DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS

ACTION: Semiannual Regulatory Agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semi-annual issuance of an inventory of rulemaking actions under development throughout the Department, with a view to offering for public review, at as early a stage as possible, summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, D.C. 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided in the Agenda presents for public review a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of Notices of Proposed Rulemaking or of Final Rules within the next 12 months.

Please note that the rulemaking 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 publication of this information in the **Federal Register**. Also available elsewhere in this issue of the **Register** is the Department's submission to the Fiscal Year 2009 Regulatory Plan, as required under Executive Order 12866. The complete Regulatory Agenda of the Department is accessible online at www.reginfo.gov.

We welcome the views of all concerned with regard to these planned rulemakings. 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: Ann C. Agnew, Executive Secretary to the Department, Suite 603H, 200 Independence Ave. SW, Washington DC 20201.

Dated: September 23, 2008.

NAME: Ann C. Agnew,
Executive Secretary to the Department.

The 236 Regulatory Agendas

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
National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906-AA41
Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
Amending the Health Center Program To Apply to the Health Care for the Homeless and Public Housing Primary Care Programs	0906-AA72
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 Resources and Services Administration - Completed Action

Title	Regulation Identifier Number
National Vaccine Injury Compensation Program; Removal of Separate Category for Vaccines Containing Live, Oral, Rhesus-Based Rotavirus From the Vaccine Injury	0906-AA75

Food and Drug Administration - PreRule

Title	Regulation Identifier Number
Food Labeling; Serving Sizes and Nutrition Labeling	0910-AF99
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--Vaginal Contraceptive Products	0910-AF44
Over-the-Counter (OTC) Drug Review--Weight Control Products	0910-AF45
Over-the-Counter (OTC) Drug Review--Stimulant Drug Products	0910-AF56
Label Requirement for Food That Has Been Refused Admission Into the United States	0910-AF61

Over-the-Counter (OTC) Drug Review--Poison Treatment Drug Products	0910-AF68
Over-the-Counter (OTC) Drug Review--Urinary Analgesic Drug Products	0910-AF70
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
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
Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph	0910-AG12

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
Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910-AA97
Additional Safeguards for Children in Clinical Investigations	0910-AC07
Prevention of Salmonella Enteritidis in Shell Eggs	0910-AC14
Institutional Review Boards: Registration Requirements	0910-AC17
Requirements for Submission of In Vivo Bioequivalence Data	0910-AC23
Exception From General Requirements for Informed Consent; Request for Comments and Information	0910-AC25
Medical Devices; Anesthesiology Devices; Proposed 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
Cochineal Extract and Carmine Label Declaration	0910-AF12
Charging for Investigational Drugs Under An Investigational New Drug Application	0910-AF13
Expanded Access to Investigational Drugs for Treatment Use	0910-AF14
Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex	0910-AF21
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--Cough/Cold (Nasal Decongestant) Products	0910-AF34

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--Labeling of Drug Products for OTC Human Use	0910-AF37
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
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
Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants	0910-AF54
Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Epinephrine]	0910-AF92
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
Revision of the Requirements for Publication of License Revocation	0910-AG11
Premarketing Safety Reporting Requirements for Human Drug and Biological Products	0910-AG13

Food and Drug Administration - Long-term Action

Title	Regulation Identifier Number
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--Ophthalmic Products	0910-AF39
Over-the-Counter (OTC) Drug Review--Oral Health Care Products	0910-AF40
Over-the-Counter Antidiarrheal Drug Products	0910-AF63
Over-the-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products	0910-AF69
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
Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution	0910-AG06

Food and Drug Administration - Completed Action

Title	Regulation Identifier Number
Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications	0910-AB34
Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910-AC35
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910-AC41

Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910-AF15
Distribution of Certain Drug Products by Registered Blood Establishments and Comprehensive Hemophilia Diagnostic Treatment Centers That Qualify as Health Care Entities; PDMA of 1987; PDA of 1992	0910-AF16
Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals	0910-AG04
Biological Products; Reporting of Biological Product Deviations in Manufacturing	0910-AG05

Agency for Healthcare Research and Quality - Final Rule

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
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
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	0920-AA26
Medical Examination of Aliens	0920-AA28

Centers for Disease Control and Prevention - Final Rule

Title	Regulation Identifier Number
Control of Communicable Diseases Foreign Quarantine	0920-AA12
Control of Communicable Diseases: Foreign Quarantine	0920-AA22

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
Control of Communicable Diseases, Interstate Quarantine, Passenger Information	0920-AA27

Centers for Disease Control and Prevention - Completed Action

Title	Regulation Identifier Number
Medical Examination of Aliens	0920-AA20
Possession, Use, and Transfer of Select Agents and Toxins	0920-AA29

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

National Institutes of Health - Final Rule

Title	Regulation Identifier Number
Grants for Research Projects	0925-AA42

National Institutes of Health - Completed Action

Title	Regulation Identifier Number
Standards for a National Chimpanzee Sanctuary System	0925-AA31

Substance Abuse and Mental Health Services Administration - Final Rule

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

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
Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition	0930-AA14

Centers for Medicare & Medicaid Services - PreRule

Title	Regulation Identifier Number
Genetic Information Nondiscrimination Act of 2008 (CMS-4137-IFC)	0938-AP37

Centers for Medicare & Medicaid Services - Proposed Rule

Title	Regulation Identifier Number
Payments for Service Provided Without Charge (Free Care) (CMS-2489-P)	0938-AO07
Cytology Proficiency Testing (CMS-2252-P)	0938-AO34

Changes To Ensure Effective and Efficient Operations of Medicaid and the State Children's Health Insurance Program (SCHIP) (CMS-2148-P)	0938-AO86
Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS-3178-P)	0938-AO91
Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938-AP32
Changes to the Hospital Inpatient 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-P)	0938-AP45
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-P)	0938-AP46
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

Centers for Medicare & Medicaid Services - Final Rule

Title	Regulation Identifier Number
Updates to Electronic Transactions (Version 5010) (CMS-0009-F)	0938-AM50
Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)	0938-AM73
Medicaid Disproportionate Share Hospital Payments--Auditing and Reporting Requirements (CMS-2198-F)	0938-AN09
Revisions to HIPAA Code Sets (CMS-0013-F)	0938-AN25
Limitation on Recoupment of Provider and Supplier Overpayments (CMS-6025-F)	0938-AN42
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
Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F)	0938-AO53
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
Home Health Prospective Payment System Refinements and Rate Update for CY 2009 (CMS-1555-N)	0938-AP20
State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals Federal Fiscal Year 2008 (CMS-2290-IFC)	0938-AP38
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 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-N)	0938-AP50
Medicare Advantage and Prescription Drug Programs: MIPPA-Related Marketing Revisions (CMS-4138-F)	0938-AP52
State Children's Health Insurance Program (SCHIP); Redistribution of Unexpended SCHIP Funds (CMS-2291-N)	0938-AP53
Fiscal Year 2010 SCHIP Allotments (CMS-2289-N)	0938-AP54
Limited Changes to the Competitive Acquisition of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)(CMS-1561-IFC)	0938-AP59

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
Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers (CMS-1910-F2)	0938-AJ17
Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)	0938-AJ29
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
Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (CMS-3156-P)	0938-AN73
Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)	0938-AO10
Targeted Case Management (CMS-2237-F)	0938-AO50
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
Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F)	0938-AO84
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
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
Revisions to Payment Policies Under the Physician Fee Schedule for CY 2009 (CMS-1403-FC)	0938-AP18
Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs (CMS-4131-Q)	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

Centers for Medicare & Medicaid Services - Completed Action

Title	Regulation Identifier Number
Medicare and Medicaid Programs; Hospice Care Conditions of Participation (CMS-3844-F)	0938-AH27
Appeals of CMS or Contractor Determination When a Provider or Supplier Fails To Meet the Requirements for Medicare Billing (CMS-6003-F)	0938-AI49
Provider Reimbursement Determinations and Appeals (CMS-1727-F)	0938-AL54
Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-F)	0938-AL80
Termination of Non-Random Prepayment Review (CMS-6022-F)	0938-AN31
Fire Safety Requirements for Long-Term Care Facilities: Automatic Sprinkler Systems (CMS-3191-F)	0938-AN79
Use of Repayment Plans (CMS-6032-F)	0938-AO27
Group Health Plans and Health Insurance Issues Under the Newborns and Mothers Health Protection Act (CMS-4116-F)	0938-AO43
High Risk Pools (CMS-2260-F)	0938-AO46
Self-Directed Personal Assistance Services State Plan Option (CMS-2229-F)	0938-AO52
Prohibition of Mid-Year Benefit Enhancements for Medicare Advantage Organizations Offering Plans in Calendar Year 2007 and Subsequent Calendar Years (CMS-4121-F)	0938-AO54
Medicare Part D Data (CMS-4119-F)	0938-AO58
Exemption of Privacy Act Disclosure of Certain Investigative Materials (CMS-0029-F)	0938-AO69
Special Enrollment Period and Medicare Premium Changes (CMS-4129-F)	0938-AO77
Inpatient Psychiatric Facility Prospective Payment System–Update for Rate Year Beginning July 1, 2008 (RY 2009) (CMS-1401-N)	0938-AO92
Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-F)	0938-AO94

Eligible Entity and Contracting Requirements Under the Medicaid Integrity Audit Program (CMS-2271-F)	0938-AO97
Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2009 (CMS-8036-N)	0938-AP00
Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2009 (CMS-8034-N)	0938-AP03
Part A Premiums for CY 2009 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8035-N)	0938-AP04
State Children's Health Insurance Program (SCHIP): Final Allotments for FYs 2008 and 2009; Redistribution of Unused Allotments; and Continued Authority for Expenditures (CMS-2265-N)	0938-AP07
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities--Update for FY 2009 (CMS-1534-F)	0938-AP11
Hospice Wage Index for FY 2009 (CMS-1548-F)	0938-AP14
Changes to the Hospital Inpatient Prospective Payment Systems and FY 2009 Rates (CMS-1390-N)	0938-AP15
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2009 (CMS-1554-F)	0938-AP19
Medicaid Program: Multiple Source Drugs Definition (CMS-2238-F)	0938-AP26
User Fees for Information, Products, and Services (CMS-6021-P)	0938-AP27
Criteria and Standards for Evaluating (Contractors) Intermediary and Carrier Performance During FY 2009 (CMS-1400-GNC)	0938-AP34
Evaluation Criteria and Standards for Quality Improvement Program Contracts (9th Scope of Work) (CMS-3189-NC)	0938-AP36

Office of Public Health and Science - Final Rule

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

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
Amendment to Final Regulations Regarding Commissioned Corps Physical Examinations	0940-AA12

Administration for Children and Families - Proposed Rule

Title	Regulation Identifier Number
Revised Head Start Performance Standards	0970-AC36
Intergovernmental Child Support Enforcement	0970-AC37

Administration for Children and Families - Final Rule

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
Adoption and Foster Care Analysis and Reporting System	0970-AC23
Child Support Provisions of the Deficit Reduction Act	0970-AC24
Limitation on Use of Funds Made Available To Monitor and Combat Trafficking in Persons	0970-AC28
Computerized Tribal IV-D System and Office Automation	0970-AC32

Advance Planning Document Reform	0970-AC33
Head Start Interim Final Rule	0970-AC34
Target Population and Conversion	0970-AC35
Elimination of Enhanced TANF Caseload Reduction Credit for Maintenance of Effort Expenditures	0970-AC38

Administration for Children and Families - Long-term Action

Title	Regulation Identifier Number
Care and Placement of Unaccompanied Alien Children	0970-AC20

Administration for Children and Families - Completed Action

Title	Regulation Identifier Number
Cost Allocation Methodology Applicable to the Temporary Assistance for Needy Families Program	0970-AC15
Medical Support	0970-AC22

Office of the Secretary - PreRule

Title	Regulation Identifier Number
State Long-Term Care Partnership Program: State Reciprocity Standard	0991-AB47

Office of the Secretary - Proposed Rule

Title	Regulation 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

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
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

Office of the Secretary - Long-term Action

Title	Regulation Identifier Number
Shared Risk Exception to the Safe Harbor Provisions	0991-AA91

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 have 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	12/00/2008	

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

Agency Contact: Darryl A. Gray
Acting Chief, Practitioner Data Banks Branch
Department of Health and Human Services
Health Resources and Services Administration
5600 Fishers Lane Room 8-103
Rockville , MD 20857
Phone: 301 443-0910

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: Long-term 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
Second NPRM	00/00/0000	
NPRM	12/24/1998	63 FR 71255
NPRM Comment Period End	02/22/1999	

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

Agency Contact: Darryl A. Gray
Acting Chief, Practitioner Data Banks Branch
Department of Health and Human Services
Health Resources and Services Administration
5600 Fishers Lane Room 8-103
Rockville , MD 20857
Phone: 301 443-0910

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 process for designating areas of health professional shortage and medical underservice that apply in several Department programs, and would improve the criteria for designating medically underserved populations and Primary Care Health Professional Shortage Areas. An NPRM was published in 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 on April 21, 2008 and June 2, 2008. Substantial comments were received that must be reviewed and considered in the development of modifications to the rule. Federal Register Notice on July 23, 2008 announced agency decision to review and develop modified proposal and publish another NPRM. Methodology is used by a variety of Federal and State programs to target resources to underserved populations. Medically Underserved Areas (MUA) have not been updated in many cases for over 20 years and may not reflect current conditions in many areas. Statutory citations above provide the legal foundation for the existing designations. There is no statutory requirement to update the MUAs. There is a statutory requirement to update the Health Professional Shortage Areas (HPSA), but no requirement to update the methodology. Alternatives are to continue to use the existing methodologies or develop another new approach. Anticipated costs are minimal. The infrastructure is in place for designations now and it would just take another approach. No direct impact on major programs that use the designation, whose funding levels depend on appropriations. Potential impact on Medicare Bonus payment, but is relatively small and depending on the results of the model could increase or decrease payments. Benefits 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. Risks are 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 Comment Period End	04/29/2008	
Second NPRM Extension Ends	05/29/2008	
Second NPRM Comment Period Extended	06/02/2008	73 FR 31418
Second NPRM Extension Ends	06/30/2008	
NPRM Status	07/23/2008	73 FR 42743

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Agency Contact: Andy Jordan
Chief, Shortage Designation Branch
Department of Health and Human Services
Health Resources and Services Administration
Room 8C-26 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 594-0197
E-Mail: ajordan@hrsa.gov

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: Long-term 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
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Shannon Dunne-Faltens
Public Health Analyst
Department of Health and Human Services
Health Resources and Services Administration
Room 17C-10 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 594-4065
E-Mail: sdunne-faltens@hrsa.gov

