

Agency Rule List - Fall 2011

Department of Health and Human Services

<u>Agency</u>	<u>Agenda Stage of Rulemaking</u>	<u>Title</u>	<u>RIN</u>
HHS/HRSA	Proposed Rule Stage	Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	<u>0906-AA73</u>
HHS/HRSA	Proposed Rule Stage	Countermeasures Injury Compensation Program; Pandemic Influenza Countermeasure Injury Table Amendment for Influenza Vaccines, Antiviral Drugs, Respiratory Protection/Support Devices, and Diagnostics	<u>0906-AA79</u>
HHS/HRSA	Proposed Rule Stage	Countermeasures Injury Compensation Program; Smallpox Injury Table Amendment	<u>0906-AA84</u>
HHS/HRSA	Proposed Rule Stage	Countermeasures Injury Compensation Program; Anthrax Injury Table Amendment	<u>0906-AA85</u>
HHS/HRSA	Proposed Rule Stage	Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank	<u>0906-AA87</u>
HHS/HRSA	Proposed Rule Stage	Amendments to the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	<u>0906-AA95</u>
HHS/HRSA	Final Rule Stage	Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations--Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients	<u>0906-AA77</u>
HHS/HRSA	Final Rule Stage	340B Orphan Drug Exclusion	<u>0906-AA94</u>
HHS/FDA	Prerule Stage	Over-the-Counter (OTC) Drug Review--Sunscreen Products	<u>0910-AF43</u>
HHS/FDA	Prerule Stage	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures	<u>0910-AG14</u>
HHS/FDA	Prerule Stage	Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products	<u>0910-AG43</u>
HHS/FDA	Prerule Stage	Reports of Distribution and Sales Information for Antimicrobial Active Ingredients Used in Food-Producing Animals	<u>0910-AG45</u>

HHS/FDA	Prerule Stage	Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents	0910-AG61
HHS/FDA	Prerule Stage	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification	0910-AG62
HHS/FDA	Proposed Rule Stage	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910-AC52
HHS/FDA	Proposed Rule Stage	Over-the-Counter (OTC) Drug Review--Internal Analgesic Products	0910-AF36
HHS/FDA	Proposed Rule Stage	Over-the-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products	0910-AF69
HHS/FDA	Proposed Rule Stage	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	0910-AF78
HHS/FDA	Proposed Rule Stage	Laser Products; Amendment to Performance Standard	0910-AF87
HHS/FDA	Proposed Rule Stage	Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes	0910-AF97
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice and Hazard Analysis and Risk-Benefit Preventive Controls for Food for Animals	0910-AG10
HHS/FDA	Proposed Rule Stage	Over-the-Counter (OTC) Drug Review-Pediatric Dosing for Cough/Cold Products	0910-AG12
HHS/FDA	Proposed Rule Stage	New Animal Drugs: Updating Tolerances for Residues in New Animal Drugs in Food	0910-AG17
HHS/FDA	Proposed Rule Stage	Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products	0910-AG18
HHS/FDA	Proposed Rule Stage	Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals--Second Phase	0910-AG20
HHS/FDA	Proposed 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	Proposed Rule Stage	Unique Device Identification	0910-AG31
HHS/FDA	Proposed Rule Stage	Produce Safety Regulation	0910-AG35
HHS/FDA	Proposed Rule Stage	Hazard Analysis and Risk-Based Preventive Controls	0910-AG36
HHS/FDA	Proposed Rule Stage	Additions to the List of Tropical Diseases in Section 524 of the Federal Food, Drug, and Cosmetic Act	0910-AG37

