Federal Register

Monday,
October 31, 2005

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

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 12866 require this semi-annual publication inventorying the rulemaking actions under development by the Department. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under our consideration. Members of the public wishing to communicate to the Department their views on the potential rule-makings outlined below are invited to do so.

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 below presents for public scrutiny 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 Final Rules within the next 12 months.

We welcome the views of all concerned with regard to these planned rulemakings. Comments may be directed to the agency officials cited in each of the summaries, or, if early attention at the Secretary's level is seen as required, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue, SW., Washington DC 20201.

Dated: September 29, 2005

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
985	Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments	0991–AB03
986	Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute	0991–AB39

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
987	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
988	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
989	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23
990	Health Insurance Portability and Accountability Act—Enforcement	0991–AB29
991	Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Under the Anti-Kickback Statute	0991–AB38

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
992	Claims Collection	0991–AB18
993	Salary Offset	0991–AB19
994	Revisions to the Waiver Provisions of the Office of Inspector General's (OIG) Exclusion Authorities	0991–AB33

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
995	Amending the Regulations Governing Nondiscrimination on the Basis of Race, Color, National Origin, Handicap, Sex, and Age To Conform to the Civil Rights Restoration Act of 1987	0991–AB10

HHS

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

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

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
997	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
998	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04
999	Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices	0920–AA10
1000	Control of Communicable Diseases, Interstate and Foreign Quarantine **(Reg Plan Seq No. 42)**	0920–AA12

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1001	Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Amendments	0920–AA13

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
1002	Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality Systems Regulations **(Section 610 Review)**	0910–AF71

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1003	Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs **(Reg Plan Seq No. 43)**	0910–AA49
1004	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
1005	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
1006	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics **(Reg Plan Seq No. 44)**	0910–AC52
1007	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
1008	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
1009	Reporting Information Regarding Falsification of Data	0910–AC59
1010	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling **(Reg Plan Seq No. 45)**	0910–AF11
1011	Cochineal Extract and Carmine Label Declaration	0910–AF12

HHS

Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1012	Charging for Investigational Drugs	0910–AF13
1013	Expanded Access to Investigational Drugs for Treatment Use **(Reg Plan Seq No. 46)**	0910–AF14
1014	Distribution of Blood Derivatives by Registered Blood Establishments That Qualify as Health Care Entities; PDMA of 1987; PDA of 1992; Policies, Requirements, and Administrative Procedures	0910–AF16
1015	Revocation of the Status of Specific Products; Group A Streptococcus	0910–AF20
1016	Obstetrical and Gynecological Devices; Designation of Special Control for Condoms and Condoms With Spermicidal Lubricant	0910–AF21
1017	Blood Initiative—Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
1018	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
1019	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
1020	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
1021	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
1022	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
1023	Substances Prohibited From Use in Animal Food or Feed	0910–AF46
1024	Over-the-Counter (OTC) Drug Review—Dandruff, Seborrheic Dermatitis, and Psoriasis Products	0910–AF49
1025	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
1026	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
1027	Designation of New Animal Drugs for Minor Use and Minor Species	0910–AF60
1028	Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation	0910–AF65
1029	Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	0910–AF67
1030	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
1031	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1032	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
1033	Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products **(Reg Plan Seq No. 47)**	0910–AA94
1034	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
1035	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
1036	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback)	0910–AB76
1037	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements **(Reg Plan Seq No. 48)**	0910–AB88
1038	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
1039	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
1040	Institutional Review Boards: Registration Requirements	0910–AC17
1041	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
1042	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
1043	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs **(Reg Plan Seq No. 49)**	0910–AC35
1044	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
1045	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
1046	Blood Initiative—Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment	0910–AF26
1047	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
1048	Infant Formula Quality Factors	0910–AF28
1049	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
1050	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
1051	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1052	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
1053	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
1054	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
1055	Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle	0910–AF48
1056	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
1057	Supplements and Other Changes to Approved New Animal Drug Applications	0910–AF59
1058	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AF62

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1059	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
1060	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
1061	Food Standards: General Principles and Food Standards Modernization	0910–AC54
1062	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
1063	Health Claims	0910–AF09
1064	Food Labeling; Prominence of Calories	0910–AF22
1065	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
1066	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
1067	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
1068	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
1069	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
1070	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
1071	Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants	0910–AF54
1072	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
1073	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
1074	Lowfat and Skim Milk and Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Rev. of Stand. of Ident.; Food Lab., Nutrient Cont. Claims for Fat, Fatty Acids, and Cholesterol Cont. of Foods **(Section 610 Review)**	0910–AF64
1075	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1076	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
1077	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
1078	Registration of Food and Animal Feed Facilities	0910–AC40
1079	Quality Standard Regulation Establishing an Allowable Level for Arsenic in Bottled Water	0910–AF10

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1080	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44
1081	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57

HHS

Health Resources and Services Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1082	Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA62
1083	National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy	0906–AA68
1084	Healthy Tomorrow's Partnership for Children (HTPC) Program	0906–AA70

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1085	Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
1086	Smallpox Vaccine Injury Compensation Program: Administrative Implementation	0906–AA61
1087	Requirements Establishing a Limitation on Administrative Expenses; Ryan White CARE Act Title IV Grants for Coordinated Services and Access to Research	0906–AA65
1088	Revision to 42 CFR Subpart D—Public Health Service (PHS) Grant Appeals Procedure	0906–AA69

Health Resources and Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1089	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906–AA41
1090	Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA63

Indian Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1091	Section 506—Limitation on Charges for Services Furnished by Medicare Participating Inpatient Hospital to Indians	0917–AA07

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1092	Grants for Research Projects — 42 CFR Part 52-NPRM	0925–AA42
1093	National Institutes of Health Loan Repayment Programs	0925–AA43
1094	National Library of Medicine Training Grants	0925–AA44
1095	Minority Biomedical Research Support Program	0925–AA45
1096	National Institute of Environmental Health Sciences Hazardous Substances Basic Research and Training Grants	0925–AA46

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1097	National Institutes of Health Training Grants	0925–AA28
1098	Standards for a National Chimpanzee Sanctuary System	0925–AA31

HHS

National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1099	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925–AA10
1100	National Institutes of Health Loan Repayment Program for Research Generally	0925–AA18
1101	National Institutes of Health AIDS Research Loan Repayment Program	0925–AA32
1102	National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers	0925–AA33
1103	National Institutes of Health Pediatric Research Loan Repayment Program	0925–AA34
1104	National Institutes of Health Loan Repayment Program for Health Disparities Research	0925–AA35
1105	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925–AA36
1106	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925–AA41

Office of Public Health and Science—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
1107	Human Subjects Protection Regulations: Additional Protections for Adult Individuals With Impaired Decision-making Capacity	0940–AA11

Office of Public Health and Science—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1108	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940–AA01
1109	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940–AA06
1110	Federal Policy for the Protection of Human Subjects Technical Amendment	0940–AA10

Office of Public Health and Science—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1111	Human Subjects Protection Regulations: Training and Ed. Requirements for Institutional Officials, Institutional Review Board Members and Staff, Human Protections Administrators, and Investigators	0940–AA08

Office of Public Health and Science—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1112	Public Health Service Policies on Research Misconduct	0940–AA04

Centers for Medicare & Medicaid Services—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
1113	Innovations in Fee-for-Service Payment Systems to Improve Quality and Outcomes (CMS-1298-ANPR) **(Reg Plan Seq No. 50)**	0938–AN91

