DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A, Chs. II, III, and XIII

Unified Agenda of Federal Regulatory and Deregulatory Actions

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual regulations agenda.

SUMMARY: The Department's semiannual Agenda of Regulatory and Deregulatory Actions forecasts the rulemaking activities that we expect to undertake over the foreseeable future. We focus primarily on those areas of work anticipated to result in publication of Notices of Proposed Rulemaking or of Final Rules within the next 12 months. (Please note that the abstracts included below relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities; the Regulatory Flexibility Act of 1980 requires dissemination of this information in the paper edition of the **Federal Register**. The complete HHS Agenda is accessible online at www.reginfo.gov.)

FOR FURTHER INFORMATION CONTACT: by e-mail, John.Gallivan@hhs.gov; by fax, (202) 205-2135; by telephone, (202) 205-9165.

SUPPLEMENTARY INFORMATION:

The Regulatory Flexibility Act of 1980 and Executive Order 12866 require semi-annual publication of an inventory outlining all current and projected rulemakings. The purpose of this exercise is to inform the public about regulatory actions under development across the Department, and to provide an opportunity for all concerned with the impact of these actions to participate in their development at an early stage.

The regulatory actions capsulized in this Agenda do not necessarily reflect the policy perspectives of the Obama Administration. The statutorily dictated timing of the Agenda caused the Department to initiate preparation of the requisite information before the Department's policy officials had the opportunity to conduct a full review. This Agenda thus reflects ongoing efforts by HHS to comply with existing statutory obligations, or to effect improvements at the program-implementation level based on experience in administering existing programs. By contrast, the timing of the October 2009 Agenda will, obviously, provide the Department with an opportunity to set out a regulatory agenda that does reflect current policy directions of the Obama Administration.

Public commentary is invited. Comments may be directed to the agency officials cited at the conclusion of each entry. If early attention at the Secretary's level appears needed, comments should be sent to: Ashley Files Flory, Acting Executive Secretary to the Department, Suite 603H, 200 Independence Avenue SW., Washington, DC 20201.

Dated: April 3, 2009.

NAME: Ashley Files Flory,
Acting Executive Secretary to the Department.

The 230 Regulatory Agendas

Health Resources and Services Administration - Proposed Rule

Title	Regulation Identifier Number
Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906-AA73
National Vaccine Compensation Program: Separate Category for Hepatitis A, Influenza, Meningococcal, Human Papillomavirus Vaccines	0906-AA74
Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations-–Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients	0906-AA77
Federal Tort Claims Act (FTCA) Coverage of Certain Grantees and Individuals: Covered acts and omissions-– Continuing Medical Education	0906-AA78

Health Resources and Services Administration - Final Rule

Title	Regulation Identifier Number
National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906-AA57

Health Resources and Services Administration - Long-term Action

Title	Regulation Identifier Number
Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
Health Center Program Regulations – Consolidation With Migrant Health Center Program Regulations and Extension of Applicability to Health Care for the Homeless And Public Housing Primary Care Health	0906-AA76

Health Resources and Services Administration - Completed Action

Title	Regulation Identifier Number
National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906-AA41
Amending the Health Center Program To Apply to the Health Care for the Homeless and Public Housing Primary Care Programs	0906-AA72

Food and Drug Administration - PreRule

Title	Regulation Identifier Number
Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution	0910-AG06
Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures	0910-AG14

Food and Drug Administration - Proposed Rule

Title	Regulation Identifier Number
Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910-AC52
Reporting Information Regarding Falsification of Data	0910-AC59

Over-The-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products	0910-AF31
Over-The-Counter (OTC) Drug Review--Laxative Drug Products	0910-AF38
Over-The-Counter (OTC) Drug Review--Sunscreen Products	0910-AF43
Over-The-Counter (OTC) Drug Review--Weight Control Products	0910-AF45
Import Tolerances for Unapproved New Animal Drugs	0910-AF78
Current Good Manufacturing Practice for Combination Products	0910-AF81
Postmarket Safety Reporting for Combination Products	0910-AF82
Medical Device Reporting; Electronic Submission Requirements	0910-AF86
Laser Products; Amendment to Performance Standard	0910-AF87
Electronic Registration and Listing for Devices	0910-AF88
Regulations on Fixed-Dose Combination and Co-Packaged Drug and/or Biological Products	0910-AF89
Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements	0910-AF96
Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes	0910-AF97
Animal Food Labeling; Declaration of Certifiable Color Additives	0910-AG02
Revision of the Requirements for Publication of License Revocation	0910-AG11
Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph	0910-AG12
Revision of the Requirements for Constituent Materials	0910-AG15
Amendments to Sterility Testing Requirements for Biological Products	0910-AG16
Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products	0910-AG18
Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals	0910-AG20

Food and Drug Administration - Final Rule

Title	Regulation Identifier Number
Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs	0910-AA49
Additional Safeguards for Children in Clinical Investigations	0910-AC07
Prevention of Salmonella Enteritidis in Shell Eggs	0910-AC14
Exception From General Requirements for Informed Consent; Request for Comments and Information	0910-AC25
Medical Devices; Anesthesiology Devices; Reclassification of Pressure Regulators for Use With Medical Oxygen and Separate Classification of Oxygen Conserving Devices	0910-AC30
Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910-AC53
Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910-AC55
Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910-AF11
Charging for Investigational Drugs Under an Investigational New Drug Application	0910-AF13
Expanded Access to Investigational Drugs for Treatment Use	0910-AF14
Blood Initiative--Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment	0910-AF26
Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910-AF27
Infant Formula Quality Factors	0910-AF28
Over-The-Counter (OTC) Drug Review--Cough/Cold (Bronchodilator) Products	0910-AF32
Over-The-Counter (OTC) Drug Review--Cough/Cold (Combination) Products	0910-AF33
Over-The-Counter (OTC) Drug Review--External Analgesic Products	0910-AF35
Over-The-Counter (OTC) Drug Review--Internal Analgesic Products	0910-AF36
Over-the-Counter (OTC) Drug Review--Skin Protectant Products	0910-AF42

Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy	0910-AF46
Use of Materials Derived From Cattle in Human Food and Cosmetics	0910-AF47
Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants	0910-AF54
Label Requirement for Food That Has Been Refused Admission Into the United States	0910-AF61
Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn, and Nedocromil]	0910-AF93
Over-The-Counter (OTC) Drug Review--Acne Drug Products Containing Benzoyl Peroxide	0910-AG00
Defining the Term "Small Numbers of Animals" for Minor Use Designation	0910-AG03
Premarketing Safety Reporting Requirements for Human Drug and Biological Products	0910-AG13
Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs	0910-AG19

Food and Drug Administration - Long-term Action

Title	Regulation Identifier Number
Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910-AA97
Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910-AB88
Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements	0910-AC50
Food Standards: General Principles and Food Standards Modernization	0910-AC54
Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910-AF08
Food Labeling; Prominence of Calories	0910-AF22
Food Labeling; Serving Sizes of Products That Can Reasonably Be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes	0910-AF23
Blood Initiative--Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910-AF25
Over-the-Counter (OTC) Drug Review--Cough/Cold (Nasal Decongestant) Products	0910-AF34
Over-The-Counter (OTC) Drug Review--Labeling of Drug Products for OTC Human Use	0910-AF37
Over-The-Counter (OTC) Drug Review--Ophthalmic Products	0910-AF39
Over-The-Counter (OTC) Drug Review--Oral Health Care Products	0910-AF40
Over-The-Counter (OTC) Drug Review--Vaginal Contraceptive Products	0910-AF44
Over-The-Counter (OTC) Drug Review--Overindulgence in Food and Drink Products	0910-AF51
Over-The-Counter (OTC) Drug Review--Antacid Products	0910-AF52
Over-The-Counter (OTC) Drug Review--Skin Bleaching Products	0910-AF53
Over-the-Counter (OTC) Drug Review--Stimulant Drug Products	0910-AF56
Over-The-Counter Antidiarrheal Drug Products	0910-AF63
Over-The-Counter (OTC) Drug Review--Poison Treatment Drug Products	0910-AF68
Over-The-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products	0910-AF69
Over-The-Counter (OTC) Drug Review--Urinary Analgesic Drug Products	0910-AF70
Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile	0910-AF90
Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients	0910-AF95
Conditional Approval of New Animal Drugs for Minor Use and Minor Species	0910-AG07
Animal Feed Ingredient Standards and Definitions	0910-AG08
Pet Food Labeling Requirements	0910-AG09
Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910-AG10
New Animal Drugs: Updating Tolerances for Residues in New Animal Drugs in Food	0910-AG17

Food and Drug Administration - Completed Action

Title	Regulation Identifier Number
Institutional Review Boards: Registration Requirements	0910-AC17
Requirements for Submission of In Vivo Bioequivalence Data	0910-AC23
Cochineal Extract and Carmine Label Declaration	0910-AF12
Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex	0910-AF21
Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Epinephrine]	0910-AF92
Food Labeling; Serving Sizes and Nutrition Labeling	0910-AF99

Agency for Healthcare Research and Quality - Completed Action

Title	Regulation Identifier Number
Patient Safety and Quality Improvement Act of 2005 Rules	0919-AA01

Centers for Disease Control and Prevention - PreRule

Title	Regulation Identifier Number
Amendments to Performance Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Approval of Respiratory Protective Devices	0920-AA17

Centers for Disease Control and Prevention - Proposed Rule

Title	Regulation Identifier Number
Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations	0920-AA14
Amendments to Specifications for Medical Examinations of Underground Coal Miners	0920-AA21
Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Nonhuman Primate Regulations	0920-AA23
Medical Examination of Aliens: Removal of HIV Infection as a Communicable Disease of Public Health Significance	0920-AA26
Medical Examination of Aliens	0920-AA28

Centers for Disease Control and Prevention - Final Rule

Title	Regulation Identifier Number
Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920-AA04
Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices	0920-AA10
Control of Communicable Diseases Foreign Quarantine	0920-AA12
Control of Communicable Diseases: Interstate Quarantine	0920-AA22
Control of Communicable Diseases: Interstate Quarantine, Passenger Information	0920-AA27

Centers for Disease Control and Prevention - Long-term Action

Title	Regulation Identifier Number
Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices	0920-AA16
Possession, Use, and Transfer of Select Agents and Toxins	0920-AA24
Possession, Use, and Transfer of Select Agents and Toxins--Biennial Review	0920-AA25

Possessions, Use, and Transfer of Select Agents and Toxins--Pandemic Influenza	0920-AA30
Possession, Use, and Transfer of Select Agents and Toxins (Sars-CoV)	0920-AA31
Possession, Use and Transfer of Select Agents and Toxins	0920-AA32

National Institutes of Health - PreRule

Title	Regulation Identifier Number
Amendment of Regulation of the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors; Request for Comments	0925-AA53

National Institutes of Health - Proposed Rule

Title	Regulation Identifier Number
National Institutes of Health Loan Repayment Programs	0925-AA43
Endowment Program	0925-AA47
Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health	0925-AA48
NIH Training Grants	0925-AA49
Procedures for Registration of Applicable Clinical Trials in the ClinicalTrials.gov Registry	0925-AA52
Reporting Results of Applicable Clinical Trials in the Clinical Trials.gov Data Bank	0925-AA54

National Institutes of Health - Final Rule

Title	Regulation Identifier Number
Grants for Research Projects	0925-AA42

Substance Abuse and Mental Health Services Administration - Proposed Rule

Title	Regulation Identifier Number
Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition	0930-AA14

Substance Abuse and Mental Health Services Administration - Long-term Action

Title	Regulation Identifier Number
Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930-AA10

Substance Abuse and Mental Health Services Administration - Completed Action

Title	Regulation Identifier Number
Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930-AA12

Centers for Medicare & Medicaid Services - PreRule

Title	Regulation Identifier Number
HIPPA Mental Health Parity and Addiction Equity Act of 2008 Request for Information (CMS-4140-NC)	0938-AP65

Centers for Medicare & Medicaid Services - Proposed Rule

	Regulation

Title	Identifier Number
Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2010 (CMS-1406-P)	0938-AP39
Revisions to Payment Policies Under the Physician Fee Schedule For CY 2010 (CMS-1413-P)	0938-AP40
Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-P)	0938-AP41
Hospice Wage Index for FY 2010 (CMS-1420-F)	0938-AP45
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-P)	0938-AP46
Children's Health Insurance Program (CHIP); Redistribution of FY 2006 Unexpended SCHIP Funds and Children's Health Insurance Program Reauthorization Act (CHIPRA) Allotment Procedures(CMS-2291-P)	0938-AP53
Home Health Prospective Payment System Refinements and Rate Update for CY 2010 (CMS-1560-P)	0938-AP55
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2010 (CMS-1538-P)	0938-AP56
ESRD Bundled Payment System (CMS-1418-P)	0938-AP57
Implementing Regulations for Reauthorization of the Children's Health Insurance Program (CHIP) (CMS-2301-P)	0938-AP68
Children's Health Insurance Program PERM Requirements (CMS-6150-P)	0938-AP69
Extension of Transitional Medical Assistance and Protections for Indians Under the American Recovery and Reinvestment Act of 2009 (CMS-2475-P)	0938-AP70
Children's Health Insurance Program Reauthorization Act (CHIPRA) Child Enrollment Contingency Fund (CMS-2488-P)	0938-AP71

Centers for Medicare & Medicaid Services - Final Rule

Title	Regulation Identifier Number
Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)	0938-AM73
Limitation on Recoupment of Provider and Supplier Overpayments (CMS-6025-F)	0938-AN42
Genetic Information Nondiscrimination Act of 2008 (CMS-4137-IFC)	0938-AP37
Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2010 (CMS-8037-N)	0938-AP42
Part A Premiums for CY 2010 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8038-N)	0938-AP43
Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2010 (CMS-8039-N)	0938-AP48
Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2009 (RY 2010) (CMS-1495-NC)	0938-AP50
Final and Preliminary Fiscal Year Disproportionate Share Hospital Allotments and Disproportionate Share Hospital Institutions for Mental Disease Limits (CMS-2300-N)	0938-AP66
Multiple Source Drug Definition Amendment (CMS-2238-F2)	0938-AP67
State Flexibility for Medicaid Benefit Packages; Delay of Effective Date (CMS-2232-IFC)	0938-AP72
Premiums and Cost Sharing--Delay of Effective Date (CMS-2244-IFC)	0938-AP73

Centers for Medicare & Medicaid Services - Long-term Action

Title	Regulation Identifier Number
Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)	0938-AG81
MedicChanges in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers (CMS-1910-F2)	0938-AJ17
Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938-AJ96
Electronic Claims Attachments Standards (CMS-0050-IFC)	0938-AK62
Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938-AL26
Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)	0938-AL88
Revisions to the Requirements for Quality Improvement Organizations (CMS-3156-P)	0938-AN73

Payments for Service Provided Without Charge (Free Care) (CMS-2489-P)	0938-AO07
Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)	0938-AO10
Cytology Proficiency Testing (CMS-2252-F)	0938-AO34
Targeted Case Management (CMS-2237-F)	0938-AO50
Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F)	0938-AO53
Rehabilitation Services: State Plan Option (CMS-2261-F)	0938-AO81
Waiver of Disapproval of Nurse Aide Training Program in Certain Cases and Nurse Aide Petition for Removal of Information for Singular Finding of Neglect (CMS-2266-F)	0938-AO82
Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process (CMS-4127-F)	0938-AO87
Establishing Additional Provider and Supplier Requirements for Enrollment Standards and Related Issues (CMS-6036-F)	0938-AO90
Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS-3178-P)	0938-AO91
Medicaid Graduate Medical Education (CMS-2279-F)	0938-AO95
Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P)	0938-AP01
Medicare Supplemental Policies (CMS-4084-P)	0938-AP10
Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938-AP32
Medicare Advantage and Prescription Drug Programs: MIPPA-Related Marketing Revisions (CMS-4138-F)	0938-AP52
Limited Changes to the Competitive Acquisition of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)(CMS-1561-F)	0938-AP59
Medicare Advantage and Prescription Drug Benefit Programs; Payments to Sponsors of Retiree Prescription Drug Plans (CMS-4131-F2)	0938-AP64

Centers for Medicare & Medicaid Services - Completed Action

Title	Regulation Identifier Number
Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)	0938-AJ29
Updates to Electronic Transactions (Version 5010) (CMS-0009-F)	0938-AM50
Medicaid Disproportionate Share Hospital Payments--Auditing and Reporting Requirements (CMS-2198-F)	0938-AN09
Revisions to HIPAA Code Sets (CMS-0013-F)	0938-AN25
Medicaid Program; Clarification of Outpatient Hospital Facility (Including Hospital Clinic) Outpatient Services Definition (CMS-2213-F)	0938-AO17
State Option To Establish Non-Emergency Medical Transportation Program (CMS-2234-F)	0938-AO45
Premiums and Cost Sharing (CMS-2244-F)	0938-AO47
State Flexibility for Medicaid Benefit Packages (CMS-2232-F)	0938-AO48
Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F)	0938-AO84
Changes To Ensure Effective and Efficient Operations of Medicaid and the State Children's Health Insurance Program (SCHIP) (CMS-2148-P)	0938-AO86
Fiscal Year Disproportionate Share Hospital Allotments and Disproportionate Share Hospital Institutions for Mental Disease Limits (CMS-2274-N)	0938-AP09
Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-F)	0938-AP17
Revisions to Payment Policies Under the Physician Fee Schedule for CY 2009 (CMS-1403-FC)	0938-AP18
Home Health Prospective Payment System Refinements and Rate Update for CY 2009 (CMS-1555-N)	0938-AP20
Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Programs (CMS-4131-FC)	0938-AP24
Changes to Long-Term Care Prospective Payment System Based on Specific Provisions in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (CMS-1493-F)	0938-AP33
State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals Federal Fiscal Year 2008 (CMS-2290-IFC)	0938-AP38
Fiscal Year 2010 SCHIP Allotments (CMS-2289-N)	0938-AP54

Office of Public Health and Science - Long-term Action

Title	Regulation Identifier Number
Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940-AA01

Office of Public Health and Science - Completed Action

Title	Regulation Identifier Number
Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940-AA06

Administration for Children and Families - Proposed Rule

Title	Regulation Identifier Number
Target Population and Conversion	0970-AC35
Performance Standards for Runaway and Homeless Youth Grantees	0970-AC43
Recompetition of Head Start Grantees	0970-AC44

Administration for Children and Families - Final Rule

Title	Regulation Identifier Number
Computerized Tribal IV-D System and Office Automation	0970-AC32
Use of TANF Funds Carried Over From Prior Year	0970-AC40
Tribal Child Welfare	0970-AC41

Administration for Children and Families - Long-term Action

Title	Regulation Identifier Number
Limitation on Use of Funds Made Available To Monitor and Combat Trafficking In Persons	0970-AC28
Advance Planning Document Reform	0970-AC33
Revised Head Start Performance Standards	0970-AC36
Intergovernmental Child Support Enforcement	0970-AC37
Interim Assistance for Trafficking Victims Under the Trafficking Victims Reauthorization Act of 2008	0970-AC39
Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008	0970-AC42

Administration for Children and Families - Completed Action

Title	Regulation Identifier Number
Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970-AC01
Developmental Disabilities and Bill of Rights Act	0970-AC07
Care and Placement of Unaccompanied Alien Children	0970-AC20
Adoption and Foster Care Analysis and Reporting System	0970-AC23
Child Support Provisions of the Deficit Reduction Act	0970-AC24
Head Start Interim Final Rule	0970-AC34
Elimination of Enhanced TANF Caseload Reduction Credit for Maintenance of Effort Expenditures	0970-AC38