HHS/FDA	Proposed 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	Proposed Rule Stage	Amendment to Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	0910-AG40
HHS/FDA	Proposed Rule Stage	Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices	0910-AG48
HHS/FDA	Proposed Rule Stage	General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps	0910-AG54
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	Foreign Supplier Verification Program	0910-AG64
HHS/FDA	Proposed Rule Stage	Accreditation of Third Parties to Conduct Food Safety Audits and for Other Related Purposes	0910-AG66
HHS/FDA	Proposed Rule Stage	Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals--Components	0910-AG70
HHS/FDA	Proposed Rule Stage	Orphan Drug Regulations	0910-AG72
HHS/FDA	Proposed Rule Stage	Use of Symbols in Labeling	0910-AG74
HHS/FDA	Proposed Rule Stage	Effective Date of Requirement for Pre-market Approval for Two Class III Preamendments Devices	0910-AG78
HHS/FDA	Proposed Rule Stage	Requirements for the Submission of Data Needed to Calculate User Fees for Manufacturers and Importers of Tobacco Products	0910-AG81
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	Blood Initiative--Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma	0910-AF26
HHS/FDA	Final Rule Stage	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors	0910-AF27
HHS/FDA	Final Rule Stage	Label Requirement for Food That Has Been Refused Admission Into the United States	0910-AF61
HHS/FDA	Final Rule Stage	Current Good Manufacturing Practice for Combination Products	0910-AF81

HHS/FDA	Final Rule Stage	Postmarket Safety Reporting for Combination Products	0910-AF82
HHS/FDA	Final Rule Stage	Medical Device Reporting; Electronic Submission Requirements	0910-AF86
HHS/FDA	Final Rule Stage	Electronic Registration and Listing for Devices	0910-AF88
HHS/FDA	Final Rule Stage	Exceptions or Alternatives To Labeling Requirements for Products Held by the Strategic National Stockpile	0910-AF90
HHS/FDA	Final Rule Stage	Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements	0910-AF96
HHS/FDA	Final Rule Stage	Amendments to Sterility Testing Requirements for Biological Products	0910-AG16
HHS/FDA	Final Rule Stage	Disqualification of a Clinical Investigator	0910-AG49
HHS/FDA	Final Rule Stage	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines	0910-AG56
HHS/FDA	Final Rule Stage	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments	0910-AG57
HHS/FDA	Final Rule Stage	Prior Notice of Imported Food	0910-AG65
HHS/FDA	Final Rule Stage	Administrative Detention of Food for Human or Animal Consumption	0910-AG67
HHS/FDA	Final Rule Stage	Additional Safeguards for Children in Clinical Investigation of FDA-Regulated Products	0910-AG71
HHS/FDA	Final Rule Stage	Food Labeling; Gluten-Free Labeling of Foods	0910-AG84
HHS/IHS	Proposed Rule Stage	Standards for the Planning, Design, Construction and Operation of Health Care and Sanitation Facilities	0917-AA08
HHS/IHS	Proposed Rule Stage	Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants	0917-AA09
HHS/IHS	Proposed Rule Stage	Catastrophic Health Emergency Fund (CHEF)	0917-AA10
HHS/CDC	Proposed Rule Stage	Amendments to Specifications for Medical Examinations of Underground Coal Miners	0920-AA21
HHS/CDC	Proposed Rule Stage	Inward Leakage Requirements for Respirators	0920-AA33
HHS/CDC	Proposed Rule Stage	Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List	0920-AA34

HHS/CDC	Proposed Rule Stage	Control of Communicable Diseases: Foreign and Possessions; Proposed Revision of CDC Etiological Agents Importation Regulations	0920-AA37
HHS/CDC	Proposed Rule Stage	Open-Circuit Self-Contained Breathing Apparatus End-of-Service-Time Indicator Performance Requirements	0920-AA38
HHS/CDC	Proposed Rule Stage	Amendments to Respirator Certification Fees	0920-AA42
HHS/CDC	Proposed Rule Stage	Establishment of Minimum Standards for Birth Certificates	0920-AA46
HHS/CDC	Proposed Rule Stage	Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples	0920-AA47
HHS/CDC	Final Rule Stage	Approval Tests and Standards for Closed-Circuit Escape Respirators	0920-AA10
HHS/CDC	Final Rule Stage	Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primate	0920-AA23
HHS/CDC	Final Rule Stage	Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Revision of Guidelines for Non-Radiogenic Cancers	0920-AA39
HHS/CDC	Final Rule Stage	World Trade Center Health Program Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement	0920-AA44
HHS/CDC	Final Rule Stage	World Trade Center Health Program Requirements for the Addition of New WTC-Related Health Conditions	0920-AA45
HHS/NIH	Proposed Rule Stage	National Institutes of Health Loan Repayment Programs	0925-AA43
HHS/NIH	Proposed Rule Stage	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health	0925-AA48
HHS/NIH	Proposed Rule Stage	Expanded Registration and Results Reporting at ClinicalTrials.gov	0925-AA55
HHS/NIH	Final Rule Stage	Privacy Act Regulation Concerning NIH Records Related to Research Misconduct Proceedings	0925-AA58
HHS/SAMHSA	Final Rule Stage	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction	0930-AA14
HHS/OIG	Proposed Rule Stage	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Safe Harbors Under the Antikickback Status, Exclusion Authorities, and Civil Monetary Penalty	0936-AA02
HHS/OIG	Final Rule Stage	Revision to Prohibition on FFP for "Data Mining" by Medicaid Fraud Control Units	0936-AA01