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

HHS

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1114	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
1115	Standard Unique National Health Plan Identifier (CMS-6017-P)	0938–AH87
1116	Appeals of Carrier Determinations That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS-6003-P2)	0938–AI49
1117	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)	0938–AJ17
1118	Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938–AL26
1119	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938–AL80
1120	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938–AM50
1121	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938–AM87
1122	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies and Residual Issues (CMS-1270-P) **(Reg Plan Seq No. 51)**	0938–AN14
1123	Revisions to HIPAA Code Sets (CMS-0013-P)	0938–AN25
1124	Payment for Clinical Laboratory Tests (CMS-1494-P)	0938–AN26
1125	Termination of Non-Random Prepayment Medical Review (CMS-6022-F)	0938–AN31
1126	Limitation on Recoupment of Overpayments (CMS-6025-P)	0938–AN42
1127	Revisions to the Oversight and Validation Program for Accrediting Organizations Approved for Deeming Authority (CMS-2255-P)	0938–AN62
1128	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements (CMS-1303-F)	0938–AN69
1129	National Plan and Provider Enumeration System (NPPES) Data Dissemination (CMS-6060-PN)	0938–AN71
1130	Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (CMS-3156-P)	0938–AN73
1131	Home Health Payment System Rate Update for Calendar Year 2007 (CMS-1304-P)	0938–AN76
1132	Fire Safety Requirements for Long-Term Care Facilities: Sprinkler Systems (CMS-3191-P)	0938–AN79
1133	Inpatient Psychiatric Facility Prospective Payment System—Update for 2006 (CMS-1306-P)	0938–AN82
1134	Prospective Payment System for Long-Term Care Hospitals FY 2007: Annual Payment Rate Updates (CMS-1485-P)	0938–AO06
1135	Payments for Service Provided Without Charge (CMS-2489-P)	0938–AO07
1136	Revisions to Payment of Ambulance Services under Medicare (CMS-1317-P)	0938–AO11
1137	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates (CMS-1488-P) **(Reg Plan Seq No. 52)**	0938–AO12
1138	Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-P)	0938–AO13
1139	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates (CMS-1506-P)	0938–AO15
1140	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2007 (CMS-1540-P)	0938–AO16
1141	Outpatient Hospital Services and Rural Health Clinic Services Amendment (CMS-2213-P)	0938–AO17
1142	Five Year Review of Work Relative Value Units Under the Physician Fee Schedule (CMS-1512-PN)	0938–AO22
1143	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 (CMS-1321-P)	0938–AO24
1144	Use of Repayment Plans (CMS-6032-P)	0938–AO27

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1145	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-F)	0938–AH73
1146	Hospital Conditions of Participation: Laboratory Services (CMS-3014-IFC) **(Section 610 Review)**	0938–AJ29
1147	Medicare Hospice Care Amendments (CMS-1022-F)	0938–AJ36
1148	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938–AJ96
1149	Organ Procurement Organization Conditions for Coverage (CMS-3064-IFR) **(Section 610 Review) (Reg Plan Seq No. 53)**	0938–AK81
1150	Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS-1167-F)	0938–AN02
1151	Enhanced DSH Treatment for Certain Hospitals (CMS-2198-F)	0938–AN09
1152	Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-IFC)	0938–AN23

HHS

Centers for Medicare & Medicaid Services—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1153	Medicare Secondary Payer Amendments (CMS-6272-IFC)	0938–AN27
1154	Home Health Prospective Payment System Rate Update for Calendar Year 2006 (CMS-1301-F)	0938–AN44
1155	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-FC) **(Reg Plan Seq No. 54)**	0938–AN46
1156	All Provider Bad Debt Payment (CMS-1126-F)	0938–AN75
1157	Payment Error Rate Measurement (PERM) Program (CMS-6026-F)	0938–AN77
1158	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-FC) **(Reg Plan Seq No. 55)**	0938–AN84
1159	Fee Schedule for Payment of Ambulance Services — Update for CY 2006 (CMS-1294-N)	0938–AN99
1160	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals (CMS-2210-F)	0938–AO04
1161	Federal Government's Adoption of Twenty (20) Healthcare Messaging and Vocabulary Standards Recommended by the Consolidated Health Informatics Initiative (CMS-0015-N)	0938–AO05
1162	Fire Safety Requirements for Religious Non-Medical Health Care Institutions: Correction to Add Written Fire Control Plans & Maintenance of Documentation (CMS-3183-IFC)	0938–AO14
1163	Part A Premiums for Calendar Year 2007 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8028-N)	0938–AO18
1164	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2007 (CMS-8029-N)	0938–AO19
1165	Fiscal Year 2007 SCHIP Allotments (CMS-2251-N)	0938–AO21
1166	Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2007 (CMS-8030-N)	0938–AO23
1167	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2007 (CMS-1530-N)	0938–AO25
1168	Hospice Wage Index for FY 2007 (CMS-1535-N)	0938–AO26

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1169	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) **(Section 610 Review)**	0938–AG82
1170	Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers To Perform Organ Transplants (CMS-3835-F)	0938–AH17
1171	Hospice Care—Conditions of Participation (CMS-3844-F) **(Section 610 Review)**	0938–AH27
1172	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)	0938–AJ10
1173	Standards for Electronic Health Care Claim Attachments (CMS-0050-P)	0938–AK62
1174	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (CMS-1810-F)	0938–AK67
1175	Provider Reimbursement Determinations and Appeals (CMS-1727-F)	0938–AL54
1176	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)	0938–AL88
1177	Electronic Medicare Claims Submission (CMS-0008-F)	0938–AM22
1178	Requirements for Long-Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information (CMS-3121-F)	0938–AM55
1179	Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)	0938–AM73
1180	Conditions for Coverage of Power Mobility Devices, Including Powered Wheelchairs and Power-Operated Vehicles Scooter (CMS-3017-F)	0938–AM74
1181	Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Post-Anesthesia Evaluations (CMS-3122-F)	0938–AM88
1182	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-F)	0938–AM98
1183	Prior Determination Process for Certain Items and Services (CMS-6024-P)	0938–AN10
1184	Nondiscrimination in Health Coverage and Wellness Plans in the Group Market (CMS-4081-F)	0938–AN29
1185	Hospital Conditions of Participation: Patients' Rights (CMS-3018-F)	0938–AN30
1186	Federal Enforcement in Group and Individual Health Insurance Markets (CMS-4091-F)	0938–AN35
1187	Fire Safety Requirements for Certain Health Care Facilities; Alcohol-Based Hand Sanitizer Amendment (CMS-3145-F)	0938–AN36
1188	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6019-F)	0938–AN48
1189	Electronic Prescribing Standards (CMS-0011-F)	0938–AN49
1190	Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F)	0938–AN58

HHS

Centers for Medicare & Medicaid Services—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
1191	Group Market Health Insurance Reform: Guaranteed Availability, Guaranteed Renewability, Disclosures to Small Employers (CMS-4102-F)	0938–AN60
1192	Individual Market Health Insurance Reform: Portability From Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules (CMS-4103-F)	0938–AN61
1193	Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements (CMS-6030-F)	0938–AN72
1194	Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services) (CMS-1908-F)	0938–AN81
1195	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-F)	0938–AN83
1196	Electronic Submission of Cost Reports: Revision to Cost Reporting Period (CMS-1199-F)	0938–AN87
1197	Loan Forgiveness Criteria for the Health Care Infrastructure Loan Program (CMS-1320-F)	0938–AN93
1198	Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care (CMS-1287-F)	0938–AO03
1199	Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)	0938–AO10

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1200	Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS-6010-P)	0938–AJ98
1201	Evaluation Criteria and Standards for Quality Improvement Program Contracts (CMS-3142-FN)	0938–AN13
1202	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)	0938–AN19
1203	Medicare Ambulance Fee Schedule Update (CMS-1492-IFC)	0938–AN24
1204	Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-F)	0938–AN28
1205	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2006 (CMS-1290-F)	0938–AN43
1206	Development of New Standards for Medigap Policies (CMS-4087-FN)	0938–AN50
1207	Fiscal Year 2006 SCHIP Allotments (CMS-2219-N)	0938–AN56
1208	Changes to the Hospital Inpatient Prospective Payment System and FY 2006 Rates (CMS-1500-F)	0938–AN57
1209	Special Payment Provisions and Standards for Suppliers of Custom Fabricated Orthotics and Prosthetics (CMS-6012-P)	0938–AN63
1210	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2006 (CMS-1282-F)	0938–AN65
1211	State Children's Health Insurance Program (SCHIP); Redistribution of Unexpended SCHIP Funds From the Appropriation for Fiscal Year (FY) 2002 (CMS-2230-FN)	0938–AN78
1212	Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F3)	0938–AN80
1213	Disproportionate Share Hospital Payments—Institutions for Mental Disease (IMDs) (CMS-2062-N2)	0938–AN88
1214	Hospice Wage Index for FY 2006 (CMS-1286-F)	0938–AN89
1215	Inpatient Rehabilitation Facility Classification Rule Compliance (CMS-1480-N)	0938–AN92
1216	Withdrawal of Ambulance Fee Schedule Issued in Accordance With Federal District Court Order in Lifestar Ambulance, Inc. v. U.S.—Medicare Covered Ambulance Services (CMS-1308-)	0938–AN94
1217	Immunization Standard for Long Term Care Facilities (CMS-3198-F)	0938–AN95
1218	Disproportionate Share Hospital Payments — Institutions for Mental Disease (IMDs) (CMS-2209-N)	0938–AN96
1219	Medicare Prescription Drug Discount Card (CMS-4063-F)	0938–AN97
1220	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2006 (CMS-8026-N)	0938–AO00
1221	Part A Premiums for Calendar Year 2006 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8025-N)	0938–AO01
1222	Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2006 (CMS-8027-N)	0938–AO02