Office of the Secretary - Proposed Rule

	Regulation

Title	Identifier Number
Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments	0991-AB03
Revisions to the Office of Inspector General's (OIG) Exclusion Authorities	0991-AB33
Revisions to OIG Regulations Governing State Medicaid Fraud Control Units	0991-AB41
Travel Reimbursement for Medicare Hearings Before Administrative Law Judges (ALJs) of the Office of Medicare Hearings and Appeals	0991-AB45
Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements	0991-AB51
Rescission of Interest Prohibition in the Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements	0991-AB52
Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Required by the Genetic Information Nondiscrimination Act of 2008	0991-AB54

Office of the Secretary - Final Rule

Title	Regulation Identifier Number
Safe Harbor for Waiver of Beneficiary Co-Insurance and Deductible Amounts for a Medicare SELECT Policy	0991-AB16
Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings	0991-AB42
State Long-Term Care Partnership Program; Reporting Requirements for Insurers	0991-AB44
Patient Safety and Quality Improvement Act of 2005; Civil Money Penalties Inflation Adjustment	0991-AB53
HIPAA Administrative Simplification; Notification in the Case of Breach	0991-AB56

Office of the Secretary - Long-term Action

Title	Regulation Identifier Number
Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
State Long-Term Care Partnership Program: State Reciprocity Standard	0991-AB47
Rescission of the Regulation Entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal law; Proposal	0991-AB49
HIPAA Administrative Simplification; Modifications to the HIPAA Enforcement Rule	0991-AB55
Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Under the Health Information Technology for Economic and Clinical Health Act	0991-AB57

Office of the Secretary - Completed Action

Title	Regulation Identifier Number
Regulation on the Organizational Integrity of Entities Implementing Leadership Act Programs and Activities	0991-AB46
Ensuring that Department of Health and Human Services Funds Do Not Support Morally Coercive or Discriminatory Policies or Practices In Violation of Federal Law	0991-AB48

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA73

View Related Documents

Title: Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)

Abstract: The Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation (DOT) plans to issue a notice of proposed rulemaking to include vascularized composite allografts (VCA) to the definition of ‘organs’ for purpose of coverage under NOTA and the OPTN final rule. NOTA authorizes the Secretary to include, by regulation, additional organs under the definition of organ. Currently, the OPTN final rule defines covered organs as “a human kidney, liver, heart, lung, or pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). VCA transplantation comprises transplants of a variety

of body parts (i.e. hand and face transplants) that are not currently regulated and which share common characteristics.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 121 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 301 of the National Organ Transplant Act (NOTA) of 1984, as amended; sec 371 to 376 of the Public Health Service Act; sec 1138 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA74

View Related Documents

Title: National Vaccine Compensation Program: Separate Category for Hepatitis A, Influenza, Meningococcal, Human Papillomavirus Vaccines

Abstract: The Department of Health and Human Services proposes to change the Vaccine Injury Table (Table) to create separate categories for hepatitis A, trivalent influenza, meningococcal and human papillomavirus (HPV) vaccines. When a vaccine is recommended for routine administration to children by the Centers for Disease Control and Prevention (CDC), and after an excise tax is imposed on it by Congress, a vaccine is added to the Table under the new vaccines category (Category XIII). These four vaccines have been recommended for routine administration to children by the CDC and have had an excise tax imposed on them. Notices were published informing the public that these four vaccines have been added to the Table under Category XIII. The next step is that new vaccines are added as their own separate categories, with associated injuries/conditions, including the time periods in which the first symptoms or significant aggravation of such injuries/conditions must occur, if applicable, once the Secretary goes through the rulemaking process. In the past, such injuries/conditions have been added based on extensive scientific reviews of medical literature for adverse events following vaccination. Because reviews for these vaccines are not expected until 2011, at the earliest, we are proceeding with rulemaking to add these four vaccines as their own separate categories in order to make clear the four vaccines are covered by the Vaccine Injury Compensation Program. Once results of the scientific reviews are published, additional rulemaking may be necessary, if certain conditions are viewed by the Department as appropriate for inclusion on the Table, including the relevant time periods of onset.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 100.3(c)(5) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 2114(e)(2)of the Public Health Service Act, 42 USC 300ea-14(e)(2); sec 13632(a)(3) PL 103-66, 42 USC CFR 100.3(c)(5)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA77

View Related Documents

Title: Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations-–Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients

Abstract: The Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA) proposes amending regulations at 42 CFR Part 6 (“FTCA Coverage of Certain Grantees and Individuals”) to include additional examples of Federal Tort Claims Act (FTCA)-covered activities. Recently, questions have arisen regarding the scope of FTCA regulations as they affect medical malpractice coverage for FTCA-deemed health centers and non-health center patients. Section 6.6(e) of the Health Center FTCA Program regulations provides examples of situations within the scope of section 6.6(d) (which authorizes FTCA medical malpractice coverage for non-health center patients). These examples include certain community-wide interventions and hospital-related activities where the health center’s health care practitioners will be covered for services provided to non-health center patients. To ensure that deemed health center providers are covered by the FTCA for services provided to non-health center patients in individual emergency situations, HRSA proposes adding an additional example of a situation where a health center provider would be covered under the FTCA for services provided to a non-health center patient. Specifically, the example that we propose be added as 42 CFR 6.6(e)(4) is: 'A health center provider is acting to provide care to a health center patient (and such care is part of the approved scope of project of the center) and the provider is then asked, as the result of a non-health center patient’s emergency situation, to temporarily treat or assist in treating that non-health center patient at that location. The health center has documentation (such as employee manual provisions, health center bylaws, or employee contract) that the provision of individual emergency treatment (when the practitioner is already on-site acting to provide care to health center patients) is a condition of employment at the health center.' In addition, we propose that some additional examples previously provided in a September 25, 1995 Federal Register Notice (Vol. 60, pp. 49417-8) be added to the examples in the regulations. The examples relate to community-wide interventions, hospital-related activities, and coverage-related activities. We plan to provide at least a 60-day comment period.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Proposed Rule
Unfunded Mandates: No
CFR Citation: 42 CFR 6 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 233
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA78

View Related Documents

Title: Federal Tort Claims Act (FTCA) Coverage of Certain Grantees and Individuals: Covered acts and omissions-– Continuing Medical Education

Abstract: The Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA) proposes amending regulations at 42 CFR Part 6 ('FTCA Coverage of Certain Grantees and Individuals') to include an additional example of Federal Tort Claims Act (FTCA)-covered activities. Recently, questions have arisen regarding the scope of FTCA regulations as they affect medical malpractice coverage for FTCA-deemed health centers and non-health center patients. Section 6.6(e) of the Health Center FTCA Program regulations provides examples of situations within the scope of section 6.6 (d) (which authorizes FTCA medical malpractice coverage for non-health center patients). These examples include community-wide interventions and hospital-related activities that are required by the health center for employment. One requirement that health centers have for providers is to maintain licensure and credentials, which requires providers to annually obtain a set number of Continuing Education Units (CEUs.) These CEUs may require the provider to provide medical services to non-health center patients. To ensure that deemed health center providers are covered by the FTCA for these services performed to obtain required CEUs for licensure and credentials, HRSA proposes adding an additional example of a situation where a health center provider would be covered under FTCA for these services.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 6 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 233
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA57

View Related Documents

Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions

Abstract: Public Law 100-93 amended section 1921 of the Social Security Act to require that each State has in effect a system of reporting disciplinary licensure actions taken against all licensed health care practitioners and entities. It also requires States to report any negative action or finding that a peer review organization, private accreditation entity, or a State has concluded against a health care practitioner or entity. Section 1921 directs the Secretary to provide for maximum appropriate coordination in the implementation of these reporting requirements with those of the Health Care Quality Improvement Act of 1986 (title IV of Pub. L. 99-660). Section 1921 requirements will be incorporated into the National Practitioner Data Bank.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 60 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1396r-2
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/21/2006	71 FR 14135
NPRM Comment Period End	05/22/2006	
Final Action	11/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA44

View Related Documents

Title: Designation of Medically Underserved Populations and Health Professional Shortage Areas

Abstract: This rule would consolidate the processes for designating areas of health professional shortage (HPSAs) and areas of medical underservice (MUAs) that apply in several Department programs, and would improve the criteria for designating medically underserved populations and Primary Care HPSAs. An NPRM was published on September 1, 1998, and due to extensive comments received, a notice was published on June 3, 1999 which announced the decision to publish a new NPRM for public comment. The second NPRM was published on February 29, 2008, with the comment period extended twice (first on April 21, 2008, and again on June 2, 2008). Substantial comments were received that must be reviewed and considered on development of modifications to the rule. A Federal Register Notice published on July 23, 2008 announced the agency decision to review and develop a modified proposal and publish another NPRM at a future date. Options are currently under development and consideration. This rule would consolidate the processes for designating areas of health professional shortage (HPSAs) and areas of medical underservice (MUAs) that apply in several Department programs, and would improve the criteria for designating medically underserved populations and Primary Care HPSAs. An NPRM was published on September 1, 1998, and due to extensive comments received, a notice was published on June 3, 1999 which announced the decision to publish a new NPRM for public comment. The second NPRM was published on February 29, 2008, with the comment period extended twice (first on April 21, 2008, and again on June 2, 2008). Substantial comments were received that must be reviewed and considered on development of modifications to the rule. A Federal Register Notice published on July 23, 2008 announced agency decision to review and develop modified proposal and publish another NPRM at a future date. Options are currently under development and consideration. Historically, a variety of methodologies have been used by a variety of Federal and state programs to target resources to underserved populations, including MUAs and HPSAs. MUAs have not been updated in many cases for over 20 years, and therefore, may not reflect current conditions in many areas. Statutory citations above provide the legal foundation for the existing designations. While there is no statutory requirement to update MUAs, there is a requirement to update HPSAs. However, there is no requirement to update the HPSA methodology. Alternatives are to continue to use the existing methodologies or develop another new approach for one or the other. Anticipated costs are minimal, in part, because

the infrastructure is already in place for designations, and it would just take a different approach. No direct impact is expected on most major programs that use the designations, whose funding levels depend on appropriations. There is potential impact on Medicare Incentive Payments (MIP), but it is relatively small, and depending on the results of the model selected, could increase or decrease payments. Potential benefits and risks of an updated methodology: A benefit would be improved targeting of resources (grants and health professionals) to areas and populations with demonstrated need for assistance to assure access to health care services. A risk would be that some areas currently qualified for some programs could lose eligibility based on lower relative need.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 5; 42 CFR 51c (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 254b; 42 USC 254e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Third NPRM	00/00/0000	
NPRM	09/01/1998	63 FR 46538
Second NPRM	02/29/2008	73 FR 11232
Second NPRM Comment Period Extended	04/21/2008	73 FR 21300
Second NPRM Initial Comment Period End	04/29/2008	
Second NPRM Extended Comment Period End	05/29/2008	
Second NPRM Second Comment Period Extended	06/02/2008	73 FR 31418
Second NPRM Second Extension of Comment Period End	06/30/2008	
NPRM Status	07/23/2008	73 FR 42743

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA76

View Related Documents

Title: Health Center Program Regulations – Consolidation With Migrant Health Center Program Regulations and Extension of Applicability to Health Care for the Homeless And Public Housing Primary Care Health

Abstract: To increase the consistency and improve the clarity of requirements across all health center types within the Health Center Program, the Bureau of Primary Health Care (BHPC) of the Health Resources and Services Administration (HRSA) proposes amending the regulations at 42 CFR part 51c (the community health center regulations) to: (1) extend the application of these regulations to grantees of the Health Care for the Homeless Program (authorized under section 330(h) of the PHS Act) and grantees of the Public Housing Primary Care Program (authorized under section 330(i)of the PHS Act); and (2) consolidate the community health center regulations and the migrant health center regulations.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 51c; 42 CFR 56 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 254b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

Energy Affected: No

Related RINs: Merge with 0906-AA72

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA41

View Related Documents

Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements

Abstract: This notice of proposed rulemaking (NPRM) proposes to require that, in addition to reporting to the National Practitioner Data Bank, medical malpractice payments made where physicians or other health care practitioners are named in medical malpractice actions or claims, judgments, or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgments or settlements but who furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health care entity to "shield" practitioners. It would also require malpractice payers, in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified, and to provide the name of the corporate health care entity.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Completed Action

Major: No

Unfunded Mandates: No

CFR Citation: 45 CFR 60.7 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 11131

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/24/1998	63 FR 71255
NPRM Comment Period End	02/22/1999	
Withdrawn	04/21/2009	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA72

View Related Documents

Title: Amending the Health Center Program To Apply to the Health Care for the Homeless and Public Housing Primary Care Programs

Abstract: BHPC proposes amending regulations at 42 CFR part 51c (the community health center regulations) to extend the application of these regulations to grantees of the Health Care for the Homeless Program (authorized under section 330(h) of the PHS Act) and grantees of the Public Housing Primary Care Program (authorized under section 330(i) of the PHS Act). The migrant health center regulations at 42 CFR part 56 would remain unchanged.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 51c (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 254b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	04/21/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG06

View Related Documents

Title: Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution

Abstract: Section 101.17(h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction if shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50, and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of

applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101.17; 21 CFR 115.50; 21 CFR 16.5(a)(4) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 42 USC 243; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Begin Review	12/00/2009	
End Review	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG14

View Related Documents

Title: Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures

Abstract: FDA is undertaking a review of 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 21 CFR 203; 21 CFR 205.3; 21 CFR 205.50 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Planned Section 610 Review	12/03/2009

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/2008	
End Review of Current Regulation	12/00/2009	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions; Organizations

Government Levels Affected: Federal; Local; State

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RIN: 0910-AC52

View Related Documents

Title: Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive. The proposal would also require that FDA periodically issue guidance on the use of standardized data structure, terminology, and code sets (e.g., the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium) to allow for more efficient and comprehensive data review.

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: No

CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2009	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC59

View Related Documents

Title: Reporting Information Regarding Falsification of Data

Abstract: The proposed rule would require sponsors to promptly report any information indicating that any person has engaged in the falsification of data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined

CFR Citation: 21 CFR 16.1; 21 CFR 58.11 and 58.12; 21 CFR 71.1; 21 CFR 101.69 and 101.70; 21 CFR 170.101; 21 CFR 171.1; 21 CFR 190.6; 21 CFR 312.56; 21 CFR 511.1; 21 CFR 571.1; 21 CFR 812.46 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 341 to 343; 21 USC 348 and 349; 21 USC 351 and 352; 21 USC 355; 21 USC 360b and 360c; 21 USC 360e; 21 USC 360i to 360k; 21 USC 361; 21 USC 371; 21 USC 379e; 42 USC 262

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Related RINs: Previously Reported as 0910-AC02

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF31

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antihistamine labeling claims for the common cold.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/2000	65 FR 51780
NPRM (Amendment) (Common Cold)	04/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF38

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Laxative Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action will address laxative drug products. The first NPRM listed will address the professional labeling for sodium phosphate drug products. The second NPRM listed will address all other professional labeling requirements for laxative drug products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Professional Labeling)	00/00/0000	
Final Action (Laxative Drug Products)	00/00/0000	
Final Action (Granular Psyllium)	03/29/2007	72 FR 14669
NPRM (Professional Labeling--Sodium Phosphate)	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF43

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Sunscreen Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses active ingredients reviewed under Time and Extent Applications. The second action is the final action that addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B and ultraviolet A radiation protection. The third action addresses combination products containing sunscreen and insect repellent ingredients.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Sunscreen and Insect Repellent)	00/00/0000	
ANPRM (Sunscreen and Insect Repellent)	02/22/2007	72 FR 7941
ANPRM Comment Period End	05/23/2007	
NPRM (UVA/UVB)	08/27/2007	72 FR 49070
NPRM Comment Period End	12/26/2007	
Final Action (UVA/UVB)	09/00/2009	
NPRM (Time and Extent)	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF45

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Weight Control Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the ingredient phenylpropanolamine, and the other actions address the ingredient benzocaine.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Benzocaine)	00/00/0000	
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
NPRM (Benzocaine)	09/00/2009	
Final Action (Phenylpropanolamine)	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF78

View Related Documents

Title: Import Tolerances for Unapproved New Animal Drugs

Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish tolerances for residues of unapproved new animal drugs in food of animal origin imported into the United States (import tolerances). It is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved in the United States, unless FDA has estalished an import tolerance for that new animal drug and the residue does not exceed that tolerance.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(a)(6); 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	
NPRM Comment Period End	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF81

View Related Documents

Title: Current Good Manufacturing Practice for Combination Products

Abstract: The proposed rule would clarify and codify the current good manufacturing practice (cGMP) requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule is intended to ensure consistency and appropriateness in the regulation of combination products. The proposed rule would provide a flexible, quality management regulatory framework that recognizes that, in most instances, for combination products, a properly implemented quality system program under one set of medical product cGMP regulations will meet the requirements of another set (e.g., application of cGMPs for finished pharmaceuticals in 21 CFR parts 210 and 211 will generally meet the requirements of the device quality system regulations in 21 CFR part 820). It would allow manufacturers the flexibility to select either the cGMP or quality system regulation to apply for the manufacture of their combination product, provided that their system incorporates select, key provisions from the regulations pertaining to the other part of their combination product. It would avoid the necessity to fully implement both sets of cGMP regulations when manufacturing combination products.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 4, subchapter A (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF82

View Related Documents

Title: Postmarket Safety Reporting for Combination Products

Abstract: The proposed rule would clarify the postmarket safety reporting requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a framework for the reporting of adverse events for combination products. The proposed rule would clarify that a combination product is subject primarily to the reporting requirements associated with the type of marketing application under which the product is approved or cleared. In addition, the proposed rule identifies unique reporting provisions that must be complied with if applicable. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 4, subchapter B (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF86

View Related Documents

Title: Medical Device Reporting; Electronic Submission Requirements

Abstract: The Food and Drug Administration (FDA) is proposing to amend its postmarket medical device reporting regulations to require that manufacturers, importers, and user facilities submit mandatory reports of medical device adverse events to the Agency in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 803 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 352; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374
Legal Deadline: None

Regulatory Plan:

Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:

Timetable:

Action	Date	FR Cite
NPRM	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RIN: 0910-AF87

View Related Documents

Title: Laser Products; Amendment to Performance Standard

Abstract: FDA is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology. The proposal would adopt portions of an IEC standard (to achieve greater harmonization and reflect current science), include an alternative mechanism for providing certification and identification, address novelty laser products, and clarify the military exemption for laser products.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Proposed Rule

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 1010; 21 CFR 1040 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 360hh-ss

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Small Entities Affected: Business

Federalism: No

Energy Affected: Undetermined

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF88

View Related Documents

Title: Electronic Registration and Listing for Devices

Abstract: FDA is proposing to amend the medical device establishment registration and listing regulations at 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Federal Food, Drug, and Cosmetic Act (the Act). Section 510(p) was added to the Act by section 207 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and later amended in September 2007 by section 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA). This proposed rule would require domestic and foreign device establishments to submit registration and listing data electronically via the Internet using FDA's Unified Registration and Listing System. This proposed rule would convert registration and listing to a paperless process. However, for those companies that do not have access to the Web, FDA would offer an avenue by which they can register, list, and update information with a paper submission. The proposed rule also would amend part 807 to reflect the timeframes for device establishment registration and listing established by sections 222 and 223 of FDAAA, and to reflect the requirement in section 510(i) of the Act, as amended by section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act), that foreign establishments provide FDA with additional pieces of information as part of their registration.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 807 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 110-85; PL 107-188, sec 321; PL 107-250, sec 207; 21 USC 360(a) through 360(j); 21 USC 360(p)
Legal Deadline: None

Regulatory Plan:
Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:
Timetable:

Action	Date	FR Cite
NPRM	08/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF89

View Related Documents

Title: Regulations on Fixed-Dose Combination and Co-Packaged Drug and/or Biological Products

