



Agency Rule List - Spring 2015

Department of Health and Human Services

Agency	Agenda Stage of Rulemaking	Title	RIN
HHS/HRSA	Prerule Stage	340B Program Omnibus Guidelines	0906-AB08
HHS/HRSA	Proposed Rule Stage	340B Civil Monetary Penalties for Manufacturers and Ceiling Price Regulations	0906-AA89
HHS/HRSA	Proposed Rule Stage	340B Drug Pricing Program; Administrative Dispute Resolution Process	0906-AA90
HHS/HRSA	Proposed Rule Stage	Teaching Health Center Graduate Medical Education Program	0906-AA98
HHS/HRSA	Proposed Rule Stage	Revision to the Vaccine Injury Table Within the National Vaccine Injury Compensation Program	0906-AB01
HHS/HRSA	Final Rule Stage	Countermeasures Injury Compensation Program; Pandemic Influenza Countermeasure Injury Table Amendment for Influenza Vaccines, Antiviral Drugs, Respiratory Protection/Support Devices, and Diagnostics	0906-AA79
HHS/HRSA	Final Rule Stage	Vaccine Injury Table: Rotavirus Vaccine Within the National Vaccine Injury Compensation Program	0906-AB00
HHS/FDA	Proposed Rule Stage	Over-the-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products	0910-AF31
HHS/FDA	Proposed Rule Stage	Over-the-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products	0910-AF69
HHS/FDA	Proposed Rule Stage	Regulations on Fixed-Dose Combination and Co-Packaged Drug and/or Biological Products	0910-AF89
HHS/FDA	Proposed Rule Stage	Abbreviated New Drug Applications and 505(b)(2)	0910-AF97
HHS/FDA	Proposed Rule Stage	Updated Standards for Labeling of Pet Food	0910-AG09
HHS/FDA	Proposed Rule Stage	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products	0910-AG18
HHS/FDA	Proposed Rule Stage	Sunlamp Products; Proposed Amendment to the Performance Standard	0910-AG30
HHS/FDA	Proposed Rule Stage	Reports of Distribution and Sales Information for Antimicrobial Active Ingredients Used in Food-Producing Animals	0910-AG45
HHS/FDA	Proposed Rule Stage	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910-AG59
HHS/FDA	Proposed Rule Stage	Registration of Food Facilities: Amendments to Food Facility Registration Requirements	0910-AG69
HHS/FDA	Proposed Rule Stage	Submission of Labels and Package Inserts for Medical Devices Listed Pursuant to Section 510(j) of the Federal Food, Drug, and Cosmetic Act	0910-AG79
HHS/FDA	Proposed Rule Stage	Establishment Registration and Product Listing for Tobacco Products	0910-AG89
HHS/FDA	Proposed Rule Stage	Pediatric Study Plan Requirements for New Drug and Biologics License Applications	0910-AG93
HHS/FDA	Proposed Rule Stage	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910-AG96
HHS/FDA	Proposed Rule Stage	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910-AH00
HHS/FDA	Proposed Rule Stage	Proposal to Ban Powdered Natural Rubber Latex and Powdered Synthetic Latex Surgeon's and Patient Examination Gloves	0910-AH02
HHS/FDA	Proposed Rule Stage	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910-AH03
HHS/FDA	Proposed Rule Stage	Mammography Quality Standards Act; Regulatory Amendments	0910-AH04
HHS/FDA	Proposed Rule Stage	Investigational New Drug Application Annual Reporting	0910-AH07
HHS/FDA	Proposed Rule Stage	National Standards for Licensing of Prescription Drug Wholesale Distributor and Third-Party Logistics Providers	0910-AH11
HHS/FDA	Proposed Rule Stage	General and Plastic Surgery Devices: Sunlamp Products	0910-AH14
HHS/FDA	Proposed Rule Stage	Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs or Devices	0910-AH19
HHS/FDA	Proposed Rule Stage	Requirements for Tobacco Product Manufacturing Practice	0910-AH22
HHS/FDA	Proposed Rule Stage	User Fees for FDA's Third-Party Accreditation Program for Food and Feed	0910-AH23
HHS/FDA	Final Rule Stage	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs	0910-AA49
HHS/FDA	Final Rule Stage	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910-AF22
HHS/FDA	Final Rule Stage	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs	0910-AF23
HHS/FDA	Final Rule Stage	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910-AF47

