

# 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-<br>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,<br>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<br>(CMS-5535)  | None                      | Proposed Rule: 2/2024        | 2/2024                      | Ad Hoc           |
| Final Notice of Methodological Changes for Calendar Year 2025 for Medicare Advantage<br>Capitation Rates and Part C and Part D Payment Policies & Draft CY 2025 Part D Redesign<br>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,<br>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<br>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<br>Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS-<br>1802)                         | None                               | Proposed Rule: 4/2024        | 8/2024                      | Annual           |
| Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term<br>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<br>Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and<br>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<br>Transactions and Electronic Signatures, and Modification to Referral Certification and<br>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<br>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<br>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<br>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<br>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<br>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><br><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<br>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<br>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<br>of the Premium Tax Credit, Cost-sharing Reductions, A Basic Health Program and<br>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,<br>Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326) | Request for Information: 1/9/2018;<br>Proposed Rule: 7/26/2022 | Final Rule: unknown          | unknown                     | Ad Hoc           |
| Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers<br>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<br>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<br>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<br>Exclusion Authorities                         | None            | Proposed Rule: 5/2024        | unknown                     | Ad Hoc           |
| Medicare and State Health Care Programs: Fraud and Abuse; Establishment of New Safe<br>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:<br><u>11/17/2021</u>                                | Proposed Rule: 5/2024        | unknown                     | Ad Hoc           |
| Operation of Automated Dispensing Systems at Long Term Care Facilities by<br>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:<br>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:<br>5/10/2023; Second Temporary Rule:<br>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:<br>5/10/2023; Second Temporary Rule:<br>10/10/2023 | Proposed Rule: unknown       | unknown                     | Ad Hoc           |
| Amending Regulations to Conform to the Controlled Substance Ordering System<br>(CSOS) Modernization                                       | Proposed Rule: 2/2/2023   | Final Rule: unknown          | unknown                     | Ad Hoc           |
| Implementation of the SUPPORT Act: Dispensing and Administering Controlled<br>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<br>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:<br>2/22/2023 | Final Rule: 4/2024           | 4/2024                      | Ad Hoc           |
| CHAMPVA Coverage of Audio-Only Telehealth, Mental Health Services, and Cost<br>Sharing for Certain Contraceptive Services and Contraceptive Products Approved,<br>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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