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1223	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01

HHS

Administration for Children and Families—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1224	Developmental Disabilities and Bill of Rights Act	0970–AC07
1225	Administrative Cost Sharing Under TANF	0970–AC15
1226	Care and Placement of Unaccompanied Alien Children	0970–AC20
1227	Chafee National Youth in Transition Database	0970–AC21
1228	Medical Support	0970–AC22
1229	Adoption and Foster Care Analysis and Reporting System	0970–AC23

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1230	Administrative Costs for Children in Title IV-E Foster Care	0970–AC14
1231	Head Start Transportation	0970–AC16
1232	Child Care and Development Fund State Match Provisions	0970–AC18
1233	Reasonable Quantitative Standard for Review and Adjustment of Child Support Orders	0970–AC19

Department of Health and Human Services (HHS) — Proposed Rule Stage

Office of the Secretary (OS)

985. REVISIONS TO REGULATIONS ADDRESSING THE OIG'S AUTHORITY TO IMPOSE CIVIL MONEY PENALTIES AND ASSESSMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320a–7a; 42 USC 1395mm; 42 USC 1395w–27; 42 USC 1396b; 42 USC 1396u–2

CFR Citation: 42 CFR 1003

Legal Deadline: None

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;'' update 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.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	
NPRM Comment Period End	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0089

RIN: 0991–AB03

986. MEDICARE AND STATE HEALTH CARE PROGRAMS: FRAUD AND ABUSE; SAFE HARBOR FOR CERTAIN ELECTRONIC PRESCRIBING ARRANGEMENTS UNDER THE ANTI–KICKBACK STATUTE

Priority: Other Significant

Legal Authority: PL 100–93, sec 14(a); PL 108–173, sec 101(a)(4)(D)(6)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule will establish a safe harbor with respect to the provision of nonmonetary remuneration—in the form of hardware, software, or information technology and training services—necessary and used solely to receive and transmit electronic prescription information in accordance with section 1860-D of the Social Security Act.

Timetable:

Action	Date	FR Cite
NPRM	10/11/05	70 FR 59015
NPRM Comment Period End	12/12/05	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0089

RIN: 0991–AB39

Department of Health and Human Services (HHS) **Final Rule Stage**

Office of the Secretary (OS)

987. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1320a–7b; 42 USC 1395hh; PL 104–191, sec 216(b)

CFR Citation: 42 CFR 1001

Legal Deadline: Final, Statutory, January 1, 1997.

Abstract: This final rule establishes a new statutory exception 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.

Timetable:

Action	Date	FR Cite
ANPRM	05/23/97	62 FR 28410
ANPRM Comment Period End	06/09/97	
Interim Final Rule	11/19/99	64 FR 63504
Final Action	03/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0089

Related RIN: Related to 0991–AB06

RIN: 0991–AA91

988. SAFE HARBOR FOR WAIVER OF BENEFICIARY COINSURANCE AND DEDUCTIBLE AMOUNTS FOR A MEDICARE SELECT POLICY

Priority: Substantive, Nonsignificant

Legal Authority: PL 100–93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This final rule will expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will protect waivers of coinsurance 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.

Timetable:

Action	Date	FR Cite
NPRM	09/25/02	67 FR 60202
NPRM Comment Period End	10/25/02	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0089

RIN: 0991–AB16

989. CLARIFICATION OF TERMS AND APPLICATION OF PROGRAM EXCLUSION AUTHORITY FOR SUBMITTING CLAIMS CONTAINING EXCESSIVE CHARGES

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 112B(6); Social Security Act, sec 112B(6)(A)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule would amend the Office of Inspector General's exclusion regulations at 42 CFR 1001.701, addressing excessive claims, by including definitions for the terms ''substantially in excess'' and ''usual charges,'' and by clarifying the ''good cause'' exception set forth in this section.

Timetable:

Action	Date	FR Cite
NPRM	09/15/03	68 FR 53939
NPRM Comment Period End	11/14/03	
Final Action	04/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0089

RIN: 0991–AB23

990. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

Priority: Other Significant

Legal Authority: Subtitle F of title II of PL 104–191; 42 USC 1320d–5

CFR Citation: 45 CFR 160, subparts C to E

Legal Deadline: None

Abstract: This rulemaking would seek to establish a framework for enforcing compliance with the ''administrative simplification'' provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996—subtitle F of title II of Public Law 104-191, through the imposition of civil money penalties under 42 U.S.C. 1320d-5.

Timetable:

Action	Date	FR Cite
NPRM	04/18/05	70 FR 20224
Final Action	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Conrad, Department of Health and Human Services, Room 5347, Office of the General Counsel, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 690–1840

RIN: 0991–AB29

HHS—OS

Final Rule Stage

991. MEDICARE AND STATE HEALTH CARE PROGRAMS: FRAUD AND ABUSE; SAFE HARBOR FOR FEDERALLY QUALIFIED HEALTH CENTERS UNDER THE ANTI–KICKBACK STATUTE

Priority: Other Significant

Legal Authority: PL 100–93, sec 14(a); PL 108–173, sec 431

CFR Citation: 42 CFR 1001

Legal Deadline: Final, Statutory, December 8, 2004.

Abstract: This rule will set forth standards for the new anti-kickback safe harbor addressing remuneration between federally qualified health centers and certain providers where significant community benefit exits.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/01/05	70 FR 38081
Interim Final Rule Comment Period End	08/01/05	
Final Action	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0089

Related RIN: Related to 0991–AB06, Related to 0991–AA91

RIN: 0991–AB38

Department of Health and Human Services (HHS)
Office of the Secretary (OS)

Long-Term Actions

992. CLAIMS COLLECTION

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 3711; 31 CFR 900 to 904

CFR Citation: 45 CFR 30

Legal Deadline: None

Abstract: The Department will amend part 30 of title 45 of the Code of Federal Regulations (CFR) to reflect the amendments to the Federal Claims Collection Act made by the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, as implemented by the Department of the Treasury at 31 CFR 900-904. The proposed rule will prescribe the standards and procedures for the Department's use in the administrative collection, offset, compromise, and suspension or termination of debts owed to the Department. The proposed rule is required in order to bring the Department's claims collection provisions in compliance with the Department of the Treasury regulations.

Timetable:

Action	Date	FR Cite
NPRM	07/13/04	69 FR 42010
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, Room 4760, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0150

RIN: 0991–AB18

993. SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 5514; 5 CFR 550

CFR Citation: 45 CFR 33

Legal Deadline: None

Abstract: The Department will add a new part 33 to title 45 of the Code of Federal Regulations (CFR) to implement the salary offset provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, codified at 5 U.S.C. 5514, as implemented by the Office of Personnel Management at 5 CFR part 550, subpart K. The proposed rule is required in order to bring the Department's salary offset provisions in compliance with Governmentwide regulations published by the Office of Personnel Management.