HHS/FDA	Final Rule Stage	Postmarket Safety Reporting for Combination Products	0910-AF82
HHS/FDA	Final Rule Stage	Laser Products; Amendment to Performance Standard	0910-AF87
HHS/FDA	Final Rule Stage	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	0910-AG10
HHS/FDA	Final Rule Stage	Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets; Implementation of Section 505(q) of the Federal Food, Drug, and Cosmetic Act	0910-AG26
HHS/FDA	Final Rule Stage	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	0910-AG35
HHS/FDA	Final Rule Stage	Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food	0910-AG36
HHS/FDA	Final Rule Stage	"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act	0910-AG38
HHS/FDA	Final Rule Stage	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910-AG48
HHS/FDA	Final Rule Stage	Foreign Supplier Verification Program	0910-AG64
HHS/FDA	Final Rule Stage	Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications	0910-AG66
HHS/FDA	Final Rule Stage	Use of Certain Symbols in Labeling	0910-AG74
HHS/FDA	Final Rule Stage	Blood Initiative--Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910-AG87
HHS/FDA	Final Rule Stage	Revision of Postmarketing Reporting Requirements Discontinuance or Interruption in Supply of Certain Products (Drug Shortages)	0910-AG88
HHS/FDA	Final Rule Stage	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910-AG94
HHS/FDA	Final Rule Stage	Veterinary Feed Directive	0910-AG95
HHS/FDA	Final Rule Stage	Sanitary Transportation of Human and Animal Food	0910-AG98
HHS/FDA	Final Rule Stage	Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness	0910-AH08
HHS/FDA	Final Rule Stage	Administrative Destruction of Certain Drugs Refused Admission to the United States	0910-AH12
HHS/FDA	Final Rule Stage	Revocation of the General Safety Test Regulations That Are Duplicative of Requirements in Biologic License Applications	0910-AH21
HHS/IHS	Proposed Rule Stage	Catastrophic Health Emergency Fund (CHEF)	0917-AA10
HHS/IHS	Final Rule Stage	Medicare-Like Rate for Non-Hospital Services	0917-AA12
HHS/CDC	Proposed Rule Stage	Medical Examination of Aliens	0920-AA28
HHS/CDC	Proposed Rule Stage	Administrative Functions, Practices, and Procedures	0920-AA55
HHS/CDC	Proposed Rule Stage	World Trade Center Health Program: Amendments to Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement	0920-AA56
HHS/CDC	Proposed Rule Stage	Possession, Use, and Transfer of Select Agents and Toxins: Addition of HPAI H5N1 Influenza Strains to the List of HHS Select Agents	0920-AA58
HHS/CDC	Proposed Rule Stage	Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review	0920-AA59
HHS/CDC	Proposed Rule Stage	World Trade Center Health Program: Addition of COPD and Traumatic Injury to the List of WTC-Related Health Conditions	0920-AA61
HHS/CDC	Proposed Rule Stage	Laboratory Fit Testing Requirements for Non-powered Air-Purifying Particulate Respirators	0920-AA62
HHS/CDC	Final Rule Stage	Specifications for Medical Examinations of Coal Miners	0920-AA57
HHS/CDC	Final Rule Stage	Closed-Circuit Escape Respirators; Extension of Transition Period	0920-AA60
HHS/NIH	Final Rule Stage	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health	0925-AA48
HHS/NIH	Final Rule Stage	Clinical Trials Registration and Results Submission	0925-AA55
HHS/NIH	Final Rule Stage	Privacy Act; Exempt Record System for NIH Police Records; Implementation	0925-AA60
HHS/NIH	Final Rule Stage	Endowments Program	0925-AA61
HHS/NIH	Final Rule Stage	Privacy Act; Exempt Record System for NIH Division of Loan Repayment Records	0925-AA62
HHS/NIH	Final Rule Stage	Privacy Act; Exempt Record System for NIH Electronic Research Administration (eRA) Records; Implementation	0925-AA63
HHS/SAMHSA	Proposed Rule Stage	SAMHSA User Fees for Data Requests	0930-AA17
HHS/SAMHSA	Proposed Rule Stage	Modernization of Confidentiality of Patient Records to Account for Health Information Technology	0930-AA19
