

Federal Regulatory Tracker

Pending and Anticipated Regulations Impacting Medicaid, Medicare and Commercial Markets

In recent months and the coming year, there will be multiple opportunities to comment on the administration's priorities for Medicare, Medicaid, and the commercial market, such as health equity and access, price transparency, mental health parity, and interoperability.

FTI Consulting's regulatory tracker highlights select anticipated or pending U.S. Department of Health and Human Services actions that may impact Medicare, Medicaid or the commercial market. The list is compiled from data in the Office of Information and Regulatory Affairs' (OIRA) [Spring 2022¹ Unified Regulatory Agenda](#) (as the Fall 2022 regulatory agenda is not yet published) and the Federal Register.

Each Regulation Identifier Number (RIN) link directs users to the OIRA landing page for the regulatory action in question. If a link is provided under the "Action" column, the user will be directed to the primary source document in the Federal Register.

To the extent that FTI Consulting has observations based on publicly available documents, they are provided below:

ACTION	STATUS	TITLE AND AGENCY DESCRIPTION	OBSERVATIONS
Proposed Rule RIN: 0938-AU93 Medicare Medicare Commercial	Initially scheduled for July 2022, publication date is TBD.	<p><i>Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021 (CMS-9902)²</i>: This rule would propose amendments to the final rules implementing the Mental Health Parity and Addiction Equity Act. The amendments would clarify plans' and issuers' obligations under the law, promote compliance with MHPAEA, and update requirements taking into account experience with MHPAEA in the years since the rules were finalized as well as amendments to the law recently enacted as part of the Consolidated Appropriations Act, 2021.</p>	Given recent reports and enforcement activities, the proposed rule may include simplification of standards across delivery systems, increased noncompliance enforcement authority for the Department of Labor (DOL) and Centers for Medicare and Medicaid Services (CMS), additional guidance pertaining to Non-Quantitative Treatment Limitations (NQTL) comparative analyses (i.e., medical management policies, network adequacy, telehealth services) and, potentially, changes in opt-out rules for state and local government plans.
Proposed Rule RIN: 0938-AU94 Commercial	Initially scheduled for August 2022, publication date is TBD.	<p><i>Coverage of Certain Preventive Services under the Affordable Care Act (CMS-9903)³</i>: This rule would propose amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under title I of the Patient Protection and Affordable Care Act.</p>	This proposed rule would probably have modified moral exemptions for contraceptive coverage implemented under the previous administration (see 83 FR 57592 (2018)⁴ primarily amending 45 CFR 147.133⁵). Publication of this proposed rule is likely to be delayed pending the outcome of <i>Braidwood Management v. Becerra</i> , which presents broad challenges to the Affordable Care Act's (ACA's) coverage of preventive services. For a summary of the litigation, see Kaiser Family Foundation's October 26, 2022 issue brief⁶ .
Proposed Rule ⁷ RIN: 0938-AU00 Medicaid	Published September 7, 2022. Comments due November 7, 2022.	<p><i>Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes (CMS-2421)⁸</i>: This proposed rule would streamline eligibility and enrollment processes for all Medicaid and Children's Health Insurance Program (CHIP) populations and create new enrollment pathways to maximize enrollment and retention of eligible individuals.</p>	CMS proposes to extend the Medicaid eligibility renewal standards for Modified Adjusted Gross Income (MAGI)-based eligibility groups to non-MAGI-based eligibility groups and to modify state data verification requirements for eligibility, among other proposals. A particular area for state comment is a reasonable timeframe in which to implement final changes, considering maintenance of eligibility unwinding at the end of the public health emergency.