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: This notice sets forth the Secretary's proposal to include transplantation of vascularized composite allografts to the

definition of human organs covered by the rules governing the operation of the Organ Procurement and Transplant Network (OPTN). These would include portions of limbs, face, and other transplantable body parts not presently defined as organs in regulation. The Secretary further proposes a corresponding change to the definition of human organs covered by section 301 of the National Organ Transplant Act, as amended.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
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 1964, 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	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Elizabeth Ortiz-Rios
Medical Officer
Department of Health and Human Services
Health Resources and Services Administration
Room 12C-06 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 443-4423
FAX: 301 584-6095
E-Mail: eortiz-rios@hrsa.gov

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 Secretary of 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 XIV). 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 XIV. The next step is that new vaccines are added as their own separate category, 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.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
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	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Dr. Geoffrey S. Evans
Acting Director, Division of Vaccine Injury Compensation
Department of Health and Human Services
Health Resources and Services Administration
Room 11C-26 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 443-6593
FAX: 301 443-8196
E-Mail: gevansr@hrsa.gov

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA75

View Related Documents

Title: National Vaccine Injury Compensation Program; Removal of Separate Category for Vaccines Containing Live, Oral, Rhesus-Based Rotavirus From the Vaccine Injury

Abstract: The Secretary of the Department of Health and Human Services plans to make a technical change to the Vaccine Injury Table (Table) by removing vaccines containing live, oral, rhesus-based rotavirus from the Table. Because the manufacturer of this vaccine voluntarily ceased distribution of it in July 1999, and because the CDC recommended that this vaccine no longer be routinely administered to children in the United States in October 1999, the Secretary concluded that it was unlikely that potential claims for this vaccine would arise after the rule's publication. Furthermore, the applicable statute of limitations requires petitioners to file claims within three years of the injury's first symptom or manifestation of onset (or four years from such onset and two years from the date of death, in death cases). Therefore, the Secretary believes that any person with a potential Vaccine Injury Table claim for this vaccine would be time-barred. See attached document for more information.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
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 300aa-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
Interim Final Rule	10/09/2008	73 FR 59528
Interim Final Rule Effective	11/10/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Dr. Geoffrey S. Evans
Acting Director, Division of Vaccine Injury Compensation
Department of Health and Human Services
Health Resources and Services Administration
Room 11C-26 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 443-6593
FAX: 301 443-8196
E-Mail: gevansr@hrsa.gov

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 part 101.9) describes the nutrition labeling requirements for foods. Section 101.12 (21 CFR part 101.2) 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 is undertaking a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review is 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 will consider, and is soliciting 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.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: PreRule
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	Planned section 610 review	03/16/2009

Timetable:

Action	Date	FR Cite
Begin Review	12/00/2008	
End Review	03/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Mary Brandt
Statistician
Department of Health and Human Services
Food and Drug Administration
Center for Food Safey and Applied Nutrition 5100 Paint Branch Parkway ONLDS (HFS-820)
College Park , MD 20740
Phone: 301 436-1788
FAX: 301 436-1191
E-Mail: mary.brandt@fda.hhs.gov

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	11/00/2008	
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
Agency Contact: Howard P. Muller
Office of Regulatory Policy
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6234
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440
E-Mail: howard.mullerjr@fda.hhs.gov

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
Agency Contact: Martha Nguyen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6224
Silver Spring , MD 20993-0002
Phone: 301 796-3471
FAX: 301 847-8440
E-Mail: martha.nguyen@fda.hhs.gov

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	03/00/2009	

Regulatory Flexibility Analysis Required: Undetermined Government Levels Affected: No
Federalism: No
Related RINs: Previously Reported as 0910-AC02
Agency Contact: Brian L. Pendleton
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drugs Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6304
Silver Spring , MD 20993-0002
Phone: 301 796-3504
FAX: 301 847-8440
E-Mail: brian.pendleton@fda.hhs.gov

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
NPRM (Amendment) (Common Cold)	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 first action will address laxative drug products. The second action will address the professional labeling for sodium phosphate drug products. The third action 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)	05/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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	
NPRM (Time and Extent)	05/00/2009	
Final Action (UVA/UVB)	06/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857

Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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 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)	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 action addresses 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
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
NPRM (Benzocaine)	05/00/2009	
Final Action (Phenylpropanolamine)	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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 (Amendment) (Hangover)	09/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 proposed rule would require owners or consignees to label imported food that is refused entry into the United States. The label would read, "UNITED STATES: REFUSED ENTRY." The proposal would describe 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: Proposed 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 Rule	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.
Agency Contact: Philip L. Chao
Senior Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Office of Policy and Planning (HF-23) Room 14C-17 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 827-0587
FAX: 301 827-4774
E-Mail: philip.chao@fda.hhs.gov

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: Proposed Rule
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)	09/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: Proposed Rule
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)	09/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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 drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerances will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act and may be imported into the United States.

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	06/00/2009	
NPRM Comment Period End	09/00/2009	

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.

Agency Contact: Frances Pell
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
Room 101 (MPN-4, HFV-235) 7500 Stadish Place
Rockville , MD 20855
Phone: 240 276-9211
FAX: 240-276-9241
E-Mail: frances.pell@fda.hhs.gov

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 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. The proposed rule is intended to ensure consistency and appropriateness in the regulation of combination products.

Priority: Other Significant
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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Government Levels Affected: Local; State; Tribal
Federalism: Yes

Agency Contact: Leigh Hayes
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Office of Combination Products Suite 200 (HFG-3) 15800 Crabbs Branch Way
Rockville , MD 20855
Phone: 301 427-1934
FAX: 301 427-1935
E-Mail: leigh.hayes@fda.hhs.gov

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: Other Significant
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	11/00/2008	

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

Agency Contact: Leigh Hayes
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Office of Combination Products Suite 200 (HFG-3) 15800 Crabbs Branch Way
Rockville , MD 20855
Phone: 301 427-1934
FAX: 301 427-1935
E-Mail: leigh.hayes@fda.hhs.gov

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: The proposed rule would require user facilities and medical device manufacturers and importers to submit medical device adverse event reports in electronic format instead of using a paper form. FDA is taking this action to improve its adverse event reporting program by enabling it to more quickly receive and process these reports.

Legal Basis: The Agency has legal authority under section 519 of the Federal Food, Drug, and Cosmetic Act to require adverse event reports. The proposed rule would require manufacturers, importers, and user facilities to change their procedures to send reports of medical device adverse events to FDA in electronic format instead of using a hard copy form.

Alternatives: The alternatives to this rulemaking include not updating the medical device reporting requirements and not requiring submission of this information in electronic format. For over 20 years, medical device manufacturers, importers, and user facilities have sent adverse event reports to FDA on paper forms. Processing paper forms is a time consuming and expensive process. FDA believes this rulemaking is the preferable alternative.

Costs and Benefits: The principal benefit would be to public health because the increased speed in the processing and analysis of the more than 200,000 medical device reports currently submitted annually on paper. In addition, requiring electronic submission would reduce FDA annual operating costs by $1.25 million. The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from $58.6 million to $79.7 million. Annually recurring costs totaled $8.5 million and included maintenance of electronic submission capabilities, including renewing the electronic certificate, and for some firms the incremental cost to maintain high-speed internet access.

Risks: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2009	

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.

Agency Contact: Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-215) 1350 Piccard Drive PI50 RM150F
Rockville , MD 20850
Phone: 240 276-2347
FAX: 240 276-2352

E-Mail: myrna.hanna@fda.hhs.gov

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 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	04/00/2009	

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.

Agency Contact: Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-215) 1350 Piccard Drive PI50 RM150F
Rockville , MD 20850
Phone: 240 276-2347
FAX: 240 276-2352
E-Mail: myrna.hanna@fda.hhs.gov

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 requirements under 21 CFR part 807 to reflect the requirements in section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) and 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 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.

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 107-188, sec 321; 21 USC 360(a) to 360(j); 21 USC 360(p)
Legal Deadline: None

Regulatory Plan:

Statement of Need: FDA is proposing to amend the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the requirements in section 321 of the the BT Act and section 510(p) of the act, which was added by section 207 of MDUFMA and later amended by section 224 of FDAAA. This proposed rule would improve FDA's device establishment registration and listing system and utilize the latest technology in the collection of this information.

Legal Basis: The statutory basis for our authority includes sections 510(a) through (j), 510(p), 701, 801, and 903 of the act.

Alternatives: The alternatives to this rulemaking include not updating the registration and listing regulations and not requiring the electronic submission of registration and listing information. Because of the new statutory requirements, and the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative to the paper system currently in place.

Costs and Benefits: The Agency believes that there may be some one-time costs associated with the rulemaking, which involve resource costs of familiarizing users with the electronic system. Recurring costs related to submission of the information by domestic firms would probably remain the same or decrease because a paper submission and postage is not required. There might be some increase in the financial burden on foreign firms since they will have to supply additional registration information as required by section 321 of the BT Act.

Risks: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2009	

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.

Agency Contact: Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-215) 1350 Piccard Drive PI50 RM150F
Rockville , MD 20850
Phone: 240 276-2347
FAX: 240 276-2352
E-Mail: myrna.hanna@fda.hhs.gov

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	03/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Brian L. Pendleton
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drugs Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6304
Silver Spring , MD 20993-0002
Phone: 301 796-3504
FAX: 301 847-8440
E-Mail: brian.pendleton@fda.hhs.gov

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	12/00/2008	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: Undetermined
Agency Contact: Audrey A. Thomas
Regulatory Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research, Office of Regulatory Policy 10903 New Hampshire Avenue Bldg. 51, Room 6364
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440
E-Mail: audrey.thomas@fda.hhs.gov

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 and 314.53; 21 CFR 314.60; 21 CFR 314.70; 21 CFR 314.90; 21 CFR 314.94 and 314.97; 21 CFR 314.99; 21 CFR 314.101; 21 CFR 314.105; 21 CFR 314.107 and 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	05/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Agency Contact: Janice L. Weiner
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research, Office of Regulatory Policy 10903 New Hampshire Avenue Bldg. 51, Room 6236
Silver Spring , MD 20993-0002
Phone: 301 796-3601

FAX: 301 847-8440
E-Mail: janice.weiner@fda.hhs.gov

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	11/00/2008	
NPRM Comment Period End	01/00/2009	

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.

Agency Contact: John P. Machado
Veterinary Medical Officer
Department of Health and Human Services
Food and Drug Administration
MPN-4 Room 2640 (HFV-228) 7519 Standish Place
Rockville , MD 20855
Phone: 240 453-6854
FAX: 240 453-6882
E-Mail: john.machado@fda.hhs.gov

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 approval, 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: Proposed 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
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		02/00/2011

Timetable:

Action	Date	FR Cite
NPRM	02/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Agency Contact: Gail Schmerfeld
Supervisory Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine 7500 Standish Place, MPN-2, Room 384 HFV-100
Rockville , MD 20855
Phone: 240 276-8304
E-Mail: gail.schmerfeld@fda.hhs.gov

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: 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 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	05/00/2009	

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.
Agency Contact: Michaela Alewynse

Supervisory Biologist
Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine MPN4, Room 2632, HFV-228
Rockville , MD 20855
Phone: 240 453-6866
E-Mail: michaela.alewynse@fda.hhs.gov

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: 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 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	05/00/2009	

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.

Agency Contact: William Burkholder
Veterinary Medical Officer
Department of Health and Human Services
Food and Drug Administration
MPN4, Room 2642, HFV-228 7519 Standish Place
Rockville , MD 20855
Phone: 240 453-6865
E-Mail: william.burkholder@fda.hhs.gov

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: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Private Sector
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	05/00/2009	

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.
Agency Contact: Kim Young
Deputy Director, Division of Compliance
Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine MPN4, Room 106, HFV-230 7519 Standish Place
Rockville , MD 20855
Phone: 240 276-9207
E-Mail: kim.young@fda.hhs.gov

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
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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, instead of the current requirement to submit the information to FDA on paper forms. 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	06/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
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.
Agency Contact: Paula S. McKeever
Senior Scientific Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Office of Critical Path Programs Office of the Commissioner 5600 Fishers Lane, Room 14B-45
Rockville , MD 20857-0001

Phone: 301 827-1520
FAX: 301 443-9718
E-Mail: paula.mckeever@fda.hhs.gov

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: Final Rule
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
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	
Final Action	07/00/2009	

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

Agency Contact: Carol Drew
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6306
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440

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	06/00/2009	

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

Agency Contact: Carol Drew
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6306
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440

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 is 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 by 50 percent by 2005 and eliminate egg-related SE illnesses by 2010. 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
Agenda Stage of Rulemaking: Final Rule

Major: Yes 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: FDA proposed regulations as part of the farm-to-table safety system for eggs outlined by the President's Council on Food Safety in its Egg Safety Action Plan. FDA intends to publish a final egg safety rule because of the continued reports of outbreaks of foodborne illness and death caused by SE that are associated with the consumption of shell eggs. The agency believes that this rule, when final, will have significant effect in reducing the risk of illness from SE-contaminated eggs and will contribute significantly to the interim public health goal of a 50 percent reduction in egg-related SE illness.

Legal Basis: FDA's legal basis derives in part from sections 402(a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the Act) ((21 U.S.C. 342(a)(4) and 371(a)). Under section 402(a)(4) of the Act, a food is adulterated if it is prepared, packed, or held in insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the Act, FDA is authorized to issue regulations for the efficient enforcement of the Act. FDA's legal basis also derives from section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which gives FDA authority to promulgate regulations to control the spread of communicable disease.

Alternatives: There are several alternatives that the Agency considered in the proposed rule. The principal alternatives included: (1) No new regulatory action; (2) alternative testing requirements; (3) alternative on-farm prevention measures; (4) alternative retail requirements; and (5) HACCP.

Costs and Benefits: The benefits from a final regulation to control Salmonella enteritidis in shell eggs derive from improved practices that reduce contamination and generate benefits measured as the value of the human illnesses prevented. FDA has produced estimates of costs and benefits for a number of options. The mitigations considered include on-farm rodent control, changes in retail food preparation practices, diversion of eggs from infected flocks to pasteurization, recordkeeping, refrigeration, and feed testing. The actual costs and benefits of the final rule will depend upon the set of mitigations chosen and the set of entities covered.

Risks: The potential for contamination of eggs with SE and its subsequent survival or growth must be considered a very serious risk because of the possibility that such contamination, survival, and growth could cause widespread foodborne illness, including some severe long-term effects and even loss of life. FDA's decision to publish a final rule to reduce this risk of SE contamination of shell eggs is based on a considerable body of evidence, literature, and expertise in this area. In addition, this decision was also based on the USDA risk assessment on SE in shell eggs and egg products and the identified public health benefits associated with controlling SE in eggs at the farm and retail levels.