Timetable:

Action	Date	FR Cite
NPRM	07/13/04	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jeffrey S. Davis, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, HHS Cohen Building, Room 4760, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0150

RIN: 0991–AB19

994. REVISIONS TO THE WAIVER PROVISIONS OF THE OFFICE OF INSPECTOR GENERAL'S (OIG) EXCLUSION AUTHORITIES

Priority: Substantive, Nonsignificant

Legal Authority: PL 108–173, sec 949; PL 105–33, sec 4331; Social Security Act, sec 1128(c)(3)(b)

CFR Citation: 42 CFR 1001

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of

HHS—OS **Long-Term Actions**

the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201

Phone: 202 619–0089

RIN: 0991–AB33

Department of Health and Human Services (HHS) — Completed Actions
Office of the Secretary (OS)

995. AMENDING THE REGULATIONS GOVERNING NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, HANDICAP, SEX, AND AGE TO CONFORM TO THE CIVIL RIGHTS RESTORATION ACT OF 1987

Priority: Other Significant

CFR Citation: 45 CFR 80; 45 CFR 84; 45 CFR 86; 45 CFR 90; 45 CFR 91

Completed:

Reason	Date	FR Cite
Final Rule	05/09/05	70 FR 24314

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Agency Contact: Robinsue Frohboese
Phone: 202 619–0403

RIN: 0991–AB10

Department of Health and Human Services (HHS) — Proposed Rule Stage
Substance Abuse and Mental Health Services Administration (SAMHSA)

996. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: PL 106–310

CFR Citation: Not Yet Determined

Legal Deadline: NPRM, Statutory, April 2001.

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.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Federalism: This action may have federalism implications as defined in EO 13132.

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

RIN: 0930–AA10

Department of Health and Human Services (HHS) — Final Rule Stage
Substance Abuse and Mental Health Services Administration (SAMHSA)

997. MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM

Priority: Other Significant

Legal Authority: PL 100–71; 5 USC 7301

CFR Citation: None

Legal Deadline: NPRM, Statutory, December 2003.

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.

Timetable:

Action	Date	FR Cite
Notice	04/13/04	69 FR 19673
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Joseph Denis Faha, Director, DLEA, SAMHSA, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 12C–15, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–7017
Fax: 301 443–1450
Email: jfaha@samhsa.gov

RIN: 0930–AA12

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Proposed Rule Stage

998. AMENDMENTS TO QUALITY ASSURANCE AND ADMINISTRATIVE PROVISION FOR APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 42 CFR 84

Legal Deadline: None

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; 4) updated and restructured fee schedule; and 5) fee retention in the respirator program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–4000

RIN: 0920–AA04

999. AMENDMENTS TO SELF–CONTAINED BREATHING APPARATUS REQUIREMENTS FOR APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

Priority: Other Significant

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

CFR Citation: 42 CFR 84

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jon Szalajada, Acting Chief, Policy and Standards Branch, HHS, CDC, NIOSH, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–4000

RIN: 0920–AA10

1000. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

Regulatory Plan: This entry is Seq. No. 42 in part II of this issue of the **Federal Register**.

RIN: 0920–AA12

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Final Rule Stage

1001. ● PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000; AMENDMENTS

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: HHS is amending its procedures to consider designating classes of employees to be added to the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000 (''EEOICPA''), 42 U.S.C. sections 7384-7385. HHS must change these procedures to implement amendments to EEOICPA enacted on October

28, 2004, as part of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375 (codified as amended in scattered sections of 42 U.S.C.).

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Larry Elliott, Director, Office of Compensation Analysis and Support, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, R44, 4676 Columbia Pkwy, MS C–46, Cincinnati, OH 45226
Phone: 513 533–6825

RIN: 0920–AA13

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

Prerule Stage

1002. ● MEDICAL DEVICES; CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FINAL RULE; QUALITY SYSTEMS REGULATIONS (SECTION 610 REVIEW)

Priority: Routine and Frequent

Legal Authority: 5 USC 610

CFR Citation: 21 CFR 808; 21 CFR 812; 21 CFR 820

Legal Deadline: None

Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 820. The purpose of this review is to determine if any of the regulations in part 820 should be continued without change, or should be amended or rescinded, to minimize adverse economic impacts on small entities. FDA will consider and solicit comments on the following; 1) The continued need for a regulation in part 820; 2) the nature of complaints or comments received concerning a regulation in part 820; 3) the complexity of a regulation in part 820; 4) the extent to which a regulation in part 820 overlaps, duplicates, or conflicts with other Federal, State, or government rules; and 5) the degree to which technology economic conditions or other factors have changed in the area affected by a regulation in part 820.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: 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, Rockville, MD 20850
Phone: 301 827–2971
Fax: 301 594–4765
Email: myh@fda.hhs.gov

RIN: 0910–AF71

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

Proposed Rule Stage

1003. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS

Regulatory Plan: This entry is Seq. No. 43 in part II of this issue of the **Federal Register**.

RIN: 0910–AA49

1004. CHRONIC WASTING DISEASE: CONTROL OF FOOD PRODUCTS AND COSMETICS DERIVED FROM EXPOSED ANIMAL POPULATIONS

Priority: Other Significant

Legal Authority: 42 USC 264; 21 USC 301 et seq

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to prohibit the use of cervids (deer, elk) for food, including dietary supplements, and cosmetics if the cervids have been exposed to chronic wasting disease (CWD). FDA is proposing this regulation because of potential risks to health.

CWD is a type of transmissible spongiform encephalopathy (TSE), a group of fatal, neurodegenerative diseases that include bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and goats, and Creutzfeldt-Jakob disease (CJD) in humans. The disease has been identified in wild and farmed elk and wild deer populations.

CWD has been found in cervid populations in certain areas of Wisconsin, Colorado, Nebraska, Wyoming, Kansas, Montana, Oklahoma, South Dakota, New Mexico, Minnesota, and Canada. In 1999, the World Health Organization said there is no evidence that CWD transmits to humans. However, it also suggested any part of a deer or elk believed to be diseased should not be eaten. Results of some studies using in vitro techniques have suggested that transmission to humans could possibly occur. However, if it does occur, it is likely to be through a very inefficient process.

Currently, there are no validated analytical tests to identify animals in the preclinical phase of CWD, or any other TSE. In addition, no test exists to ensure food safety. CWD typically exhibits a long incubation period, during which time animals appear normal but are potentially infectious. Therefore, DA is proposing to require that food or cosmetic products derived from animals exposed to CWD not enter into commerce.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740
Phone: 301 436–1486
Fax: 301 436–2632
Email: rebecca.buckner@cfsan.fda.gov

RIN: 0910–AC21

1005. MEDICAL DEVICES; ANESTHESIOLOGY DEVICES; PROPOSED RECLASSIFICATION OF PRESSURE REGULATORS FOR USE WITH MEDICAL OXYGEN

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360c; 21 USC 360i; 21 USC 371

CFR Citation: 21 CFR 868.2700

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to reclassify pressure regulators for use with medical oxygen from class I to class II and to establish a special

control for oxygen pressure regulators to address problems of fire and explosion associated with use of these devices. The special control will be a guidance document that includes standardized testing, performance, and labeling guidance for industry. Devices that meet the special control will be exempt from the premarket notification requirements of the Act. The agency believes it is taking a least burdensome approach for industry. This proposed rule will phase-in a compliance approach that will minimize the cost. FDA seeks to reclassify these devices under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1)).

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: 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, Rockville, MD 20850
Phone: 301 827–2971
Fax: 301 594–4765
Email: myh@fda.hhs.gov

RIN: 0910–AC30

1006. SUBMISSION OF STANDARDIZED ELECTRONIC STUDY DATA FROM CLINICAL STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Regulatory Plan: This entry is Seq. No. 44 in part II of this issue of the **Federal Register**.

RIN: 0910–AC52

1007. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 353

CFR Citation: 21 CFR 201.161(a); 21 CFR 210.3(b); 21 CFR 211.94

Legal Deadline: None

Abstract: The Food and Drug Administration is proposing to amend 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 proposed 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.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Elaine H. Tseng, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC53

1008. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

Priority: Other Significant

Legal Authority: PL 105–115, sec 121

CFR Citation: 21 CFR 212

Legal Deadline: Final, Statutory, November 21, 1999.