HHS/OIG	Final Rule Stage	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of the Inspector General's Civil Monetary Penalty Rules	0936-AA04
HHS/OIG	Final Rule Stage	Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities	0936-AA05
HHS/OIG	Final Rule Stage	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing	0936-AA06
HHS/OASH	Proposed Rule Stage	Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators	0937-AA02
HHS/CMS	Proposed Rule Stage	Programs of All-Inclusive Care for the Elderly (PACE) Update (CMS-4168-P)	0938-AR60

HHS/CMS	Proposed Rule Stage	Reform of Requirements for Long-Term Care Facilities (CMS-3260-P)	0938-AR61
HHS/CMS	Proposed Rule Stage	Post-Eligibility Treatment of Income, Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP (CMS-2379-P)	0938-AS23
HHS/CMS	Proposed Rule Stage	Mental Health Parity and Addiction Equity Act of 2008; Application of Mental Health Parity Requirements to Medicaid Managed Care Organizations, CHIP, and Alternative Benefit Plans (CMS-2333-P)	0938-AS24
HHS/CMS	Proposed Rule Stage	Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability (CMS-2390-P)	0938-AS25
HHS/CMS	Proposed Rule Stage	Electronic Health Record (EHR) Incentive Programs--Stage 3 (CMS-3310-F)	0938-AS26
HHS/CMS	Proposed Rule Stage	Medicare Clinical Diagnostic Laboratory Test Payment System (CMS-1621-P)	0938-AS33
HHS/CMS	Proposed Rule Stage	FY 2016 Hospice Rate Update (CMS-1629-F)	0938-AS39
HHS/CMS	Proposed Rule Stage	CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1631-P)	0938-AS40
HHS/CMS	Proposed Rule Stage	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2016 Rates (CMS-1632-F)	0938-AS41
HHS/CMS	Proposed Rule Stage	CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1633-P)	0938-AS42
HHS/CMS	Proposed Rule Stage	FY 2016 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (CMS-1622-F)	0938-AS44
HHS/CMS	Proposed Rule Stage	FY 2016 Inpatient Rehabilitation Facility Prospective Payment System (CMS-1624-F)	0938-AS45
HHS/CMS	Proposed Rule Stage	CY 2016 Home Health Prospective Payment System Refinements and Rate Update (CMS-1625-P)	0938-AS46
HHS/CMS	Proposed Rule Stage	FY 2016 Inpatient Psychiatric Facilities Prospective Payment System--Rate Update (CMS-1627-F)	0938-AS47
HHS/CMS	Proposed Rule Stage	CY 2016 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-1628-P)	0938-AS48
HHS/CMS	Proposed Rule Stage	Medicaid Mechanized Claims Processing and Information Retrieval Systems (CMS-2392-F)	0938-AS53
HHS/CMS	Proposed Rule Stage	Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP (CMS-2334-P2)	0938-AS55
HHS/CMS	Proposed Rule Stage	CY 2017 Notice of Benefit and Payment Parameters (CMS-9937-P)	0938-AS57
HHS/CMS	Proposed Rule Stage	Electronic Health Record Incentive Program--Modifications to Meaningful Use in 2015 through 2017 (CMS-3311-F)	0938-AS58
HHS/CMS	Proposed Rule Stage	Revisions to Requirements for Discharge Planning for Hospitals, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Home Health Agencies, and Critical Access Hospitals (CMS-3317-P)	0938-AS59
HHS/CMS	Proposed Rule Stage	Medicaid State Payment Adjustment (CMS-2393-P)	0938-AS61
HHS/CMS	Proposed Rule Stage	Conditions for Coverage for Advanced Diagnostic Imaging Services (CMS-3309-P)	0938-AS62
HHS/CMS	Final Rule Stage	Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health (CMS-2348-F)	0938-AQ36
HHS/CMS	Final Rule Stage	Covered Outpatient Drugs (CMS-2345-F)	0938-AQ41
HHS/CMS	Final Rule Stage	Methods for Assuring Access to Covered Medicaid Services (CMS-2328-F)	0938-AQ54
HHS/CMS	Final Rule Stage	Reporting and Returning of Overpayments (CMS-6037-F)	0938-AQ58
HHS/CMS	Final Rule Stage	Medicare Shared Savings Program; Final Waivers (CMS-1439-F)	0938-AR30
HHS/CMS	Final Rule Stage	Flexibility, Efficiency and Modernization in Child Support Enforcement Programs (CMS-2343-F)	0938-AR92
HHS/CMS	Final Rule Stage	Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP (CMS-2334-F2)	0938-AS27