Abstract: The proposed rule would amend FDA regulations on fixed-combination prescription and OTC drugs. The current regulations require, among other things, that the sponsor of a fixed-combination drug demonstrate that each of the components makes a contribution to the drug's claimed effects. The proposed rule would create a single set of regulations for prescription and OTC combination drugs and codify existing policy on what kinds of studies are needed to show that the combination drug requirements are met. The proposed rule also would apply these regulations to combinations of biological drug products and to drug-biological product combinations. In addition, the proposed rule would clarify application of FDA's requirements regarding fixed-dose combinations to certain natural source drugs and certain synthetic drugs. The regulation would also establish circumstances under which the agency might waive the combination requirements for a particular drug or biological product. The proposed rule will also address the issue of co-packaging.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 300.50; 21 CFR 330.10; 21 CFR 610.17 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 371; 42 USC 262; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF96

View Related Documents

Title: Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

Abstract: The proposed rule would amend FDA's postmarketing safety reporting regulations for human drug and biological

products (21 CFR part 310.305, 314.80, 314.98, 600.80, and 600.81) to require that safety reports submitted to the Agency by persons subject to mandatory reporting requirements be transmitted electronically in a form that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed rule creates a requirement for manufacturers to submit postmarketing safety reports electronically in a compatible format using either direct submission or a Web-based form. The rule will allow the Agency to review safety reports more quickly, to identify emerging safety problems, and disseminate safety information more rapidly in support of FDA's public health mission. The proposed amendments would be a key element in harmonizing FDA's postmarketing safety reporting regulations with international and ICH standards for the electronic submission of safety information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 310.305; 21 CFR 314.80; 21 CFR 314.98; 21 CFR 600.80 and 600.81 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 355a; 21 USC 356 to 356b; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	11/05/1998	63 FR 59746
ANPRM Comment Period End	02/03/1999	
NPRM	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF97

View Related Documents

Title: Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes

Abstract: Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) amended provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that govern the approval of new drug applications (NDAs) described by section 505(b)(2) of the Act (505(b)(2) applications) and abbreviated new drug applications (ANDAs) described by section 505(j) of the Act. This proposed rule would implement portions of title XI of the MMA that pertain to: (1) Provision of notice to each patent owner and the NDA holder of certain patent certifications made by applicants submitting 505(b)(2) applications or ANDAs; (2) the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; (3) submission of amendments and supplements to 505(b)(2) applications and ANDAs; and (4) the types of bioavailability and bioequivalence data that can be used to support these applications. This proposed rule also would amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 314.3; 21 CFR 314.50; 21 CFR 314.52; 21 CFR 314.53; 21 CFR 314.60; 21 CFR 314.70; 21 CFR

314.90; 21 CFR 314.93; 21 CFR 314.94; 21 CFR 314.95; 21 CFR 314.96; 21 CFR 314.97; 21 CFR 314.99; 21 CFR 314.101; 21 CFR 314.105; 21 CFR 314.107; 21 CFR 314.108; 21 CFR 314.125; 21 CFR 314.127; 21 CFR 320.1; 21 CFR 320.23 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 108-173, title XI; 21 USC 355; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG02

View Related Documents

Title: Animal Food Labeling; Declaration of Certifiable Color Additives

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods. FDA is proposing this amendment in response to the Nutrition Labeling and Education Act of 1990 (PL 101-535), which amended section 403 of the Federal Food, Drug, and Cosmetic Act (21 USC 343) by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The proposed rule also suggests appropriate terminology for the declaration of certification-exempt color additives on the labels of animal food.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Proposed Rule

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 501.22(k) (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 343(i)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2009	
NPRM Comment Period End	12/00/2009	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Federalism: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG11

View Related Documents

Title: Revision of the Requirements for Publication of License Revocation

Abstract: The Food and Drug Administration (FDA) is amending the biologics regulations to clarify the regulatory procedures for notifying the public about the revocation of a biologics license. We are taking this action as part of our continuing effort to eliminate or modify those regulations that are outdated or otherwise in need of reform without diminishing public health protection.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 601.8 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1451 to 1561; 21 USC 321; 21 USC 351 to 353; 21 USC 355; 21 USC 356b; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262 and 263; 42 USC 264, sec 122; PL 105-115, 111 Stat. 2322 (21 USC 355 note)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	06/00/2009	
NPRM-Companion to Direct Final Rule	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG12

View Related Documents

Title: Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360(a); 21 USC 371 to 371(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Related to 0910-AF31; Related to 0910-AF32; Related to 0910-AF33; Related to 0910-AF34
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG15

View Related Documents

Title: Revision of the Requirements for Constituent Materials
Abstract: The Food and Drug Administration (FDA) is issuing a proposed rule to permit the Directors of the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER), to approve exceptions or alternatives to the regulations for constituent materials, when either Director determines that such an exception or alternative is in the interest of public health. This action will allow flexibility for manufacturing biological products, including innovative lifesaving products, that do not currently comply with the requirements for constituent materials but have been demonstrated to be safe, pure, and potent products.

Priority: Info./Admin./Other Agenda Stage of Rulemaking: Proposed Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 610.15 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: No Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG16

View Related Documents

Title: Amendments to Sterility Testing Requirements for Biological Products

Abstract: The Food and Drug Administration (FDA) is issuing a proposed rule to amend the sterility testing requirements for biological products. This proposed rule is intended to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art methodologies to ensure the safety of biological products.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 610.12 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG18

View Related Documents

Title: Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products

Abstract: This rule would require electronic package inserts for human drug and biological prescription products, in lieu of paper, which is currently used. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG20

View Related Documents

Title: Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

Abstract: The Food and Drug Administration (FDA) periodically reassesses and revises the cGMP regulations to accommodate advances in technology and other scientific knowledge that further safeguard the drug manufacturing process and the public health. In August 2002, FDA announced the Pharmaceutical cGMPs for the 21st Century Initiative. As part of the Initiative, FDA created a cGMP Harmonization Analysis Working Group to analyze related cGMP requirements in the United States and internationally. The cGMP working group compared 21 CFR parts 210 and 211 with the cGMPs of the European Union, as well as other FDA regulations (such as the Quality Systems Regulation in 21 CFR part 820) to identify differences and consider the value of supplementing or changing the current regulations. Based on the cGMP Working Group's analysis, FDA decided to take an incremental approach to modifying 21 CFR parts 210 and 211. In September of 2008, FDA published a final rule revising the cGMP regulations primarily in the areas of aseptic processing, use of asbestos filters, and verification of operations by a second individual; this final rule represented the culmination of the first increment of modifications to the cGMP regulations. The proposed rule identified on this Unified Agenda would begin the second increment of modifications to the cGMP regulations.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 210; 21 CFR 211 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AA49

View Related Documents

Title: Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations at 21 CFR part 207 concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted for initial registration and listing and for changes to registration and listing. The rule will require that this information be submitted electronically. The rule will also make certain changes to the National Drug Code (NDC) system and would require that the appropriate human-readable NDC number appear on certain drug labels.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 330; 21 CFR 514 and 515; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 1271 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/29/2006	71 FR 51276
NPRM Comment Period End	02/26/2007	72 FR 5944
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC07

View Related Documents

Title: Additional Safeguards for Children in Clinical Investigations

Abstract: The final rule will finalize the interim final rule that published in April 2001, providing additional protections for children involved as subjects in clinical investigations of FDA-regulated products, as required by the Children's Health Act of 2000.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 50; 21 CFR 56 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346 to 346a; 21 USC 348; 21 USC 350a and 350b; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/24/2001	66 FR 20589
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC14

View Related Documents

Title: Prevention of Salmonella Enteritidis in Shell Eggs

Abstract: Publication of this final rule was an action item in the Food Protection Plan announced by the Department of Health and Human Services (HHS) in November 2007. In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of Salmonella Enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses. The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan. On September 22, 2004, FDA published a proposed rule that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. The proposal also solicited comment on whether recordkeeping requirements should include a written SE prevention plan and records for compliance with the SE prevention measures, and whether safe egg handling and preparation practices should be mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers). The proposed egg production SE prevention measures included: (1) Provisions for procurement of chicks and pullets; (2) a biosecurity program; (3) a rodent and pest control program; (4) cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm. Additionally, to verify that the measures have been effective, the rule proposes that producers test the poultry house environment for SE. If the environmental test is positive, eggs from that environment must be tested for SE, and if the egg test is positive, the eggs must be diverted to egg products processing or a treatment process that achieves at least a five-log destruction of SE. The proposed rule was a step in a broader farm-to-table egg safety effort that includes FDA's requirements for safe handling statements on egg cartons, and refrigerated storage of shell eggs at retail, and egg safety education for consumers and retail establishments. The rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings: October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA. The comment period was reopened until July 25, 2005, to solicit further comment and information on industry practices and programs that prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: Private Sector

CFR Citation: 21 CFR 16; 21 CFR 116; 21 CFR 118 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271; ...
Legal Deadline: None

Regulatory Plan:
Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:
Timetable:

Action	Date	FR Cite
NPRM	09/22/2004	69 FR 56824
NPRM Comment Period End	12/21/2004	
NPRM Reopened Comment Period End	06/09/2005	70 FR 24490
NPRM Extension of Reopened Comment Period End	07/25/2005	70 FR 33404
Final Action	07/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: State
Federalism: Yes
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC25

View Related Documents

Title: Exception From General Requirements for Informed Consent; Request for Comments and Information
Abstract: This final rule will add an exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 50.23 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346 to 346a; 21 USC 348; 21 USC 350a to 350b; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/07/2006	71 FR 32827

Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
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Government Levels Affected: State
Federalism: Yes

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC30

View Related Documents

Title: Medical Devices; Anesthesiology Devices; Reclassification of Pressure Regulators for Use With Medical Oxygen and Separate Classification of Oxygen Conserving Devices

Abstract: The Food and Drug Administration (FDA) is reclassifying pressure regulators for use with medical oxygen from class I to class II, establishing a separate classification for oxygen conserving devices, and establishing a special control for these devices to address problems of fire and explosion associated with use of these devices. The special control will be a guidance document that includes standardized testing, performance, and labeling guidance for industry. Devices that meet the standard identified in the special controls guidance document will be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the Act). The requirements of the final rule will be phased-in to minimize the cost of complying with the special control.

Priority: Routine and Frequent
Major: No
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No
CFR Citation: 21 CFR 868.2700; 21 CFR 868.2750; 21 CFR 868.5905; 21 CFR 868.5910 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360j; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/27/2007	72 FR 8643
NPRM Comment Period End	05/29/2007	
Final Action	10/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
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Government Levels Affected: Undetermined

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC53

View Related Documents

Title: Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas mixups, do not occur in the future.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 351 to 21 USC 353
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/10/2006	71 FR 18039
NPRM Comment Period End	07/10/2006	
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC55

View Related Documents

Title: Positron Emission Tomography Drugs; Current Good Manufacturing Practices

Abstract: Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The final rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 212 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 105-115, sec 121
Legal Deadline:

Action	Source	Description	Date

Other	Statutory		11/21/1999

Timetable:

Action	Date	FR Cite
NPRM	09/20/2005	70 FR 55038
NPRM Comment Period End	12/19/2005	
Final Action	08/00/2009	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions

Government Levels Affected: Federal; State

Federalism: No

Energy Affected: No

RIN Information URL: www.fda.gov/cder/regulatory/pet

Related RINs: Previously Reported as 0910-AB63

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF11

View Related Documents

Title: Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling

Abstract: To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR parts 201.56, 201.57, and 201.80).

Priority: Other Significant

Agenda Stage of Rulemaking: Final Rule

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 201.56 and 201.57; 21 CFR 201.80 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/29/2008	73 FR 30831
NPRM Comment Period End	08/27/2008	
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: State

Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF13

View Related Documents

Title: Charging for Investigational Drugs Under an Investigational New Drug Application

Abstract: On December 14, 2006 (71 FR 75168), FDA published a proposed rule to amend FDA's investigational new drug regulation concerning charging for investigational drugs. The rule will clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of treatment uses described in the Agency's rule on expanded access to investigational drugs for treatment use, and clarify what costs can be recovered for an investigational drug. The rule is intended to permit charging for a broader range of investigational uses than is explicitly permitted in current regulations.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312.7 and 312.8 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 356; 21 USC 371; 21 USC 381 to 383; 21 USC 393; 42 USC 262
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/14/2006	71 FR 75168
NPRM Comment Period End	03/14/2007	
Final Action	08/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF14

View Related Documents

Title: Expanded Access to Investigational Drugs for Treatment Use

Abstract: The Food and Drug Administration proposed in the Federal Register of December 14, 2006 (75 FR 75147), to amend the regulations governing investigational new drugs (IND) to describe the ways patients may obtain investigational drugs for treatment use under expanded access programs. Such use of investigational drugs would be available to: (1) Individual patients, including in emergencies; (2) intermediate-size patient populations; and (3) larger populations under a treatment protocol or treatment IND.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312.42; 21 CFR 312.300; 21 CFR 312.305; 21 CFR 312.310; 21 CFR 312.315; 21 CFR 312.320 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360bbb; 21 USC 371; 42 USC 262
Legal Deadline: None

Regulatory Plan:
Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:
Timetable:

Action	Date	FR Cite
NPRM	12/14/2006	71 FR 75147
NPRM Comment Period End	03/14/2007	
Final Action	08/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Organizations
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF26

View Related Documents

Title: Blood Initiative--Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment
Abstract: The Food and Drug Administration (FDA) is amending the regulations regarding container labels and instruction circulars for certain human blood and blood components, including Source Plasma, to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the Government Accountability Office (previously, the General Accounting Office), and the Institute of Medicine, as well as on public comments. This action is intended to help ensure the continued safety of the blood supply and to help ensure consistency in container labeling.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 640 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360d; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262 and 263; 42 USC 263a; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/30/2003	68 FR 44678
NPRM Comment Period End	10/28/2003	
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Split From 0910-AB26
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF27

View Related Documents

Title: Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports

Abstract: The Agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003. On August 1, 2006, FDA reopened the comment period on selected topics. The comment period closed on September 15, 2006.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 106 and 107 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/09/1996	61 FR 36154
NPRM Comment Period End	12/06/1996	
NPRM Comment Period Reopened	04/28/2003	68 FR 22341
NPRM Comment Period Extended	06/27/2003	68 FR 38247
NPRM Comment Period End	08/26/2003	
NPRM Comment Period Reopened	08/01/2006	71 FR 43392
NPRM Comment Period End	09/15/2006	
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Split From 0910-AA04
Agency Contact: Benson Silverman Department of Health and Human Services
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF28

View Related Documents

Title: Infant Formula Quality Factors

Abstract: The Agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003. The comment period was reopened on August 1, 2006, to end on September 15, 2006.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 106 and 107 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/09/1996	61 FR 36154
NPRM Comment Period End	12/06/1996	
NPRM Comment Period Reopened	04/28/2003	68 FR 22341
NPRM Comment Period Extended	06/27/2003	68 FR 38247
NPRM Comment Period End	08/26/2003	
NPRM Comment Period Reopened	08/01/2006	71 FR 43392
NPRM Comment Period End	09/15/2006	
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Split From 0910-AA04
Agency Contact: Benson Silverman Department of Health and Human Services
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF32

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Cough/Cold (Bronchodilator) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for single ingredient bronchodilator products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment--Ephedrine Single Ingredient)	07/13/2005	70 FR 40237
Final Action (Technical Amendment)	11/30/2007	72 FR 63679
Final Action (Amendment--Ephedrine Single Ingredient)	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF33

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Cough/Cold (Combination) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The technical amendment revises a paragraph designation in the CFR. The other action finalizes cough/cold combination products containing oral bronchodilators and expectorants.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/2005	70 FR 40232
Final Action (Technical Amendment)	03/19/2007	72 FR 12730
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
Agency Contact: Walter J. Ellenberg

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF35

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--External Analgesic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	00/00/0000	
Final Action (GRASE dosage forms)	12/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF36

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Internal Analgesic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for

children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses other miscellaneous issues relating to internal analgesics. The fifth document finalizes the document regarding the required warnings and other labeling. The last document finalizes the Internal Analgesic Products monograph.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Pediatric)	00/00/0000	
Final Action (Internal Analgesics)	00/00/0000	
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/2006	71 FR 77314
NPRM Comment Period End	05/25/2007	
Final Action (Required Warnings and Other Labeling)	05/00/2009	
NPRM (Amendment) (Miscellaneous Issues)	05/00/2010	
NPRM (Amendment) (Overindulgence/Hangover)	05/00/2010	
NPRM (Amendment) (Combinations With Sodium Bicarbonate)	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF42

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Skin Protectant Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses skin protectant products used to treat fever blisters and cold sores. The second action addresses astringent active ingredients. The third action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Fever Blisters/Cold Sores)	00/00/0000	
Final Action (Technical Amendments)	02/01/2008	73 FR 6014
Final Action (Aluminum Acetate) (Technical Amendment)	03/06/2009	74 FR 9759
Final Action (Diaper Rash)	12/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF46

View Related Documents

Title: Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy

Abstract: On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE, which resulted in this rulemaking. FDA is correcting the final rule on BSE that appeared in the Federal Register of April 25, 2008 (73 FR 22719-22758). The final rule inadvertently published with incorrect dollar amounts in two separate areas: the summary of economic impacts and the paperwork burden table.