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	04/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: State

Federalism: Yes

Agency Contact: John F. Sheehan
Director
Department of Health and Human Services
Food and Drug Administration
Division of Plant and Dairy Food Safety (HFS-315) Room 3B-012 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-2367
FAX: 301 436-2632
E-Mail: john.sheehan@fda.hhs.gov

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: Final Rule
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	12/00/2008	

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.

Agency Contact: Philip L. Chao
Senior Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Office of Policy and Planning (HF-23) Room 14C-17 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 827-0587
FAX: 301 827-4774
E-Mail: philip.chao@fda.hhs.gov

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: Final Rule
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	12/00/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Agency Contact: Jennifer L. Stevens
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Ave. Bldg. 51, Room 6316
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440
E-Mail: jennifer.stevens@fda.hhs.gov

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	04/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: Yes
Agency Contact: Claudia M. Gaffey
Medical Officer
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health 2098 Gaither Road
Rockville , MD 20850-4015
Phone: 240 276-0718
FAX: 240 276-0652
E-Mail: claudia.gaffey@fda.hhs.gov

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

View Related Documents

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

Abstract: The Food and Drug Administration (FDA) is proposing to reclassify pressure regulators for use with medical oxygen from class I to class II, establish a separate classification for oxygen conserving devices, and establish a special control for these devices to address problems of fire and explosion associated with use of these devices. The special control would 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 would be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the Act). The requirements of the proposed rule would be phased-in to minimize the cost of complying with the special control.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
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
Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

Agency Contact: Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-215) 1350 Piccard Drive PI50 RM150F
Rockville , MD 20850
Phone: 240 276-2347
FAX: 240 276-2352
E-Mail: myrna.hanna@fda.hhs.gov

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	06/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Agency Contact: Quynh H. Nguyen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6370
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440
E-Mail: quynh.h.nguyen@fda.hhs.gov

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	03/00/2009	

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
Agency Contact: Brian L. Pendleton
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drugs Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6304
Silver Spring , MD 20993-0002
Phone: 301 796-3504
FAX: 301 847-8440
E-Mail: brian.pendleton@fda.hhs.gov

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	09/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: State
Federalism: Yes
Energy Affected: No
Agency Contact: Elena N. Cohen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Ave. Bldg. 51, Room 6356
Silver Spring , MD 20993-0002
Phone: 301 796-3602
FAX: 301 847-8440
E-Mail: elena.cohen@fda.hhs.gov

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 proposed rule on January 30, 2006, 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 proposal was issued in response to adverse event reports received by FDA and to a citizen petition submitted to FDA. The comment period ended on May 1, 2006. FDA intends to issue a final rule after reviewing comments.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
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	11/00/2008	

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.

Agency Contact: Mical E. Honigfort
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
HFS-265 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-1278
FAX: 301 436-2972
E-Mail: mical.honigfort@fda.hhs.gov

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 371; 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	11/00/2008	

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

Agency Contact: Elena N. Cohen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Ave. Bldg. 51, Room 6356
Silver Spring , MD 20993-0002
Phone: 301 796-3602
FAX: 301 847-8440
E-Mail: elena.cohen@fda.hhs.gov

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 355; 21 USC 360bbb; 21 USC 371; 42 USC 262
Legal Deadline: None

Regulatory Plan:

Statement of Need: The Food and Drug Administration Modernization Act of 1997 (Modernization Act) amended the Federal Food, Drug, and Cosmetic Act (the Act) to include specific provisions concerning expanded access to investigational drugs for treatment use. In particular, section 561(b) of the Act permits any person, acting through a licensed physician, to request access to an investigational drug to diagnose, monitor, or treat a serious disease or condition provided that a number of conditions are met. The rule is needed to incorporate into FDA's regulations this and other provisions of the Modernization Act concerning access to investigational drugs. In addition, the agency seeks to increase awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs for treatment use. The rule will assist in achieving this goal by describing in detail the criteria, submission requirements, and safeguards applicable to different types of treatment uses.

Legal Basis: FDA has the authority to impose requirements concerning the treatment use of investigational drugs under various sections of the Act, including sections 505(i), 561, and 701(a) (21 U.S.C. 355(i), 360bbb, and 371(a)). Section 505(i) of the Act directs the Secretary to promulgate regulations exempting from the operation of the new drug approval requirements drugs intended solely for investigational use by experts qualified by scientific training and expertise to investigate the safety and effectiveness of drugs. The rule explains procedures and criteria for obtaining FDA authorization for treatment uses of investigational drugs. The Modernization Act provides significant additional authority for this rulemaking. Section 561(a) states that the Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations. Section 561(b) allows any person, acting through a physician licensed in accordance with State law, to request from a manufacturer or distributor an investigational drug for the diagnosis, monitoring, or treatment of a serious disease or condition if certain conditions are met. Section 561(c) closely tracks FDA's existing regulation at 21 CFR part 312.34 providing for treatment use by large patient populations under a treatment protocol or treatment IND if a number of conditions are met. Section 701(a) provides the Secretary with the general authority to promulgate regulations for the efficient enforcement of the Act. By clarifying the criteria and procedures relating to treatment use of investigational products, this rule is expected to aid in the efficient enforcement of the Act.

Alternatives: One alternative to this rulemaking that FDA considered was not to promulgate regulations implementing the expanded access provisions of the Modernization Act. However, the agency believes that promulgating regulations would further improve the availability of investigational drugs for treatment use by providing clear direction to sponsors, patients, and licensed physicians about the criteria for authorizing treatment use and what information must be submitted to FDA. Another alternative FDA considered was a regulation describing only individual patient and large scale expanded access criteria. However, the agency concluded that it would be preferable to have a third category of expanded access for intermediate-size patient populations.

Costs and Benefits: FDA expects that the costs of the rule will range from a low of about $109,350 to $218,700 in the first year following implementation of the final rule, to a high of about $325,500 to $567,825 in the fourth and fifth years. These estimates suggest that total annual costs for the rule would be between $1.2 million and $2.2 million for the 5-year period following implementation of the final rule. The agency also expects that the estimated incremental cost burdens associated with this rule are likely to be widely dispersed among affected entities. The benefits of the rule are expected to result from improved patient access to investigational drugs generally and from treatment use being made available for a broader variety of disease conditions and treatment settings. In particular, the clarification of eligibility criteria and submission requirements would enhance patient access by easing the administrative burdens on individual physicians seeking investigational drugs for their patients and on sponsors who make investigational drugs available for treatment use.

Risks: The agency foresees no risks associated with the rule.

Timetable:

Action	Date	FR Cite
NPRM	12/14/2006	71 FR 75147
NPRM Comment Period End	03/14/2007	
Final Action	11/00/2008	

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

Agency Contact: Elena N. Cohen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Ave. Bldg. 51, Room 6356
Silver Spring , MD 20993-0002
Phone: 301 796-3602
FAX: 301 847-8440
E-Mail: elena.cohen@fda.hhs.gov

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
Major: No
Agenda Stage of Rulemaking: Final Rule
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	12/00/2008	

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.
Agency Contact: Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-215) 1350 Piccard Drive PI50 RM150F
Rockville , MD 20850
Phone: 240 276-2347
FAX: 240 276-2352
E-Mail: myrna.hanna@fda.hhs.gov

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	06/00/2009	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: No Federalism: No
Related RINs: Split From 0910-AB26

Agency Contact: Brenda Friend
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research 1401 Rockville Pike Suite 200N (HFM-17)
Rockville , MD 20852-1448
Phone: 301 827-6210

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	06/00/2009	

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
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-024) 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-1459
E-Mail: benson.silverman@fda.hhs.gov

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	06/00/2009	

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
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-024) 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-1459
E-Mail: benson.silverman@fda.hhs.gov

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)	04/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 Rule	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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) (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)	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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
Final Action (GRASE dosage forms)	05/00/2009	
NPRM (Amendment)	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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)	03/00/2009	
NPRM (Amendment) (Miscellaneous Issues)	09/00/2009	
NPRM (Amendment) (Overindulgence/Hangover)	09/00/2009	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	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

Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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 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	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 identifies safe and effective skin protectant active

ingredients to treat and prevent diaper rash. The third action addresses astringent active ingredients.

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)	05/00/2009	
Final Action (Diaper Rash)	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
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 and 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	11/00/2008	

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.

Agency Contact: Burt Pritchett
Biologist
Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine HFV-222 7519 Standish Place, MPN-4
Rockville , MD 20855
Phone: 240 453-6860
FAX: 240 453-6882
E-Mail: burt.pritchett@fda.hhs.gov

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	06/00/2009	

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

Agency Contact: Amber McCoig
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-316) 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-2131
FAX: 301 436-2644
E-Mail: amber.mccoig@fda.hhs.gov

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
Major: No
Agenda Stage of Rulemaking: Final Rule
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	09/00/2009	

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

Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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 (Overindulgence Labeling)	09/00/2009	
Final Action (Sodium Bicarbonate Labeling)	09/00/2009	

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

Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: 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	08/29/2006	71 FR 51146
NPRM Comment Period End	12/27/2006	
Final Action	09/00/2009	

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

Federalism: Yes

Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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	06/00/2009	

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

Agency Contact: Eric Flamm
Senior Policy Advisor, Office of Policy
Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner Room 14C-17, HF-23 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 827-0591

FAX: 301 827-4774
E-Mail: eric.flamm@fda.hhs.gov

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: Final Rule
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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Martha Nguyen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6224
Silver Spring , MD 20993-0002
Phone: 301 796-3471
FAX: 301 847-8440
E-Mail: martha.nguyen@fda.hhs.gov

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 Rule	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Martha Nguyen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6224
Silver Spring , MD 20993-0002
Phone: 301 796-3471
FAX: 301 847-8440
E-Mail: martha.nguyen@fda.hhs.gov

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	05/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane

Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 proposing to amend 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	07/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Agency Contact: Margaret Oeller
Director, Office of Minor Use and Minor Species Animal Drug Development
Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (HFV-50, MPN-4) 7500 Standish Place Room 150
Rockville , MD 20855
Phone: 240 276-9005
FAX: 240 276-9001
E-Mail: margaret.oeller@fda.hhs.gov

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: Final 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
Small Entities Affected: No
Government Levels Affected: No
Federalism: No

Agency Contact: Paul E. Levine Jr.
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research 1401 Rockville Pike Suite 200N (HFM-17)
Rockville , MD 20852
Phone: 301 827-6210
E-Mail: paul.levine@fda.hhs.gov

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 post-marketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and post-market 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	04/00/2009	

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

Agency Contact: Elizabeth J. Sadove
Regulatory Counsel
Department of Health and Human Services

Food and Drug Administration
Center for Drug Evaluation and Research, Office of Regulatory Policy 10903 New Hampshire Avenue Bldg. 51, Room 6368
Silver Spring , MD 20993-0002
Phone: 301 796-3522
FAX: 301 847-8440
E-Mail: elizabeth.sadove@fda.hhs.gov

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.

Agency Contact: Linda Kahl
Senior Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-024) 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-2784
FAX: 301 436-2657
E-Mail: linda.kahl@fda.hhs.gov

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

Agency Contact: Julie Moss
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-830) 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-2373
FAX: 301 436-2639
E-Mail: julie.moss@fda.hhs.gov

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

Agency Contact: Ritu Nalubola
Staff Fellow
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition Harvey Wiley Building 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-2371
FAX: 301 436-2636
E-Mail: ritu.nalubola@fda.hhs.gov

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
Agency Contact: Howard P. Muller
Office of Regulatory Policy
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6234
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440
E-Mail: howard.mullerjr@fda.hhs.gov

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
Agency Contact: Jill Kevala
Chemist
Department of Health and Human Services

Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-830) 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-1450
FAX: 301 436-2636
E-Mail: jillone.kevala@fda.hhs.gov

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
Agency Contact: Anna Marie Brown Department of Health and Human Services
Food and Drug Administration
5100 Paint Branch Parkway HFS-840
College Park , MD 20740
Phone: 301 436-1450
FAX: 301 436-2636
E-Mail: annamarie.brown@fda.hhs.gov

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 proposing to amend 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
Agency Contact: Brenda Friend
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research 1401 Rockville Pike Suite 200N (HFM-17)
Rockville , MD 20852-1448
Phone: 301 827-6210

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 Eyelashes)	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
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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. This action addresses products containing antidiarrheal drug ingredients.

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	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Related to 0910-AC82
Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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 third action addresses consumer products. The last action addresses healthcare antiseptic 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
NPRM (Consumer)	00/00/0000	
NPRM (Testing)	00/00/0000	
Final Action (Healthcare)	00/00/0000	
NPRM (Food Handlers)	00/00/0000	

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

Federalism: Yes

Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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

Agency Contact: Tiffany J. Brown
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research 1401 Rockville Pike Suite 200N (HFM-17)
Rockville , MD 20852-1448
Phone: 301 827-6210

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

Agency Contact: Walter J. Ellenberg
Regulatory Project Management Officer, Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
HFD-560 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 796-0885
FAX: 301 796-9899
E-Mail: walter.ellenberg@fda.hhs.gov

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: Long-term Action

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

Agency Contact: Geraldine A. June
Supervisor, Product Evaluation and Labeling Team
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway ONLDS (HFS-820)
College Park , MD 20740
Phone: 301 436-1802
FAX: 301 436-2636
E-Mail: geraldine.june@fda.hhs.gov

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AB34

View Related Documents

Title: Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications

Abstract: The rule amends the regulations on marketing approval of new drugs to discontinue the use of approvable and not approvable letters when taking action on a marketing application and instead use complete response letters. The rule also amends the regulations on extension of the review clock because of amendments to applications.

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

Major: No Unfunded Mandates: No

CFR Citation: 21 CFR 312; 21 CFR 314 (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 371; 21 USC 374; 21 USC 379e

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/20/2004	69 FR 43357
NPRM Comment Period End	10/18/2004	
Final Action	07/10/2008	73 FR 39588

Regulatory Flexibility Analysis Required: No Government Levels Affected: No

Small Entities Affected: No Federalism: No

Agency Contact: Brian L. Pendleton
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drugs Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6304
Silver Spring , MD 20993-0002
Phone: 301 796-3504

FAX: 301 847-8440
E-Mail: brian.pendleton@fda.hhs.gov

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC35

View Related Documents

Title: Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs

Abstract: To require certain labeling of human drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act to include a toll-free number for reports of adverse events, and a statement that the number is to be used for reporting purposes only and not to receive medical advice.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 208; 21 CFR 209 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 355b
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/04/2003

Timetable:

Action	Date	FR Cite
NPRM	04/22/2004	69 FR 21778
NPRM Comment Period End	07/21/2004	
Interim Final Rule	01/03/2008	73 FR 402
Final Action	10/28/2008	73 FR 63886

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

Agency Contact: Carol Drew
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6306
Silver Spring , MD 20993-0002
Phone: 301 796-3601
FAX: 301 847-8440

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC41

View Related Documents

Title: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the Act), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), requires notification to FDA prior to the entry of imported food. The regulation explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided. Section 307 authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. FDA and the Bureau of Customs and Border Protection (CBP) issued an interim final rule (IFR) on October 10, 2003 (68 FR 58974). The IFR originally provided a 75-day comment period to ensure that those that

comment on the IFR have the benefit of our outreach and educational efforts and have the experience with the systems, timeframes, and data elements. We reopened the comment period for an additional 90 days in April through July 2004, to allow for additional comment on the industry's experience with the prior notice system, and comment on the Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes. The final rule currently is under development, and it will confirm or amend the IFR, as appropriate. This final rule is not expected to have a significant impact on a substantial number of small entities.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1.276 et seq (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188, sec 307
Legal Deadline: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 307, directs the Secretary, through FDA, to issue final regulations establishing prior notice requirements for all imported food by December 12, 2003. If FDA fails to issue final regulations by this date, the statute is self-executing on this date, and requires FDA to receive prior notice of not less than 8 hours, nor more than 5 days, until final regulations are issued.