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	Home and Community-Based State Plan Services Program and Provider Payment Reassignments (CMS-2249-P2)	0938-AO53
HHS/CMS	Proposed Rule Stage	Administrative Simplification: Standard Unique Identifier for Health Plans (CMS-0040-P)	0938-AQ13
HHS/CMS	Proposed Rule Stage	Medicaid Disproportionate Share Hospital Payments Uninsured Definition (CMS-2315-P)	0938-AQ37
HHS/CMS	Proposed Rule Stage	Covered Outpatient Drugs (CMS-2345-P)	0938-AQ41
HHS/CMS	Proposed Rule Stage	Reporting and Returning of Overpayments (CMS-6037-P)	0938-AQ58
HHS/CMS	Proposed Rule Stage	Payments for Primary Care Services Under the Medicaid Program (CMS-2370-P)	0938-AQ63
HHS/CMS	Proposed Rule Stage	Medicare and Medicaid Electronic Health Record Incentive Program--Stage 2 (CMS-0044-P)	0938-AQ84
HHS/CMS	Proposed Rule Stage	Administrative Simplification: Compliance: Health Plan Certification (CMS-0037-P)	0938-AQ85
HHS/CMS	Proposed Rule Stage	Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 (CMS-4157-F)	0938-AQ86
HHS/CMS	Proposed Rule Stage	Medicare and Medicaid Programs: Reform of Hospital and Critical Access Hospital Conditions of Participation (CMS-3244-P)	0938-AQ89
HHS/CMS	Proposed Rule Stage	Long Term Care: Ethics and Compliance (CMS-3226-P)	0938-AQ93
HHS/CMS	Proposed Rule Stage	Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-9070-P)	0938-AQ96
HHS/CMS	Proposed Rule Stage	Establishment of Exchange Program Part II; Appeals of Eligibility Determinations and Oversight and Financial Integrity (CMS-9980-P)	0938-AR03
HHS/CMS	Proposed Rule Stage	Medicaid Eligibility Changes Under the Affordable Care Act—Part II (CMS-2334-P)	0938-AR04
HHS/CMS	Proposed Rule Stage	Proposed Changes to Hospital OPPS and CY 2013 Payment Rates; ASC Payment System and CY 2013 Payment Rates (CMS-1589-P)	0938-AR10
HHS/CMS	Proposed Rule Stage	Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2013 (CMS-1590-P)	0938-AR11
HHS/CMS	Proposed Rule Stage	Changes to the Hospital Inpatient an Long-Term Care Prospective Payment System for FY 2013 (CMS-1588-P)	0938-AR12