Priority: Economically Significant Agenda Stage of Rulemaking: Final Rule
Major: Yes Unfunded Mandates: No
CFR Citation: 21 CFR 589.2001 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/14/2004	69 FR 42288
ANPRM Comment Period End	08/13/2004	
NPRM	10/06/2005	70 FR 58569
NPRM Comment Period End	12/20/2005	
Final Rule	04/25/2008	73 FR 22720
Final Rule-Correction	10/23/2008	73 FR 63072
Final Rule Effective	04/27/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF47

View Related Documents

Title: Use of Materials Derived From Cattle in Human Food and Cosmetics

Abstract: On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle material and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. On September 7, 2005, FDA amended the IFR to permit the use of small intestine in human food and cosmetics if it is effectively removed from the distal ileum. The amendment also clarified that milk and milk products, hides, and tallow derivatives are not prohibited for use in human food and cosmetics. On April 17, 2008, FDA amended the IFR so that FDA may designate a country as not subject to certain BSE-related restrictions relating to prohibited cattle materials applicable to human food and cosmetics. Comments submitted in response to the July 14, 2004 IFR that were not addressed in the September 7, 2005 and April 17, 2008 amendments will be addressed in the final rule. The final rule also will respond to comments submitted following the September 7, 2005 and April 17, 2008 amendments.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 189.5; 21 CFR 700.27 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	07/14/2004	
Interim Final Rule	07/14/2004	69 FR 42256
Interim Final Rule Comment Period End	10/12/2004	
Interim Final Rule (Amendments)	09/07/2005	70 FR 53063
Interim Final Rule (Amendments) Effective	10/07/2005	
Interim Final Rule (Amendments) Comment Period End	11/07/2005	
Interim Final Rule (Amendments)	04/17/2008	73 FR 20785
Interim Final Rule (Amendments) Effective	07/16/2008	
Interim Final Rule (Amendments) Comment Period End	07/16/2008	
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF54

View Related Documents

Title: Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants

Abstract: The regulation would prohibit the use of certain cattle material in the manufacture of medical products for humans and drugs for ruminants, and would require recordkeeping for products containing or manufactured with cattle materials to enable monitoring and enforcement of the prohibitions. The rule would prohibit the same cattle material that is prohibited in the previous FDA IFR that applies to foods and cosmetics. These include certain high risk tissues (e.g., brain, skull, eyes, spinal cord, trigeminal ganglia, parts of the vertebral column, and dorsal root ganglia) from cattle 30 months and older, tonsils and the distal ileum of cattle of any age, mechanically separated beef, material from nonambulatory disabled cattle, and material from cattle not inspected and passed for human consumption. The prohibitions would apply only to materials derived from animals slaughtered after the effective dates of the rule. The prohibitions would not apply to tallow that met a specified purity standard. The rule would provide criteria for deviations from the requirements based on a showing of safety or appropriate benefit-to-risk ratio.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 211.116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500.200; 21 CFR 530; 21 CFR 600.16; 21 CFR 895.102; 21 CFR 1271.465; 21 CFR 1271.470 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 360f; 21 USC 360i; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 262; 42 USC 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/12/2007	72 FR 1582
NPRM Comment Period End	03/13/2007	
NPRM Comment Period Reopened	03/30/2007	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Related RINs: Merge with 0910-AF55

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF61

View Related Documents

Title: Label Requirement for Food That Has Been Refused Admission Into the United States

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, "UNITED STATES: REFUSED ENTRY." The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 1.98 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 342 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	09/18/2008	73 FR 54106
NPRM Comment Period End	12/02/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined

Federalism: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF93

View Related Documents

Title: Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn, and Nedocromil]

Abstract: Medical products using chlorofluorocarbons (CFCs) and other ozone-depleting substances may only be legally marketed if they are listed in 21 CFR part 2.125 as "essential uses." This final rule would remove the essential use designations after a specified date for metered-dose inhalers (MDIs) containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. Under the provisions of this final rule, these MDIs would have to be removed from the market. This final rule is consistent with obligations under the Clean Air Act and the Montreal Protocol on Substances That Deplete the Ozone Layer.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 2.125 (Revision); 40 CFR 82.4; 40 CFR 82.64; 40 CFR 82.66 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 361 and 362; 21 USC 371 and 372; 21 USC 374; 42 USC 7671 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/11/2007	72 FR 32030
NPRM Comment Period End	09/10/2007	
Final Action	06/00/2009	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Martha Nguyen
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG00

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Acne Drug Products Containing Benzoyl Peroxide
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will address acne drug products containing benzoyl peroxide.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	10/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Agency Contact: Walter J. Ellenberg
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG03

View Related Documents

Title: Defining the Term "Small Numbers of Animals" for Minor Use Designation

Abstract: The designation provision of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) (21 USC 360ccc-1, 360ccc-2, 371) provides incentives to animal drug sponsors to encourage drug development and approval for minor species and for minor uses in major animal species. Congress provided a statutory definition of “minor use” that relied on the phrase "small numbers of animals" to characterize such use. At this time, FDA is amending 21 CFR part 516 (the implementing regulations of the MUMS Act) to further define “minor use” by defining a specific "small number of animals" for each of the seven major animal species, to be used in determining whether any particular intended use in a major species is a minor use.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 516 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360ccc-1; 21 USC 360ccc-2; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/18/2008	73 FR 14411
NPRM Comment Period End	07/16/2008	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

Agency Contact: Margaret Oeller
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG13

View Related Documents

Title: Premarketing Safety Reporting Requirements for Human Drug and Biological Products

Abstract: The final rule would amend the premarketing safety reporting requirements for human drugs and biological products to codify the Agency's expectations for timely acquisition, evaluation, and submission of relevant and useful safety information, to improve the overall quality of safety reporting, to implement internationally consistent definitions, to subject bioavailability and bioequivalence studies to safety reporting requirements, and to make other minor revisions. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312; 21 CFR 320 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371;

21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/14/2003	68 FR 12406
NPRM Comment Period Extended	06/18/2003	
NPRM Comment Period End	07/14/2003	
NPRM Comment Period Extended End	10/14/2003	
Final Action	10/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG19

View Related Documents

Title: Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

Abstract: The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that FDA publish a list of all authorized generic drugs identified in an annual report since 1999, and that the agency update the list quarterly. The final rule would, among other things, require submission of a copy of the portion of annual reports containing the authorized generic information identified in FDAAA to a central office in FDA that compiles and updates the list, to permit easier identification of the information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 314.3(b); 21 CFR 314.81(b)(2)(ii)(b) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 355(t)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/29/2008	73 FR 56529
NPRM Comment Period End	12/15/2008	
Final Action	07/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AA97

View Related Documents

Title: Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

Abstract: These regulations are one component of the Secretary's initiative to reduce medical errors. The final rule would amend the expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: Yes Unfunded Mandates: No
CFR Citation: 21 CFR 310; 21 CFR 314; 21 CFR 600 and 601; 21 CFR 606 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	03/14/2003	68 FR 12406
NPRM Comment Period Extended	06/18/2003	
NPRM Comment Period End	07/14/2003	
NPRM Comment Period Extension End	10/14/2003	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AB88

View Related Documents

Title: Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. The final rule (the CGMP rule) was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, labeling, or holding dietary supplements, they do so in a manner that will ensure the quality of the dietary supplements--i.e., to ensure that the dietary supplement consistently meets the established specifications for identity, purity,

strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act. FDA also published an interim final rule (IFR) in the June 25, 2007 Federal Register (72 FR 34959) that sets forth a procedure for requesting an exemption from the requirement in the final rule described above that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 111 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	02/06/1997	62 FR 5700
ANPRM Comment Period End	06/06/1997	
NPRM	03/13/2003	68 FR 12157
NPRM Comment Period End	08/11/2003	
Interim Final Rule	06/25/2007	72 FR 34959
Final Action	06/25/2007	72 FR 34752
Interim Final Rule Comment Period End	10/24/2007	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AC50

View Related Documents

Title: Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements

Abstract: The Food and Drug Administration issued an Advance Notice of Proposed Rulemaking on July 11, 2003 (68 FR 41507), to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The Agency also requested comments on whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining

healthy dietary practices.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	07/11/2003	68 FR 41507
ANPRM Comment Period End	10/09/2003	
ANPRM Comment Period Reopened for 45 days	03/01/2004	69 FR 9559
ANPRM Comment Period Extended for Additional 60 days	04/19/2004	69 FR 20838
ANPRM Comment Period End	06/18/2004	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Related to 0910-AB66
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AC54

View Related Documents

Title: Food Standards: General Principles and Food Standards Modernization

Abstract: In 1995, the FDA and FSIS reviewed their regulatory procedures and requirements for food standards to determine whether any were still needed, and if so, which ones should be modified or streamlined. To request public comment to assist them in their review of the need for food standards, both Agencies published advance notices of proposed rulemaking (ANPRMs) on food standards in December 1995 (60 FR 47453 and 60 FR 67492). These ANPRMs discussed the Agencies' regulations and policy governing food standards, the history of food standards, and the possible need to revise the food standards. Several comments in response to the ANPRMs recommended that the Agencies establish general principles or a fundamental philosophy for reviewing food standards and revising them. The Agencies agreed with these comments and determined that it would be appropriate to develop general principles for reviewing and revising food standards regulations. The Agencies also agreed with the comments that stated that the Agencies should work in concert to develop consistent food standards regulations. FDA and FSIS proposed a set of general principles that define how modern food standards should be structured (70 FR 29214, May 20, 2005). If this proposed rule is adopted, FDA and FSIS will require that a citizen petition for establishing, revising, or eliminating a food standard in 21 CFR parts 130 to 169 and 9 CFR part 319 be submitted in accordance with the general principles. Conversely, the Agencies may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 130.5 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	12/29/1995	60 FR 67492
ANPRM Comment Period End	04/29/1996	
NPRM	05/20/2005	70 FR 29214
NPRM Comment Period End	08/18/2005	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0583-AC72
Related Agencies: Joint: FSIS

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF08

View Related Documents

Title: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls

Abstract: The proposed rule would amend the packaging and labeling control provisions of the current good manufacturing practice regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. The proposal would also permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling is used.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 211.122 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	07/29/1997	62 FR 40489
NPRM Comment Period End	10/27/1997	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF22

View Related Documents

Title: Food Labeling; Prominence of Calories

Abstract: In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the Agency issued on April 4, 2005, an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation's obesity problem. The ANPRM requested comments on ways to give more prominence to calories on the food label.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101.9 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	04/04/2005	70 FR 17008
ANPRM Comment Period End	06/20/2005	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF23

View Related Documents

Title: Food Labeling; Serving Sizes of Products That Can Reasonably Be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

Abstract: In response to the Report of the Working Group on Obesity that FDA issued on March 12, 2004, the Agency issued on April 4, 2005, an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation's obesity problem. The ANPRM requested comments on possible changes to the Agency's nutrition labeling regulations on serving size and comments on other approaches for promoting consumption of smaller portion sizes.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 101.9; 21 CFR 101.12; 21 CFR 101.60(b) (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	04/04/2005	70 FR 17010
ANPRM Comment Period End	06/20/2005	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF25

View Related Documents

Title: Blood Initiative--Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use

Abstract: The Food and Drug Administration (FDA) is amending the biologics regulations, particularly those related to blood donor eligibility, by removing, revising, or updating specific regulations applicable to blood, blood components, source plasma, and source leukocytes to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also responsive to reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the Government Accountability Office (previously, the General Accounting Office), and the Institute of Medicine, and to public comments. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Priority: Other Significant

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 630; 21 CFR 640; 21 CFR 660; 21 CFR 820; 21 CFR 1270 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360e; 21 USC 360h to 360j; 21 USC 360l; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 21 USC 383; 42 USC 216; 42 USC 243; 42 USC 262 and 263; 42 USC 263a; 42 USC 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	11/08/2007	72 FR 63416
NPRM Comment Period Extended	01/11/2008	73 FR 1983
NPRM Comment Period End	02/06/2008	
NPRM Comment Period End	08/04/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Related RINs: Split From 0910-AB26
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF34

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Nasal Decongestant) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient phenylpropanolamine.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/2004	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/2004	69 FR 63482
Final Action (Amendment) (Sinusitis Claim)	10/31/2005	70 FR 58974
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
Final Action (Phenylephrine Bitartrate)	08/01/2006	71 FR 83358
Final Action (Phenylpropanolamine)	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF37

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Labeling of Drug Products for OTC Human Use

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for convenience (small) size OTC drug packages.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 UCS 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/2006	71 FR 74474
Final Action	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF39

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Ophthalmic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses emergency first aid eyewash products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes)	00/00/0000	
NPRM (Amendment) (Emergency First Aid Eyewashes)	02/19/2003	68 FR 7917

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF40

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Oral Health Care Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM (Plaque Gingivitis)	00/00/0000	
ANPRM (Plaque Gingivitis)	05/29/2003	68 FR 32232
ANPRM Comment Period End	08/27/2003	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF44

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Vaginal Contraceptive Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The proposed rule addresses vaginal contraceptive drug products.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360 to 360a; 21 USC 360gg to 360ss; 21 USC 371 to 371a; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	12/19/2007	72 FR 71769
NPRM (Vaginal Contraceptive Drug Products)	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF51

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Overindulgence in Food and Drink Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	01/05/2005	70 FR 741
Final Action	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State

Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF52

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Antacid Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the labeling of products containing sodium bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Overindulgence Labeling)	05/00/2010	
Final Action (Sodium Bicarbonate Labeling)	05/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF53

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Skin Bleaching Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses skin bleaching

drug products containing hydroquinone.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/29/2006	71 FR 51146
NPRM Comment Period End	12/27/2006	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF56

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Stimulant Drug Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the use of stimulant active ingredients to relieve symptoms associated with a hangover.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF63

View Related Documents

Title: Over-The-Counter Antidiarrheal Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. These actions address new labeling for antidiarrheal drug products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (New Labeling)	00/00/0000	
NPRM (Proposed New Labeling)	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Previously Reported as 0910-AC82
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF68

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Poison Treatment Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient ipecac syrup.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal

Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (IPECAC)	06/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State

Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF69

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses food handler products. The second action addresses testing requirements. The final actions listed will address the healthcare, consumer, and first aid antiseptic drug products respectively.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action

Major: No Unfunded Mandates: No

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (First Aid Antiseptic)	00/00/0000	
Final Action (Consumer)	00/00/0000	
NPRM (Consumer)	00/00/0000	
NPRM (Testing)	00/00/0000	
Final Action (Healthcare)	00/00/0000	
NPRM (Food Handlers)	00/00/0000	
NPRM (Healthcare)	06/17/1994	59 FR 31402

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State

Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF70

View Related Documents

Title: Over-The-Counter (OTC) Drug Review--Urinary Analgesic Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF90

View Related Documents

Title: Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

Abstract: FDA issued regulations to permit FDA Center Directors to grant an exception or alternative to certain regulatory labeling provisions applicable to human drugs, biological products, or medical devices that are or will be included in the Strategic National Stockpile (SNS). Under this rule, the appropriate FDA Center Director may grant an exception or alternative to such labeling requirements if he or she determines that compliance with such requirements could adversely affect the safety, effectiveness, or availability of specified lots, batches, or other units of human drugs, biological products, or medical devices that are or will be included in the SNS. A grant of an exception or alternative under these regulations will include any safeguards or conditions deemed appropriate by the FDA Center Director to ensure that the labeling of such products includes information for the safe and effective use of the products given their anticipated circumstances of use. This rule will facilitate the safety, effectiveness, and availability of appropriate medical countermeasures in the event of a public health emergency.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 201; 21 CFR 312; 21 CFR 314; 21 CFR 601; 21 CFR 610; 21 CFR 801; 21 CFR 807; 21 CFR 809; 21 CFR 812; 21 CFR 814 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 15 USC 1451 to 1561; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 and 356; 21 USC 358; 21 USC 360; 21 USC 371 to 375; 21 USC 379; 21 USC 381 and 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 262 to 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	12/28/2007	72 FR 73589
Interim Final Rule Comment Period End	03/27/2008	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal; State

Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RIN: 0910-AF95

View Related Documents

Title: Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients

Abstract: The Food and Drug Administration (FDA) is proposing that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this proposed rule because we did not receive any data and information on these ingredients in response to our request on December 31, 2003 (68 FR 75585). This proposed rule is part of FDA's ongoing review of OTC drug products.

Priority: Routine and Frequent

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	06/19/2008	73 FR 34895
NPRM Comment Period End	09/17/2008	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: Local; State

Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG07

View Related Documents

Title: Conditional Approval of New Animal Drugs for Minor Use and Minor Species

Abstract: This proposed rule implements section 571 of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act). The MUMS act added three sections to the Federal Food, Drug, and Cosmetic Act (the Act) (571, 572, and 573), and it established new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species, as well as uncommon diseases in major animal species. Section 571 of the Act provides for animal drug conditional approval after all safety and manufacturing components of a new animal drug approval have met the standards of section 512 of the Act. For the effectiveness component of a new animal drug review, a reasonable expectation of effectiveness must be established prior to conditional approval under section 571 of the Act. Sponsors then have up to 5 years to complete the demonstration of effectiveness by the standards of section 512 of the Act and achieve a complete new animal drug approval.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 516 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360ccc
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		02/00/2011

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG08

View Related Documents

Title: Animal Feed Ingredient Standards and Definitions

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007. The FDAAA includes several provisions pertaining to food safety, including the safety of pet food. FDAAA section 1002(a) directs FDA to issue new final regulations within 2 years to establish pet food ingredient standards and definitions. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action

Major: No Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 341; 21 USC 371; PL 110-85, sec 1002(a)(1)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	07/00/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG09

View Related Documents

Title: Pet Food Labeling Requirements
Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007 (Pub. L. 110-85). Title X of the FDAAA includes several provisions pertaining to food safety, including the safety of pet food. Section 1002(a) of the new law directs that, within 2 years, FDA is to issue new regulations to establish updated standards for the labeling of pet food that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 343; 21 USC 371; PL 110-85, sec 1002(a)(3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	07/00/2010	

Regulatory Flexibility Analysis Required: Undetermined Government Levels Affected: No
Small Entities Affected: Business Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG10

View Related Documents

Title: Process Controls for Animal Feed Ingredients and Mixed Animal Feed

Abstract: The Food and Drug Administration (FDA) is proposing regulations for process controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. The proposed process controls will apply to animal feed ingredients and mixed animal feed including pet food. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007. Section 1002(a) directs FDA to establish by regulation processing standards for pet food. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 228 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 371; PL 110-85, sec 1002(a)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	07/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)

Food and Drug Administration (FDA) RIN: 0910-AG17

View Related Documents

Title: New Animal Drugs: Updating Tolerances for Residues in New Animal Drugs in Food

Abstract: FDA is proposing to revise 21 CFR 556 to reformat the listings of tolerances for residues of approved new animal drugs in food. This revision will standardize, simplify, and clarify these listings, and improve the readability of the regulations. Currently, part 556 employs a patchwork of various styles for listing tolerances that have evolved over the past 40 years as each additional animal drug has been approved. The listings in part 556 are not uniform in format, and FDA does not always provide relevant information in a clear and straightforward manner. For example, FDA provides the acceptable daily intake (ADI) and safe concentrations for some, but not all drugs; FDA lists some tolerances as being for "negligible" residues, and FDA presents some listings in a text paragraph format while others are presented in outline form. Moreover, sometimes FDA specifies “no residue,” “zero tolerance,” or tolerance “not required” but does not define or make distinction between these important terms.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 556 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	07/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC17

View Related Documents

Title: Institutional Review Boards: Registration Requirements

Abstract: The final rule would require institutional review boards (IRB) to register with the Department of Health and Human Services. The registration information would include the name of the IRB; the name of the institution operating the IRB; and names, addresses, phone numbers, facsimile (fax) numbers, and electronic mail (e-mail) addresses of the senior officer of the institution and IRB chair or contact; the number of active protocols involving FDA-regulated products reviewed in the previous calendar year; and a description of the types of FDA-regulated products reviewed. The final rule would make it easier for FDA to inspect IRBs and to convey information to IRBs.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 56.106 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 346 to 346a; 21 USC 348; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/06/2004	69 FR 40556
NPRM Comment Period End	10/04/2004	
Final Action	01/15/2009	74 FR 2358

Regulatory Flexibility Analysis Required: No Government Levels Affected: No

Federalism: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC23

View Related Documents

Title: Requirements for Submission of In Vivo Bioequivalence Data

Abstract: The Food and Drug Administration (FDA) published a proposed regulation on October 29, 2003 (68 FR 61640), that would amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. If finalized, this rule would require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

Priority: Substantive, Nonsignificant Agenda Stage of Rulemaking: Completed Action

Major: No Unfunded Mandates: No

CFR Citation: 21 CFR 314.96(a)(1); 21 CFR 314.94(a)(7); 21 CFR 320.21(b)(1) (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 355a; 21 USC 356; 21 USC 356a to 356c; 21 USC 371; 21 USC 374; 21 USC 379

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/29/2003	68 FR 61640
Final Action	01/16/2009	74 FR 2849

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No

Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF12

View Related Documents

Title: Cochineal Extract and Carmine Label Declaration

Abstract: The Agency published a final rule on January 5, 2009, to require the label declaration of all foods and cosmetics containing the color additives cochineal extract and carmine in order to protect consumers with allergies to these additives. This final rule was issued in response to adverse event reports received by FDA and to a citizen petition submitted to FDA.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 73.100(d); 21 CFR 73.2087(c); 21 CFR 101.22(k) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 379e(b)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/30/2006	71 FR 4839
NPRM Comment Period End	05/01/2006	
Final Action	01/05/2009	74 FR 207
Final Rule--Objection Period End	02/04/2009	
Final Rule-Confirmation of Effective Date	03/11/2009	74 FR 10483

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF21

View Related Documents

Title: Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex

Abstract: The classification regulation for condoms would be amended to specify a labeling guidance document as a special control for condoms made from natural rubber latex. The new special control guidance document would identify issues presented by these devices, and would provide detailed recommendations for labeling to address these issues. FDA believes that addressing the issues identified in the guidance, either by following the recommendations in the guidance or by some other means that provide equivalent assurances of safety and effectiveness, together with the general controls, will provide a reasonable assurance of the safety and effectiveness of these devices. These labeling recommendations are also consistent with the labeling requirements of 21 CFR part 801. The rule will demonstrate how the Agency is addressing the congressional directive of Public Law 106-554 that FDA review condom labeling to assure that the information regarding the overall

effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases is medically accurate.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 884.5300 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360c
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/14/2005	70 FR 69102
NPRM Comment Period End	02/13/2006	
Final Action	11/10/2008	73 FR 66522