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 proposed rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

Timetable:

Action	Date	FR Cite
NPRM	09/20/05	70 FR 55038
NPRM Comment Period End	12/19/05	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Federal, State

URL For More Information: www.fda.gov/cder/regulatory/pet

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: mitchellw@cder.fda.gov

Related RIN: Previously reported as 0910–AB63

RIN: 0910–AC55

1009. REPORTING INFORMATION REGARDING FALSIFICATION OF DATA

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 58.11; 21 CFR 71.1; 21 CFR 101.69; 21 CFR 101.70; 21 CFR 171.1; 21 CFR 190.6; 21 CFR 312.3; 21 CFR 312.56; 21 CFR 511.1; 21 CFR 812.46

Legal Deadline: None

Abstract: The proposed rule would require sponsors to promptly report any information indicating that any person

has or may have engaged in the falsification of data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: pendletonb@cder.fda.gov

Related RIN: Previously reported as 0910–AC02

RIN: 0910–AC59

1010. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

Regulatory Plan: This entry is Seq. No. 45 in part II of this issue of the **Federal Register**.

RIN: 0910–AF11

1011. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 379e(b)

CFR Citation: 21 CFR 73.100(d); 21 CFR 73.1100(c); 21 CFR 73.2087(c); 21 CFR 101.22(k)

Legal Deadline: None

Abstract: The purpose of this proposed rule is to protect consumers who have allergies to the color additives carmine and cochineal extract by requiring label declaration on products under FDA jurisdiction. This action responds to adverse event reports received by FDA and to a citizen petition submitted to FDA.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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
Email: mhonigfo@cfsan.fda.gov

RIN: 0910–AF12

1012. CHARGING FOR INVESTIGATIONAL DRUGS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 312.7; 21 CFR 312.8

Legal Deadline: None

Abstract: The proposed rule would amend FDA's investigational new drug regulation concerning charging for investigational drugs. The proposed rule would 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 to be described in the agency's proposed rule on treatment use of investigational drugs, and clarify what costs can be recovered for an investigational drug. The proposed rule is intended to permit charging for a broader range of investigational uses than is explicitly permitted in current regulations.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Rockville, MD 20852
Phone: 301 594–2041
Fax: 301–827–5562
Email: rogersc@cder.fda.gov

RIN: 0910–AF13

1013. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Regulatory Plan: This entry is Seq. No. 46 in part II of this issue of the **Federal Register**.

RIN: 0910–AF14

1014. DISTRIBUTION OF BLOOD DERIVATIVES BY REGISTERED BLOOD ESTABLISHMENTS THAT QUALIFY AS HEALTH CARE ENTITIES; PDMA OF 1987; PDA OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351 to 353; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 203.3(q); 21 CFR 203.22(h); 21 CFR 205.3(h)

Legal Deadline: None

Abstract: FDA is proposing to 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 and the FDA Modernization Act of 1997. Certain provisions of that final rule that published on December 3, 1999, (64 FR 67720), do not allow a registered blood establishment that provides health care services to concurrently distribute blood derivatives. The effective date of those provisions of that rule is December 1, 2006, as published on February 23, 2004, (69 FR 8105). FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services related to its activities as a blood establishment to also distribute blood derivatives.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Additional Information: Delayed effective date of portion of rule to 12/01/06, effective date of non-stayed portion of final rule, 64 FR 67720, December 3, 1999

Agency Contact: Kathleen E. Swisher, Supervisory 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
Fax: 301 827–9434

RIN: 0910–AF16

1015. REVOCATION OF THE STATUS OF SPECIFIC PRODUCTS; GROUP A STREPTOCOCCUS

Priority: Info./Admin./Other

Legal Authority: 42 USC 262

CFR Citation: 21 CFR 610.19

Legal Deadline: None

Abstract: FDA is issuing a direct final rule and companion proposed rule to revoke 21 CFR 610.19, Status of specific products; Group A streptococcus. The products had been licensed by the National Institutes of Health prior to 1972, when regulatory authority over these products was transferred to FDA. The regulation prohibits the use of Group A streptococcus organisms and derivatives of Group A streptococcus as ingredients in Bacterial Vaccines and Bacterial Antigens with ''No U.S. Standard of Potency.'' The regulation was written to apply to a group of products that are no longer on the market, namely, streptococcus vaccines and antigens with ''No U.S. Standard of Potency'' that were not purified. The regulation was never intended to refer to purified streptococcus vaccines, which were not developed at that time. Therefore, the regulation is being revoked.

Timetable:

Action	Date	FR Cite
NPRM – Companion to Direct Final Rule	10/00/05	
Direct Final Rule	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AF20

1016. OBSTETRICAL AND GYNECOLOGICAL DEVICES; DESIGNATION OF SPECIAL CONTROL FOR CONDOMS AND CONDOMS WITH SPERMICIDAL LUBRICANT

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 360c

CFR Citation: 21 CFR 884.5300; 21 CFR 884.5310

Legal Deadline: None

Abstract: The classification regulations for male 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 compliance with the recommendations in the guidance, or with some equivalent means of addressing the identified issues 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 801. The rule will demonstrate how the agency is moving forward to meet 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.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: 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, Rockville, MD 20850
Phone: 301 827–2971
Fax: 301 594–4765
Email: myh@fda.hhs.gov

RIN: 0910–AF21

1017. BLOOD INITIATIVE—REQUIREMENTS FOR HUMAN BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

Priority: Other Significant

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; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 630; 21 CFR 640; 21 CFR 660; 21 CFR 820; 21 CFR 1270

Legal Deadline: None

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 based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, and on public comments. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
Email: mckeever@cber.fda.gov

Related RIN: Split from 0910–AB26

RIN: 0910–AF25

1018. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 labeling intended to better inform consumers of potential risks associated with these products. The second action addresses products marketed for children under two 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 products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	01/00/06	
NPRM (Amendment) (Pediatric)	03/00/06	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	10/00/06	
NPRM (Amendment) (Overindulgence/ Hangover)	01/00/06	
NPRM (Amendment) (Steven's Johnson Warnings)	03/00/06	
NPRM (Amendment) (Cardiovascular Warnings)	03/00/06	
Final Action (Internal Analgesics)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF36

1019. OVER–THE–COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF37

1020. OVER–THE–COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes)	03/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF39

1021. OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection, and the other action addresses combination products containing sunscreen and insect repellent ingredients.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	10/00/06	
NPRM (UVA/UVB)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF43

1022. OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Phenyl propanolamine)	12/00/05	
NPRM (Benzocaine)	12/00/05	
Final Action (Phenyl propanolamine)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF45

1023. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 349; 21 USC 371

CFR Citation: 21 CFR 589.2001

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing 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.

Timetable:

Action	Date	FR Cite
ANPRM	07/14/04	69 FR 42288
ANPRM Comment Period End	08/13/04	
NPRM	10/06/05	70 FR 58569
NPRM Comment Period End	12/20/05	
Final Action	07/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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
Email: burt.pritchett@fda.hhs.gov

RIN: 0910–AF46

1024. OVER–THE–COUNTER (OTC) DRUG REVIEW—DANDRUFF, SEBORRHEIC DERMATITIS, AND PSORIASIS PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 combinations containing coal tar solution and menthol in a shampoo product.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AF49

1025. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 drug products containing hydroquinone.

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AF53

1026. OVER–THE–COUNTER (OTC) DRUG REVIEW—STIMULANT DRUG PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AF56

1027. DESIGNATION OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

Priority: Other Significant

Legal Authority: 21 USC 360ccc–2

CFR Citation: 21 CFR 514.1(d)(1)(i)

Legal Deadline: NPRM, Statutory, August 2, 2005.
Final, Statutory, August 2, 2006.