<p>Request for Information⁹ RIN: 0938-ZB72 Medicaid Medicare Commercial</p>	<p>Published October 7, 2022. Comments due December 6, 2022.</p>	<p>National Directory of Healthcare Providers and Services (CMS-0058-NC): The Request for Information (RFI) solicits public comments on establishing a National Directory of Health Providers and Services (NDH) that could serve as a “centralized data hub” for healthcare provider, facility, and entity directory information nationwide.</p>	<p>CMS requests comment on the platform and technical standards for the National Directory of Health Providers and Services (NDH) and integration of provider information from other CMS systems, incentives and policies to support use of the NDH, standardized provider directory elements and broader considerations for implementation.</p>
<p>Proposed Rule RIN: 0938-AU97 Commercial</p>	<p>Initially scheduled for September 2022, publication date is TBD.</p>	<p>HHS Notice of Benefit and Payment Parameters for 2024 (CMS-9899)¹⁰: The annual proposed rule would set forth payment parameters and provisions related to the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It would also provide additional standards for several other Affordable Care Act programs.</p>	<p>Publicly available information on the full scope of potential benefit and payment parameters for 2024 is unclear. In accordance with past annual notices, the potential proposals to be addressed are the use of 2020 Enrollee-Level External Data Gathering Environment (EDGE) data for 2024 risk-adjustment models, updated user fees, and policies to improve health equity and to address social determinants of health.</p>
<p>Proposed Rule RIN: 0938-AU87 Medicare Medicaid CHIP Commercial</p>	<p>Initially scheduled for September 2022, publication date is TBD.</p>	<p>Interoperability and Prior Authorization for MA Organizations, Medicaid and CHIP Managed Care and State Agencies, FFE QHP Issuers, MIPS Eligible Clinicians, Eligible Hospitals and CAHs (CMS-0057)¹¹: This proposed rule would place new requirements on Medicare Advantage (MA) organizations, Medicaid managed care plans, Children’s Health Insurance Program (CHIP) managed care entities, state Medicaid and CHIP fee-for-service (FFS) programs, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFE) to improve the electronic exchange of health care data and streamline processes related to prior authorization, while continuing CMS’ drive toward interoperability, and reducing burden in the health care market. This proposed rule would also add a new measure for eligible hospitals and critical access hospitals under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians under the Promoting Interoperability performance category of MIPS. These policies taken together would play a key role in reducing overall payer and provider burden and improving patient access to health information.</p>	<p>The anticipated proposed rule expands the scope of interoperability and prior authorization provisions to Medicare Advantage Organizations, which were excluded from the December 2020 proposed rule . The December 2020 proposed rule¹² also excluded prescription drugs and covered outpatient drugs from items and services subject to patient, provider and payer-to-payer Application Programming Interfaces (APIs). The full scope of the forthcoming proposals awaits determination.</p>
<p>Proposed Rule RIN: 0938-AU28 Medicaid</p>	<p>Initially scheduled for October 2022, publication date is TBD.</p>	<p>Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434)¹³: This rule proposes requirements related to manufacturers’ misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it proposes beneficiary protections, as well as MDRP program integrity and administration changes.</p>	<p>While publicly available information on the full scope of potential proposals related to the Medicaid Drug Rebate Program (MDRP) is unclear, the proposed rule could impact relevant regulations related to state fiscal administration (42 CFR part 433¹⁴), managed care (42 CFR part 438)¹⁵ and payment for services (42 CFR part 447)¹⁶.</p>
<p>RProposed Rule RIN: 0938-AU96 Medicare</p>	<p>Initially scheduled for October 2022, publication date is TBD.</p>	<p>Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024 (CMS-4201)¹⁷: This proposed rule would implement changes to strengthen and improve the Medicare Advantage (Part C) and prescription drug (Part D) programs.</p>	<p>The full scope of potential proposals related to Medicare Advantage and Medicare Part D for 2024 is unclear; however, forthcoming proposals are likely to be informed by CMS’ August 2022 Request for Information¹⁸ , focusing on health equity, expanded access to services, social determinants of health, person-centered care, affordability and broad stakeholder engagement.</p>