Action	Source	Description	Date
Other	Statutory		12/12/2003

Timetable:

Action	Date	FR Cite
NPRM	02/03/2003	68 FR 5428
Interim Final Rule	10/10/2003	68 FR 58974
Interim Final Rule Comment Period Reopened	04/14/2004	69 FR 19763
Interim Final Rule Comment Period Reopened End	07/13/2004	
Final Action	11/07/2008	73 FR 66294
Final Action Effective	05/06/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: Business
Federalism: No
Energy Affected: No
Agency Contact: May Nelson
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway
College Park , MD 20740
Phone: 301 436-1722
FAX: 301 436-2637
E-Mail: may.nelson@fda.hhs.gov

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF15

View Related Documents

Title: Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application
Abstract: This final rule follows a proposed rule, which proposed to update the standards for the acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. We proposed to replace the requirement in 21 CFR part 312.120 that non-IND foreign clinical studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki or with the laws and regulations of the country that is the research site, whichever provide greater protection to subjects. We have replaced that with a requirement that such studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee. The GCP standard is consistent with the standard of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for GCP and is sufficiently flexible to accommodate differences in how countries regulate the conduct of clinical research and obtain the informed consent of subjects.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312.120 (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	06/10/2004	69 FR 32467
NPRM Comment Period End	09/08/2004	
Final Action	04/28/2008	73 FR 22800

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Brian L. Pendleton
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drugs Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6304
Silver Spring , MD 20993-0002
Phone: 301 796-3504
FAX: 301 847-8440
E-Mail: brian.pendleton@fda.hhs.gov

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF16

View Related Documents

Title: Distribution of Certain Drug Products by Registered Blood Establishments and Comprehensive Hemophilia Diagnostic Treatment Centers That Qualify as Health Care Entities; PDMA of 1987; PDA of 1992

Abstract: The final rule would amend certain limited provisions of the implementing regulations of the Prescription Drug Marketing Act (PDMA) of 1987, as modified by the Prescription Drug Amendments (PDA) of 1992. Certain provisions of that final rule that published on December 3, 1999 (64 FR 67720), would not allow registered blood establishments or hemophilia treatment centers that provide health care services to concurrently distribute drugs, including blood derivatives. The effective date of those provisions of that rule is delayed until December 1, 2008, as published on November 13, 2006 (71 FR 66108)--final rule; the applicability date was delayed in order to consider comments on the proposed rule published in the Federal Register February 1, 2006 (71 FR 5200). FDA's amendment to the final rule would allow registered blood establishments that provide health care services related to their drug activities as blood establishments and certain hemophilia treatment centers to also distribute certain drug products, including blood derivatives.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 203.3(q); 21 CFR 203.22(h); 21 CFR 203.22(i); 21 CFR 205.3(h) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351 to 353; 21 USC 371; 21 USC 374
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/01/2006	71 FR 5200
NPRM Comment Period End	05/02/2006	
Delay of Applicability	11/13/2006	71 FR 66108
Final Action	10/09/2008	73 FR 59496

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Federalism: No

Agency Contact: Jennifer Ross
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research 1401 Rockville Pike Suite 200N (HFM-10)
Rockville , MD 20852
Phone: 301 827-0372

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG04

View Related Documents

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

Abstract: The Food and Drug Administration (FDA) is amending certain sections of 21 CFR parts 210 and 211 as the first phase of an incremental approach to modifying the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals in 21 CFR parts 210 and 211. We are amending the regulations to modernize or clarify some of the CGMP requirements, as well as harmonize some of the CGMP requirements with those of other foreign regulators and other FDA regulations. These amendments are also consistent with current industry practice. We are taking this action as part of our continuing effort to revise outdated regulations without diminishing public health protection.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 210 to 211 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 351 to 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a to 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	12/04/2007	72 FR 68113
NPRM-Companion to Direct Final Rule	12/04/2007	72 FR 68064
NPRM Comment Period End	02/19/2008	
Direct Final Rule; Withdrawal	04/04/2008	73 FR 18440
Final Action	09/08/2008	73 FR 51919

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

Agency Contact: Brian L. Pendleton
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drugs Evaluation and Research 10903 New Hampshire Avenue Bldg. 51, Room 6304
Silver Spring , MD 20993-0002
Phone: 301 796-3504
FAX: 301 847-8440
E-Mail: brian.pendleton@fda.hhs.gov

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG05

View Related Documents

Title: Biological Products; Reporting of Biological Product Deviations in Manufacturing

Abstract: Section 600.14 (21 CFR 600.14) requires licensed manufacturers of biological products to report to FDA biological

product deviations in manufacturing. Section 606.170 requires licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered establishments, and transfusion services to report to FDA biological product deviations in manufacturing. Under section 610 of the Regulatory Flexibility Act, FDA has undertaken a review of these regulations in parts 600 and 606 under section 610. The purpose of this review was to determine whether the regulations in parts 600 and 606 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 solicited comments on the following: 1) The continued need for the regulations; 2) the nature of complaints or comments received concerning the regulations; 3) the complexity of the regulations; 4) the extent to which a regulation in parts 600 or 606 overlaps, duplicates, or conflicts with other Federal rules, and to the extent feasible, with State and local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations. FDA did not receive any comments during the review process of these regulations under section 610 review, therefore these regulations will continue without change. The section 610 review has been carried out along with a regulations review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory program more effective in achieving its goals, less burdensome, or in great alignment with the President's priorities and the principles set forth in the Executive order.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 600.14; 21 CFR 606.170 (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 360i; 21 USC 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262 and 263; 42 USC 263a; 42 USC 264; 42 USC 300aa-25
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Begin Review	05/05/2008	
End Review	11/03/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Agency Contact: Stephen M. Ripley
Team Leader
Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research 1401 Rockville Pike Suite 200N (HFM-17)
Rockville , MD 20852-1448
Phone: 301 827-6210

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: Final Rule
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	02/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: William Munier Department of Health and Human Services
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville , MD 20850
Phone: 301 427-1219
FAX: 301 443-0251
E-Mail: william.munier@ahrq.hhs.gov

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	03/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: Undetermined
Agency Contact: Bill Hoffman Department of Health and Human Services
Centers for Disease Control and Prevention
626 Cochran Mill Road
Pittsburgh , PA 15236
Phone: 412 386-5200
FAX: 412 386-4089
E-Mail: whoffman@cdc.gov

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; 3) revised approval label requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed 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	11/00/2008	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Agency Contact: Bill Hoffman Department of Health and Human Services
Centers for Disease Control and Prevention
626 Cochran Mill Road
Pittsburgh , PA 15236
Phone: 412 386-5200
FAX: 412 386-4089
E-Mail: whoffman@cdc.gov

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: Proposed 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	11/00/2008	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
Agency Contact: Tim Rehak Department of Health and Human Services
Centers for Disease Control and Prevention
626 Cochran Mill Road
Pittsburgh , PA 15236
Phone: 412 386-5200
FAX: 412 386-4089

E-Mail: trehak@cdc.gov

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: The Centers for Disease Control and Prevention (CDC) is issuing this Advance Notice of Proposed Rulemaking (ANPRM) to begin the process of revising the regulations for importation of dogs, cats, and other animals into the United States (42 CFR parts 71.51 and 71.56). The input received from stakeholders via the ANPRM will guide CDC in drafting a rule proposal with the aim of improving CDC's ability to prevent importation of communicable diseases. The scope of this ANPRM does not include the nonhuman primate regulations.

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	06/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

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	05/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Lee Petsonk Department of Health and Human Services
Centers for Disease Control and Prevention

Morgantown , WV 26505
Phone: 304 285-5842
FAX: 304 285-6111
E-Mail: petsonk@cdc.gov

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: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 71.53 (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	02/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

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

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 supports 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: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 34 (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	12/00/2008	

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

Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

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 the definition of "communicable disease of public health significance" in 42 CFR part 34.2(b), the scope of examination, and the evaluation criteria for tuberculosis in 42 CFR 34.3. Part 34 lists the aliens ineligible for entry into the U.S. We are taking this action to afford CDC the maximum flexibility it needs to identify and respond to newly emerging and reemerging diseases. The existing definition is outdated, and immediate changes are urgently 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. Annually, approximately 500,000 immigrants and refugees enter the United States to reside permanently. These changes will reduce the health-security threat to the U.S. from emerging diseases without imposing an undue burden on either the aliens or the health care systems in the 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: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/00/2009	

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

Energy Affected: Yes

Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

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. The rule will also modify current Federal regulations governing the apprehension, 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 re-emergent 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 70 and 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Regulatory Plan:

Statement of Need: The quarantine or isolation of persons believed to be infected with or exposed to a communicable disease are public health prevention measures that have been used effectively to contain the spread of disease. As diseases evolve due to natural occurrences or man-made events, it is important to ensure that prevention procedures reflect new threats and uniform ways to contain them. Recent experiences with emerging infectious diseases such as West Nile Virus, SARS, and monkeypox have illustrated both the rapidity with which disease may spread throughout the world and the impact that communicable diseases, when left unchecked, may have on the global economy. Stopping an outbreak—whether it is naturally occurring or intentionally caused—requires the use of the most rapid and effective public health tools available. Two of these tools are isolation and quarantine. Isolation refers to the separation or restriction of movement of ill persons with an infectious disease in order to prevent transmission to those who are not ill. Quarantine refers to the separation and restriction of movement of persons who, while not yet ill, have been exposed to an infectious agent and therefore may become infectious. Isolation and quarantine of ill and exposed persons may be one of the best initial strategies to prevent the uncontrolled spread of highly dangerous biologic agents—especially when combined with other health strategies such as vaccination, prophylactic drug treatment, and other appropriate infection control measures.

Legal Basis: These regulations would be proposed under the authority of 25 U.S.C. 198, 231, 2001; 42 U.S.C. 243, 264 to 271. In addition, section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)) authorizes the “apprehension, detention, or conditional release” of persons to prevent the introduction, transmission, and spread of specified communicable diseases from foreign countries into the United States and from one State or possession into another. Among other public health powers, the lawful ability to inspect property, to medically examine and monitor persons, and to detain or quarantine exists in current regulations. Acknowledging the critical importance of protecting the public’s health, long-standing court decisions uphold the ability of Congress and State legislatures to enact quarantine and other public health laws and to have them executed by public health officials.

Alternatives: These regulations are necessary to ensure that HHS has the tools it needs to respond to public health emergencies and disease threats. Any less stringent alternatives would prevent the Department from the most effective possible

pursuit of this objective.

Costs and Benefits: The primary cost impact of the proposed rule would be data collection, transmission, storage and retrieval, and costs associated with contact tracing. The benefits of this rule will offer procedures that more completely describe the 21st century implementation of disease containment measures such as isolation and quarantine. These procedures are expected to expedite and improve CDC operations by allowing immediate medical follow-up of potentially infected passengers and their contacts. The benefits of the rule would be measured in terms of the number of deaths and illnesses prevented by rapid intervention.

Risks: Failure to move forward with this rulemaking would hinder the Nation's ability to use the most rapid and effective public health tools available when responding to public health emergencies and disease threats.

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
Final Action	04/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No

Federalism: No

Energy Affected: No

Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

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: 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 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 70 (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	11/30/2005	70 FR 71892
Final Action	12/00/2008	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: Undetermined
Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

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
Agency Contact: Frank Palya Department of Health and Human Services
Centers for Disease Control and Prevention
626 Cochran Mill Road
Pittsburgh , PA 15236
Phone: 412 386-5200
FAX: 412 386-4089
E-Mail: fpalya@cdc.gov
Agency Contact: Bill Hoffman Department of Health and Human Services
Centers for Disease Control and Prevention
626 Cochran Mill Road
Pittsburgh , PA 15236
Phone: 412 386-5200
FAX: 412 386-4089
E-Mail: whoffman@cdc.gov

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
Agency Contact: Robbin Weyant Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 20, Room 4202 1600 Clifton Road NE.
Atlanta , GA 30333
Phone: 404 718-2000

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
Agency Contact: Robbin Weyant Department of Health and Human Services

Centers for Disease Control and Prevention
CLFT Building 20, Room 4202 1600 Clifton Road NE.
Atlanta , GA 30333
Phone: 404 718-2000

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. Because CDC has separated this provision from the rest of 42 CFR 70, CDC is requesting a separate entry in the Unified Agenda and a new RIN for this regulation.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
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: Not Yet Determined
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
Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA20

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 the definition of "communicable disease of public health significance" in 42 CFR part 34.2(b), the scope of examination, and the evaluation criteria for tuberculosis in 42 CFR 34.3. Part 34 list the aliens ineligible for entry into the U.S. We are taking this action to afford CDC the maximum flexibility it needs to identify and respond to newly emerging and reemerging diseases. The existing definition is outdated, and immediate changes are urgently 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. Annually, approximately 500,000 immigrants and refugees enter the United States to reside permanently. These changes will reduce the health-security threat to the U.S. from emerging diseases without imposing an undue burden on either the aliens or the health care systems in the U.S. resettlement communities.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
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
Interim Final Rule	10/06/2008	73 FR 58047
Correction Notice	10/20/2008	73 FR 62210

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: Undetermined
Agency Contact: Stacy Howard Department of Health and Human Services
Centers for Disease Control and Prevention
CLFT Building 16, Room 4324 MS E03
Atlanta , GA 30329
Phone: 404 718-1056

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA29

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 result 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 any 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.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
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	10/16/2008	73 FR 61363
Final Action Effective	11/17/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Robbin Weyant Department of Health and Human Services

Centers for Disease Control and Prevention
CLFT Building 20, Room 4202 1600 Clifton Road NE.
Atlanta , GA 30333
Phone: 404 718-2000

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 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: Substantive, Nonsignificant
Agenda Stage of Rulemaking: PreRule
Major: Undetermined
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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard Room 601, MSC 7669
Rockville , MD 20852
Phone: 301 496-4607
FAX: 301 402 0169
E-Mail: jm40z@nih.gov

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	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606
FAX: 301 402-0169
E-Mail: jm40z@nih.gov

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	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606

FAX: 301 402-0169
E-Mail: jm40z@nih.gov

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	06/00/2009	

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

Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606
FAX: 301 402-0169
E-Mail: jm40z@nih.gov

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 non-profit 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	06/00/2009	

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

Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606
FAX: 301 402-0169
E-Mail: jm40z@nih.gov

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
Major: No
Agenda Stage of Rulemaking: Proposed Rule
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	06/00/2009	

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

Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606
FAX: 301 402-0169

E-Mail: jm40z@nih.gov

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	01/00/2009	

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

Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606
FAX: 301 402-0169
E-Mail: jm40z@nih.gov

Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA31

View Related Documents

Title: Standards for a National Chimpanzee Sanctuary System

Abstract: NIH is establishing standards for operating a national chimpanzee sanctuary system to provide for the retirement of federally owned or supported chimpanzees no longer needed for research.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 9 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 287a-3a
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		06/18/2001

Timetable:

Action	Date	FR Cite
NPRM	01/11/2005	70 FR 1843
Final Action	10/10/2008	73 FR 60410
Final Action Effective	11/10/2008	

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

Agency Contact: Jerry Moore
NIH Regulations Officer
Department of Health and Human Services
National Institutes of Health
6011 Executive Boulevard
Rockville , MD 20852
Phone: 301 496-4606
FAX: 301 402-0169
E-Mail: jm40z@nih.gov

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: HHS is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluids at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers.