Abstract: This proposed rule is being issued in response to the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The proposed rule implements section 573 of the MUMS Act which sets forth the functional requirements for drug sponsors requesting MUMS designation for proposed new animal drugs. MUMS designation of a new animal drug will allow drug sponsors to be granted seven years of exclusive marketing rights for these limited demand new animal drugs once the drugs are approved or conditionally approved. This regulation will define content and format requirements for designation, requests changing designation ownership, and annual reporting requirements. This rule will also describe the criteria CVM will use for granting or denying these requests. Specific sections of the rule will be dedicated to documentation of MUMS status in a request, granting MUMS designation, and revocation of MUMS designation. This is a voluntary program for animal drug sponsors. While we do not have estimates of the impact on the animal drug industry, we expect that this rule will have a net beneficial impact on the industry with those firms participating who hope to profit as a result of the market exclusivity provided by the MUMS Act. A large number of these drug companies are classified as small businesses.

Timetable:

Action	Date	FR Cite
NPRM	09/27/05	70 FR 56394

Action	Date	FR Cite
NPRM Comment Period End	12/12/05	
Final Rule	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Andrew J. Beaulieu, 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, 7519 Standish Place, Room 180, HFV–50, MPN–4, Rockville, MD 20855
Phone: 240 276–9090
Fax: 240–276–9001
Email: abeaulie@cvm.fda.gov

RIN: 0910–AF60

1028. ● BLOOD VESSELS RECOVERED WITH ORGANS AND INTENDED FOR USE IN ORGAN TRANSPLANTATION

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271; 42 USC 273 to 274d; 42 USC 1302; 42 USC 1306

CFR Citation: 21 CFR 1271; 42 CFR 121

Legal Deadline: None

Abstract: FDA and Health Resources and Services Administration (HRSA) are issuing a direct final rule and companion proposed rule to amend the regulations to consider as part of an organ (and regulated by HRSA) those blood vessels recovered with vascularized human organs that are intended for use in organ transplantation; and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products (regulated by FDA). We are taking this action to provide that blood vessels recovered with organs and intended for use in organ transplantation will be governed by the regulations pertaining to organs. We believe this change will eliminate unnecessary burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA requirements with respect to vascular tissue (FDA jurisdiction) and organs (HRSA jurisdiction).

Timetable:

Action	Date	FR Cite
NPRM – Companion to Direct Final Rule	12/00/05	
Direct Final Rule	12/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
Email: mckeever@cber.fda.gov

RIN: 0910–AF65

1029. ● INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES

Priority: Other Significant

Legal Authority: 21 USC 360 ccc–1

CFR Citation: 21 CFR 516

Legal Deadline: NPRM, Statutory, February 2, 2006.
Final, Statutory, August 2, 2007.

Abstract: This proposed rule is being issued in response to the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The proposed rule implements section 572 of the MUMS Act which provides for a public index listing of legally-marketed unapproved new animal drugs for minor species of animals (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). The drugs in this index will only be indicated for use in non-food minor species or for use in early non-food life stages to food-producing minor species. This proposed rule, will, among other things, specify the procedures for requesting eligibility for indexing and for requesting addition to the index as well as the reporting requirements for index holders. This rule will also describe the criteria requestors will use for assembling a qualified expert panel to evaluate for FDA the safety and effectiveness of a new animal drug proposed for indexing.

Timetable:

Action	Date	FR Cite
NPRM	02/00/06	
NPRM Comment Period End	05/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Andrew J. Beaulieu, 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, 7519 Standish Place, Room 180, HFV–50, MPN–4, Rockville, MD 20855
Phone: 240 276–9090
Fax: 240–276–9001
Email: abeaulie@cvm.fda.gov

RIN: 0910–AF67

1030. ● OVER–THE–COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug

HHS—FDA **Proposed Rule Stage**

Administration, CRP2 RMS214, HFD–560, Rockville, MD 20850
Phone: 301 827–2279
Fax: 301–827–2316
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF68

1031. ● OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Consumer Products)	03/00/06	
NPRM (Food Handlers)	03/00/06	
NPRM (Healthcare Antiseptics)	03/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, CRP2 RMS214, HFD–560, Rockville, MD 20850
Phone: 301 827–2279
Fax: 301–827–2316
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF69

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

Final Rule Stage

1032. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: The final rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the rule would provide four different routes for exporting an unapproved new drug product for investigational use. One route would permit exportation, if the drug is the subject of an investigational new drug application (IND) and is being exported for use in the investigation. A second route would permit exportation, without prior Food and Drug Administration (FDA) approval and without an IND, if the product is to be exported for use in a clinical investigation and has received marketing authorization in certain developed countries. The third route would permit exportation, without prior FDA approval and without an IND, if the product is to be exported for use in a clinical investigation in certain specified developed countries. The fourth route would permit exportation without an IND, to any country provided that the exporter sends a written certification to FDA at the time the drug is first exported. Drugs exported under any of the first three routes would, however, be subject to certain statutory requirements, such as not conflicting with the foreign country's laws and not being sold or offered for sale in the United States. Drugs exported under either the second or third routes would be subject to additional statutory requirements, such as being in substantial conformity with the current good manufacturing practices and certain labeling requirements. These provisions would implement changes in FDA's export authority resulting from the FDA Export Reform and Enhancement Act of 1996 and streamline another mechanism for exporting investigational new drugs while providing safeguards.

Timetable:

Action	Date	FR Cite
NPRM	06/19/02	67 FR 41642
Final Action	02/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
Phone: 301 827–0587
Fax: 301 827–4774
Email: philip.chao@fda.hhs.gov

RIN: 0910–AA61

1033. REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS

Regulatory Plan: This entry is Seq. No. 47 in part II of this issue of the **Federal Register**.

RIN: 0910–AA94

1034. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a to 263–n; 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

CFR Citation: 21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 320; 21 CFR 600; 21 CFR 601; 21 CFR 606

Legal Deadline: None

Abstract: This regulation is 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 propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AA97

1035. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

Abstract: The proposed rule would amend 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 proposed rule would also amend the regulations on extension of the review clock because of amendments to applications.

Timetable:

Action	Date	FR Cite
NPRM	07/20/04	69 FR 43357
Final Action	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: pendletonb@cder.fda.gov

RIN: 0910–AB34

1036. CGMPS FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV INFECTION (LOOKBACK)

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 21 USC 372; 21 USC 381; 42 USC 263

CFR Citation: 21 CFR 606; 21 CFR 610

Legal Deadline: None

Abstract: This rulemaking is one of a number of actions being taken to amend the biologics regulations to remove, revise, or update the regulations applicable to blood, blood components, and blood derivatives. These actions are based on FDA's comprehensive review of the biologics regulations and on reports by the U.S. House of Representatives Committee on Government Reform and Oversight's, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. In this rulemaking, FDA will amend the biologics regulations to require that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components pose an increased risk for transmitting hepatitis C virus (HCV) infection because they have been collected from a donor who, at a later date, tested reactive for evidence of HCV. The HIV lookback regulations will be amended for consistency.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69377
NPRM Comment Period End	02/14/01	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434
Email: mckeever@cber.fda.gov

Related RIN: Related to 0910–AB26

RIN: 0910–AB76

1037. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

Regulatory Plan: This entry is Seq. No. 48 in part II of this issue of the **Federal Register**.

RIN: 0910–AB88

1038. ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS OF FDA–REGULATED PRODUCTS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 350a; 21 USC 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

CFR Citation: 21 CFR 50; 21 CFR 56

Legal Deadline: None

Abstract: The final rule will finalize the interim 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.

Timetable:

Action	Date	FR Cite
Interim Rule	04/24/01	66 FR 20589
Final Action	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC07

1039. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect the private sector under PL 104-4.

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; . . .

CFR Citation: 21 CFR 16; 21 CFR 116; 21 CFR 118

Legal Deadline: None

Abstract: 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. This proposal would reduce SE prevalence in the egg production environment and consequently in the eggs themselves. Most SE contamination of eggs is a result of SE infection in the laying hen's reproductive tract, called transovarian contamination. The proposed measures are designed to reduce the likelihood of this transovarian contamination and include: (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 5-log destruction of SE.

The proposed rule is one 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.