<p>Proposed Rule RIN: 0938-AU51 Medicare</p>	<p>Scheduled for December 2022 release.</p>	<p>Alternative Payment Model (CMS-5535)¹⁹: This rule would propose a new mandatory Medicare payment model under section 1115A of the Social Security Act. This model would test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.</p>	<p>The subject of the new mandatory model for Medicare providers is not clear; however, if finalized, the model would be the third mandatory payment model implemented under the Center for Medicare and Medicaid Innovation's (CMMI) authority. Mandatory payment models apply to selected geographic areas (see Comprehensive Care for Joint Replacement²⁰ and Radiation Oncology²¹, pending final rulemaking for start date).</p>
<p>Proposed Rule RIN: 0938-AU90 Medicaid Medicare CHIP</p>	<p>Scheduled for December 2022 release.</p>	<p>Medicare and Medicaid Program Integrity (CMS-6084)²²: This proposed rule includes provisions that would promote payment accuracy and efficiency and help CMS identify and deter fraud, waste, and abuse in a timely, effective manner, enabling the Agency to protect the Medicare and Medicaid programs and CHIP.</p>	<p>The extent of proposed changes to the following existing improper payment measurement programs is unclear: Comprehensive Error Rate Testing (CERT) for traditional Medicare, payment of the Medicaid Payment Error Rate Measurement (PERM) process, Improper Payment Measurement for Medicare Part C and D or Payment Error Rate Measurement for Medicaid and CHIP.</p>
<p>Proposed Rule RIN: 0938-AU98 Commercial Self-Insured</p>	<p>Scheduled for January 2023 release.</p>	<p>Requirements Related to Advanced Explanation of Benefits and Other Provisions Under the Consolidated Appropriations Act 2021 (CMS-9900)²³: This proposed rule would implement section 9816 of the Internal Revenue Code of 1986 (Code), section 716 of the Employee Retirement Income Security Act of 1974 (ERISA), and section 2799A1 of the Public Health Service (PHS Act), as directed by section 111 of the No Surprises Act (NSA); and may include other provisions under the Consolidated Appropriations Act, 2021.</p>	<p>When an individual schedules or requests services, a provider or facility must provide a good faith estimate of charges for services. The provider or facility then transmits the good faith estimate to the individual's health plan for the creation of an Advanced Explanation of Benefits. This provision for insured individuals was supposed to be in effect as of January 1, 2022; however, the respective agencies have delayed final rulemaking because of complications in developing the systems for required shared information. Proposals will probably be informed by public comments solicited in the September 2022 Request for Information²⁴.</p>
<p>Proposed Rule RIN: 0938-AU99 Medicaid</p>	<p>Scheduled for February 2023 release.</p>	<p>Medicaid Managed Care (CMS-2439)²⁵: This rule would propose changes to Medicaid managed care regulations, including additional parameters on states' use of In Lieu of Services or Settings (ILOS) and state directed payments under Medicaid managed care contracts, as well as other policy and reporting changes to ensure the efficient operation of state managed care delivery systems and access to care for Medicaid managed care enrollees.</p>	<p>Rulemaking has the potential for significant impact on CMS scrutiny and state reporting on In Lieu of Services or Settings (ILOS) relating to California's CalAIM 1915(b) waiver²⁶ terms and conditions, such as demonstrating medical appropriateness and cost effectiveness of the ILOS (see 42 CFR 438.3(e)(2)²⁷ for current requirements). For state directed payments, CMS is likely to propose limits on reimbursement, standardize the average commercial rate benchmark, limit the use of separate payment terms, clarify evaluation requirements and seek comment on transparency of documentation (see 42 CFR 438.6(c)²⁸ for current requirements).</p>
<p>Proposed Rule RIN: 0938-AU68 Medicaid CHIP</p>	<p>Scheduled for February 2023 release.</p>	<p>Assuring Access to Medicaid Services (CMS-2442)²⁹: This rule proposes to address elements related to assuring access in Medicaid and/or CHIP. These elements could include processes that support the implementation of a comprehensive access strategy as well as payment processes, such as those related to specific payment systems.</p>	<p>Forthcoming proposals are likely to be informed by the CMS' February 2022 Request for Information³⁰ seeking comment on minimum federal standards for timely access in Medicaid-managed care and fee-for-service delivery systems that take into account geography, provider-reimbursement arrangements and cultural competency. The proposals may extend to network adequacy standards; Medicaid-managed care requirements are not currently aligned with Medicare Advantage or the Marketplace, as states have discretion to establish quantitative standards for a set of specified provider types (see 42 CFR 438.68³¹).</p>