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: 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	12/00/2008	

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

Agency Contact: Joseph Denis Faha
Director, DLEA, SAMHSA
Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville , MD 20857
Phone: 301 443-7017
FAX: 301 443-1450
E-Mail: jfaha@samhsa.gov

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
Agency Contact: Paolo Del Vecchio Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Room 13-103, Parklawn Building 5600 Fishers Lane
Rockville , MD 20857
Phone: 301 443-2619

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: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
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	00/00/0000	

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

Agency Contact: Nicholas Reuter Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
One Choke Cherry Rd Suite 2-1063
Rockville , MD 20857
Phone: 240 276-2716

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: PreRule
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. Each agency's counsel has advised that the regulation can be interim final with a comment period.

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

Agency Contact: Adam M Shaw
Senior Technical Adviser
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop C1-22-06 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1091
E-Mail: adam.shaw@cms.hhs.gov

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: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 435 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: None
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2008	

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

Agency Contact: Melissa L. Harris
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Disability and Elderly Health Programs Group Mailstop S2-14-26 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3397
E-Mail: melissa.harris@cms.hhs.gov

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-P)

Abstract: This proposed rule would revise certain Clinical Laboratory Improvement Amendments (CLIA) of 1988 proficiency testing requirements for clinical laboratories offering cytology services and individuals examining gynecological cytology specimens. Revisions would also be 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
Agenda Stage of Rulemaking: Proposed Rule
Major: No
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: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2009	

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

Agency Contact: Cheryl B. Wiseman
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop S2-12-25 7500 Security Boulevard

Baltimore , MD 21244
Phone: 410 786-3340 Extension: 6-3340
E-Mail: cheryl.wiseman@cms.hhs.gov

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: Proposed Rule
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
NPRM	12/00/2008	

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

Agency Contact: Susan Gratzer
Director, State Children's Health Insurance Program
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers of Medicaid State Operations Mailstop S2-01-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-8694
FAX: 410 786-5882
E-Mail: susan.gratzer@cms.hhs.gov

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: Proposed Rule
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	05/00/2009	

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

Agency Contact: Janice A. Graham RN
Health Insurance Specialist, Clinical Standards Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244-1850
Phone: 410 786-8020
FAX: 410 786-2532
E-Mail: janice.graham@cms.hhs.gov

Agency Contact: Monique Howard
Senior Health Insurance Specialist, Clincal Standards Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Clincial Standards and Quality Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244-1850
Phone: 410 786-3869
E-Mail: monique.howard@cms.hhs.gov

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: Proposed Rule
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	12/00/2008	

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

Agency Contact: Trish Brooks
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4561
E-Mail: trish.brooks@cms.hhs.gov

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 Prospective Payment System for FY 2010 (CMS-1406-P)

Abstract: This major rule proposes to revise the Medicare hospital inpatient 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: Undetermined
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: CMS annually revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. The proposed rule solicits comments on the proposed IPPS payment rates and new policies. CMS will issue a final rule containing the payment rates for the 2010 IPPS at least 60 days before October 1, 2009.

Legal Basis: The Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. The Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system (PPS). Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. These changes would be applicable to services furnished on or after October 1, 2009.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for FY 2010.

Risks: If this regulation is not published timely, inpatient hospital services will not be paid appropriately beginning October 1, 2009.

Timetable:

Action	Date	FR Cite
NPRM	04/00/2009	

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

Agency Contact: Tiffany Swygert
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Div of Acute Care, Hosp and Ambulatory Policy Group Mailstop C4-25-11 7500 Security Blvd
Baltimore , MD 21244
Phone: 410 786-4642
E-Mail: tiffany.swygert@cms.hhs.gov

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: The statute requires that we establish each year, by regulation, payment amounts for all physicians' services furnished in all fee schedule areas. This major proposed rule would make changes affecting Medicare Part B payment to physicians and other Part B suppliers. The final rule has a statutory publication date of November 1, 2009, and implementation of January 1, 2010.

Legal Basis: Section 1848 of the Social Security Act (the Act) establishes the payment for physician services provided under Medicare. Section 1848 of the Act imposes a deadline of no later than November 1 for publication of the final physician fee schedule rule.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for CY 2010.

Risks: If this regulation is not published timely, physician services will not be paid appropriately.

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

Agency Contact: Diane Milstead
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicaid Mangement Mailstop C4-03-06 7500 Security Blvd
Baltimore , MD 21244
Phone: 410 786-3355
E-Mail: diane.milstead@cms.hhs.gov

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
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Regulatory Plan:

Statement of Need: Medicare pays over 4,200 hospitals for outpatient department services under the hospital outpatient prospective payment system (OPPS). The OPPS is based on groups of clinically similar services called ambulatory payment classifications (APCs). CMS annually revises the APC payment amounts based on claims data, proposes new payment polices, and updates the payments for inflation using the market basket. The proposed rule solicits comments on the proposed OPPS payment rates and new policies. This rule does not impact payments to critical access hospitals as they are not paid under the OPPS. CMS will issue a final rule containing the payment rates for the 2010 OPPS at least 60 days before January 1, 2010.

Legal Basis: Section 1833 of the Social Security Act establishes Medicare payment for hospital outpatient services. The final rule revises the Medicare hospital OPPS 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 and final rules describe changes to the outpatient APC system, relative payment weights, outlier adjustments, and other amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2010.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for CY 2010.

Risks: If this regulation is not published timely, outpatient hospital services will not be paid appropriately beginning January 1, 2010.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2009	

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

Agency Contact: Alberta Dwivedi
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicare Management Mailstop C5-01-26 7500 Security Blvd
Baltimore , MD 21244
Phone: 410 786-0763
E-Mail: alberta.dwivedi@cms.hhs.gov

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-P)

Abstract: This rule proposes the annual update to the hospice wage index for FY 2010. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
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	05/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: Undetermined
Agency Contact: Randy Throndset
Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare Management Mailstop C5-07-28 7500 Security Boulevard
Baltimore , ME 21244
Phone: 410 786-0130
FAX: 410 786-0765
E-Mail: randy.hrondset@cms.hhs.gov

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 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1886(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: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: Undetermined
Agency Contact: William Ullman

Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicare Management Mailstop C5-06-27 7500 Security Boulvard
Baltimore , MD 21244
Phone: 410 786-5667
FAX: 410 786-0765
E-Mail: bill.ullman@cms.hhs.gov

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	06/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined
Agency Contact: Randy Throndset
Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare Management Mailstop C5-07-28 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0131
FAX: 410 786-0765
E-Mail: randy.throndset@cms.hhs.gov

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: Undetermined
Energy Affected: Undetermined
Agency Contact: Susanne Seagrave
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicare Mangement Mailstop C5-06-27 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0044
E-Mail: susanne.seagrave@cms.hhs.gov

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: Section 153 of MIPPA requires implementation of a bundled payment system for ESRD facilities by January 1, 2011.

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
Agency Contact: Janet Samen
Director of Chronic Care Mangement
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicare Management Mailstop C5-05-27 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-9161
E-Mail: janet.samen@cms.hhs.gov

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 adopt's 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: Final Rule
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments
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	11/00/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal; Local; State; Tribal
Federalism: Yes
Energy Affected: No

Agency Contact: Gladys C. Wheeler
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of E-Health Standards and Services Mailstop S2-24-18 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0273
E-Mail: gladys.wheeler@cms.hhs.gov

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
Final Action	03/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Related RINs: Related to 0938-AK69
Government Levels Affected: Federal
Federalism: No

Agency Contact: Katherine L. Hosna
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C2-12-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4993
E-Mail: katherine.hosna@cms.hhs.gov

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
Major: No
Agenda Stage of Rulemaking: Final Rule
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	11/00/2008	

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

Agency Contact: James Frizzera
Director, National Institutional Payment Policy
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations Mailstop S3-13-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-9535
E-Mail: james.frizzera@cms.hhs.gov

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 revise 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: Final Rule
Major: Yes
Unfunded Mandates: Undetermined
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	11/00/2008	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions; Organizations
Government Levels Affected: Federal; Local; State; Tribal
Federalism: No
Energy Affected: Yes

Agency Contact: Denise Buenning
Health Insurance Specialist, Office of E-Health Standards and Services
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop S2-26-17 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6711
E-Mail: denise.buenning@cms.hhs.gov

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		12/08/2003

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
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

Agency Contact: Deborah A. Miller Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management Mailstop C3-14-00 7500 Security Boulevard
Baltimore , MD 21244-1850
Phone: 410 786-0331
E-Mail: deborah.miller3@cms.hhs.gov

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
Major: No
Agenda Stage of Rulemaking: Final Rule
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: None

Timetable:

Action	Date	FR Cite
NPRM	09/28/2007	72 FR 55158
Final Action	11/00/2008	

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

Agency Contact: Jeremy Silanskis
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations Mailstop S3-13-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1592
FAX: 410 786-8533
E-Mail: jeremy.silanskis@cms.hhs.gov

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: Final Rule
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	11/00/2008	

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

Agency Contact: Frances Crystal
Director, Family and Children's Health Programs Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid State Operations Mailstop S2-01-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1195
E-Mail: frances.crystal@cms.hhs.gov

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: 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: 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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: Yes
Agency Contact: Donna Schmidt Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicaid State Operations Mailstop S2-01-16 7500 Security Boulevard
Baltimore , MD 21244-1850
Phone: 410 786-5532
E-Mail: donna.schmidt@cms.hhs.gov

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: Final Rule
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments
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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: Yes
Energy Affected: No
Agency Contact: Dianne Heffron
Director, Family and Children's Health Programs Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid State Operation Mailstop, S3-13-15 7500 Security Boulvard
Baltimore , MD 21244
Phone: 410 786-3247
FAX: 410 786-1008
E-Mail: dianne.heffron@cms.hhs.gov

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 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: Final Rule
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
NPRM	04/04/2008	73 FR 18676
NPRM Comment Period End	06/03/2008	
Final Action	11/00/2008	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions
Government Levels Affected: Federal
Federalism: No
Energy Affected: No

Agency Contact: Suzanne Bosstick Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1301
E-Mail: suzanne.bosstick@cms.hhs.gov

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: Final Rule
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	11/00/2008	

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

Agency Contact: Richard Strauss Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop S2-26-12 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1236
E-Mail: richard.strauss@cms.hhs.gov

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: Final Rule
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	11/00/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AL80

Agency Contact: Alberta Dwivedi
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-01-26 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0763
E-Mail: alberta.dwivedi@cms.hhs.gov

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

Action	Source	Description	Date
Other	Statutory		11/01/2008

Timetable:

Action	Date	FR Cite
Notice	11/00/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
Agency Contact: Randy Throndset
Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-07-28 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0131
FAX: 410 786-0765
E-Mail: randy.throndset@cms.hhs.gov

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: Final Rule
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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Agency Contact: Richard Strauss
Health Insurance Specialist

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop S3-13-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-2019
E-Mail: richard.strauss@cms.hhs.gov

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
Agency Contact: Clare McFarland
Deputy Director, Medicare and Medicaid Cost Estimates Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of the Acturary Mailstop, N3-26-00 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6390
E-Mail: clare.mcfarland@cms.hhs.gov

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 Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8038-N)

Abstract: This nonmajor 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 13951-2(d)(2); 42 USC 13951-2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A60(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
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

Agency Contact: Clare McFarland
Deputy Director, Medicare and Medicaid Cost Estimates Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of the Actuary Mailstop N3-26-00 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6390
E-Mail: clare.mcfarland@cms.hhs.gov

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
Major: Undetermined
Agenda Stage of Rulemaking: Final Rule
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
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

Agency Contact: Suzanne Codespote
Deputy Director, Medicare and Medicaid Cost Estimates Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of the Actuary Mailstop N3-26-00 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-7737

E-Mail: suzanne.codespote@cms.hhs.gov

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-N)

Abstract: This notice updates the Inpatient Psychiatric Facility Prospective Payment System for RY 2010.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
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: Undetermined
Government Levels Affected: Local
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: Undetermined
Agency Contact: Janet Samen
Division Director of Chronic Care Management
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicare Mangement Mailstop C5-05-27 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-9161
E-Mail: janet.samen@cms.hhs.gov

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), prescription drug benefit program (Part D), and Section 1876 cost plans.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
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		01/01/2009

Timetable:

Action	Date	FR Cite

Interim Final Rule	09/18/2008	73 FR 54225
Interim Final Rule Comment Period End	11/17/2008	
Final Action	11/00/2011	

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

Agency Contact: Jerry Mulcahy
Division Director of Policy Anaylsis & Planning Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Drug & Healthplan Choice Mailstop C4-23-07 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1142
E-Mail: jerry.mulcahy@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP53

View Related Documents

Title: State Children's Health Insurance Program (SCHIP); Redistribution of Unexpended SCHIP Funds (CMS-2291-N)

Abstract: This notice announces the procedure for redistribution of States' unexpended funds to those States that fully expended the SCHIP allotment. These redistributed allotments will be available through the end of FY 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Final 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
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	05/00/2009	

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

Agency Contact: Richard Strauss
Technical Director
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid State Operations Mailstop S3-13-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1850
E-Mail: richard.strauss@cms.hhs.gov

