

2024 CHART OF ADDITIONAL HEALTHCARE REGULATIONS

UPDATED FEBRUARY 21, 2024

McDermott+ Consulting During this election year, McDermottPlus is actively monitoring <u>annual regulations</u> that federal agencies are expected to release, as well as "ad hoc" regulations that will be released at the discretion of federal agencies.

This chart displays health related regulations that may be issued this year, organized by federal agency and date of potential release.

This list is subject to change and McDermottPlus will keep it updated throughout the year.

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Centers for Medicare and Medicaid Services (CMS)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Contract Year 2025 Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, and Medicare Cost Plan Programs, and PACE (CMS-4205)	Proposed Rule: 11/6/2023	Final Rule: 2/2024	2/2024	Annual
HHS Notice of Benefit and Payment Parameters for 2025 (CMS-9895)	Proposed Rule: 11/15/2023	Final Rule: 2/2024	2/2024	Annual
Administrative Simplification: Modifications to NCPDP Retail Pharmacy Standards (CMS- 0056)	Proposed Rule: 11/9/2022	Final Rule: 2/2024	2/2024	Ad Hoc
Amendments to Rules Governing Organ Procurement Organizations (CMS-3409)	None	Proposed Rule: 2/2024	unknown	Ad Hoc
Disproportionate Share Hospital (DSH) Third Party Payer (CMS-2445)	Proposed Rule: 2/24/2023	Final Rule: 2/2024	2/2024	Ad Hoc
Streamlining the Medicaid, CHIP, and BHP Application, Eligibility Determination, Enrollment, and Renewal Processes (CMS-2421)	Proposed Rule: 9/7/2022;	Final Rule: 2/2024	2/2024	Ad Hoc
Alternative Payment Model Updates; Increasing Organ Transplant Access (IOTA) Model (CMS-5535)	None	Proposed Rule: 2/2024	2/2024	Ad Hoc
Final Notice of Methodological Changes for Calendar Year 2025 for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies & Draft CY 2025 Part D Redesign Program Instructions	Advance Notice: 1/31/2024	Final Notice: 4/1/2024	4/2024	Annual
Ensuring Access to Medicaid Services (CMS-2442)	Proposed Rule: 5/3/2023	Final Rule: 4/2024	4/2024	Ad Hoc
Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS-2439)	Proposed Rule: 5/3/2023	Final Rule: 4/2024	4/2024	Ad Hoc

Centers for Medicare and Medicaid Services (CMS) CONT.

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Episode-Based Payment Model (CMS-5540)	Request for Information: 7/18/2023	Proposed Rule: 4/2024	unknown	Ad Hoc
FY 2025 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1810)	None	Proposed Rule: 4/2024	8/2024	Annual
FY 2025 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS-1806)	None	Proposed Rule: 4/2024	8/2024	Annual
FY 2025 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update and Quality Reporting Program (CMS-1804)	None	Proposed Rule: 4/2024	8/2024	Annual
FY 2025 Skilled Nursing Facility (SNFs) Prospective Payment System and Consolidated Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS- 1802)	None	Proposed Rule: 4/2024	8/2024	Annual
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2025 Rates (CMS-1808)	None	Proposed Rule: 4/2024	8/2024	Annual
Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance (CMS-9904)	Proposed Rule: 7/12/2023	Final Rule: 4/2024	4/2024	Ad Hoc
Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Standard (CMS-0053)	Proposed Rule: 12/21/2022	Final Rule: 6/2024	6/2024	Ad Hoc
CY 2025 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program (CMS-1805)	None	Proposed Rule: 6/2024	11/2024	Annual
CY 2025 Home Health Prospective Payment System Rate Update and Home Infusion Therapy and Home IVIG Services Payment Update (CMS-1803)	None	Proposed Rule: 6/2024	11/2024	Annual
CY 2025 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1809)	None	Proposed Rule: 6/2024	11/2024	Annual



Centers for Medicare and Medicaid Services (CMS) CONT.