Timetable:

Action	Date	FR Cite
NPRM	09/22/04	69 FR 56824
Final Action	07/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Louis J. Carson, Deputy Director, Food Safety Initiative, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–032), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–2130
Fax: 301 436–2632
Email: louis.carson@cfsan.fda.gov

RIN: 0910–AC14

1040. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS

Priority: Info./Admin./Other

Legal Authority: 21 USC 321; 21 USC 346; 21 USC 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

CFR Citation: 21 CFR 56.106

Legal Deadline: None

Abstract: The final rule would require institutional review boards (IRB) to register with FDA. 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 range of active protocols (small, medium, or large) 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.

Timetable:

Action	Date	FR Cite
NPRM	07/06/04	69 FR 40556
Final Action	03/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning (HF–23), 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
Phone: 301 827–0587
Fax: 301 827–4774
Email: philip.chao@fda.hhs.gov

RIN: 0910–AC17

1041. EXCEPTION FROM GENERAL REQUIREMENTS FOR INFORMED CONSENT; REQUEST FOR COMMENTS AND INFORMATION

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360bbb; 21 USC 360c; 21 USC 360d; 21 USC 360e; 21 USC 360f; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 381

CFR Citation: 21 CFR 50.23

Legal Deadline: None

Abstract: This interim 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.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Catherine Lorraine, Director, Policy Development and Coordination Group, Office of Policy and Planning, Department of Health and Human Services, Food and Drug Administration, 14–101–11, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827–3360
Fax: 301 594–6777

RIN: 0910–AC25

1042. MEDICAL DEVICES; PATIENT EXAMINATION AND SURGEONS' GLOVES; ADULTERATION

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 800.20

Legal Deadline: None

Abstract: The final rule amends the sampling plans, test method, and acceptable quality levels in 21 CFR 800.20. As prescribed by this regulation, FDA samples patient examination and surgeons' gloves and examines them for visual defects and water leaks. Glove lots are considered adulterated if they do not meet specified quality levels. This rule would clarify sampling plans and the scoring of defects, lower acceptance rates for leaking gloves, raise rejection rates for leaking gloves, and add tightened inspection schemes for reexamined glove lots. The rule is intended to facilitate industry compliance and enhance the safety and effectiveness of gloves.

Timetable:

Action	Date	FR Cite
NPRM	03/31/03	68 FR 15404
NPRM Comment Period End	06/30/03	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: 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, Rockville, MD 20850
Phone: 301 827–2971
Fax: 301 594–4765
Email: myh@fda.hhs.gov

RIN: 0910–AC32

1043. TOLL–FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

Regulatory Plan: This entry is Seq. No. 49 in part II of this issue of the **Federal Register**.

RIN: 0910–AC35

1044. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: PL 107–188, sec 307

CFR Citation: 21 CFR 1.276 et seq

Legal Deadline: Final, Statutory, December 12, 2003.
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 eight hours, nor more than five days until final regulations are issued.

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 (FFDCA), 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 required prior notice would provide the identity of

the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation identifies the parties responsible for providing the notice and 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 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.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5428
Interim Final Rule	10/10/03	68 FR 58974
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19763
Interim Final Rule Comment Period Reopened End	07/13/04	
Final Rule	07/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–32, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1722
Fax: 301 436–2637
Email: may.nelson@cfsan.fda.gov

RIN: 0910–AC41

1045. HUMAN SUBJECT PROTECTION; FOREIGN CLINICAL STUDIES NOT CONDUCTED UNDER AN INVESTIGATIONAL NEW DRUG APPLICATION

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 355(d)(5); 21 USC 355(i); 21 USC 371(a); 42 USC 262(a)(2)(A); 42 USC 262(a)(2)(B)(i)(l)

CFR Citation: 21 CFR 312.120

Legal Deadline: None

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 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 would replace 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 proposed 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 patients.

Timetable:

Action	Date	FR Cite
NPRM	06/10/04	69 FR 32467
Final Action	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: pendletonb@cder.fda.gov

RIN: 0910–AF15

1046. BLOOD INITIATIVE—REVISIONS TO LABELING REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA; AND TECHNICAL AMENDMENT

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 360j; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa to 25; 21 USC 331; 21 USC 310

CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 640

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is amending the regulations regarding container labels and instruction circulars for certain blood, 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 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.

Timetable:

Action	Date	FR Cite
NPRM	07/30/03	68 FR 44678
NPRM Comment Period End	10/28/03	
Final Action	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Brenda R. Friend, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, HFM–17, 1410 Rockville Pike, Suite 200N, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434

Related RIN: Split from 0910–AB26

RIN: 0910–AF26

1047. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; . . .

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End	12/06/96	
Other/NPRM Comment Period Reopened	04/28/03	68 FR 22341
Other/NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1720
Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF27

1048. INFANT FORMULA QUALITY FACTORS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; . . .

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End	12/06/96	
Other/NPRM Comment Period Reopened	04/28/03	68 FR 22341
Other/NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1720
Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF28

1049. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 claims for the common cold.

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Common Cold)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF31

HHS—FDA **Final Rule Stage**

1050. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 phenylephrine bitartrate, and the other action addresses the ingredient phenylpropanolamine.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482
NPRM (Phenyl propanolamine)	12/00/05	
Final Action (Amendment) (Sinusitis Claim)	10/31/05	70 FR 58974
Final Action (Phenyl propanolamine)	10/00/06	
Final Action (Phenylephrine Bitartrate)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF34

1051. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 laxative drug products.

Timetable:

Action	Date	FR Cite
Final Action (Laxative Drug Products)	03/00/06	
Final Action (Granular Psyllium)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF38

1052. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 labeling for products formulated and marketed as lip protectants. The second action addresses skin protectant products to protect and treat fever blisters and cold sores.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	12/00/05	
Final Action (Fever Blisters/Cold Sores)	10/00/06	
Final Action (Diaper Rash)	03/00/06	
NPRM (Amendment) (Diaper Rash Drug Product)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF42

1053. OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 358; 21 USC 360; 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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 warning statements for products containing nonoxynol 9.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	12/00/05	
NPRM (Vaginal Contraceptive Drug Products)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF44

1054. USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN FOOD AND COSMETICS

Priority: Other Significant

Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 189.5; 21 CFR 700.27

Legal Deadline: None

Abstract: On July 14, 2004, FDA issued an interim final rule, effective immediately, to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials 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. After reviewing comments received to the interim final rule, FDA intends to issue a final rule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/14/04	69 FR 42256
Interim Final Rule Comment Period End	10/12/04	
Final Action	07/00/06	
Interim Final Rule (Ammendments)	09/07/05	70 FR 53063
Interim Final Rule (Ammendments) Comment Period End	11/07/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740
Phone: 301 436–1486
Fax: 301 436–2632
Email: rebecca.buckner@cfsan.fda.gov

RIN: 0910–AF47

1055. RECORDKEEPING REQUIREMENTS FOR HUMAN FOOD AND COSMETICS MANUFACTURED FROM, PROCESSED WITH, OR OTHERWISE CONTAINING MATERIAL FROM CATTLE

Priority: Other Significant

Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371; 21 USC 381

CFR Citation: 21 CFR 189.5; 21 CFR 700.27

Legal Deadline: None

Abstract: On July 14, 2004, FDA proposed to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. This is a companion rulemaking to FDA's interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics.'' FDA intends to finalize this proposal after reviewing any comments received.

Timetable:

Action	Date	FR Cite
NPRM	07/14/04	69 FR 42275
NPRM Comment Period End	08/13/04	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740
Phone: 301 436–1486
Fax: 301 436–2632
Email: rebecca.buckner@cfsan.fda.gov

RIN: 0910–AF48

1056. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS

Priority: Routine and Frequent

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

HHS—FDA **Final Rule Stage**

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Sodium Bicarbonate Labeling)	01/00/06	
Final Action (Overindulgence Labeling)	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AF52

1057. SUPPLEMENTS AND OTHER CHANGES TO APPROVED NEW ANIMAL DRUG APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 356a

CFR Citation: 21 CFR 25; 21 CFR 500; 21 CFR 514; 21 CFR 558

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is amending its regulations on supplements and other changes to approved new animal drug applications (NADAs) or abbreviated new animal drug applications (ANADAs) to implement the manufacturing changes provision of the Food and Drug Modernization Act of 1997. The final rule requires manufacturers to assess the effect of a manufacturing change on the identity, strength, quality, purity, and potency of a drug as those factors relate to the safety or effectiveness of the drug. The final rule sets forth requirements for changes requiring submission and approval of a supplement before the distribution of the drug made using the change, changes requiring the submission of a supplement at least 30 days prior to the distribution of the drug, changes requiring the submission of a supplement at the time of distribution of the drug, and changes to be described in an annual report.