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 funding 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: Final Rule
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
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	08/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Richard Strauss
Technical Director
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid State Operations Mailstop S3-13-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1850
E-Mail: richard.strauss@cms.hhs.gov

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-IFC)

Abstract: This interim 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: Final Rule
Major: Undetermined
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: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/2008	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Agency Contact: Martha Kuespert
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-08-27 7500 Security Boulevard

MD 21244
Phone: 410 786-4605
E-Mail: martha.kuespert@cms.hhs.gov

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
Agenda Stage of Rulemaking: Long-term Action
Major: No
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
Government Levels Affected: No
Small Entities Affected: Business; Organizations
Federalism: No
Energy Affected: No

Agency Contact: Commander Mercedes Benitez-McCrary
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-05-14 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-5716
E-Mail: mercedes.benitezmccrary@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AJ17

View Related Documents

Title: Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers (CMS-1910-F2)

Abstract: This 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: None

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
Agency Contact: John Warren
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicare Management Mailstop C4-01-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3633
E-Mail: john.warren@cms.hhs.gov

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 non major 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: Long-term 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	08/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: No
Related RINs: Related to 0910-AB76
Government Levels Affected: No
Federalism: No

Agency Contact: Mary Collins
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3189
E-Mail: mary.collins@cms.hhs.gov

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
Major: No
Agenda Stage of Rulemaking: Long-term Action
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
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: No
Federalism: No

Agency Contact: Thomas Shenk
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Division of Benefits and Coverage Policy Mailstop S2-14-26 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3295
E-Mail: thomas.shenk@cms.hhs.gov

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: Federal; Local; State; Tribal
Federalism: Yes
Energy Affected: No

Agency Contact: Elizabeth Holland
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of E-Health Standards and Services Mailstop S2-26-17 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1309
E-Mail: elizabeth.holland@cms.hhs.gov,

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
Agency Contact: Carla McGregor
Technical Director, Survey and Certification Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid State Operations Mailstop S2-12-25 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0663
E-Mail: carla.mcgregor@cms.hhs.gov

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
Government Levels Affected: Federal; Local; State
Small Entities Affected: Business; Organizations
Federalism: Yes
Energy Affected: No
Agency Contact: Adam Shaw
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices Employer and Policy Operations Group 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1091
E-Mail: adam.shaw@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN73

View Related Documents

Title: Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (CMS-3156-P)

Abstract: This proposed rule would add a provision to the existing Quality Improvement Organization (QIO) confidentiality regulations allowing the release of Medicare beneficiary-specific information, with patient consent, from the QIO to practitioners and providers in a treatment relationship with the beneficiary. This release may only be permitted after the beneficiary has consented to the release and has been provided notice of the release. The new provisions will also permit the release of Medicare beneficiary-specific information, with patient consent, from the QIO to other QIOs, subcontractors to QIOs, and CMS for educational and quality improvement purposes. Additionally, the rule would add provisions for the Medicare beneficiary complaint system that is required by the statute and administered by the QIOs.

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: 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
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

Agency Contact: Thomas Kessler
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality Improvement Group Mailstop, S3-02-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1991
E-Mail: thomas.kessler2@cms.hhs.gov

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 proposed rule would establish, in regulations, certain provisions under the Balanced Budget Act of 1997 and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA). In addition, this rule would allow States to provide health services to employed individuals with disabilities who lose eligibility for disability benefits due to improvement in medical conditions or because their income exceeds the income limitations. This rule would also provide a definition for "medically determinable severe impairment" under the TWWIIA. Under this definition, States would determine eligibility standards for the Medical Improvement Group authorized under the TWWIIA legislation, thereby permitting eligible individuals to retain their Medicaid coverage. Additionally, this rule would give States offering Medicaid buy-in programs for employed individuals with disabilities the option of applying a minimum work standard to two Medicaid buy-in groups.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 435 and 436 (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
Government Levels Affected: State

Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Joseph Razes
Technical Director, Disabled and Elderly Health Program Group Div. of Advocacy and Special Issues
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations Mailstop, S2-14-26 7500 Security Boulvard
Baltimore , MD 21244
Phone: 410 786-6126
FAX: 410 786-9004
E-Mail: joseph.razer@cms.hhs.gov

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 managment 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:

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
Agency Contact: Theresa A. Pratt
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop S2-14-26 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-5831
E-Mail: theresa.pratt@cms.hhs.gov

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 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: None

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
Federalism: No
Energy Affected: Undetermined

Agency Contact: Melissa Hulbert
Acting Director, Division of Coverage and Integration
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Disabled and Elderly Health Programs Group, Center for Medicaid State Operations Mailstop S2-14-26 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6568
FAX: 410 786-3262
E-Mail: melissa.hulbert@cms.hhs.gov

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 rule permits a waiver or nurse aide training disapproval for skilled nursing facilities and nursing facilities that are assessed a civil money penalty of at least $5,000 for noncompliance that is not related to quality of care. The purpose of this regulation is to implement the legislative waiver provision enacted on December 8, 2003, in section 932(c)(2) of the MMA. The ability to make these waiver determinations could allow continued and consistent operation of a nursing home's nurse aide training program in facilities having non-quality of care deficiencies, which ultimately benefits residents. This rule also codifies statutory provisions at sections 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act that permits the State to establish a procedure to permit a nurse aide to petition the State to have a singular finding of neglect removed from the nurse aide registry if the State determines that the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect and the neglect involved in the original finding was a singular occurrence.

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: None

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
Agency Contact: Patricia Miller
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations Mailstop S2-19-14 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6780
FAX: 410 786-0194
E-Mail: patricia.miller@cms.hhs.gov

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: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: No 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	08/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Frank Whelan
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management Mailstop C3-02-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1302
E-Mail: frank.whelan@cms.hhs.gov

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: The voluntary prescription drug benefit program was enacted into law by section 101 of title 1 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). The implementing regulations for the Part D program were published in a final rule on January 28, 2005, and became effective March 22, 2005. These regulations provide that the Medicare Advantage (MA) rules regarding appeals and reopenings will apply to the Part D appeals process to the extent they are appropriate. The MA regulations in turn apply the fee-for-service (FFS) appeals regulations (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) to the extent they are appropriate. Based on this regulatory framework, we noted in the January 28, 2005, rule that differences in the appeals procedures for Part D enrollees would be addressed in a future Part D rulemaking document. This rule provides additional guidance on the differences in appeals procedures for Part D enrollees by proposing more detailed regulations governing Part D appeals at the ALJ, MAC, and Federal district court levels and reopenings of determinations and decisions that follow the Part A and Part B procedures set forth in the part 405 rule, as appropriate.

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: None

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
Agency Contact: Anthony Culotta
Director, Medicare Enrollment & Appeals Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C2-12-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4661 Extension: 64661
E-Mail: anthony.culotta@cms.hhs.gov

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: The number of providers and suppliers enrolling and maintaining enrollment within the Medicare Program are of such a large magnitude that CMS must be able to ensure that quality care is given to beneficiaries while at the same time guaranteeing the protection of the Medicare Trust Fund. This rule finalizes new standards to help to maintain an acceptable level of care for the 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: None

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
Agency Contact: August Rudolph Nemec III
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management Mailstop C3-07-08 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0612
FAX: 410 786-7259
E-Mail: august.nemec@cms.hhs.gov

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: None

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: No Government Levels Affected: State
Federalism: No
Energy Affected: No
Agency Contact: Dianne Heffron Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicaid State Operations Mailstop S3-13-15 7500 Security Boulevard
Baltimore , MD 21224
Phone: 410 786-3247
FAX: 410 786-1008
E-Mail: dianne.heffron@cms.hhs.gov

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

Agency Contact: August Nemec Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C3-07-08 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0612
E-Mail: august.nemec@cms.hhs.gov

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: The regulation outlines procedures for the States and for CMS to certify the Medigap policies of private issuers. This 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 et seq (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

Agency Contact: Cathy Windfield-Jones Department of Health and Human Services

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6674
E-Mail: cathy.windfield@cms.hhs.gov

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: Long-term 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
Final Action	00/00/0000	
NPRM	07/07/2008	73 FR 38502
NPRM Comment Period End	08/29/2008	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions

Government Levels Affected: Federal

Federalism: Yes

Energy Affected: No

Agency Contact: Diane Milstead
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C4-03-06 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3355
E-Mail: diane.milstead@cms.hhs.gov

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 Benefit Programs (CMS-4131-Q)

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: Other Significant

Agenda Stage of Rulemaking: Long-term Action

Major: No

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	05/00/2011	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Federalism: Yes

Energy Affected: No

Agency Contact: Chris McClintick
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Drug Health Plan Choices Mailstop C4-22-04 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4682
E-Mail: chris.mcclintick@cms.hhs.gov

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: Long-term 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
Final Action	05/00/2011	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AO94
Agency Contact: Tzvi Hefter
Director, Division of Acute Care & Ambulatory Policy Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C4-08-06 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4487
E-Mail: tzvi.hefter@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AH27

View Related Documents

Title: Medicare and Medicaid Programs; Hospice Care Conditions of Participation (CMS-3844-F)
Abstract: This final rule is a regulatory reform initiative that revises existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, and allow hospices greater flexibility in meeting quality standards. 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
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 418 (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	05/27/2008

Timetable:

Action	Date	FR Cite
NPRM	05/27/2005	70 FR 30840
Final Action	06/05/2008	73 FR 32087

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Mary Rossi-Coajou
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6051 Extension: 6-6051
E-Mail: mary.rossicoajou@cms.hhs.gov
Agency Contact: Danielle Shearer
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244

Phone: 410 786-6617
E-Mail: danielle.shearer@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AI49

View Related Documents

Title: Appeals of CMS or Contractor Determination When a Provider or Supplier Fails To Meet the Requirements for Medicare Billing (CMS-6003-F)

Abstract: This final rule extends appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations. In addition, certain appeal provisions are revised to correspond with the existing appeal provisions in those other sections of our regulations. It also extends appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. This rule incorporates provisions from section 936 of the Medicare Modernization Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 405.874; 42 CFR 424.525; 42 CFR 424.535; 42 CFR 424.545; 42 CFR 498.1 and 498.2; 42 CFR 498.5; 42 CFR 498.22; 42 CFR 498.40; 42 CFR 498.44; 42 CFR 498.56; 42 CFR 498.78 and 498.79; 42 CFR 498.86; 42 CFR 498.88; 42 CFR 405.802; 42 CFR 424.510; ... (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b) and 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/25/1999	64 FR 57431
Second NPRM	03/02/2007	72 FR 9479
Second NPRM Comment Period End	05/02/2007	
Final Action	06/27/2008	73 FR 36448

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
Agency Contact: August Nemec
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management, Program Integrity Group Mailstop C3-02-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0612
E-Mail: august.nemec@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AL54

View Related Documents

Title: Provider Reimbursement Determinations and Appeals (CMS-1727-F)

Abstract: This final rule redefines, clarifies, and updates the guidelines and procedures for Provider Reimbursement Review Board appeals based on recent court decisions.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No

CFR Citation: 42 CFR 405; 42 CFR 413; 42 CFR 417 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: sec 1878 of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec 902.	06/25/2008

Timetable:

Action	Date	FR Cite
NPRM	06/25/2004	69 FR 35716
NPRM Comment Period End	08/24/2004	
Notice of Extension	06/22/2007	72 FR 34425
Final Action	05/23/2008	73 FR 30190

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

Agency Contact: Morton Marcus
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C4-25-02 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4477
E-Mail: morton.marcus@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AL80

View Related Documents

Title: Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-F)

Abstract: This rule revises the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement. The focus is to improve outcomes of health care and satisfaction for Medicare beneficiaries, while streamlining structural and procedural requirements when possible.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No

CFR Citation: 42 CFR 416 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1102 and 1871 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/31/2007	72 FR 50470
NPRM Comment Period End	10/30/2007	
Merged With RIN 0938-AP17	08/26/2008	

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

Agency Contact: Commander Jacqueline Morgan
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-02-01 7500 Security Boulevard

Baltimore , MD 21244
Phone: 410 786-4282
E-Mail: jacqueline.morgan@cms.hhs.gov
Agency Contact: Joan Moliki
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-5526
E-Mail: joan.brooks@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN31

View Related Documents

Title: Termination of Non-Random Prepayment Review (CMS-6022-F)

Abstract: This rule implements the statutory requirements regarding the termination of non-random prepayment review under section 934 of the Medicare Prescription Drug Improvement and Modernization Act beginning December 8, 2003. This rule provides guidelines for terminating a provider of services or supplier from non-random payment review.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 421 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 934 of the MMA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec 902.	10/07/2008

Timetable:

Action	Date	FR Cite
NPRM	10/07/2005	70 FR 58649
Final Action	09/26/2008	73 FR 55753
Final Action Effective	11/25/2008	

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

Agency Contact: Debbie Skinner
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management, Program Integrity Group Mailstop C3-02-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-7480
E-Mail: debbie.skinner@cms.hhs.gov
Agency Contact: Daniel Schwartz
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management, Program Integrity Group Mailstop C3-02-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4197
E-Mail: daniel.schwartz@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN79

View Related Documents

Title: Fire Safety Requirements for Long-Term Care Facilities: Automatic Sprinkler Systems (CMS-3191-F)

Abstract: On July 16, 2004, the GAO published a report on Federal fire safety standards and procedures in nursing facilities. The GAO report cited automatic sprinkler systems in all nursing facilities. As the single most effective fire safety device in long-term care facilities and it is recommended that CMS explore requiring automatic sprinkler systems in all nursing facilities and request public comments on the length of a phase-in period to allow nursing facilities to comply with the new requirement. On October 27, 2006, CMS published a proposed rule that would require automatic sprinkler systems. We received numerous public comments supporting the proposed rule. This rule finalizes the content of the proposed rule.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
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	10/27/2006	71 FR 62957
NPRM Comment Period End	12/26/2006	
Final Action	08/13/2008	73 FR 47075

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

Agency Contact: Danielle N. Shearer
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group Mailstop S3-02-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6617
FAX: 410 786-8532
E-Mail: danielle.shearer@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO27

View Related Documents

Title: Use of Repayment Plans (CMS-6032-F)

Abstract: This rule modifies Medicare regulations to implement a provision of the Medicare Prescription Drug Improvement and Modernization Act of 2003 pertaining to the use of repayment plans (also known as extended repayment schedules). Under this provision, we will grant a provider or a supplier an extended repayment schedule under certain terms and conditions as defined in the statute. The final rule establishes criteria and procedures to apply this requirement and to define the concepts of "hardship" and "extreme hardship."