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
CY 2025 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1807)	None	Proposed Rule: 6/2024	11/2024	Annual
Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS-4198)	None	Proposed Rule: 6/2024	unknown	Ad Hoc
Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434)	Proposed Rule: 5/26/2023	Final Rule: 6/2024	6/2024	Ad Hoc
Coverage of Certain Preventive Services Under the Affordable Care Act (CMS-9903)	Proposed Rule: 2/2/2023	Final Rule: 8/2024	8/2024	Ad Hoc
Provider Nondiscrimination Requirements for Group Health Plans and Health Insurance Issuers in the Group and Individual Markets (CMS-9910)	None	Proposed Rule: 8/2024	unknown	Ad Hoc
<u>CY 2025 Inpatient Hospital Deductible and Hospital and Extended Care Services</u> <u>Coinsurance Amounts (CMS-8086)</u>	None	Notice: 9/2024	9/2024	Annual
CY 2025 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8087)	None	Notice: 9/2024	9/2024	Annual
Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2025 (CMS-8088)	None	Notice: 9/2024	9/2024	Annual
Requirements Related to Air Ambulance Services, Agent and Broker Disclosures and Provider Enforcement (CMS-9907)	Proposed Rule: 9/16/2021	Final Rule: 9/2024	9/2024	Ad Hoc
Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting (CMS-3442)	Proposed Rule: 9/6/2023	Final Rule: unknown	unknown	Ad Hoc
Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021	Proposed Rule: 8/3/2023	Final Rule: unknown	unknown	Ad Hoc
Clarifying Eligibility for a Qualified Health Plan Through an Exchange, Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, A Basic Health Program and Medicaid and CHIP (CMS-9894)	Proposed Rule: 4/26/2023	Final Rule: unknown	unknown	Ad Hoc



Centers for Medicare and Medicaid Services (CMS) CONT.

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
CMS Enforcement of State Compliance With Reporting and Federal Medicaid Renewal Requirements Under Section 1902(tt) of the Social Security Act (CMS-2447)	None	Interim Final Rule: unknown	unknown	Ad Hoc
Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326)	Request for Information: 1/9/2018; Proposed Rule: 7/26/2022	Final Rule: unknown	unknown	Ad Hoc
Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers II (CMS-3426)	None	Proposed Rule: unknown	unknown	Ad Hoc
Independent Dispute Resolution Operations (CMS-9897)	Proposed Rule: 11/3/2023	Final Rule: unknown	unknown	Ad Hoc

Office of the National Coordinator for Health Information Technology (ONC)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability	None	Proposed Rule: unknown	unknown	Ad Hoc
Electronic Prior Authorization in the ONC Health IT Certification Program	Request for Information: 1/24/2022	Proposed Rule: unknown	unknown	Ad Hoc
Establishment of Disincentives for Health Care Providers Who Have Committed Information Blocking	Proposed Rule: 11/1/2023	Final Rule: unknown	unknown	Ad Hoc

Health and Human Services (HHS) Office for Civil Rights (OCR)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Nondiscrimination in Health Programs and Activities	Proposed Rule: 8/4/2022	Final Rule: 2/2024	2/2024	Ad Hoc
Proposed Modifications to the HIPAA Privacy Rule to Support Reproductive Health Care Privacy	Proposed Rule: 4/17/2023	Final Rule: 3/2024	3/2024	Ad Hoc
Rulemaking on Discrimination on the Basis of Disability in Health and Human Services Programs or Activities	Proposed Rule: 9/14/2023	Final Rule: 4/2024	4/2024	Ad Hoc
Proposed Modifications to the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information	None	Proposed Rule: 9/2024	unknown	Ad Hoc

Office of Inspector General (OIG)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities	None	Proposed Rule: 5/2024	unknown	Ad Hoc
Medicare and State Health Care Programs: Fraud and Abuse; Establishment of New Safe Harbors Under the Federal Anti-Kickback Statute	None	Proposed Rule: 8/2024	unknown	Ad Hoc

HHS Office of the Secretary (OS)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
CY 2023 Civil Monetary Penalties Inflation Adjustment	None	Interim Final Rule:5/2024	5/2024	Ad Hoc
Privacy Act Regulations	None	Proposed Rule: 8/2024	unknown	Ad Hoc

Food and Drug Administration (FDA)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Medical Devices; Laboratory Developed Tests	Proposed Rule: 10/3/2023	Final Rule: 4/2024	4/2024	Ad Hoc
Medication Guide; Patient Medication Information	Proposed Rule: 5/31/2023	Final Rule: unknown	unknown	Ad Hoc