HHS/CMS	Final Rule Stage	CY 2016 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts (CMS-8059-N)	0938-AS36
HHS/CMS	Final Rule Stage	CY 2016 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8060-N)	0938-AS37
HHS/CMS	Final Rule Stage	CY 2016 Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible (CMS-8061-N)	0938-AS38
HHS/CMS	Final Rule Stage	Coverage of Certain Preventive Services; Eligible Organizations (CMS-9940-F)	0938-AS50
HHS/CMS	Final Rule Stage	Summary of Benefits and Coverage and Uniform Glossary (CMS-9938-F)	0938-AS54
HHS/CMS	Final Rule Stage	Changes to the Requirements for Part D Prescribers (CMS-6107-F)	0938-AS60
HHS/OCR	Prerule Stage	HIPAA Enforcement: Distribution of a Percentage of Civil Money Penalties or Monetary Settlements to Harmed Individuals	0945-AA04
HHS/OCR	Proposed Rule Stage	Nondiscrimination Under the Patient Protection and Affordable Care Act	0945-AA02
HHS/OCR	Proposed Rule Stage	Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule; Modifications to Ensure the Equal Rights of Same-Sex Spouses	0945-AA07
HHS/OCR	Final Rule Stage	HIPAA Privacy Rule and the National Instant Criminal Background Check System (NICS)	0945-AA05
HHS/ACF	Proposed Rule Stage	Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008	0970-AC42
HHS/ACF	Proposed Rule Stage	Standards for Data Exchange	0970-AC58

HHS/ACF	Proposed Rule Stage	Statewide Automated Child Welfare Information Systems (SACWIS)	0970-AC59
HHS/ACF	Proposed Rule Stage	Revisions and Amendments to Regulations Governing Native American Programs Authorized Under the Native American Programs Act of 1974	0970-AC60
HHS/ACF	Proposed Rule Stage	Family Violence Prevention and Services Program Regulation	0970-AC62
HHS/ACF	Proposed Rule Stage	Head Start Performance Standards	0970-AC63
HHS/ACF	Proposed Rule Stage	Refugee Medical Assistance	0970-AC64
HHS/ACF	Proposed Rule Stage	CCDBG Act Reauthorization Implementation	0970-AC67
HHS/ACF	Final Rule Stage	Performance Standards for Runaway and Homeless Youth Grantees	0970-AC43
HHS/ACF	Final Rule Stage	Adoption and Foster Care Analysis and Reporting System (AFCARS)	0970-AC47
HHS/ACF	Final Rule Stage	Flexibility, Efficiency, and Modernization of Child Support Enforcement Programs	0970-AC50
HHS/ACF	Final Rule Stage	Temporary Assistance for Needy Families (TANF) Assistance and Electronic Benefits Transfer Actions	0970-AC56
HHS/ACF	Final Rule Stage	Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Violence Against Women Reauthorization Act of 2013	0970-AC61
HHS/ACL	Proposed Rule Stage	Independent Living Program Revisions in Support of the Workforce Innovation and Opportunity Act	0985-AA10
HHS/ACL	Proposed Rule Stage	State Health Insurance Assistance Programs Conforming Changes	0985-AA11
HHS/ACL	Proposed Rule Stage	Disability and Rehabilitation Research Projects and Centers Program; Disability and Rehabilitation Research; Research Fellowships; Special Projects and Demonstrations for Spinal Cord Injuries	0985-AA12
HHS/ACL	Final Rule Stage	Developmental Disabilities Assistance and Bill of Rights	0985-AA09
HHS/OS	Proposed Rule Stage	Revise, Update, and Reissue Health and Human Services Acquisition Regulation (HHSAR)	0991-AB86
HHS/OS	Proposed Rule Stage	2015 Edition Health Information Technology (Health IT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications	0991-AB93
HHS/OS	Proposed Rule Stage	Equal Participation of Religious Organizations in HHS Programs and Activities	0991-AB96
HHS/OS	Proposed Rule Stage	Organizational Integrity of Entities Implementing Programs and Activities Under the Leadership Act	0991-AC00
HHS/OS	Proposed Rule Stage	Medicare Program: Changes to the Medicare Claim, Organization Determination, and Coverage Determination Appeals Procedures	0991-AC02
HHS/OS	Final Rule Stage	Revise, Update, and Re-Issue HHS Grants Administration Regulations	0991-AB94
HHS/OS	Final Rule Stage	Health Resources Priority and Allocations System (HRPAS)	0991-AB95
HHS/OS	Final Rule Stage	Removal of Obsolete Provisions From the CFR	0991-AB98