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 401.601, 42 CFR 401.607 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1893(i)(1) of the Social Security Act as amended by sec 935(i)(1) of Medicare Modernization Act (MMA)
Legal Deadline:

Action	Source	Description	Date

Other	Statutory	MMA Sec 902.	11/27/2009

Timetable:

Action	Date	FR Cite
NPRM	11/27/2006	71 FR 68519
NPRM Comment Period End	01/26/2007	
Final Action	06/27/2008	73 FR 36443

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Thomas A. Noplock
Health Insurance Specialist, Division of Medicare Overpayments
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Financial Management Mailstop C3-15-01 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3378
FAX: 410 786-7030
E-Mail: thomas.noplock@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO43

View Related Documents

Title: Group Health Plans and Health Insurance Issues Under the Newborns and Mothers Health Protection Act (CMS-4116-F)
Abstract: This final rule sets forth the post-childbirth hospitalization length-of-stay requirements for group health plans and health insurance issuers that cover such length of stays.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 45 CFR 144; 45 CFR 146; 45 CFR 148 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 300gg to 300gg-63; 42 USC 300gg-91 and 300gg-92
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	10/20/2008	73 FR 62409
Final Action Effective	12/19/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Small Entities Affected: No
Federalism: Yes
Energy Affected: No
Related RINs: Related to 0938-AI17
Agency Contact: Adam Shaw
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices, Employer & Policy Operations Group Mailstop C5-14-15 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-1091 Extension: 61091
E-Mail: adam.shaw@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO46

View Related Documents

Title: High Risk Pools (CMS-2260-F)

Abstract: Section 6202 of the Deficit Reduction Act of 2005 extends the funding and authorizes and appropriates for FY 2006 $75 million for grants to help fund existing qualified State high-risk pools and $15 million for grants to assist States to create and initially fund qualified high-risk pools. The bill also authorizes appropriations of $75 million for each year FY 2007 through 2010. The section 6202 provision establishes: (1) Seed grants to States for the creation and initial operation of a qualified high-risk pool for those States that do not have one; (2) grants to States to reimburse them for a percentage of losses incurred based on a methodology that allocates funding by 40 percent among all States, 30 percent to States based on their number of uninsured residents, and 30 percent based on the number of people in State risk pools operating as an existing qualified high-risk pool during specified years; and (3) bonus grants for supplemental consumer benefits.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 148 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6202
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		02/08/2006

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/27/2007	72 FR 41232
Interim Final Rule Comment Period End	08/27/2007	
Final Action	04/25/2008	73 FR 22281

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No
Agency Contact: Jessica Kahn
Director, Family and Children's Health Programs Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicaid Services Operations Mailstop C2-01-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-9361
E-Mail: jessica.kahn@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO52

View Related Documents

Title: Self-Directed Personal Assistance Services State Plan Option (CMS-2229-F)

Abstract: The regulation is in support of the Deficit Reduction Act. This final rule provides guidance to States that want to administer self-directed personal assistance services as a State plan option.

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: Deficit Reduction Act of 2005; PL 109-171, sec 6087
Legal Deadline:

Action	Source	Description	Date

Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
NPRM	01/18/2008	73 FR 3546
NPRM Comment Period End	02/19/2008	
Final Action	10/03/2008	73 FR 57854
Final Action Effective	11/03/2008	

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

Agency Contact: Marguerite Schevish
Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Medicaid State Operations Mailstop S2-14-26 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-7200
E-Mail: marguerite.schevish@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO54

View Related Documents

Title: Prohibition of Mid-Year Benefit Enhancements for Medicare Advantage Organizations Offering Plans in Calendar Year 2007 and Subsequent Calendar Years (CMS-4121-F)

Abstract: This rule implements new policy to prohibit Medicare Advantage (MA) organizations from offering mid-year benefit enhancements (MYBEs). In order to fully comply with the statute (MMA), CMS can no longer permit MYBEs as these threaten the integrity of the competitive bidding process established by the statute.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 422.2 (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	09/01/2006	71 FR 52014
NPRM Comment Period End	10/31/2006	
Final Action	07/28/2008	73 FR 43688

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

Agency Contact: Christopher McClintick
Health Insurance Specialist, Center for Beneficiary Choices
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Medicare Advantage Group Division of Plan Policy 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4682 Extension: 64682
E-Mail: christopher.mcclintick@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO58

View Related Documents

Title: Medicare Part D Data (CMS-4119-F)

Abstract: CMS is required by Congress to conduct a number of Part D related research demonstration and evaluation studies that require Part D claims data. This regulation addresses the use of Part D claims information for other research, analysis, reporting, and public health functions.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed 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 1860 D-12 of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec. 902.	10/18/2009

Timetable:

Action	Date	FR Cite
NPRM	10/18/2006	71 FR 61445
NPRM Comment Period End	12/18/2006	
Final Action	05/28/2008	73 FR 30664

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Organizations
Federalism: No
Energy Affected: No
Agency Contact: Alissa M. Deboy
Acting Division Director, Center for Beneficiary Choices
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Drug Plan Policy and Analysis Division Mailstop C1-26-16 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6041
E-Mail: alissa.deboy@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO69

View Related Documents

Title: Exemption of Privacy Act Disclosure of Certain Investigative Materials (CMS-0029-F)

Abstract: This rule exempts the ASPEN Complaint/Incident Tracking System (ACTS), Organ Procurement Organizations Systems (OPOS), Fraud Investigation Database (FID), and HIPAA Information Tracking System (HITS) from the notification, access, correction, and amendment provisions of the Privacy Act concerning records compiled for law enforcement purposes.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 5b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 301; 5 USC 552a
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902.	05/25/2010

Timetable:

Action	Date	FR Cite
NPRM	05/25/2007	72 FR 29289

NPRM Comment Period End	07/24/2007	
Final Action	09/26/2008	73 FR 55772
Final Action Effective	10/27/2008	

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

Agency Contact: Walter Stone
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Information Services Mailstop, N2-06-03 7500 Security Boulvard
Baltimore , MD 21244
Phone: 410 786-5357
FAX: 410 786-5636
E-Mail: walter.stone@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO77

View Related Documents

Title: Special Enrollment Period and Medicare Premium Changes (CMS-4129-F)

Abstract: Section 5115 of the Deficit Reduction Act of 2005 (DRA) provides a special enrollment period for Medicare Part B/Part A and waiver of late enrollment penalty for individuals who are serving as a volunteer outside the United States through a program that covers at least a 12-month period and who have health insurance while providing the voluntary service outside of the United States. Section 811 of the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 as amended by section 5111 of the DRA requires an additional amount be assessed to the Part B premium of individuals who have a modified adjusted gross income that reaches certain levels. The effective date for these provisions is January 1, 2007. Since SSA has the responsibility for calculating the additional premium amount, the explanation of this statutory requirement is in its part of the regulations (20 CFR part 418). CMS will include a reference to the SSA regulation in its change to 42 CFR part 408.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 406 to 408 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 5115; PL 108-173, sec 811
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
NPRM	09/28/2007	72 FR 55152
NPRM Comment Period End	11/27/2007	
Final Action	06/27/2008	73 FR 36463

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

Agency Contact: Denice Cox
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Healthplan and Prescription Drug Choices Mailstop, C2-10-23 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-3195

E-Mail: denise.cox@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO92

View Related Documents

Title: Inpatient Psychiatric Facility Prospective Payment System–Update for Rate Year Beginning July 1, 2008 (RY 2009) (CMS-1401-N)

Abstract: This notice updates the Inpatient Psychiatric Facility Prospective Payment System for rate year (RY) 2009.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412 (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		05/01/2008

Timetable:

Action	Date	FR Cite
Notice	05/07/2008	73 FR 25709

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: No

Agency Contact: Janet Samen
Director, Division of Chronic Care Management
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-05-07 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4533 Extension: 64533
E-Mail: janet.samen@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO94

View Related Documents

Title: Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-F)

Abstract: This major rule finalizes changes to the Medicare long-term care hospitals (LTCH) prospective payment system (PPS) and updates the payment rates for rate year (RY) 2009.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
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 123 PL 106-113; sec 307(b) PL 106-554; sec 114 of PL 110-173
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/01/2008

Timetable:

Action	Date	FR Cite
NPRM	01/29/2008	73 FR 5342
NPRM Comment Period End	03/24/2008	

Final Action	05/09/2008	73 FR 26788

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Agency Contact: Michele Hudson
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C4-16-07 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-5490
E-Mail: michele.hudson@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO97

View Related Documents

Title: Eligible Entity and Contracting Requirements Under the Medicaid Integrity Audit Program (CMS-2271-F)
Abstract: This non-major rule provides the requirements of an eligible entity to enter into a contract under the Medicaid Integrity Audit Program. The rule also establishes the contracting requirements of the eligible entity. This regulation is a mandate under section 6034 of the Deficit Reduction Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 455 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1936; Deficit Reduction Act, sec 6034
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/23/2007	72 FR 65686
NPRM Comment Period End	12/24/2007	
Final Action	09/26/2008	73 FR 55765
Final Action Effective	10/27/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Barbara Rufo
Director, Division of Medicaid Integrity Contracting, Medicaid Integrity Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
B2-02-24 7111 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0711
E-Mail: barbara.rufo@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP00

View Related Documents

Title: Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2009 (CMS-8036-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 2009. It also announces the monthly Part B premiums and the Part B deductible during CY 2009.

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: 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		09/30/2008

Timetable:

Action	Date	FR Cite
Final Action	09/24/2008	73 FR 55089

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Suzanne Codespote
Deputy Director, Medicare & Medicaid Cost Estimates Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop N3-26-00 Office of the Actuary 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-7737
E-Mail: suzanne.codespote@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP03

View Related Documents

Title: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2009 (CMS-8034-N)

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2009 under Medicare's Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

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

Action	Source	Description	Date
Other	Statutory		09/15/2008

Timetable:

Action	Date	FR Cite
Final Action	09/24/2008	73 FR 55086
Final Action Effective	01/01/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Clare McFarland

Deputy Director, Medicare and Medicaid Cost Estimates Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of the Actuary Mailstop N3-26-00 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6390
E-Mail: clare.mcfarland@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP04

View Related Documents

Title: Part A Premiums for CY 2009 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8035-N)

Abstract: This notice announces the Hospital Insurance premium for calendar year 2009 under Medicare's Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

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: 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		09/30/2008

Timetable:

Action	Date	FR Cite
Final Action	09/24/2008	73 FR 55096
Final Action Effective	01/01/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Clare McFarland
Deputy Director, Medicare and Medicaid Cost Estimates Group
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of the Actuary Mailstop, N3-26-00 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-6390
E-Mail: clare.mcfarland@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP07

View Related Documents

Title: State Children's Health Insurance Program (SCHIP): Final Allotments for FYs 2008 and 2009; Redistribution of Unused Allotments; and Continued Authority for Expenditures (CMS-2265-N)

Abstract: This notice describes the implementation of certain funding provisions under title XXI of the Social Security Act (SCHIP) as amended by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), (Pub. L. 110-173), and other related SCHIP legislation. These funding provisions include: The retrospective adjustment of the additional allotments to eliminate fiscal year (FY) 2007 SCHIP funding shortfalls; the final FYs 2008 and 2009 SCHIP allotments; the redistribution of the amounts of States' unused FY 2005 allotments to eliminate FY 2008 SCHIP funding shortfalls; the provision of additional

allotments to eliminate FY 2008 SCHIP funding shortfalls; and the provision for "qualifying States" to elect to use a portion of their available SCHIP allotments as increased Federal matching funds for certain expenditures in their Medicaid programs under title XIX of the Act.

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 1397dd(g); 42 USC 1397ee(g); secs 2104 (e) and 2104(f) of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Notice	05/23/2008	73 FR 30112

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

Agency Contact: Richard Strauss
Technical Director
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-22-25 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-2019
E-Mail: richard.strauss@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP11

View Related Documents

Title: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities--Update for FY 2009 (CMS-1534-F)
Abstract: This major rule updates the payment rates used under the Skilled Nursing Facilities Prospective Payment System beginning October 1, 2008.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1886(e)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/31/2008

Timetable:

Action	Date	FR Cite
NPRM	05/07/2008	73 FR 25918
NPRM Comment Period End	06/30/2008	
Final Action	08/08/2008	73 FR 46415

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

Agency Contact: Bill Ullman
Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-06-27 7500 Security Boulevard

Baltimore , MD 21244
Phone: 410 786-5667
E-Mail: bill.ullman@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP14

View Related Documents

Title: Hospice Wage Index for FY 2009 (CMS-1548-F)

Abstract: This rule updates the annual hospice wage index for FY 2009. The wage index is used to reflect local differences in wage levels.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
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		08/01/2008

Timetable:

Action	Date	FR Cite
NPRM	05/01/2008	73 FR 24000
NPRM Comment Period End	06/27/2008	
Final Action	08/08/2008	73 FR 46463

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Terri Deutsch
Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-08-18 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-9462
E-Mail: terri.deutsch@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP15

View Related Documents

Title: Changes to the Hospital Inpatient Prospective Payment Systems and FY 2009 Rates (CMS-1390-N)

Abstract: This major rule revises the Medicare hospital Inpatient Prospective Payment Systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In additon, we are making changes relating to disclosure of physician ownership in hospitals and reporting of financial relationships between hospitals and physicians, payments for graduate medical education on certain emergency situations, and updates to the long term care prospective payment system & certain IPPS excluded hospitals.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments; Private Sector
CFR Citation: 42 CFR 411 to 413; 42 CFR 422; 42 CFR 489 (To search for a specific CFR, visit the Code of Federal

Regulations)
Legal Authority: sec 1886(b) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/01/2008
Other	Statutory		08/01/2008

Timetable:

Action	Date	FR Cite
NPRM	04/30/2008	73 FR 23527
NPRM Comment Period End	06/13/2008	
Final Action	08/19/2008	73 FR 48433
Notice	10/03/2008	73 FR 57887

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: Business
Federalism: Yes
Energy Affected: No
Agency Contact: Tzvi Hefter
Division Director
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers for Medicare Manangement Mailstop, C4-07-07 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0614
E-Mail: tzvi.hefter@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP19

View Related Documents

Title: Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2009 (CMS-1554-F)
Abstract: This major rule updates rates for the prospective payment system for inpatient rehabilitation facilities for FY 2009.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
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 105-33; PL 106-113; PL 106-554
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2008

Timetable:

Action	Date	FR Cite
NPRM	04/25/2008	73 FR 22674
NPRM Comment Period End	06/20/2008	
Final Action	08/08/2008	73 FR 46415

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Susanne Seagrave
Technical Advisor
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C5-06-27 7500 Security Boulevard

Baltimore , MD 21244
Phone: 410 786-0044
FAX: 410 786-0765
E-Mail: susanne.seagrave@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP26

View Related Documents

Title: Medicaid Program: Multiple Source Drugs Definition (CMS-2238-F)

Abstract: On July 17, 2007, we published a final with comment period in the Federal Register that implemented provisions of the Deficit Reduction Act of 2005 pertaining to prescription drugs under the Medicaid program. In that rule, we finalized certain provisions of the Medicaid drug rebate program, including definitions concerning average manufacturer price, best price, single source drug, and multiple source drug. This rule finalizes the interim final rule with comment period published on March 14, 2008 which revised the definition of "multiple source drug" to better conform with the statutory provisions.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447.502 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: DRA 2005
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/14/2008	73 FR 13785
Interim Final Rule Effective	04/14/2008	
Interim Final Rule Comment Period End	04/14/2008	
Final Action	10/07/2008	73 FR 54891
Final Action Effective	12/19/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Gail Sexton
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-4583
E-Mail: gail.sexton@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP27

View Related Documents

Title: User Fees for Information, Products, and Services (CMS-6021-P)

Abstract: This proposed rule would set forth the general rule that CMS may charge a user fee for information, services, or other items that confer a special benefit on identifiable recipients.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 401 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: title V of the Independent Office Appropriations Act of 1952
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	06/19/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Agency Contact: Chris A. Washington
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop N3-05-06 7500 Security Boulevard
Baltimore , MD 21244
Phone: 410 786-0507
E-Mail: chris.washington@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP34

View Related Documents

Title: Criteria and Standards for Evaluating (Contractors) Intermediary and Carrier Performance During FY 2009 (CMS-1400-GNC)
Abstract: This general notice with comment period describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries and carriers in the administration of the Medicare program. The results of these evaluations are considered when we enter into, renew, or terminate an intermediary agreement, carrier contract, or take other contract actions, e.g., assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries. We are requesting public comment on these criteria and standards. The criteria and standards are effective October 1, 2008.