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: Yes
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF92

View Related Documents

Title: Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Epinephrine]

Abstract: Medical products using chlorofluorocarbons (CFCs) and other ozone-depleting substances may only be legally marketed if they are listed in 21 CFR part 2.125 as "essential uses." The final rule would remove the essential use designations after a specified date for metered-dose inhalers (MDIs) containing epinephrine. Under the provisions of this final rule, these MDIs would have to be removed from the market. This rulemaking is consistent with obligations under the Clean Air Act and the Montreal Protocol on Substances That Deplete the Ozone Layer.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 2.125 (Revision); 40 CFR 82.4; 40 CFR 82.64; 40 CFR 82.66 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 361 and 362; 21 USC 371 and 372; 21 USC 374; 42 USC 7671 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/20/2007	72 FR 53711
NPRM Comment Period End	12/19/2007	
Final Action	11/19/2008	73 FR 69532

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF99

View Related Documents

Title: Food Labeling; Serving Sizes and Nutrition Labeling

Abstract: Section 101.9 (21 CFR 101.9) describes the nutrition labeling requirements for foods. Section 101.12 (21 CFR 101.12) specifies the reference amount customarily consumed per eating occasion for each food category. The reference amount customarily consumed of a food is the basis for the serving size that is declared in the food's nutrition labeling. Under section 101.9, the serving size must be expressed in a common household measure that is appropriate to the food. The most recent change to sections 101.9 and 101.12 was in 1999, when FDA amended these regulations to reduce the reference amount customarily consumed for baking powder, baking soda, and pectin, and to include 1/8 teaspoon as an allowable unit of household measure for nutrition labeling purposes. FDA has completed a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review was to determine whether the regulations in sections 101.9 and 101.12 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA solicited comments on the following: (1) The continued need for the regulations in sections 101.9 and 101.12; (2) the nature of complaints or comments received concerning the regulations in sections 101.9 and 101.12; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.9 and 101.12 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.9 and 101.12. FDA received no comments and concluded that there is a continuing need for the nutrition labeling and serving size regulations in sections 101.9 and 101.12 and that these regulations should be retained without change.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Deadline for Section 610 review	03/16/2009

Timetable:

Action	Date	FR Cite
Begin Review	12/12/2008	
End Review	02/10/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Agency for Healthcare Research and Quality (AHRQ) RIN: 0919-AA01

View Related Documents

Title: Patient Safety and Quality Improvement Act of 2005 Rules

Abstract: The proposed rules to implement the Patient Safety and Quality Improvement Act of 2005 establish a framework in which hospitals, doctors, and other health care providers may voluntarily contract with Patient Safety Organizations (PSOs) to report and analyze health care errors. Providers contract with PSOs for expertise in the collection of patient safety event reports and analysis of the cause of adverse events. The proposed rules outline the requirements that entities must meet and certify to the Secretary for acceptance as a PSO. The proposed rules establish legal boundaries of privilege and confidentiality within which reporting and analysis occurs, and sets forth procedures for the imposition of civil money penalties for the knowing or reckless disclosure of patient safety work product.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 299b-12 to 299b-26; PL 109-41
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/12/2008	73 FR 8112
NPRM Comment Period End	04/14/2008	
Final Action	11/21/2008	73 FR 70732

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA17

View Related Documents

Title: Amendments to Performance Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Approval of Respiratory Protective Devices

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of closed-circuit, self-contained breathing apparatus; supplied air respirators; and combination (supplied air and air purifying capable) respirators against CBRN respiratory hazards. These respirators are used in emergency response situations.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 29 USC 651; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 11; 30 USC 842l; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	06/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA14

View Related Documents

Title: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations
Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents and vectors deemed to be of public health significance. Currently the regulations restrict the importation of nonhuman primates, dogs, cats, small turtles, etiologic agents, hosts and vectors, such as bats (42 CFR sections 71.53, 71.51, 71.52, 71.54). In addition, CDC has recently issued a series of emergency orders, restricting the importation of African rodents (42 CFR section 71.56) and civets (67 FR 3364-01). CDC is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations for importation of certain animals and vectors into the Unite States (42 CFR parts 71, Subpart F).

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/31/2007	72 FR 41676
Notice Extending ANPRM Comment Period	10/01/2007	72 FR 55729
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA21

View Related Documents

Title: Amendments to Specifications for Medical Examinations of Underground Coal Miners

Abstract: NIOSH plans to modify sections of 42 part 37 to allow for the use of digital radiography in medical screening of coal miners for coal workers' pneumoconiosis. Current provisions of these regulations require the use of film radiography which is being phased out of use at medical facilities in the United States.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 37 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 30 USC 843
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA23

View Related Documents

Title: Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Nonhuman Primate Regulations

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 71.53 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 U.S.C. 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA26

View Related Documents

Title: Medical Examination of Aliens: Removal of HIV Infection as a Communicable Disease of Public Health Significance
Abstract: Under the authority of section 212(a)(1)(A) of the Immigration and Nationality Act (INA) and section 325 of the Public Health Service Act, the Secretary of Health and Human Services promulgates regulations outlining the requirements for the medical examination of aliens and a list of any “communicable disease of public health significance” that make aliens ineligible for entry into the United States. HIV is currently included in this list of communicable diseases as defined in 42 CFR part 34: Medical Examination of Aliens. CDC is proposing to remove HIV as a “communicable disease of public health significance” in 42 CFR part 34.2(b). This action aligns with an amendment in the United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008, signed on July 30, 2008, that removed language in the Immigration and Nationality Act that explicitly prohibited HIV-positive non-citizens from entering the United States without a visa waiver.

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 34 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 252; 8 USC 1182; 8 USC 1222
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA28

View Related Documents

Title: Medical Examination of Aliens
Abstract: CDC is amending its regulations that govern medical examinations that aliens must undergo before they may be admitted to the United States. Specifically, HHS/CDC is amending its regulations to update vaccination requirements, definitional changes for drug abuse and drug addition, scope of medical examination and revise outdated diseases from the list of “communicable diseases of public health significance”. We are taking this action to afford CDC the maximum flexibility it

needs to identify and respond to newly emerging and re-emerging diseases. These changes are needed to improve the U.S. Government's ability to prevent the importation of infectious diseases that are currently causing severe illness and death in regions of the world where large numbers of U.S.-bound immigrants and refugees reside These changes will reduce the health-security threat to the United States from emerging diseases without imposing an undue burden on either the aliens or the health-care system in U.S. resettlement communities.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 34 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 8 USC 1182; 8 USC 1222; 42 USC 252
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: Yes
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA04

View Related Documents

Title: Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices
Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: 1) Upgrade of quality assurance requirements; 2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; and 3) revised approval label requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842(h); 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/10/2008	73 FR 75045
NPRM Comment Period End	02/09/2009	
Final Action	01/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA10

View Related Documents

Title: Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of closed-circuit, self-contained breathing apparatus. These respiratory protective devices are used in emergencies for the protection of miners and workers in other industries.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/10/2008	73 FR 75027
NPRM Comment Period End	02/09/2009	
Final Action	01/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA12

View Related Documents

Title: Control of Communicable Diseases Foreign Quarantine

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine isolation and conditional release of individuals suspected of carrying a quarantinable disease while respecting individual autonomy. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive Order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause a pandemic.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 243; 42 USC 248 and 249
Legal Deadline: None

Regulatory Plan:
Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:
Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA22

View Related Documents

Title: Control of Communicable Diseases: Interstate Quarantine

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR part 70) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine, isolation and conditional release of individuals suspected of carrying a quarantine disease, while respecting individual autonomy. Entities affected by the rule are those that are directly involved in the movement of persons, animals, and articles in interstate traffic. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive Order which diseases may subject individuals to quarantine or isolation. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 198; 28 USC 231; 25 USC 1661; 42 USC 243; 42 USC 248 and 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA27

View Related Documents

Title: Control of Communicable Diseases: Interstate Quarantine, Passenger Information

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The CDC Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among interstate travelers is thus not limited to those known or suspected of having a quarantinable disease, but rather all communicable diseases that may necessitate a public health response. Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of individuals who may have been exposed. This provision, which was proposed section 70.4, would require any airline operating in interstate traffic to solicit and electronically submit certain passenger information to CDC for use in contact tracing when necessary to protect the vital interests of an individual, or other persons, in regard to significant health risks.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 70 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 25 USC 198.231; 25 USC 1661; 42 USC 243; 42 USC 248; 42 USC 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA16

View Related Documents

Title: Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of powered air-purifying respirators. These respirators are used in a variety of workplace applications, including emergency response activities.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 651; 30 USC 3; 30 USC 7; 30 USC 11; 30 USC 842; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA24

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins

Abstract: The biological agents and toxins listed in section 73.3 of title 42 of the Code of Federal Regulations have been determined by the Secretary of the U.S. Department of Health and Human Services (HHS) to have the potential to pose a severe threat to public health and safety. On October 20, 2005, we published in the Federal Register an interim final rule adding the reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the list of HHS select agents and toxins. Based on public comments we received, we are proposing to revise the entry for the 1918 pandemic influenza virus from “reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments” to “Chimeric influenza viruses containing gene segments from the 1918 pandemic influenza strain.” We are also proposing to add SARS-associated coronavirus (SARS-CoV) to the list of HHS select agents and toxins. We are proposing this action because SARS-CoV (1) causes significant mortality, especially in the elderly; (2) has the capability of easily being transmitted from human to human; (3) there is currently no method to treat or prevent infections caused by the SARS-CoV virus; and (4) it has been documented that the virus may persist in the environment.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action

Major: Undetermined Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: No Federalism: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA25

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins--Biennial Review
Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, subtitle A of Public Law 107-188 (42 U.S.C. 262a), requires the HHS Secretary to establish by regulation a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

Priority: Economically Significant Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/28/2007	72 FR 166
NPRM Comment Period End	10/29/2007	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: No Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA30

View Related Documents

Title: Possessions, Use, and Transfer of Select Agents and Toxins--Pandemic Influenza
Abstract: The biological agents and toxins listed in section 73.3 of title 42 of the Code of Federal Regulations have been

determined by the Secretary of the U.S. Department of Health and Human Services (HHS) to have the potential to pose a severe threat to public health and safety. On October 20, 2005, we published in the Federal Register an interim final rule adding the reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the list of HHS select agents and toxins. Based on public comments we received, we are proposing to revise the entry for the 1918 pandemic influenza virus from "reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments" to "Chimeric influenza viruses containing gene segments from the 1918 pandemic influenza strain.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0920-AA09
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA31

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins (Sars-CoV)

Abstract: The biological agents and toxins listed in section 73.3 of title 42 of the Code of Federal Regulations have been determined by the Secretary of the U.S. Department of Health and Human Services (HHS) to have the potential to pose a severe threat to public health and safety. We are also proposing to add SARS-associated coronavirus (SARS-CoV) of HHS select agents and toxins. We are proposing this action because SARS-CoV (1) causes significant mortality, especially in the elderly; (2) has the capability of easily to transmit from human to human; (3) there is currently no method to treat or prevent infections caused by the SARS-CoV virus; and (4) it has been documented that the virus persists in the environment.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Robbin Weyant Department of Health and Human Services
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA32

View Related Documents

Title: Possession, Use and Transfer of Select Agents and Toxins

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: 1) the effect on human health as a reuslt of exposure to the agent or toxin, 2) the degree of contagiousness of the agent or toxin, 3) the methods by which the agent or toxin is transferred to humans, 4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent andy illness resulting from infection by the agent or toxin, and 5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA53

View Related Documents

Title: Amendment of Regulation of the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors; Request for Comments

Abstract: On behalf of the Department of Health and Human Services (HHS) and the Public Health Service (PHS), a component of DHHS, the National Institutes of Health (NIH), proposes to issue an Advanced Notice of Proposed Rulemaking (ANPRM) to seek comments from the public on whether DHHS should amend the regulations on the Responsibility of

Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought (42 CFR part 50 subpart F) and Responsible Prospective Contractors (45 CFR part 94). The existing regulations provide standards to ensure that there is no reasonable expectation that the design, conduct, and reporting of PHS-funded research will be biased by a conflicting financial interest of an investigator. Since the regulations' publication in 1995, biomedical research has progressively become more complex, the Federal Government, PHS-funded institutions and researchers, and the private sector have increasingly interacted in an effort to meet common public health goals, and recent public scrutiny has raised the question of whether a more rigorous approach to investigator disclosure, management of conflicts, and Federal oversight is required.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 289b-1; 42 USC 299c-4
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA43

View Related Documents

Title: National Institutes of Health Loan Repayment Programs

Abstract: NIH proposes to issue a single set of regulations to govern all of its loan repayment (LRP) authorities. This action will include rescinding the current regulations at 42 CFR part 68a and at 42 CFR part 68c replaced by the new consolidated set of LRP regulations. This action will also include withdrawing the previously announced planned actions concerning NIH LRP authorities.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 68 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 288-5a; 42 USC 287c-33; 42 USC 288-1; 42 USC 288-3; 42 USC 288-5 and 288-6
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA47

View Related Documents

Title: Endowment Program

Abstract: The Director of the National Center for Minority Health and Health Disparities Research is authorized under section 485E(h)(1) of the Public Health Service Act to carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments at centers of excellence under section 736 (Public Health Service Act). NIH plans to issue implementing regulations to govern these research endowments.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 52i (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 287c-31
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA48

View Related Documents

Title: Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health

Abstract: Section 487D of the Public Health Service Act, as added by NIH Revitalization Act of 1993, creates a program offering scholarships to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for careers in professions needed by NIH. For each year of scholarship support, the recipient agrees to service (employment) after graduation, at NIH, for 1 year. Additionally, the individual agrees to at least 10 consecutive weeks of service (employment) at NIH during which the individual is attending the educational institution and receiving the NIH scholarship. The proposed new regulations will govern this program.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 68b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 288-4
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA49

View Related Documents

Title: NIH Training Grants
Abstract: NIH plans to amend the Agency's existing training grants regulations to: (1) Reflect their applicability to the training authorities set forth in sections 464W and 485F of the Public Health Service Act; (2) reflect their applicability to the National Center on Minority Health and Health Disparities (NCMHD) and Fogarty International Center (FIC) Minority Health and Health Disparities International Research Training (MHIRT) awards; and (3) reflect their applicability for grants that the National Institute of Nursing Research (NINR) makes to nonprofit institutions to provide training and instruction in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 63a (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 2421; 42 USC 285q-1; 42 USC 287c-31 and 287c-32
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA52

View Related Documents

Title: Procedures for Registration of Applicable Clinical Trials in the ClinicalTrials.gov Registry

Abstract: NIH plans to issue new regulations that will prescribe specific procedures for registering clinical trails in the expanded ClinicalTrials.gov registry, and define the information that must be provided. Required information will include descriptive information, recruitment information, location and contact information, and administrative information. The regulations will define additional information needed to comply with specific statutory requirements related to search capabilities, enforcement, posting of information related to trials of uncleared/unapproved devices, as well as to support efficient entry of valid data, link the trials in the registry database to their results, and to provide a comprehensive registry of clinical trials for the public.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 282(i)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business; Organizations
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA54

View Related Documents

Title: Reporting Results of Applicable Clinical Trials in the Clinical Trials.gov Data Bank

Abstract: The National Institutes of Health plans to issue new regulations that will prescribe specific procedures for reporting results information to the expanded ClinicalTrials.gov data bank and will define the information that must be provided to meet the requirements established in the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85). The regulations will include deadlines for reporting results informastion, procedures for requesting extensions and waivers for delaying submission, and the format for submitting results information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule

Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 282(j)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA42

View Related Documents

Title: Grants for Research Projects

Abstract: NIH proposes to amend the regulations governing grants for research projects by revising the definition of Principal Investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of principal investigator to one single individual when that more accurately reflects the management needs of a research project.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 52 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/25/2007	72 FR 34655
NPRM Comment Period End	08/24/2007	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA14

View Related Documents

Title: Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition

Abstract: This proposed rule, when finalized will modify the regulatory dispensing restrictions under 42 CFR part 8 for the drug substance buprenorphine. This medication is used to treat kersin and other opioid addiction.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 8-12 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd-2; 42 USC 300xx-23; 42 USC 300x-27(a); 42 USC 300y-11
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA10

View Related Documents

Title: Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth

Abstract: The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-310, 42 USC 290jj to 290jj-2
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/00/2001

Timetable:

Action	Date	FR Cite

NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: State
Federalism: Yes
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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA12

View Related Documents

Title: Mandatory Guidelines for the Federal Workplace Drug Testing Program

Abstract: This Final Notice addressed the collection and testing of urine specimens, the requirements for the certification of Instrumented Initial Test Facilities (IITFs), and the role of and standards for collectors and Medical Review Officers (MROs). Additional notices of Proposed Revisions to the Mandatory Guidelines addressing the use of point of collection testing (POCT), oral fluid testing, sweat patch testing, hair testing, and associated issues will be published at a later date. With regard to the use of alternative specimens including hair, oral fluid, and sweat patch specimens in Federal Workplace Drug Testing Programs, significant issues have been raised by Federal agencies during the review process which require further examination, and may require additional study and analysis. As part of the review process for these alternative tests, the Department plans to issue a notice in the Federal Register requesting information and assistance from the general public to provide or identify data and research findings that address specific areas of interest.

Priority: Other Significant Agenda Stage of Rulemaking: Completed Action
Major: No Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 100-71; 5 USC 7301
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		12/00/2003

Timetable:

Action	Date	FR Cite
Notice	04/13/2004	69 FR 19673
Final Action	11/25/2008	73 FR 71858
Correction	12/10/2008	73 FR 75122

Regulatory Flexibility Analysis Required: No Government Levels Affected: Federal
Small Entities Affected: No Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP65

View Related Documents

Title: HIPPA Mental Health Parity and Addiction Equity Act of 2008 Request for Information (CMS-4140-NC)

Abstract: Regulations are necessary to implement statutory changes to the Public Health Services Act (PHSA) affecting the group health insurance markets and non-federal governmental plans, made by the Mental Health Parity and Addiction Equity Act of 2008 (Pub. L. 110- 343). Information received from this notice will assist in the development of an interim final rule that statute requires be published by October 3, 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 146 136 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Mental Health Parity and Addication Equity Act of 2008 (P.L.110-343)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Interim final regulation	10/03/2009

Timetable:

Action	Date	FR Cite
ANPRM	04/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP39

View Related Documents

Title: Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2010 (CMS-1406-P)

Abstract: This major rule proposes to revise the Medicare hospital inpatient and Long Term Care prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 1886(d) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/01/2009
Other	Statutory		08/01/2009

Regulatory Plan:

Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:

Timetable:

Action	Date	FR Cite
NPRM	04/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal

Federalism: No

Energy Affected: No

Related RINs: Related to 0938-AP32; Related to 0938-AP63

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP40

View Related Documents

Title: Revisions to Payment Policies Under the Physician Fee Schedule For CY 2010 (CMS-1413-P)

Abstract: This major proposed rule would revise payment polices under the physician fee schedule, as well as other policy changes to payment under Part B.

