established Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement.
- **April 2023:** After a series of listening sessions earlier this year, CMS indicates it expects to [propose](#) a rule that would establish the criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies.

WIC

- **September 2022:** The Food and Nutrition Service (FNS) is expected to issue a [proposed rule](#) amending the regulations that govern food packages in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to meet scientific guidelines and other administrative revisions.
- **November 2022:** FNS is expected to issue a [proposed rule](#) addressing regulatory barriers to online ordering in WIC.

Child Nutrition Programs

- **January 2023:** FNS is expected to issue a [proposed rule](#) revising meal patterns in child nutrition programs to be consistent with the Dietary Guidelines for Americans including feedback from the February 2022 interim final rule on milk, whole grain, and sodium standards and requests for information.
- **May 2023:** FNS is expected to issue a [final rule](#) that will codify three provisions of the Healthy, Hunger-Free Kids Act of 2010 including criteria for imposing fines against schools or state agencies that fail to correct severe mismanagement or violations, procedures for the termination and disqualification of organizations participating in the Summer Food Service Program, and requirements that any institution or organization that has been terminated may not be authorized to administer other similar programs.
- **May 2024:** FNS is expected to issue a [final rule](#) with regulations to conform to requirements in the Healthy, Hunger-Free Kids Act of 2010 requiring school food authorities to provide the same level of financial support for lunches served to students who are not eligible for free or reduced-price lunches as is provided for lunches served to students eligible for free lunches and requires that all food sold in a school and purchased with funds from the nonprofit school food service account other than meals and supplements must generate revenue at least proportionate to the cost.

SNAP

- **July 2022:** FNS expects to issue an [interim final rule](#) to establish an interstate data system that state agencies will use to prevent multiple issuances of SNAP benefits by more than one state simultaneously.
- **February 2023:** FNS expects to issue a [final rule](#) establishing that states electing to use a heating or cooling standard utility allowance in the Supplemental Nutrition Assistance Program (SNAP) eligibility

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determinations must make the allowance available to households that receive a Low-Income Home Energy Assistance Program or other similar program payment greater than \$20 annually.

Other Nutrition Programs

- **August 2022:** FNS is expected to issue a [final rule](#) that will codify several waivers and flexibility to streamline program administration in the Summer Food Service Program.
- **March 2023:** FNS is expected to issue a [proposed rule](#) amending regulatory provisions to make access and parity improvements within the Commodity Supplemental Food Program, the Food Distribution Program on Indian Reservations, the Emergency Food Assistance Program, and USDA Foods disaster response.
- **May 2023:** FNS is expected to issue a [proposed rule](#) to update the Child and Adult Care Food Program (CACFP) serious deficiency process and establish a process for unaffiliated centers and the Summer Food Service Program for terminations and disqualification of participating organizations.
- **May 2024:** FNS is expected to issue a [final rule](#) codifying provisions of the Healthy, Hunger-Free Kids Act of 2010 that develop policies for submitting a CACFP application, allow day care homes to assist families in transmitting program forms, modify the structure and formula for determining administrative payments to sponsoring organizations of family day care homes, and allow sponsoring organizations to carry over up to ten percent of their administrative funding into the next fiscal year.