Drug Enforcement Administration (DEA)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Suspicious Orders of Controlled Substances	Proposed Rule: 11/2/2020	Final Rule: 2/2024	2/2024	Ad Hoc
Disaster Registration Emergency Authorities	None	Proposed Rule: 2/2024	unknown	Ad Hoc
Federal Regulations on Telepharmacy	Advanced Notice of Proposed Rulemaking: <u>11/17/2021</u>	Proposed Rule: 5/2024	unknown	Ad Hoc
Operation of Automated Dispensing Systems at Long Term Care Facilities by Hospital/Clinic Pharmacies	None	Proposed Rule: 8/2024	unknown	Ad Hoc
Providing Controlled Substances to Ocean Vessels	Proposed Rule: 7/18/2022	Final Rule: 9/2024	9/2024	Ad Hoc
Electronic Prescriptions for Controlled Substances	Interim Final Rule comment reopened: 4/21/2020	Final Rule: unknown	unknown	Ad Hoc
Medical Marijuana and Cannabidiol Research Expansion	None	Proposed Rule: unknown	unknown	Ad Hoc
Medical Missions	None	Proposed Rule: unknown	unknown	Ad Hoc
Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017	Proposed Rule: 10/5/2020	Final Rule: unknown	unknown	Ad Hoc
Expansion of Induction of Buprenorphine via Telemedicine Encounter	Proposed Rule: 3/1/2023; Temporary Rule: 5/10/2023; Second Temporary Rule: 10/10/2023	Proposed Rule: unknown	unknown	Ad Hoc
Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have not had a Prior In-Person Medical Evaluation	Proposed Rule: 3/1/2023; Temporary Rule: 5/10/2023; Second Temporary Rule: 10/10/2023	Proposed Rule: unknown	unknown	Ad Hoc
Amending Regulations to Conform to the Controlled Substance Ordering System (CSOS) Modernization	Proposed Rule: 2/2/2023	Final Rule: unknown	unknown	Ad Hoc
Implementation of the SUPPORT Act: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment	Interim Final Rule: 11/2/2020	Final Rule: unknown	unknown	Ad Hoc
Changes to a Prescription	None	Proposed Rule: unknown	unknown	Ad Hoc
Schedules of Controlled Substances; Exempted Prescription Products	Proposed Rule: 4/12/2022	Final Rule: unknown	unknown	Ad Hoc

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Federal Trade Commission (FTC)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Health Breach Notification Rule	Proposed Rule: 6/9/2023	Final Rule: unknown	unknown	Ad Hoc
Non-Compete Clause Rule	Proposed Rule: 1/19/2023	Final Rule: unknown	unknown	Ad Hoc

Occupational Safety and Health Administration (OSHA)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Infectious Diseases	Request for Information: 5/6/2010	Proposed Rule: 6/2024	unknown	Ad Hoc
Emergency Response	None	Proposed Rule: unknown	unknown	Ad Hoc
Occupational Exposure to COVID-19 in Healthcare Settings	Interim Final Rule: 6/21/2021	Final Rule: unknown	unknown	Ad Hoc

Department of Labor (DOL)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Definition of 'Employer' Under Section 3(5) of ERISA-Association Health Plans	Proposed Rule: 12/20/2023	Final Rule: 4/2024	4/2024	Ad Hoc

Veterans Affairs (VA)

Name of Rule	Previous Action	Expected Date of Publication	Expected Date of Final Rule	Annual or Ad Hoc
Changes to the Provision of Health Care for World War II Veterans	None	Final Rule: 2/2024	2/2024	Ad Hoc
Behavioral Health Care for Certain Former Members of the Armed Forces	None	Proposed Rule: 4/2024	unknown	Ad Hoc
Home Visits in Program of Comprehensive Assistance for Family Caregivers During COVID-19 National Emergency	Interim Final Rule: 6/5/2020	Final Rule: 4/2024	4/2024	Ad Hoc
Reimbursement for Emergency Treatment	Interim Final Rule: 1/9/2018; Final Rule: 2/22/2023	Final Rule: 4/2024	4/2024	Ad Hoc
CHAMPVA Coverage of Audio-Only Telehealth, Mental Health Services, and Cost Sharing for Certain Contraceptive Services and Contraceptive Products Approved, Cleared, or Granted by FDA	Proposed Rule: 10/24/2022	Final Rule: 5/2024	5/2024	Ad Hoc
Health Care Professionals Practicing Via Telehealth	Proposed Rule: 8/23/2022	Final Rule: 6/2024	6/2024	Ad Hoc
Payments Under State Home Care Agreements for Nursing Home Care	Proposed Rule: 12/21/2022	Final Rule: 6/2024	6/2024	Ad Hoc
Modifying Copayments for Veterans at High Risk for Suicide	Proposed Rule: 1/5/2022	Final Rule: 9/2024	9/2024	Ad Hoc
Reporting to the National Practitioner Data Bank	Proposed Rule: 4/3/2023	Final Rule: 9/2024	9/2024	Ad Hoc
Right to Try	None	Proposed Rule: 9/2024	unknown	Ad Hoc
Determining Eligibility for Domiciliary Care	Proposed Rule: 9/1/2023	Final Rule: 10/2024	10/2024	Ad Hoc
Removal of Exclusion of Gender Alterations From the Medical Benefits Package	None	Proposed Rule: unknown	unknown	Ad Hoc
Reproductive Health Services	Proposed Rule: 9/9/2022	Final Rule: unknown	unknown	Ad Hoc
VA Pilot Program on Graduate Medical Education and Residency	Proposed Rule: 2/4/2023	Final Rule: unknown	unknown	Ad Hoc
Authority of VA Professionals to Practice Health Care	Interim Final Rule: 11/12/2020	Final Rule: unknown	unknown	Ad Hoc
Center for Innovation for Care and Payment Update	None	Final Rule: unknown	unknown	Ad Hoc



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