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule

Major: Yes Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Regulatory Plan:

Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:

Timetable:

Action	Date	FR Cite
NPRM	06/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal

Federalism: Undetermined

Energy Affected: Undetermined

Related RINs: Related to 0938-AN04

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP41

View Related Documents

Title: Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-P)

Abstract: This major rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also proposes changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1 annually.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 42 CFR 410; 42 CFR 410 to 413; 42 CFR 416; 42 CFR 419 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: BBA; PPRA; BIPA; MMA; MMSEA; MIPPA; DRA; TRHCA

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Regulatory Plan:

Statement of Need:

Legal Basis:

Alternatives:

Costs and Benefits:

Risks:

Timetable:

Action	Date	FR Cite
NPRM	06/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: Yes
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP45

View Related Documents

Title: Hospice Wage Index for FY 2010 (CMS-1420-F)
Abstract: This major rule announces the annual update to the hospice wage index for FY 2010. The wage index is used to reflect local differences in wage levels.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 418 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1814(i)(1) and 1814(i)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2009

Timetable:

Action	Date	FR Cite
NPRM	04/24/2009	74 FR 18911
NPRM Comment Period End	06/22/2009	
Final Action	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP46

View Related Documents

Title: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-P)
Abstract: This major rule proposes updates to the payment rates used under the SNF PPS beginning October 1, 2009.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 413,409, and 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1888(e)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/31/2009

Timetable:

Action	Date	FR Cite
NPRM	05/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP53

View Related Documents

Title: Children's Health Insurance Program (CHIP); Redistribution of FY 2006 Unexpended SCHIP Funds and Children's Health Insurance Program Reauthorization Act (CHIPRA) Allotment Procedures(CMS-2291-P)

Abstract: This proposed rule announces the procedure for redistribution of States' unexpended funds to those States that fully expended the SCHIP allotment. The redistributed allotments will only be available through the end of FY 2010. This rule also includes allotment provisions of the Children's Health Insurance Program Reauthorization Act of 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 457.600 to 457.630 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); secs 2104(e) and 2104(f) of the Social Security Act; CHIPRA of 2009 (Pub.L. No: 111-3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
NPRM	07/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: Undetermined
Related RINs: Related to 0938-AP54
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Department of Health and Human Services (HHS)

Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP55

View Related Documents

Title: Home Health Prospective Payment System Refinements and Rate Update for CY 2010 (CMS-1560-P)

Abstract: This major proposed rule would update the 60-day national episode rate and the national per visit rate amounts under the Medicare Prospective Payment System for home health agencies, effective January 1, 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No

CFR Citation: 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 42 USC 1395(hh); Social Security Act, sec 1895; 42 USC 1395(fff)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Timetable:

Action	Date	FR Cite
NPRM	07/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP56

View Related Documents

Title: Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2010 (CMS-1538-P)

Abstract: This proposed major rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No

CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, sec 1886(j); PL 106-554; PL 106-113

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2009

Timetable:

Action	Date	FR Cite
NPRM	04/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP57

View Related Documents

Title: ESRD Bundled Payment System (CMS-1418-P)
Abstract: This major rule proposes to implement a bundled payment system for ESRD facilities by January 1, 2011, as required by section 153 of MIPAA.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 153 of MIPPA; sec 1881(b) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2011

Timetable:

Action	Date	FR Cite
NPRM	07/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP68

View Related Documents

Title: Implementing Regulations for Reauthorization of the Children's Health Insurance Program (CHIP) (CMS-2301-P)
Abstract: This proposed rule would reauthorize the Children's Health Insurance Program (CHIP) and introduce several new features as a result of the passage of the Children's Health Insurance Program Reauthorization Act of 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: CHIPRA of 2009 (Pub.L. No: 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
Energy Affected: Undetermined
Related RINs: Related to 0938-AP54

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP69

View Related Documents

Title: Children's Health Insurance Program PERM Requirements (CMS-6150-P)

Abstract: Under the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), this rule would establish Payment Error Rate Measurement (PERM) requirements and include information regarding PERM measurement. In addition, this proposed rule would establish state-specific sample sizes beginning in FY 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: CHIPRA of 2009 (Pub.L. No: 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP70

View Related Documents

Title: Extension of Transitional Medical Assistance and Protections for Indians Under the American Recovery and Reinvestment Act of 2009 (CMS-2475-P)

Abstract: This proposed rule would extend the Transitional Medical Assistance (TMA) program through December 31, 2010 as a result of the American Recovery and Reinvestment Act of 2009. This rule would also establish protections for Indians under the Medicaid and CLIA programs.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: American Recovery and Reinvestment Act of 2009 (PL No: 111-5)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State; Tribal
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP71

View Related Documents

Title: Children's Health Insurance Program Reauthorization Act (CHIPRA) Child Enrollment Contingency Fund (CMS-2488-P)

Abstract: This proposed rule would establish the "CHIP contingency fund" to eliminate State shortfalls in funding beginning in FY 2009 as a result of the Children's Health Insurance Program Reauthorization Act of 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. No: 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: State
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AM73

View Related Documents

Title: Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)

Abstract: This final rule revises the Medicare appeals process by adding five levels of review. It will remove the distinction between the processing of initial determinations and appeals under part A and part B required by section 521 of Benefits Improvement and Protection Act of 2000 (BIPA).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 401 and 405 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1869 (b) of the Act, as amended by sec 521 of BIPA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec 902.	03/08/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/08/2005	70 FR 11419
Second Interim Final Rule	06/30/2005	70 FR 37700
Third Interim Final Rule	08/26/2005	70 FR 50214
Notice	02/29/2008	73 FR 11043
Second Notice	02/27/2009	74 FR 8867
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AK69
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN42

View Related Documents

Title: Limitation on Recoupment of Provider and Supplier Overpayments (CMS-6025-F)

Abstract: This rule implements one provision of section 935 of the Medicare Prescription Drug Improvement and

Modernization Act, which added a new subsection to section 1893 of the Social Security Act. It adjusts Medicare's ability to recover an overpayment when the Qualified Independent Contractor (QIC) receives a valid appeal from the provider or supplier. This rule defines the overpayments to which the limitation applies, how the limitation works in concert with the appeals process, and the change in Medicare's obligation to pay interest to a provider or supplier whose appeal is successful at levels above the QIC.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 405 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1893(f)(2) of the Social Security Act added by sec 935 of the MMA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	09/22/2009

Timetable:

Action	Date	FR Cite
NPRM	09/22/2006	71 FR 55404
NPRM Comment Period End	11/21/2006	
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP37

View Related Documents

Title: Genetic Information Nondiscrimination Act of 2008 (CMS-4137-IFC)
Abstract: Regulations are necessary to implement statutory changes to the PHSA affecting the group and individual health insurance markets, non-federal governmental plans, and Medicare supplemental insurance (Medigap) made by the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-223).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 144.103; 45 CFR 146.121; 45 CFR 146.180; 45 CFR 148.120; 45 CFR 148.128; 45 CFR 148.210; 45 CFR 150.130; 45 CFR 150.301 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Genetic information Nondiscrimination Act of 2008 (PL 110-223), enacted May 21, 2008.
Legal Deadline: The statue requires regulations be issued 12 months after enactment, which was May 21, 2008, by the 3 agencies with shared jurisdiction-HHS, Treasury and Labor.

Action	Source	Description	Date
Other	Statutory	Interim final regulation	05/21/2009

Timetable:

Action	Date	FR Cite
ANPRM	10/10/2008	73 FR 60208
ANPRM Comment Period End	12/09/2008	
Interim Final Rule	05/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP42

View Related Documents

Title: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2010 (CMS-8037-N)

Abstract: This major notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2010 under Medicare's Hospital Insurance program (Medicare part A). The Medicare statute specifies the formulae used to determine these amounts.

Priority: Other Significant

Agenda Stage of Rulemaking: Final Rule

Major: Yes

Unfunded Mandates: No

CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1395e-2(b)(2); Social Security Act, sec 1813 (b)(2)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/15/2009

Timetable:

Action	Date	FR Cite
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Small Entities Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP43

View Related Documents

Title: Part A Premiums for CY 2010 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8038-N)

Abstract: This notice announces the Hospital Insurance premium for calendar year 2010 under Medicare's Hospital Insurance

program (Medicare part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A(d)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP48

View Related Documents

Title: Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2010 (CMS-8039-N)
Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in part B of Medicare for CY 2010. It also announces the monthly part B premiums and the part B deductible during CY 2010.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395r; Social Security Act, sec 1839; MMA, sec 629; MMA, sec 811; DRA, sec 5111; ...
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP50

View Related Documents

Title: Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2009 (RY 2010) (CMS-1495-NC)

Abstract: This notice with comment period is necessary in order to update the rates for Inpatient Psychiatric Facilities with discharges occurring during July 1, 2009 through June 30, 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412.400, subpart N (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-113, sec 124 BBRA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/01/2009

Timetable:

Action	Date	FR Cite
Final Action	05/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP66

View Related Documents

Title: Final and Preliminary Fiscal Year Disproportionate Share Hospital Allotments and Disproportionate Share Hospital Institutions for Mental Disease Limits (CMS-2300-N)

Abstract: This nonmajor final notice sets forth the States' final and preliminary fiscal year disproportionate share hospital (DSH) payment allotments and States' institutions for mental disease (IMD) DSH limits in the Medicaid program. This notice also announces provisions of the American Recovery and Reinvestment Act, which revises DSH allotments and extends the Qualifying Individual (QI) program.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Title XIX of the Social Security Act, sec 1923(f) and (h); American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Detemination of Fiscal year DSH allotment and IMD DSH Limits	09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	11/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
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Government Levels Affected: State
Federalism: No

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP67

View Related Documents

Title: Multiple Source Drug Definition Amendment (CMS-2238-F2)

Abstract: This rule amends provisions published in the October 7, 2008 final rule. It also responds to additional public comments received on the March 14, 2008 interim final rule with comment period.

Priority: Other Significant
Major: No
CFR Citation: 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
Final Action	06/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Related RINs: Related to 0938-AP26
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Government Levels Affected: State
Federalism: No

Department of Health and Human Services (HHS)

Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP72

View Related Documents

Title: State Flexibility for Medicaid Benefit Packages; Delay of Effective Date (CMS-2232-IFC)

Abstract: This rule makes changes to the final rule published on December 3, 2008 that revised the coverage of medical assistance under approved State plans. It provided States increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid recipients.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 440 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6044
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/31/2006

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AO48

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP73

View Related Documents

Title: Premiums and Cost Sharing--Delay of Effective Date (CMS-2244-IFC)

Abstract: This rule makes changes to the final rule published on November 25, 2008 that provided State Medicaid agencies with increased flexibility to implement premium and cost sharing requirements for certain Medicaid recipients. This authority is in addition to the current authority States already had under the Social Security Act to implement premiums and cost sharing.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 447; 42 CFR 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6041 and 6042; PL 109-432, sec 6043; PL 111-5
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/31/2006
Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: Yes
Related RINs: Related to 0938-AO47
Government Levels Affected: State
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AG81

View Related Documents

Title: Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)

Abstract: This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No
CFR Citation: 42 CFR 409, 42 CFR 418, 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Second NPRM	00/00/0000	
NPRM	03/10/1997	62 FR 11005
NPRM Comment Period End	06/09/1997	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Business; Organizations
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AJ17

View Related Documents

Title: MedicChanges in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers (CMS-1910-F2)

Abstract: This nonmajor final rule reissues the final rule published December 24, 2003, with modifications. This final rule amends the Medicare certification and payment requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997. It changes the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establishes criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated medically underserved; and limits nonphysician practitioner staffing requirements. This rule imposes payment limits on provider-based RHCs and prohibits the use of RHC space, professional staff, equipment, and other RHC resources by another Medicare entity. The rule also requires RHCs to establish a quality assessment and performance improvement program. In addition, we are finalizing new policy revisions to the RHC and FQHC programs to improve and strengthen this rural safety net benefit that addresses section 5114 of the Deficit Reduction Act of 2005.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 405; 42 CFR 491 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh; Deficit Reduction Act of 2005 (PL 109-171), sec 6083
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	06/27/2011

Timetable:

Action	Date	FR Cite
NPRM	12/24/2003	68 FR 74792
Interim Final Rule	09/22/2006	71 FR 55341
Interim Final Rule Comment Period End	11/21/2006	
Second NPRM	06/27/2008	73 FR 36463
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AJ96

View Related Documents

Title: Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)

Abstract: This final rule addresses standards of practice that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints (including psychoactive drugs) and seclusion.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 441 and 442; 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1396d
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	01/22/2001	66 FR 7148
Interim Final Rule Effective	03/23/2001	
Interim Final Rule Comment Period End	03/23/2001	
60-Day Delay of Effective Date to 05/22/2001	03/21/2001	66 FR 15800
Interim Final Rule Amendment with Clarification	05/22/2001	66 FR 28110
Interim Final Rule Comment Period End	07/23/2001	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AK62

View Related Documents

Title: Electronic Claims Attachments Standards (CMS-0050-IFC)

Abstract: This rule sets forth electronic standards for health care claims attachments. The standards are required by the Health Insurance Portability and Accountability Act of 1996. They will be used to transmit clinical or administrative data for claims adjudication purposes.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments
CFR Citation: 45 CFR 162 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320d-2(a)(2)(B)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		02/21/1999

Timetable:

Action	Date	FR Cite
Interim Final Rule	00/00/0000	
NPRM	09/23/2005	70 FR 55989

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: Yes
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AL26

View Related Documents

Title: Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)

Abstract: This proposed rule would implement provisions of the Children's Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 101; 42 CFR 418; 42 CFR 482 and 483; 42 CFR 485 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-554 (BIPA 2000 of the Children's Health Act)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AL88

View Related Documents

Title: Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)

Abstract: This final rule will clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. It also implements changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 300gg; PL 104-191
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	12/30/2004	69 FR 78800

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business; Organizations
Energy Affected: No
Government Levels Affected: Federal; Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN73

View Related Documents

Title: Revisions to the Requirements for Quality Improvement Organizations (CMS-3156-P)

Abstract: This proposed rule would revise existing regulations that govern Quality Improvement Organizations responsibilities under the Medicare program. These revisions are required by the Medicare, Medicaid, and Benefits Improvement and Protection Act of 2000 (BIPA); recommendations from the Institute of Medicine and the Government Accountability Office; Agency initiatives related to Health Information Technology, Prevention, and beneficiary centeredness; and to improve program efficiencies. The proposed rule will also add to existing regulations certain established Medicare policies that currently are available only in policy memoranda and payment requirements.

Priority: Other Significant
Major: Undetermined
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1154 to 1160 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO07

View Related Documents

Title: Payments for Service Provided Without Charge (Free Care) (CMS-2489-P)

Abstract: The proposed rule would clarify that Federal Financial Participation (FFP) is not available to States on behalf of Medicaid beneficiaries for Medicaid-covered services provided without charge (that is, free care) to individuals receiving the services. Free care means a particular service is available without charge to an individual who receives the service or to any third party on behalf of the individual.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447 and 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: None
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Governmental Jurisdictions
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO10

View Related Documents

Title: Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)

Abstract: This is a nonmajor proposed rule. In order to provide health services to employed individuals whose medical conditions have improved to the point where they are no longer eligible for disability benefits, this proposed rule would provide a definition of "medically determinable severe impairment" under the Ticket to Work and Work Incentives Improvement Act of 1999 (Ticket to Work). Under this definition, States can determine eligibility standards for the Medical Improvement Group authorized under the Ticket to Work law, thereby permitting individuals to retain their Medicaid coverage. Additionally, this proposed rule would give States offering Medicaid buy-in programs for employed individuals with disabilities the option of selecting a minimum work standard for participation.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 435 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 105-33, sec 4733 Balanced Budget Act of 1997; PL 106-170, sec 201 Ticket to Work and Work Incentives Improvement Act of 1999
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: State
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO34

View Related Documents

Title: Cytology Proficiency Testing (CMS-2252-F)

Abstract: This rule revises certain Clinical Laboratory Improvement Amendments (CLIA) of 1988 proficiency testing requirements for clinical laboratories offering cytology services and individuals examining gynecological cytology specimens. Revisions are also made to CMS approval requirements for programs offering proficiency testing for gynecologic cytology under (CLIA) of 1988 program. Evaluating the competency of each individual who examines gynecologic cytology specimens (pap smears) is required by Federal law and regulations. Identifying these individuals is essential in providing quality patient care.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No

CFR Citation: 42 CFR 493 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 263a, Clinical Laboratory Improvement Amendments of 1988; 42 USC 1395x, secs 1861s(15) to 1861s(17); of the Social Security Act

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	01/16/2012

Timetable:

Action	Date	FR Cite
NPRM	01/16/2009	74 FR 3264
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO50

View Related Documents

Title: Targeted Case Management (CMS-2237-F)

Abstract: This final rule revises current Medicaid regulations to incorporate changes made by section 6052 of the Deficit Reduction Act of 2005. In addition, it incorporates provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, the Omnibus Budget Reconciliation Act of 1986, the Tax Reform Act of 1986, the Omnibus Budget Reconciliation Act of 1987, and the Technical and Miscellaneous Revenue Act of 1988, concerning case management and targeted case management services. This final rule will provide for optional coverage of case management services or targeted case management services furnished according to section 1905(a)(19) and section 1915(g) of the Social Security Act. This final rule clarifies what Medicaid will pay for case management activities, when payment will not be consistent with proper and efficient operation of the Medicaid program, and when payment is not available.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 431, 42 CFR 440 to 441 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6052
Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extends the moratorium to March 31, 2009. Public Law 111-5 extends moratorium to June 30, 2009.

Action	Source	Description	Date
Other	Statutory		01/01/2006

Timetable:

Action	Date	FR Cite
Interim Final Rule	00/00/0000	
Final Action	12/04/2007	72 FR 68077

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Governmental Jurisdictions
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO53

View Related Documents

Title: Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F)

Abstract: This major rule amends the Medicaid regulations to define and describe the home- and community-based State plan services implementing the new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 431; 42 CFR 440 and 441 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6086
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	04/04/2008	73 FR 18676
NPRM Comment Period End	06/03/2008	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions

Government Levels Affected: State

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO81

View Related Documents

Title: Rehabilitation Services: State Plan Option (CMS-2261-F)

Abstract: This major rule amends the definition of Medicaid rehabilitative services in order to provide for important beneficiary protections such as a person-centered written rehabilitation plan and maintenance of case records. The rule also ensures the fiscal integrity of claimed Medicaid expenditures by clarifying the service definition and providing that Medicaid rehabilitative services must be coordinated with, but do not include services furnished by, other programs that are focused on social or educational development goals and are available as part of other services or programs. These services and programs include, but are not limited to, foster care, child welfare, education, child care, prevocational and vocational services, housing, parole and probation, juvenile justice, public guardianship, and any other non-Medicaid services from Federal, State, or local programs.

Priority: Economically Significant

Agenda Stage of Rulemaking: Long-term Action

Major: Yes

Unfunded Mandates: No

CFR Citation: 42 CFR 440 to 441 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: sec 1905(a)(13) of the Social Security Act

Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extends the moratorium to March 31, 2009.