<p>Proposed Rule RIN: 0938-AU91 Medicaid Medicare</p>	<p>Scheduled for March 2023 release.</p>	<p><i>Culturally Competent and Person-Centered Requirements to Increase Access to Care and Improve Quality for All (CMS-3418)</i>³² : The proposed rule would establish culturally competent and person-centered requirements for all provider and supplier types that participate in Medicare and Medicaid programs. These requirements revise the Conditions of Participations/ Conditions for Coverage pertaining to governance, patient/resident/client rights (such as nondiscrimination and accessibility), clinical quality standards, quality assessment and performance improvement, staff training, discharge planning, and care planning in an effort to increase quality and improve access to health care. These proposals are in accordance with Executive Orders 13985, 13988, 13995, and 14031 on advancing racial equity and support for underserved communities through the Federal government, preventing and combating discrimination on the basis of gender identity or sexual orientation, and ensuring an equitable pandemic response and recovery.</p>	<p>The full scope of the proposed rule, including identification of entities responsible for oversight of provider compliance and supports available for practice transformation, is yet to be determined.</p>
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- ¹Office of Information and Regulatory Affairs (OIRA). "Agency Rule List Spring 2022." Filter for Department of Health and Human Services. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaMain>.
- ²OIRA. "Proposed Rule: Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021 (CMS-9902)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU93>.
- ³OIRA. "Proposed Rule: Coverage of Certain Preventive Services under the Affordable Care Act (CMS-9903)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU94>.
- ⁴Internal Revenue Service, Department of the Treasury, Employee Benefits Security Administration, Department of Labor, and Centers for Medicare & Medicaid Services, "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act," Federal Register Vol. 83, no. 221 (November 15, 2018): 57592, <https://www.federalregister.gov/documents/2018/11/15/2018-24514/moral-exemptions-and-accommodations-for-coverage-of-certain-preventive-services-under-the-affordable>.
- ⁵Moral Exemptions in Connection with Coverage of Certain Preventive Health Services, 45 C.F.R. § 147.133 (2022), <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-147/section-147.133>.
- ⁶Sobel, Laurie, Usha, Ranji, et al., "Explaining Litigation Challenging the ACA's Preventive Services Requirements: Braidwood Management Inc. v. Becerra," Kaiser Family Foundation Issue Brief, October 26, 2022. <https://www.kff.org/womens-health-policy/issue-brief/explaining-litigation-challenging-the-acas-preventive-services-requirements-braidwood-management-inc-v-becerra/>.
- ⁷Centers for Medicare & Medicaid Services, "Streamlining the Medicaid, Children's Health Insurance Program (CHIP), and the Basic Health Program (BHP) Application, Eligibility Determination, Enrollment and Renewal Process," Federal Register Vol. 87, no. 172 (September 7, 2022): 54760, <https://www.federalregister.gov/documents/2022/09/07/2022-18875/streamlining-the-medicaid-childrens-health-insurance-program-and-basic-health-program-application>.
- ⁸OIRA. "Proposed Rule: Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes (CMS-2421)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU00>.
- ⁹Centers for Medicare & Medicaid Services, "Request for Information; National Directory of Healthcare Providers & Services," Federal Register, Vol. 87, no. 194 (October 7, 2022): 61018, <https://www.federalregister.gov/documents/2022/10/07/2022-21904/request-for-information-national-directory-of-healthcare-providers-and-services>.
- ¹⁰OIRA. "Proposed Rule: HHS Notice of Benefit and Payment Parameters for 2024 (CMS-9899)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU97>.
- ¹¹OIRA. "Proposed Rule: Interoperability and Prior Authorization for MA Organizations, Medicaid and CHIP Managed Care and State Agencies, FFE QHP Issuers, MIPS Eligible Clinicians, Eligible Hospitals and CAHs (CMS-0057)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU87>.
- ¹²Centers for Medicare & Medicaid Services, "Proposed Rule: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications," Federal Register Vol. 85, no. 244 (December 18, 2020): 82586, <https://www.govinfo.gov/content/pkg/FR-2020-12-18/pdf/2020-27593.pdf>.
- ¹³OIRA. "Proposed Rule: Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU28>.
- ¹⁴State Fiscal Administration, 42 C.F.R. part 433 (2022), <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433>.
- ¹⁵Managed Care, 42 C.F.R. part 438 (2022), <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438>.
- ¹⁶Payment for Services, 42 C.F.R. part 447 (2022), <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447>.
- ¹⁷OIRA. "Proposed Rule: Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024 (CMS-4201)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU96>.
- ¹⁸Centers for Medicare & Medicaid Services, "Medicare Program; Request for Information on Medicare," Federal Register Vol. 87, no. 146 (August 1, 2022): 46918, <https://www.govinfo.gov/content/pkg/FR-2022-08-01/pdf/2022-16463.pdf>.
- ¹⁹OIRA. "Proposed Rule: Alternative Payment Model (CMS-5535)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU51>.
- ²⁰Center for Medicare & Medicaid Innovation. "Comprehensive Care for Joint Replacement Model." CMS.gov. October 24, 2022. <https://innovation.cms.gov/innovation-models/cjr>.
- ²¹Center for Medicare & Medicaid Innovation. "Radiation Oncology Model." CMS.gov. October 24, 2022. <https://innovation.cms.gov/innovation-models/radiation-oncology-model>.
- ²²OIRA. "Proposed Rule: Medicare and Medicaid Program Integrity (CMS-6084)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU90>.