HHS/CMS	Proposed Rule Stage	Changes to the End-Stage Renal Disease Prospective Payment System for CY 2013 (CMS-1352-P)	0938-AR13
HHS/CMS	Proposed Rule Stage	Hospice Wage Index for FY 2013 (CMS-1434-P)	0938-AR17
HHS/CMS	Proposed Rule Stage	Home Health Prospective Payment System Rate for CY 2013 (CMS-1358-P)	0938-AR18
HHS/CMS	Proposed Rule Stage	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2013 (CMS-1432-P)	0938-AR20
HHS/CMS	Proposed Rule Stage	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2013 (CMS-1433-P)	0938-AR21
HHS/CMS	Proposed Rule Stage	Inpatient Psychiatric Facility Prospective Payment System—Update for Fiscal Year 2013 (CMS-1440-P)	0938-AR22
HHS/CMS	Proposed Rule Stage	Disproportionate Share Hospital Payment Reduction (CMS-2367-P)	0938-AR31
HHS/CMS	Proposed Rule Stage	Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS-5060-F)	0938-AR33
HHS/CMS	Final Rule Stage	Medicare Advantage and Prescription Drug Benefit Programs; Payments to Sponsors of Retiree Prescription Drug Plans (CMS-4131-F2)	0938-AP64
HHS/CMS	Final Rule Stage	Administrative Simplification: Adoption of Standards for Electronic Funds Transfer (EFT) (CMS-0024-IFC)	0938-AQ11
HHS/CMS	Final Rule Stage	Medicaid and Children's Health Insurance Programs; Disallowance of Claims for FFP and Technical Corrections (CMS-2292-F)	0938-AQ32
HHS/CMS	Final Rule Stage	Community First Choice Option (CMS-2337-F)	0938-AQ35
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	Review and Approval Process for Section 1115 Demonstrations (CMS-2325-F)	0938-AQ46
HHS/CMS	Final Rule Stage	Emergency Medical Treatment and Labor Act: Applicability to Hospital Inpatients and Hospitals with Specialized Capabilities (CMS-1350-N)	0938-AQ51
HHS/CMS	Final Rule Stage	Methods for Assuring Access to Covered Medicaid Services (CMS-2328-F)	0938-AQ54
HHS/CMS	Final Rule Stage	Medicaid Eligibility Expansion Under the Affordable Care Act of 2010 (CMS-2349-F)	0938-AQ62
HHS/CMS	Final Rule Stage	Establishment of Exchanges and Qualified Health Plans Part I (CMS-9989-F)	0938-AQ67

HHS/CMS	Final Rule Stage	Uniform Disclosure to Consumers: Benefit Design, Cost Sharing, & Standards for Definitions (CMS-9982-F)	0938-AQ73
HHS/CMS	Final Rule Stage	Affordable Care Act Waiver for State Innovation; Review and Approval Process (CMS-9987-F)	0938-AQ75
HHS/CMS	Final Rule Stage	Student Health Insurance Coverage (CMS-9981-F)	0938-AQ95
HHS/CMS	Final Rule Stage	Administrative Simplification: Adoption of Operating Rules for Electronic Funds Transfer (EFT) and Remittance Advice (RA) (CMS-0028-IFC)	0938-AR01
HHS/CMS	Final Rule Stage	State Requirements for Exchange--Reinsurance and Risk Adjustments (CMS-9975-F)	0938-AR07
HHS/CMS	Final Rule Stage	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2013 (CMS-8046-N)	0938-AR14
HHS/CMS	Final Rule Stage	Part A Premiums for CY 2013 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8047-N)	0938-AR15
HHS/CMS	Final Rule Stage	Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2013 (CMS-8048-N)	0938-AR16
HHS/CMS	Final Rule Stage	Medicare Shared Savings Program; Final Waivers (CMS-1439-IFC)	0938-AR30
HHS/OCR	Final Rule Stage	HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act	0945-AA00
HHS/OCR	Final Rule Stage	Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules	0945-AA03
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	Performance Standards for Runaway and Homeless Youth Grantees	0970-AC43
HHS/ACF	Proposed Rule Stage	Flexibility and Efficiency in Child Support	0970-AC50
HHS/ACF	Proposed Rule Stage	Federal Case Registry System of Records Exemption	0970-AC52
HHS/ACF	Proposed Rule Stage	Child Care and Development Fund Reforms to Support Child Development and Working Families	0970-AC53
HHS/ACF	Final Rule Stage	Tribal Child Welfare	0970-AC41

HHS/ACF	Final Rule Stage	Head Start Eligibility Determinations	0970-AC46
HHS/AOA	Proposed Rule Stage	Older Americans Act--Ombudsman Program	0985-AA08
HHS/OS	Prerule Stage	Governance for a Nationwide Health Information Network	0991-AB83
HHS/OS	Proposed Rule Stage	Health Information Technology: New and Revised Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology	0991-AB82