Action	Source	Description	Date
Other	Statutory		03/31/2009

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/13/2007	72 FR 45201
NPRM Comment Period End	10/12/2007	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Small Entities Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO82

View Related Documents

Title: Waiver of Disapproval of Nurse Aide Training Program in Certain Cases and Nurse Aide Petition for Removal of Information for Singular Finding of Neglect (CMS-2266-F)

Abstract: This final rule will permit a waiver of a nurse aide training disapproval as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program, that are assessed a civil money penalty of at least $5,000 for noncompliance that is not related to quality of care. This is a statutory provision enacted by section 932 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted December 8, 2003.) This rule also codifies statutory provisions at sections 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act that permit the State to establish a procedure for a nurse aide to petition the State to have a singular finding of neglect removed from the nurse aide registry.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 932 (c) (2) MMA; secs 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	11/23/2010

Timetable:

Action	Date	FR Cite
NPRM	11/23/2007	72 FR 65692
NPRM Comment Period End	12/24/2007	
Final Action	11/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO87

View Related Documents

Title: Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process (CMS-4127-F)

Abstract: This final rule will implement the procedures that the Department of Health and Human Services will follow at the Administrative Law Judge and Medicare Appeals Council levels in deciding appeals brought by individuals who have enrolled in the Medicare prescription drug benefit program. In addition, it will implement the reopening procedures that will be followed at all levels of appeal.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1102, 1860D-1 to 1860D-42, and 1871 of the Social Security Act (42 USC 1302, 1395w-101 to 1395w-152, and 1395hh)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	03/17/2011

Timetable:

Action	Date	FR Cite
NPRM	03/17/2008	73 FR 14341
NPRM Comment Period End	05/16/2008	
Final Action	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO90

View Related Documents

Title: Establishing Additional Provider and Supplier Requirements for Enrollment Standards and Related Issues (CMS-6036-F)
Abstract: This rule finalizes new standards to maintain the level of care for beneficiaries without adding increased risk of loss to the Medicare Trust Fund.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sections 1102 and 1871 of the Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	01/25/2011

Timetable:

Action	Date	FR Cite
NPRM	01/25/2008	73 FR 4503
NPRM Comment Period End	03/25/2008	
Final Action	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO91

View Related Documents

Title: Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS-3178-P)

Abstract: This rule proposes emergency preparedness requirements for a variety of providers and suppliers that participate in the Medicare and Medicaid programs, to ensure that if a natural or man-made disaster occurs, providers and suppliers can continue to meet the health care needs of their patients, residents, and clients.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO95

View Related Documents

Title: Medicaid Graduate Medical Education (CMS-2279-F)

Abstract: As part of the President's 2008 Budget, this major rule establishes that States may not include GME as a

reimbursable cost or program under their approved Medicaid State Plan. The rule enhances fiscal integrity and improves accountability with respect to payment for medical services in the Medicaid program.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 438; 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: title XIX; Social Security Act
Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extended the moratorium to March 31, 2009.

Action	Source	Description	Date
Other	Statutory		03/31/2009

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	05/23/2007	72 FR 28930
NPRM Comment Period End	06/22/2007	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP01

View Related Documents

Title: Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P)
Abstract: This proposed rule would expand existing provider and supplier enrollment requirements to obtain or maintain Medicare billing privileges.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 424.40; 42 CFR 424.44; 42 CFR 424.525 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec. 4312(a) of BBA of 1997
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP10

View Related Documents

Title: Medicare Supplemental Policies (CMS-4084-P)

Abstract: This proposed rule would outline procedures for the States and CMS to certify the Medigap policies of private issuers. This proposed rule is authorized under the Medigap program.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 403.200 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1882 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP32

View Related Documents

Title: Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)

Abstract: This proposed rule would establish requirements that long-term care (LTC) facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined

Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP52

View Related Documents

Title: Medicare Advantage and Prescription Drug Programs: MIPPA-Related Marketing Revisions (CMS-4138-F)
Abstract: This final rule revises the regulations governing the Medicare Advantage program (part C), and the prescription drug benefit program (part D).

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 417; 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395w-28(f)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	09/18/2011

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/18/2008	73 FR 54225
Interim Final Rule	11/14/2008	73 FR 67406
Interim Final Rule Comment Period End	11/17/2008	
Interim Final Rule	01/16/2009	74 FR 2881
Final Action	09/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP59

View Related Documents

Title: Limited Changes to the Competitive Acquisition of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)(CMS-1561-F)
Abstract: This final rule as mandated by section 154 of MIPPA requires the temporary delay of Round 1 of the DMEPOS

Competitive Bidding Program such that a new competition occurs excluding certain services. Section 154 of MIPPA establishes other requirements for the program such as providing a process for giving suppliers feedback on missing financial documents and mandating the disclosure of subcontractors under a competitive bidding program. Section 154 also mandates additional refinements to be implemented before phasing in future rounds of the program.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 414 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395rr(b)(1)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	01/16/2012

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/16/2009	74 FR 2873
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP64

View Related Documents

Title: Medicare Advantage and Prescription Drug Benefit Programs; Payments to Sponsors of Retiree Prescription Drug Plans (CMS-4131-F2)

Abstract: This rule codifies an interpretation of the statutory waiver provision in section 1857(i) of the Social Security Act, which permit CMS to waive provisions that would otherwise apply to Plan Sponsors participating in the Retiree Drug Subsidy (RDS) Program. Under current rules, that waiver provision applies only to Medicare Part D plans.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302,1395w-101 to 1395w-152, and 1395hh
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	01/12/2012

Timetable:

Action	Date	FR Cite
NPRM	01/12/2009	74 FR 1550
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AJ29

View Related Documents

Title: Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)

Abstract: This nonmajor final rule requires hospitals that transfuse blood and blood components to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospital received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 482 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec 902	08/24/2010

Timetable:

Action	Date	FR Cite
NPRM	11/16/2000	65 FR 69416
Interim Final Rule	08/24/2007	72 FR 48562
Interim Final Rule Comment Period End	10/23/2007	
Final Action	06/27/2008	73 FR 36469

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
Related RINs: Related to 0910-AB76

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AM50

View Related Documents

Title: Updates to Electronic Transactions (Version 5010) (CMS-0009-F)

Abstract: This rule adopts new versions of the X12 suite of HIPAA transactions and allows the industry to use the most up-to-date versions of the HIPAA transactions for claims and remittance advice. The rule will also adopt an updated pharmacy transactions standard for retail pharmacy claims.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 162 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1171 to 1179 of the Social Security Act; Deficit Reduction Act of 2005, PL 109-171, sec 6035
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/22/2008	73 FR 49741
NPRM Comment Period End	10/21/2008	
Final Action	01/16/2009	74 FR 3296

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal; Local; State; Tribal
Federalism: Yes
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AN09

View Related Documents

Title: Medicaid Disproportionate Share Hospital Payments--Auditing and Reporting Requirements (CMS-2198-F)

Abstract: This rule implements section 1001(d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, which requires States to report additional information about their disproportionate share hospital (DSH) programs in their annual report. This section also requires States to independently audit and submit these certified audits annually to the Secretary.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447; 42 CFR 455 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1923(a)(2)(D) of the Social Security Act, MMA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	sec 1001(d) of MMA.	12/08/2003

Timetable:

Action	Date	FR Cite
NPRM	08/26/2005	70 FR 50262
Final Action	12/19/2008	73 FR 77904

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN25

View Related Documents

Title: Revisions to HIPAA Code Sets (CMS-0013-F)

Abstract: This rule revises some of the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 45 CFR 160 and 162 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 104-191
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/22/2008	73 FR 49795
NPRM Comment Period End	10/21/2008	
Final Action	01/16/2009	74 FR 3328

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions; Organizations
Government Levels Affected: Federal; Local; State; Tribal
Federalism: No
Energy Affected: Yes

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO17

View Related Documents

Title: Medicaid Program; Clarification of Outpatient Hospital Facility (Including Hospital Clinic) Outpatient Services Definition (CMS-2213-F)

Abstract: This rule amends the definition of outpatient hospital services for the Medicaid program. The purpose of this amendment is to clarify the scope of services available for Federal financial participation (FFP) under the outpatient hospital services benefit category.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No

CFR Citation: 42 CFR 440.20 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1102 of the Social Security Act
Legal Deadline: PL 111-5 established moratorium on rule until June 30, 2009.

Action	Source	Description	Date
Other	Statutory		06/30/2009

Timetable:

Action	Date	FR Cite
NPRM	09/28/2007	72 FR 55158
Final Action	11/07/2008	73 FR 66187

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO45

View Related Documents

Title: State Option To Establish Non-Emergency Medical Transportation Program (CMS-2234-F)

Abstract: Enactment of section 6083 of the Deficit Reduction Act of 2005 (DRA) amends section 1902(a) of the Social Security Act (the Act) by adding a new section 1902(a)(70) that provides States with the ability to establish, under the State plan, a non-emergency medical transportation (NEMT) brokerage program. Such a program may be managed through a contract with a broker(s) as a method of assuring NEMT services for beneficiaries who need access to medical care but have no other means of transportation.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 440 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005 (PL 109-171), sec 6083
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		02/08/2006

Timetable:

Action	Date	FR Cite
NPRM	08/24/2007	72 FR 48604
Final Action	12/19/2008	73 FR 77519

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO47

View Related Documents

Title: Premiums and Cost Sharing (CMS-2244-F)

Abstract: This rule incorporates sections 6041, 6042, and 6043 of the Deficit Reduction Act of 2005 (DRA), which provide State Medicaid agencies with increased flexibility to implement premium and cost sharing requirements for certain Medicaid recipients. This authority is in addition to the current authority States already had under section 1916 of the Social Security Act to implement premiums and cost sharing.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No

CFR Citation: 42 CFR 447; 42 CFR 457 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Deficit Reduction Act of 2005; PL 109-171; secs 6041 to 6043; Tax Relief and Health Care Act of 2006; PL 109-432, sec 405(a)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	secs 6041 and 6042.	03/31/2006
Other	Statutory	sec 6043.	01/01/2007

Timetable:

Action	Date	FR Cite
NPRM	02/22/2008	73 FR 9727
NPRM Comment Period End	03/24/2008	
Final Action	11/25/2008	73 FR 71828

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: Yes

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO48

View Related Documents

Title: State Flexibility for Medicaid Benefit Packages (CMS-2232-F)

Abstract: This rule implements provisions of section 6044 of the Deficit Reduction Act of 2005, which amends the Social Security Act by adding a new section related to the coverage of medical assistance under approved State plans. Under this new section, States have increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid recipients.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No

CFR Citation: 42 CFR 440.300; 440.385 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; sec 6044; sec 1102 of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/31/2006

Timetable:

Action	Date	FR Cite
NPRM	02/22/2008	73 FR 9714
NPRM Comment Period End	03/24/2008	
Final Action	12/03/2008	73 FR 73694

Regulatory Flexibility Analysis Required: No Government Levels Affected: State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO84

View Related Documents

Title: Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F)
Abstract: This rule implements section 4312(a) of the Balanced Budget Act of 1997, which requires a Medicare supplier of durable medical equipment (DME) to furnish CMS with a surety bond.

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 424.57 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 4312(a) of BBA of 1997
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec. 902.	08/01/2010

Timetable:

Action	Date	FR Cite
NPRM	08/01/2007	72 FR 42001
NPRM Comment Period End	10/01/2007	
Final Action	01/02/2009	74 FR 166

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO86

View Related Documents

Title: Changes To Ensure Effective and Efficient Operations of Medicaid and the State Children's Health Insurance Program (SCHIP) (CMS-2148-P)

Abstract: The proposed rule would amend Medicaid regulations by revising the definition of "optional targeted low-income child" to exclude children eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency, children who are inmates of a public institution, and children who are patients in an institution for mental diseases.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 457.1010; 42 CFR 457.310 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	11/07/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP09

View Related Documents

Title: Fiscal Year Disproportionate Share Hospital Allotments and Disproportionate Share Hospital Institutions for Mental Disease Limits (CMS-2274-N)

Abstract: This notice sets forth the States' final fiscal year (FY) 2007, preliminary FY 2008, and preliminary FY 2009 disproportionate share hospital (DSH) payment allotments and States' institutions for mental disease (IMD) DSH limits in the Medicaid program.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, secs 1923(f) and 1923(h)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Determination of Fiscal Year DSH Allotment and IMD DSH Limits	09/30/2008

Timetable:

Action	Date	FR Cite
Notice	12/19/2008	73 FR 77704

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP17

View Related Documents

Title: Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-F)

Abstract: This rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from continuing experience with this system and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1 annually.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No

CFR Citation: 42 CFR 410 to 413; 42 CFR 416; 42 CFR 419; 42 CFR 482; 42 CFR 485 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: BBA; PPRA; BIPA; MMA; 42 USC 1302 et al

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2008

Timetable:

Action	Date	FR Cite
NPRM	07/18/2008	73 FR 41416
NPRM Comment Period End	09/02/2008	
Final Action	11/18/2008	73 FR 68501

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AL80

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP18

View Related Documents

Title: Revisions to Payment Policies Under the Physician Fee Schedule for CY 2009 (CMS-1403-FC)

Abstract: This major rule makes changes affecting Medicare Part B payment to physicians and other Part B suppliers.

Priority: Economically Significant

Agenda Stage of Rulemaking: Completed Action

Major: Yes

Unfunded Mandates: State, Local, Or Tribal Governments; Private Sector

CFR Citation: 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2008

Timetable:

Action	Date	FR Cite
NPRM	07/07/2008	73 FR 38502
NPRM Comment Period End	08/29/2008	
Final Action	11/19/2008	73 FR 69725

Regulatory Flexibility Analysis Required: Governmental Jurisdictions

Government Levels Affected: Federal

Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP20

View Related Documents

Title: Home Health Prospective Payment System Refinements and Rate Update for CY 2009 (CMS-1555-N)

Abstract: Section 1895 of the Act requires that the Home Health PPS be adjusted in a prospective manner specified by the Secretary by the home health increase percentage applicable to the year involved.

Priority: Other Significant

Agenda Stage of Rulemaking: Completed Action

Major: Yes

Unfunded Mandates: No

CFR Citation: 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, secs 1102 and 1871; (42 USC 1302 and 1395(hh)); Social Security Act, sec 1895 (42 USC 1395fff)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2008

Timetable:

Action	Date	FR Cite
Notice	11/03/2008	73 FR 65351

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP24

View Related Documents

Title: Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Programs (CMS-4131-FC)

Abstract: This rule codifies guidance and makes changes related to the Medicare Advantage and Prescription Drug Benefit Programs. The rule codifies guidance for special needs plans and medical savings accounts (MA program), clarifies the prescription drug bidding and novation processes, and clarifies the enrollment, appeals, and marketing processes for both programs.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments; Private Sector

CFR Citation: 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: MMA (PL 108-173)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/16/2008	73 FR 28556
NPRM Comment Period End	07/15/2008	
Final Action	09/15/2008	73 FR 54207
Second Final Action	01/12/2009	74 FR 1494

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP33

View Related Documents

Title: Changes to Long-Term Care Prospective Payment System Based on Specific Provisions in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (CMS-1493-F)

Abstract: This rule implements provisions of the Medicare, Medicaid, and SCHIP Extension Act of 2007 relating to long-term care hospitals. In addition to amending section 1861 of the Act with a new definition of LTCHs, this rule includes provisions that are effective on the date of enactment (December 29, 2007). Specifically, the statute imposes a 3-year delay in implementation of certain payment policies that set percentage thresholds for LTCH patients admitted from certain referring hospitals and raises the percentage threshold for those LTCHs unaffected by the 3-year delay. The legislation imposes the same 3-year delay on the implementation of a particular payment adjustment for short-stay patients and also for the possible application of a one-time adjustment to the standard Federal rate. The statute also required a change in the Federal rate for RY 2008, (effective April 1, 2008). Additionally, the statute created a 3-year moratorium on the establishment of new LTCHs and LTCH satellites and on bed expansion in existing LTCHs, subject to significant exceptions.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No

CFR Citation: 42 CFR 412.500; 42 CFR 412.523; 42 CFR 412.529; 42 CFR 412.534; 42 CFR 412.536 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Provisions of sec 114 of PL 110-173 (MMSE Act of 2007); sec 1886(d) of the Social Security Act as amended by sec 114 of PL 110-173 (MMSE Act of 2007)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Some provisions implemented upon enactment (12/29/2007)	12/00/2007

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/06/2008	73 FR 24871
Interim Final Rule	05/22/2008	73 FR 29699
Withdrawn	01/29/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AO94; Merge with 0938-AP39

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP38

View Related Documents

Title: State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals Federal Fiscal Year 2008 (CMS-2290-IFC)

Abstract: This interim final rule with comment period sets forth the methodology and process used to compute and issue each State's preliminary allotment for the first three quarters of fiscal year FY 2008, that is available to pay the Medicare part B

premiums for qualifying individuals; it revises the existing regulations to conform them with the continued funding of this program; and, finally, it provides the preliminary allotments for the first three quarters of FY 2008, determined in accordance with the methodology and process.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 433 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/24/2008	73 FR 70886

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP54

View Related Documents

Title: Fiscal Year 2010 SCHIP Allotments (CMS-2289-N)

Abstract: This notice sets forth the final allotments of Federal fuding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year 2010.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: title XXI of the Social Security Act, sec 2104; CHIPRA of 2009 (Pub.L. No: 111-3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Withdrawn	04/17/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Merge with 0938-AP53

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Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS) RIN: 0940-AA01

View Related Documents

Title: Public Health Service Standards for the Protection of Research Misconduct Whistleblowers

Abstract: To implement section 493(e) of the Public Health Service Act (added by sec. 163 of the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: 1) Persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to an allegation of research misconduct; and 2) persons who cooperate in good faith with an investigation of research misconduct.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 289b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/28/2000	65 FR 70830
NPRM Comment Period End	01/29/2001	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Related to 0940-AA04

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Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS) RIN: 0940-AA06

View Related Documents

Title: Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements

Abstract: This notice of proposed rulemaking proposes to add subpart F to Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, to require registration of institutional review boards (IRBs) with HHS. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for the Office for Human Research Protections (OHRP) to convey information to IRBs, and will support the current IRB registration operated by OHRP. Under the current OHRP IRB registration system, the submission of certain registration information is required by human subjects protection regulations, and certain other information may be submitted voluntarily. This proposed information collection was submitted to the Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single

HHS IRB Registration system. FDA simultaneously published a proposed rule regarding FDA IRB registration requirements.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 46 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 301; 42 USC 289
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/04/2004	69 FR 40584
NPRM Comment Period End	10/04/2004	
Final Action	01/15/2009	74 FR 2399

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC35

View Related Documents

Title: Target Population and Conversion
Abstract: This proposed rule will address provisions from the Improving Head Start for School Readiness Act of 2007, (Pub. L. 110-134) allowing grantees to request conversion of Head Start slots to serve additional infant and toddler age children upon application, and align Head Start program regulations with new requirements affecting children with disabilities. This rule also would address policies and procedures for removing barriers from serving homeless children and make conforming changes to reflect Public Law 110-134.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1301; 45 CFR 1305 and 1306; 45 CFR 1308 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC43

View Related Documents

Title: Performance Standards for Runaway and Homeless Youth Grantees

Abstract: This rule would implement section 8 of the Reconnecting Homeless Youth Act requiring the Secretary of Health and Human Services to issue rules that specify performance standards for public and nonprofit private entities that receive grants under the Runaway and Homeless Youth Program.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1351 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Reconnecting Homeless Youth Act, PL 110-378
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Statutory	10/08/2009

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: Organizations
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC44

View Related Documents

Title: Recompetition of Head Start Grantees

Abstract: This rule would implement provisions of the Improving Head Start for School Readiness Act of 2007, (Pub. L. 110-134) requiring the Secretary to develop a system that will evaluate each grantee's performance every five years to determine which grantees are providing services of such high quality that they should be given another five year grant and need not recompete for a continuation of their Head Start grant.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: S/B Improving Head Start for School Readiness Act of 2007, PL 110-134
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC32

View Related Documents

Title: Computerized Tribal IV-D System and Office Automation

Abstract: This rule would amend the Federal child support regulation by adding a new part 310, Computerized Tribal IV-D System and Office Automation. The rule would set forth the conditions for Federal funding and requirements governing computerized Tribal IV-D system and office automation.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 104-193
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/11/2008	73 FR 33048
NPRM Comment Period End	08/11/2008	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Tribal
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC40

View Related Documents

Title: Use of TANF Funds Carried Over From Prior Year

Abstract: This rule would implement section 2103 of the American Recovery and Reinvestment Act of 2009 to provide that a State or Tribe may use reserve Temporary Assistance for Needy Families (TANF) grant funds for any benefit or service activity under the TANF program.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 263 and 286 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: American Recovery and Reinvestment Act of 2009
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: Local; State; Tribal
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC41