²³OIRA. "Proposed Rule: Requirements Related to Advanced Explanation of Benefits and Other Provisions Under the Consolidated Appropriations Act 2021 (CMS-9900)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU98>.

²⁴Office of Personnel Management (OPM), Internal Revenue Service, Department of the Treasury, Employee Benefits Security Administration (EBSA), Department of Labor (DOL), and Centers for Medicare & Medicaid Services, "Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals," Federal Register Vol 87, no. 179 (September 16, 2022): 56905, <https://www.govinfo.gov/content/pkg/FR-2022-09-16/pdf/2022-19798.pdf>.

²⁵OIRA, "Proposed Rule: Medicaid Managed Care (CMS-2439)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU99>.

²⁶Centers for Medicare & Medicaid Services, "California Advancing & Innovating Medi-Cal (CalAIM) Waiver Special Terms and Conditions, waiver Control # CA 17.R10." December 29, 2021. <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ca-calaim-ca-17-stc.pdf>.

²⁷Standard Contract Requirements, 42 C.F.R. §438.3(e)(2) (2022), <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438/subpart-A/section-438.3>.

²⁸Special Contract Provisions Related to Payment, 42 C.F.R. 438.6(c) (2022), <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438/subpart-A/section-438.6>.

²⁹OIRA. "Proposed Rule: Assuring Access to Medicaid Services (CMS-2442)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU68>.

³⁰Centers for Medicare & Medicaid Services. "Questions Included in the Request for Information: Access to Coverage and Care in Medicaid & CHIP." February 17, 2022. <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

³¹Network Adequacy Standards, 42 C.F.R. 438.68 (2022), <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438/subpart-B/section-438.68>.

³²OIRA. "Proposed Rule: Culturally Competent and Person-Centered Requirements to Increase Access to Care and Improve Quality for All (CMS-3418)." Agency Rule List Spring 2022. October 24, 2022. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0938-AU91>.