Priority: Info./Admin./Other
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: secs 1102 and 1811 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	06/27/2008	73 FR 36522

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Agency Contact: Lee A. Crochunis Department of Health and Human Services
Centers for Medicare & Medicaid Services
Centers of Medicare Management Mailstop S1-14-17 7500 Security Bouldvard
Baltimore , MD 21244
Phone: 410 786-3362
E-Mail: leeann.crochunis@cms.hhs.gov

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP36

View Related Documents

Title: Evaluation Criteria and Standards for Quality Improvement Program Contracts (9th Scope of Work) (CMS-3189-NC)

Abstract: This notice with comment period describes what we intend to use to evaluate the efficiency and effectiveness of the Quality Improvement Organizations (QIOs) who will enter into contract with CMS under the 9th Scope of Work (SOW) on August 1, 2008. The evaluation of the QIOs' performance related to their SOW will be based on evaluation criteria specified within the themes, tasks, and subtasks set forth in the QIO's 9th SOW. The 9th SOW includes four themes: Beneficiary Protection, Patient Safety, Patient Pathways (Care Transitions), and Prevention with specific tasks included under all theme areas.

Priority: Info./Admin./Other
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: sec 1153(h)(2) of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Notice	07/21/2008	73 FR 42352
Comment Period End	08/20/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Public Comment URL: www.regulations.gov

Agency Contact: Cynthia Pamon
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop S3-02-01 7500 Security Blvd
Baltimore , MD 21244
Phone: 410 786-9167 Extension: 69167
E-Mail: cynthia.pamon@cms.hhs.gov

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: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 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	02/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Irene Stith-Coleman Ph.DDepartment of Health and Human Services
Office of Public Health and Science
The Tower Building 1101 Wootten Parkway
Rockville , MD 20852
Phone: 240 453-6900
FAX: 301 402-2071
E-Mail: irene.stith-coleman@hhs.gov

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	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Related to 0940-AA04
Agency Contact: Chris Pascal
Director, Office of Research Integrity
Department of Health and Human Services
Office of Public Health and Science
1101 Wootten Parkway
Rockville , MD 20852
Phone: 240 453-8200
FAX: 301 443-5351

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)
RIN: 0940-AA12

View Related Documents

Title: Amendment to Final Regulations Regarding Commissioned Corps Physical Examinations

Abstract: This document contains an amendment to the final regulation currently published at 42 CFR 21.24 to allow the Assistant Secretary for Health greater flexibility in the assessment of the physical qualifications of candidates for appointment as commissioned officers in the Commissioned Corps of the U.S. Public Health Service (Corps). This approach would allow for the appointment of candidates prior to the completion of a physical examination, with the expectation that their commissions may be terminated or they may be given a limited tour of duty if they are thereafter found not to be physically qualified for extended active duty.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 21.24 (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
Withdrawn	08/20/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: Undetermined
Agency Contact: Denise Sharon Canton
Director, Office of Commissioned Corps Force Management
Department of Health and Human Services
Office of Public Health and Science
1101 Wootton Parkway
Rockville , MD 20892
Phone: 240 453-6161

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
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 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Camille Loya Department of Health and Human Services

Administration for Children and Families
1250 Maryland Avenue SW.
Washington , DC 20024
Phone: 202 401-5964
E-Mail: cloya@acf.hhs.gov

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: Proposed Rule
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	12/00/2008	

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
Director, Policy and Planning Division
Department of Health and Human Services
Administration for Children and Families
Office of Child Support Enforcement 370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-9386
E-Mail: bmatheson@acf.hhs.gov

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: Final Rule
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	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Federalism: No
Agency Contact: Elizabeth C. Matheson
Director, Policy and Planning Division
Department of Health and Human Services
Administration for Children and Families
Office of Child Support Enforcement 370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-9386
E-Mail: bmatheson@acf.hhs.gov

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: Final Rule
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	
Final Action	10/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: Governmental Jurisdictions; Organizations
Federalism: No
Agency Contact: Elsbeth Wyatt
Program Specialist
Department of Health and Human Services

Administration for Children and Families
370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 690-5841

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: Final Rule
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	
Final Action	10/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Kathleen McHugh
Director, Division of Policy, Children's Bureau, ACYF/ACF/HHS
Department of Health and Human Services
Administration for Children and Families
370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-5789
FAX: 202 205-8221
E-Mail: kmchugh@acf.hhs.gov

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
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: Not Yet Determined (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	11/00/2008	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal; Local; State; Tribal

Small Entities Affected: Governmental Jurisdictions

Federalism: No

Agency Contact: Elizabeth C. Matheson
Director, Policy and Planning Division
Department of Health and Human Services
Administration for Children and Families
Office of Child Support Enforcement 370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-9386
E-Mail: bmatheson@acf.hhs.gov

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: Final Rule

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	12/00/2008	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Small Entities Affected: Business

Federalism: No

Energy Affected: No

Agency Contact: Kenneth Tota
Chief of Operations--Office of Refugee Resettlement
Department of Health and Human Services
Administration for Children and Families
370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-4858
E-Mail: ktota@acf.hhs.gov

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	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Tribal
Federalism: No

Agency Contact: Paige Hausburg Department of Health and Human Services
Administration for Children and Families
370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-5635
E-Mail: paige.hausburg@acf.hhs.gov

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: Final Rule
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	10/00/2009	

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

RIN Information URL: regulations.acf.hhs.gov

Agency Contact: Robin Rushton
Director, Division of State and Tribal Systems
Department of Health and Human Services
Administration for Children and Families
370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 690-1244
E-Mail: robin.rushton@acf.hhs.gov

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: 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: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/2008	

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

Agency Contact: Craig Turner Department of Health and Human Services
Administration for Children and Families
1250 Maryland Avenue SW. 8th Floor Portals Building
Washington , DC 20024
Phone: 202 205-8236
E-Mail: cturner@acf.hhs.gov

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 interim final 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.

Priority: Other Significant
Agenda Stage of Rulemaking: Final 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
Interim Final Rule	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Camille Loya Department of Health and Human Services
Administration for Children and Families
1250 Maryland Avenue SW.
Washington , DC 20024
Phone: 202 401-5964
E-Mail: cloya@acf.hhs.gov

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: Final Rule
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	
Final Action	10/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Robert Shelbourne
Director of Policy, Office of Family Assistance
Department of Health and Human Services
Administration for Children and Families
901 D Street SW.
Washington , DC 20447
Phone: 202 401-5150
E-Mail: rshelbourne@acf.hhs.gov

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: 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: 6 USC 279
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

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

Agency Contact: Maureen Dunn Department of Health and Human Services
Administration for Children and Families
370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-5523
E-Mail: mdunn@acf.hhs.gov

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC15

View Related Documents

Title: Cost Allocation Methodology Applicable to the Temporary Assistance for Needy Families Program

Abstract: This final rule applies to the Temporary Assistance for Needy Families (TANF) program and requires States, the District of Columbia and the Territories (hereinafter referred to as the “States”) to use the “benefiting program” cost allocation methodology in U.S. Office of Management and Budget (OMB) Circular A-87 (2 CFR part 225). It is the judgment and determination of HHS/ACF that the “benefiting program” cost allocation methodology is the appropriate methodology for the proper use of Federal TANF funds. The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996 gave federally-recognized tribes the opportunity to operate their own Tribal TANF programs. Federally-recognized Indian tribes operating approved Tribal TANF programs have always followed the “benefiting program” cost allocation methodology in accordance with OMB Circular A-87 (2 CFR part 225) and the applicable regulatory provisions at 45 CFR 286.45(c) and (d). This final rule contains no substantive changes to the proposed rule published on September 27, 2006.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 263; 45 CFR 263.14 (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	09/27/2006	71 FR 56440
NPRM Comment Period End	11/27/2006	
Final Action	07/23/2008	73 FR 42718

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Agency Contact: Robert Shelbourne
Deputy Director, Office of Family Assistance, Office of Policy
Department of Health and Human Services
Administration for Children and Families
5th Floor East 370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-5150
E-Mail: rshelbourne@acf.hhs.gov

Government Levels Affected: Local; State
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

RIN: 0970-AC22

View Related Documents

Title: Medical Support

Abstract: These rules require that all support orders in the IV-D program address medical support, redefine reasonable-cost health insurance, require health insurance to be accessible, and make conforming changes to audit and self-assessment requirements.

Priority: Other Significant
Major: No
CFR Citation: 45 CFR 302 to 305 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	09/20/2006	71 FR 54965
NPRM Comment Period End	11/20/2006	
Final Action	07/21/2008	73 FR 42416

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Governmental Jurisdictions
Energy Affected: No
Agency Contact: Elizabeth C. Matheson
Director, Policy and Planning Division
Department of Health and Human Services
Administration for Children and Families
Office of Child Support Enforcement 370 L'Enfant Promenade SW.
Washington , DC 20447
Phone: 202 401-9386
E-Mail: bmatheson@acf.hhs.gov

Government Levels Affected: Local; State
Federalism: No

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: PreRule
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
Notice	11/00/2008	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Agency Contact: Hunter McKay Department of Health and Human Services
Office of the Secretary
200 Independence Avenue NW.
Washington , DC 20202
Phone: 202 205-8999

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; modify the current definition for the term "claim;" 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	04/00/2009	
NPRM Comment Period End	06/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Marco A. Villagrana Department of Health and Human Services
Office of the Secretary
Office of the Inspector General 330 Independence Avenue SW.
Washington , DC 20201
Phone: 202 401-2206

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	04/00/2009	
NPRM Comment Period End	06/00/2009	

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

Agency Contact: Marco A. Villagrana Department of Health and Human Services
Office of the Secretary
Office of the Inspector General 330 Independence Avenue SW.
Washington , DC 20201
Phone: 202 401-2206

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: Undetermined
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	04/00/2009	
NPRM Comment Period End	06/00/2009	

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

Agency Contact: Marco A. Villagrana Department of Health and Human Services
Office of the Secretary
Office of the Inspector General 330 Independence Avenue SW.
Washington , DC 20201
Phone: 202 401-2206

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	02/00/2009	

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

Agency Contact: Mathew Murphy Department of Health and Human Services
Office of the Secretary
BP Tower, Suite 1300 200 Public Square
Cleveland , OH 44114
Phone: 216 615-7021

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	02/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Marco A. Villagrana Department of Health and Human Services
Office of the Secretary
Office of the Inspector General 330 Independence Avenue SW.
Washington , DC 20201
Phone: 202 401-2206

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 notice of proposed rulemaking (NPRM) 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	02/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Randy Pate Department of Health and Human Services
Office of the Secretary
200 Independence Avenue SW.
Washington , DC 20201
Phone: 202 690-6870

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 proposed rule sets forth 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: 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
NPRM	05/23/2008	73 FR 30030
NPRM Comment Period End	07/22/2008	
Final Action	02/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
Agency Contact: Hunter McKay Department of Health and Human Services
Office of the Secretary
200 Independence Avenue SW.
Washington , DC 20201
Phone: 202 205-8999

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) is issuing this Notice of Proposed Rulemaking (NPRM) to obtain input from stakeholders and other interested parties regarding the separation that must exist between a recipient of HHS funds to implement programs and activities under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (the Leadership Act), Pub. L. No. 108-25 (May 27, 2003), and an affiliate organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking, as required under section 301(f) of the Leadership Act. The proposed rule provides additional information on the policy requirement expressed in this law for entities that receive grants, contracts, or cooperative agreements from the U.S. Department of Health and Human Services (HHS) to implement programs or projects under the authority of the Leadership Act. Specifically, it describes the legal, financial, and organizational separation that must exist between these recipients of HHS funds and an affiliate organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking.

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	04/17/2008	73 FR 20900
NPRM Comment Period End	05/19/2008	
Final Action	11/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Small Entities Affected: No
Federalism: No
Agency Contact: Jeanne Monahan Department of Health and Human Services
Office of the Secretary
Global Health Affairs 200 Independence Avenue SW. Room 639H
Washington , DC 20201
Phone: 202 690-6174

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: The Department of Health and Human Services proposes to promulgate regulations to ensure that Department funds do not support morally coercive or discriminatory practices or policies in violation of federal law, pursuant to the Church Amendments (42 U.S.C. section 300a-7), Public Health Service (PHS) Act section 245 (42 U.S.C. section 238n), and the Weldon Amendment (Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, section 508(d), 121 Stat. 1844, 2209).This notice of proposed rulemaking proposes to define certain key terms. Furthermore, in order to ensure that recipients of Department funds know about their legal obligations under these nondiscrimination provisions, the Department proposes to require written certification by certain recipients that they will comply with all three statutes, as applicable.

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: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/26/2008	73 FR 50274
NPRM Comment Period End	09/25/2008	
Final Action	12/00/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: No
Agency Contact: Jennifer Claypool Department of Health and Human Services
Office of the Secretary
200 Independence Avenue SW.
Washington , DC 20202
Phone: 202 690-8082

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
Agency Contact: Marco A. Villagrana Department of Health and Human Services
Office of the Secretary
Office of the Inspector General 330 Independence Avenue SW.
Washington , DC 20201
Phone: 202 401-2206