View Related Documents

Title: Tribal Child Welfare

Abstract: This rule would implement title III, Tribal Foster Care and Adoption Access, of the Fostering Connections to Success and Increasing Adoptions Act of 2008 (the Act). Under section 301 of that Act, the Secretary is required to promulgate interim final regulations to carry out the title III provisions, including providing for transfer of responsibility for the placement and care of a child under a State plan approved under section 471 of the Social Security Act to a tribal plan. This rule also will address in-kind expenditures from third-party sources for purposes of determining the non-Federal share of administrative and training expenditures as required in section 301 of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1355, 1356 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Fostering Connections to Success and Increasing Adoptions Act of 2008
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Statutory	10/09/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: State; Tribal
Federalism: No

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Department of Health and Human Services (HHS)

Administration for Children and Families (ACF) RIN: 0970-AC28

View Related Documents

Title: Limitation on Use of Funds Made Available To Monitor and Combat Trafficking In Persons

Abstract: This rule will implement provisions of the Trafficking Victims Protection Act which prohibit programs from using trafficking funds to promote, support, or advocate the legalization or practice of prostitution and make organizations ineligible to receive such funds that promote, support, or advocate the legalization or the practice of prostitution if the program operates a program that targets several forms of trafficking unless the organization provides services to individuals solely after they are no longer engaged in activities that resulted from such activities being trafficked.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC ch 78 Trafficking Victims Protection Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/26/2008	73 FR 10210
NPRM Comment Period End	04/28/2008	
Final Action	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC33

View Related Documents

Title: Advance Planning Document Reform

Abstract: This rule updates existing regulations at 45 CFR 95 to make conforming changes reflecting transfer of HHS grant authority from 45 CFR 74 to part 92; to make technical updates to accurately reflect current terminology such as HCFA to CMS; and to make revisions designed to reduce the amount of Federal oversight and monitoring based on risk.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 95 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 301, 42 USC 622(b); 42 USC 629(b); 42 USC 629b(a), 42 USC 652(a), 42 USC 654(a), 42 USC 671(a), 42 USC 1302, 42 USC 1396(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/07/2008	73 FR 12341
NPRM Comment Period End	05/06/2008	
Final Action	04/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
RIN Information URL: regulations.acf.hhs.gov
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Government Levels Affected: State
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC36

View Related Documents

Title: Revised Head Start Performance Standards

Abstract: This proposed rule would modify Head Start program performance standards as necessary to reflect reauthorization changes. Changes could include items like performance standards related to health, parent involvement, nutritional and social services, transition and other services, education performance standards and measures, and standards related to family service workers, home visitors, and the condition and location of facilities. As required by statute, regulations will be drafted following consultations with experts and consideration of the National Academy of Sciences study on Developmental Outcomes and Assessments for Young Children.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
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Government Levels Affected: No
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC37

View Related Documents

Title: Intergovernmental Child Support Enforcement

Abstract: These regulations would revise Federal requirements for establishing and enforcing intergovernmental support obligations in Child Support Enforcement (IV-D) program cases receiving services under title IV-D of the Social Security Act (the

Act). The changes would: Revise current interstate requirements to apply to case processing in all intergovernmental cases; require the responding State IV-D agency to pay the cost of genetic testing; clarify responsibility for determining in which State tribunal a controlling order determination is made where multiple support orders exist; recognize and incorporate electronic communication advancements; and make conforming changes to the Federal substantial-compliance audit and State self-assessment requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 301 to 303; 45 CFR 305; 45 CFR 308 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/08/2008	73 FR 74408
Final Action	04/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Elizabeth C. Matheson
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC39

View Related Documents

Title: Interim Assistance for Trafficking Victims Under the Trafficking Victims Reauthorization Act of 2008
Abstract: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (the Act), Public Law 110-457, revised and reauthorized the Trafficking Victims Protection Program. This rule would implement changes to the program that authorize interim assistance to child victims under section 212(a) of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC 7101 note, William Wilberfore Trafficking Victims Protection Reauthorization Act of 2008
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Small Entities Affected: Governmental Jurisdictions; Organizations
Federalism: No
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Department of Health and Human Services

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC42

View Related Documents

Title: Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008

Abstract: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (the Act), Public Law 110-457, made significant changes concerning the care and placement of unaccompanied alien children while they are in the care of the Office of Refugee Resettlement (ORR). This rule would implement changes to the program under section 235 of the Act addressing issues like age determinations, placement determinations, suitability assessments and home studies. This rule also will address provisions of the Flores Settlement agreement that were not addressed in Public Law 110-457.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 410 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC 7101 note, William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC01

View Related Documents

Title: Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information

Abstract: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 made far-reaching amendments to title IV-D of the Social Security Act, which governs the child support enforcement program. The Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997, and the Child Support Performance and Incentive Act of 1998 further amended title IV-D. A significant result of this legislation is an expansion in the scope of information available to State IV-D child support enforcement agencies. The legislation has rendered obsolete or inconsistent several regulations at 45 CFR chapter III, Office of Child Support Enforcement, including the regulations on the Federal Parent Locator Service, the State Parent Locator Services, the offset of Federal payments for purposes of collecting child support, and the safeguarding of information. This regulation would update various sections in 45 CFR chapter III to reflect the statutory changes.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 303.3; 45 CFR 303.21; 45 CFR 303.70 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 652 to 654A; 42 USC 663; 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/14/2005	70 FR 60038
NPRM Comment Period End	12/13/2005	
Final Action	09/26/2008	73 FR 56421

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Federalism: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC07

View Related Documents

Title: Developmental Disabilities and Bill of Rights Act
Abstract: This rule amends current regulations to implement changes made by the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1385 to 1388 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-402; 42 USC 15001 et seq
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		10/30/2001

Timetable:

Action	Date	FR Cite
NPRM	04/10/2008	73 FR 19708
NPRM Comment Period End	06/09/2008	73 FR 43904
NPRM Comment Period Extended	09/29/2008	
Withdrawn	03/06/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: Governmental Jurisdictions; Organizations
Federalism: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC20

View Related Documents

Title: Care and Placement of Unaccompanied Alien Children

Abstract: This rule concerns the placement of unaccompanied alien children in appropriate facilities and homes, the services provided for the children while they are in the care of the Office of Refugee Resettlement (ORR), and the criteria for release of these children from Federal custody to sponsors. The rule also implements ORR's role in Flores class-action settlement agreement.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 410 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 6 USC 279
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	03/06/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC23

View Related Documents

Title: Adoption and Foster Care Analysis and Reporting System

Abstract: This rule will amend the Adoption and Foster Care Analysis and Reporting System (AFCARS) regulations at 45 CFR part 1355.40 and the appendices to part 1355 to modify the requirements for States to collect and report data to ACF on children in foster care and in subsidized adoption or guardianship arrangements with the State. The rule also implements the AFCARS penalty requirements of the Adoption Promotion Act of 2003 (Pub. L. 108-145).

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1355 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 679
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/11/2008	73 FR 2081
NPRM Comment Period End	03/11/2008	

Withdrawn	03/06/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: State
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC24

View Related Documents

Title: Child Support Provisions of the Deficit Reduction Act

Abstract: The rule would implement provisions of the Deficit Reduction Act of 2005 related to review and adjustment of child support orders, Federal financial participation in the program, and fees for program services.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No

CFR Citation: 45 CFR 301 to 304 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/24/2007	72 FR 3093
NPRM Comment Period End	03/26/2007	
Final Action	12/09/2008	73 FR 74897

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Governmental Jurisdictions
Government Levels Affected: Federal; Local; State; Tribal
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC34

View Related Documents

Title: Head Start Interim Final Rule

Abstract: This interim final rule will address requirements from the recent Head Start reauthorization which provide no

agency discretion in implementation as well as conforming changes to existing regulations. Examples include definitional changes, grantee reporting requirements, and prescriptive policy changes made by statute that dictate regulatory construction.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	03/06/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC38

View Related Documents

Title: Elimination of Enhanced TANF Caseload Reduction Credit for Maintenance of Effort Expenditures

Abstract: This proposed rule will revise Temporary Assistance for Needy Families program regulations to eliminate the provision that allows a State to receive additional caseload reduction credit for maintenance-of-effort (MOE) expenditures in excess of its required MOE spending. This provision is no longer necessary and not consistent with Congressional direction in the Deficit Reduction Act of 2005.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 261 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/08/2008	73 FR 46230
NPRM Comment Period End	10/08/2008	
Withdrawn	03/06/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB03

View Related Documents

Title: Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments

Abstract: This proposed rule would revise part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; clarify the availability of exclusion for certain violations in addition to civil money penalties and assessments; date various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e-mail communications.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1003 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320a-7a; 42 USC 1395mm; 42 USC 1395w-27; 42 USC 1396b; PL 99-660; PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2009	
NPRM Comment Period End	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB33

View Related Documents

Title: Revisions to the Office of Inspector General's (OIG) Exclusion Authorities

Abstract: In accordance with section 949 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, this rule would revise the OIG's exclusion authority to permit any Federal health care program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), 1128(a)(3), or 1128(a)(4) of the Social Security Act. In addition, the proposed rule would revise current exclusion provisions in 42 CFR parts 1001, 1002, and 1005 to further clarify OIG's existing exclusion authorities.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1001, 1002, and 1005 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 108-173, sec 949; PL 105-33, sec 4331; Social Security Act, sec 1128
Legal Deadline: None

Timetable:

Action	Date	FR Cite

NPRM	10/00/2009	
NPRM Comment Period End	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB41

View Related Documents

Title: Revisions to OIG Regulations Governing State Medicaid Fraud Control Units

Abstract: This proposed rule would revise and update part 1007, addressing the Office of Inspector General's authority regarding the requirements and procedures for establishing and operating a State Medicaid Fraud Control Unit. The current regulations were originally promulgated in 1978 and recodified in 1992.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 1007 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302, 42 USC 1396b(a)(6), 42 USC 1396b(b)(3); 42 USC 1396b(q)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2009	
NPRM Comment Period End	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB45

View Related Documents

Title: Travel Reimbursement for Medicare Hearings Before Administrative Law Judges (ALJs) of the Office of Medicare Hearings and Appeals

Abstract: The Office of Medicare Hearings and Appeals (OMHA) is proposing a rule to implement the provisions of section 1817(i) of the Social Security Act. Section 1817(i) allows expenditures from the Trust fund for the payment of travel expenses for certain individuals that participate in a hearing before an Administrative Law Judge (ALJ) with respect to any determination under title XVIII of the Social Security Act. Section 1817(i) requires the Secretary to enact regulations that establish the eligibility and procedures for reimbursement under title XVIII were conduct by the Social Security Administration (SSA) regulations. OMHA regulations are needed to comply with section 1817(i) of the Social Security Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1817(i) and 1871 of the Social Security Act; 42 USC 1395i, 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB51

View Related Documents

Title: Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements
Abstract: This notice of proposed rulemaking will publish for a thirty-day comment period revisions to 45 CFR part 74, appendix E: Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements (hereinafter referred to as the Hospital Cost Principles or HCP.) It is the culmination of a comprehensive review process begun in 2005 and incorporates relevant elements of the Office of Management and Budget circulars for Colleges and Universities (OMB Circular A-21), Non-Profit Institutions (OMB Circular A-122), and State and Local Governments (OMB Circular A-87). These other principles were revised by OMB in the early 1990's, but the Hospital Cost Principles were not. This NPRM is subsequent to the recent final rule that clearly establishes the Department of Health and Human Services as the proponent agency for appendix E of 45 CFR part 74. With that authority is the inherent responsibility to review and revise the document as well as approve and deny requests for waiver to those Hospital Cost Principles.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 74, appendix E (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB52

View Related Documents

Title: Rescission of Interest Prohibition in the Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements

Abstract: This Notice of Proposed Rulemaking (NPRM) would rescind the current prohibition against interest as an allowable expense. The recision applies only to interest endured for new construction, facility acquisitions and interest debt to acquire or replace facility acquisitions. It makes the Hospital Cost Principles consistent with the Office of Management and Budget circulars for Colleges and Universities (OMB Circular A-21), Non-Profit Institutions (OMB Circular A-122), and State and Local Governments (OMB Circular A-87) concerning the allowance of interest debt. These other principles were revised in the early 1990's, but the Hospital Cost Principles were not. In 2000, the current interest request waiver process was established as a temporary practice to align the Hospital Cost Principles with A-21 and A-87 until a permanent revision could be published. Since then, twelve such waivers have been granted by the Department. The standards in this NPRM would be the same as those in A-21 and A-87. This NPRM establish the Department of Health and Human Services as the proponent agency for appendix E of 45 CFR part 74 with inherent responsibility to review, approve, and deny requests for waiver to Hospital Cost Principles.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 74 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB54

View Related Documents

Title: Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Required by the Genetic Information Nondiscrimination Act of 2008

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules to implement the modifications to the HIPAA Privacy Rule required by section 105 of the Genetic Information Nondiscrimination Act of 2008. The rule will prohibit certain health plans from using or disclosing genetic information about an individual for underwriting purposes.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320d-9
Legal Deadline:

Action	Source	Description	Date

Other	Statutory		05/21/2009

Timetable:

Action	Date	FR Cite
NPRM	05/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)

RIN: 0991-AB16

View Related Documents

Title: Safe Harbor for Waiver of Beneficiary Co-Insurance and Deductible Amounts for a Medicare SELECT Policy

Abstract: This final rule will expand the existing safe harbor for certain waivers of beneficiary co-insurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will protect waivers of co-insurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Final Rule

Major: No

Unfunded Mandates: No

CFR Citation: 42 CFR 1001 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 100-93, sec 14(a)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/25/2002	67 FR 60202
NPRM Comment Period End	10/25/2002	
Final Action	08/00/2009	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Small Entities Affected: No

Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)

RIN: 0991-AB42

View Related Documents

Title: Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings

Abstract: This Final Rule would amend Departmental regulations governing administrative review by the Departmental Appeals Board (DAB) to ensure that the final administrative decision of the Department reflects the considered judgment of the Secretary. Specifically, it would provide a process for Secretarial review of DAB decisions, and would make clear that the DAB must follow published guidance. The NPRM would address DAB review under a number of different authorities, and would also make technical changes to the DAB's regulations.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/28/2007	72 FR 73708
NPRM Comment Period End	01/28/2008	
Final Action	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB44

View Related Documents

Title: State Long-Term Care Partnership Program; Reporting Requirements for Insurers

Abstract: This Final Rule will establish the proposed reporting requirements that must be met by private insurers that issue qualified long-term care insurance policies in States participating in the State Long-Term Care Partnership Program established under the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171). Section 6021 of the Deficit Reduction Act of 2005 requires that the Secretary specify a set of reporting requirements and collect data from insurers on qualifying long-term care insurance policies issued under the program and the subsequent use of the benefits under these policies

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/23/2008	73 FR 30030
NPRM Comment Period End	07/22/2008	
Final Action	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB53

View Related Documents

Title: Patient Safety and Quality Improvement Act of 2005; Civil Money Penalties Inflation Adjustment

Abstract: In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, the rule will incorporate the penalty inflation adjustment for civil money penalties under the Patient Safety and Quality Improvement Act of 2005

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 3.404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 2461 note Federal Civil Penalties Inflation Adjustment Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/29/2009

Timetable:

Action	Date	FR Cite
Final Action	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB56

View Related Documents

Title: HIPAA Administrative Simplification; Notification in the Case of Breach

Abstract: The Department will issue rules for HIPAA covered entities and business associates with respect to breach notification of unsecured protected health information, as required by section 13402 of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13402
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/17/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)

RIN: 0991-AA91

View Related Documents

Title: Shared Risk Exception to the Safe Harbor Provisions

Abstract: This final rule establishes a new safe harbor for risk-sharing arrangements under the Federal health care programs' anti-kickback provisions. The rule sets forth an exception from liability for remuneration between an eligible organization and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at "substantial financial risk" for the cost or utilization of the items or services that the individual or entity is obligated to provide.

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 42 CFR 1001 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1302; 42 USC 1320a-7b; 42 USC 1395hh; PL 104-191, sec 216(b)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/1997

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	05/23/1997	62 FR 28410
ANPRM Comment Period End	06/09/1997	
Interim Final Rule	11/19/1999	64 FR 63504

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Federalism: No

Related RINs: Related to 0991-AB06

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)

RIN: 0991-AB47

View Related Documents

Title: State Long-Term Care Partnership Program: State Reciprocity Standard

Abstract: Under section 6021 of Public Law 109-171, the Deficit Reduction Act of 2005 (DRA), States may provide asset disregards (and related estate recovery offsets) for Medicaid applicants who receive benefits under qualified long term care insurance policies (Partnership policies) that were purchased in the same State. This notice sets forth standards for states that choose to enter into a reciprocity agreement under section 6021(b) of the DRA, under which they agree to provide the same disregards and offsets for qualified Partnership policies that a Medicaid applicant purchased in another State that participates in the reciprocity agreement.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Undetermined	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB49

View Related Documents

Title: Rescission of the Regulation Entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal law; Proposal

Abstract: The Department of Health and Human Services proposes to rescind the December 19, 2008 final rule entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law," 73 FR 78072.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Undetermined	00/00/0000	
NPRM	03/10/2009	74 FR 10207

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB55

View Related Documents

Title: HIPAA Administrative Simplification; Modifications to the HIPAA Enforcement Rule

Abstract: The Department of Health and Human Services will issue rules to modify the HIPAA Administrative Simplification Enforcement Rule as needed to implement the provisions of section 13410 of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13410
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB57

View Related Documents

Title: Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Under the Health Information Technology for Economic and Clinical Health Act

Abstract: The Department of Health and Human Services will issue rules to modify the HIPAA Privacy Rule as necessary to implement the privacy provisions of subtitle D of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, secs 13404-13408
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Effective date for most statutory provisions	02/17/2010

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB46

View Related Documents

Title: Regulation on the Organizational Integrity of Entities Implementing Leadership Act Programs and Activities

Abstract: The Office of Global Health Affairs within the U.S. Department of Health and Human Services (HHS) issued this final rule to clarify that recipients of HHS funds to implement HIV/AIDS programs and activities under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (the Leadership Act), Public Law 108-25 (May 27, 2003), that are required to have a policy opposing prostitution and sex trafficking, and must submit certification of this policy with the grant or contract application, may, consistent with this policy requirement, maintain an affiliation with organizations that do not have such a policy, provided such affiliations do not threaten the integrity of the Government's programs and its message opposing prostitution and sex trafficking. The rule describes the separation that must exist between a recipient of HHS HIV/AIDS funds that has a policy opposing prostitution and sex trafficking, as required under section 301(f) of the Leadership Act, 22 U.S.C. 7631(f), and another organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 89 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 301; 22 USC 7631(f)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/17/2008	73 FR 20900
NPRM Comment Period End	05/19/2008	
Correction	05/20/2008	73 FR 29096
Comment Period Extended	06/26/2008	73 FR 36293
Extension Ends	07/28/2008	
Final Action	12/24/2008	73 FR 78997
Correction	01/16/2009	74 FR 2888

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB48

View Related Documents

Title: Ensuring that Department of Health and Human Services Funds Do Not Support Morally Coercive or Discriminatory Policies or Practices In Violation of Federal Law

Abstract: HHS issued a final rule entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Morally Coercive Or Discriminatory Practices".

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 88 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 238n; 42 USC 300a-7; Public Health Service Act 245; PL 110-161, Div G, 508(d); 121 Stat 1844; 121 Stat 2209
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/26/2008	73 FR 50274
NPRM Comment Period End	09/25/2008	
Final Rule	12/19/2008	73 FR 78072

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

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