Timetable:

Action	Date	FR Cite
NPRM	10/01/99	64 FR 53281
Final Action	01/00/06	
Final Action Effective	03/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Dennis Bensley Jr., Chemist, Department of Health and Human Services, Food and Drug Administration, 7500 Standish Place, MPN–2, Room 320, HFV–140, Rockville, MD 20855
Phone: 301 827–6956
Email: dbensley@cvm.fda.gov

RIN: 0910–AF59

1058. BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW

Priority: Substantive, Nonsignificant

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 to 360d; 21 USC 360h; 21 USC 360i; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264

CFR Citation: 21 CFR 201.59; 21 CFR 610.21

Legal Deadline: None

Abstract: On December 13, 1985, the Food and Drug Administration (FDA) proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel's report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the United States District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004 (69 FR 78280), FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (December 2004 proposal) (69 FR 78281) to provide notice and to give interested persons an opportunity to comment. FDA is proposing to amend the biologics regulations in response to the report and recommendations of the Panel and in consideration of comments submitted to the Division of Dockets Management. FDA intends to classify these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category IIIB (off the market pending completion of studies permitting a determination of effectiveness).

The December 2004 proposal included a proposed order for Anthrax Vaccine Absorbed. The final order Anthrax Vaccine Absorbed will be published separately in the same issue of the Federal Register as the final rule and final order for the other products included in the December 2004 proposal.

Timetable:

Action	Date	FR Cite
NPRM	12/29/04	69 FR 78281
NPRM Comment Period End	03/29/05	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Astrid L. Szeto, Senior Regulatory Review Officer,

HHS—FDA **Final Rule Stage**

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
Fax: 301–827–9434

RIN: 0910–AF62

Department of Health and Human Services (HHS) Food and Drug Administration (FDA) — Long-Term Actions

1059. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 314.96(a)(1); 21 CFR 314.94(a)(7); 21 CFR 320.21(b)(1)

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to 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. FDA is proposing to 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.

Timetable:

Action	Date	FR Cite
NPRM	10/29/03	68 FR 61640
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFD–7, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101, Rockville, MD 20857
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC23

1060. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING: CONSUMER RESEARCH TO CONSIDER NUTRIENT CONTENT AND HEALTH CLAIMS AND POSSIBLE FOOTNOTE OR DISCLOSURE STATEMENTS

Priority: Other Significant

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

CFR Citation: 21 CFR 101

Legal Deadline: None

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.

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal

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

Related RIN: Related to 0910–AB66

RIN: 0910–AC50

1061. FOOD STANDARDS: GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371

CFR Citation: 21 CFR 130.5

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
ANPRM	12/29/95	60 FR 67492
ANPRM Comment Period End	04/29/96	
NPRM	05/20/05	70 FR 29214
NPRM Comment Period End	08/18/05	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Ritu Nalubola, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, HFS–820, 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
Email: ritu.nalubola@cfsan.fda.gov

Related RIN: Related to 0583–AC72

RIN: 0910–AC54

1062. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; REVISION OF CERTAIN LABELING CONTROLS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 351

CFR Citation: 21 CFR 211.122

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	07/29/97	62 FR 40489
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: mullerh@cder.fda.gov

RIN: 0910–AF08

1063. HEALTH CLAIMS

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 343; 21 USC 371

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: On November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. This ANPRM was signaled in the July 11, 2003 (68 FR 41387) notice that announced the availability of the final report of the FDA Task Force on the Consumer Health Information for Better Nutrition Initiative.

Comments on the regulatory alternatives and additional topics identified in the ANPRM will inform FDA decisions about regulation of qualified health claims.

Timetable:

Action	Date	FR Cite
ANPRM	11/25/03	68 FR 66040
ANPRM Comment Period Extended	01/27/04	69 FR 3868
ANPRM Comment Period End	02/25/04	
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Nancy Crane, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1456
Fax: 301 436–2636
Email: nancy.crane@cfsan.fda.gov

RIN: 0910–AF09

1064. FOOD LABELING; PROMINENCE OF CALORIES

Priority: Other Significant

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

CFR Citation: 21 CFR 101.9

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17008
ANPRM Comment Period End	06/20/05	
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Jill Kevala, Chemist, Department of Health and Human Services, Food and Drug Administration, HFS–830, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1450
Fax: 301 436–2636
Email: jkevala@cfsan.fda.gov

RIN: 0910–AF22

1065. 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

Priority: Other Significant

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

CFR Citation: 21 CFR 101.9; 21 CFR 101.12; 21 CFR 101.60(b)

Legal Deadline: None

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 changes to the agency's nutrition labeling regulations on serving size and comments on allowance of truthful, nonmisleading, and useful approaches for promoting consumption of smaller portion sizes.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End	06/20/05	
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Lori LeGault, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–840, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1791
Fax: 301 436–2635
Email: llegault@cfsan.fda.gov

RIN: 0910–AF23

1066. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 these products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40237
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF32

1067. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 combination products containing an oral bronchodilator.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40232
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241

Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF33

1068. OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 external analgesic drug products.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF35

1069. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Plaque Gingivitis)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF40

1070. OVER–THE–COUNTER (OTC) DRUG REVIEW—OVERINDULGENCE IN FOOD AND DRINK PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	01/05/05	70 FR 741
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AF51

1071. USE OF MATERIALS DERIVED FROM CATTLE IN MEDICAL PRODUCTS INTENDED FOR USE IN HUMANS AND DRUGS INTENDED FOR USE IN RUMINANTS

Priority: Other Significant

Legal Authority: 21 USC 501; 21 USC 502; 21 USC 505; 21 USC 512; 21 USC 516; 21 USC 519; 21 USC 701; 21 USC 704; 21 USC 801; 42 USC 351; 42 USC 361

CFR Citation: 21 CFR 116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500; 21 CFR 600.16; 21 CFR 895; 21 CFR 1271.465; 21 CFR 1271.470

Legal Deadline: None

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 rules. 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.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Eric Flamm, Senior Policy Advisor, Office of Policy, Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, 5600 Fishers Lane, Room 14C–17, HF–23, Rockville, MD 20857
Phone: 301 827–0891
Fax: 301 827–4774
Email: eric.flamm@fda.hhs.gov

Related RIN: Merged with 0910–AF55

RIN: 0910–AF54

1072. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

Priority: Other Significant

Legal Authority: 15 USC 1453 to 1455 ; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

CFR Citation: 21 CFR 1.98

Legal Deadline: None

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).

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
Phone: 301 827–0587
Fax: 301 827–4774
Email: philip.chao@fda.hhs.gov

RIN: 0910–AF61

1073. ● OVER–THE–COUNTER ANTIDIARRHEAL DRUG PRODUCTS

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 products.

Timetable:

Action	Date	FR Cite
Proposed Rule	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, CRP2 RMS214, HFD–560, Rockville, MD 20850
Phone: 301 827–2279
Fax: 301–827–2316
Email: walter.ellenberg@fda.hhs.gov

Related RIN: Related to 0910–AC82

RIN: 0910–AF63

1074. ● LOWFAT AND SKIM MILK AND LOWFAT AND NONFAT YOGURT PRODUCTS, LOWFAT COTTAGE CHEESE: REV. OF STAND. OF IDENT.; FOOD LAB., NUTRIENT CONT. CLAIMS FOR FAT, FATTY ACIDS, AND CHOLESTEROL CONT. OF FOODS (SECTION 610 REVIEW)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 379

CFR Citation: 21 CFR 101; 21 CFR 131; 21 CFR 133

Legal Deadline: None

Abstract: Part 131 (21 CFR Part 131) describes regulations for standards of identity for milk and milk products. Part 133 (21 CFR Part 133) describes regulations for standards of identity for cheese and cheese products. The 1996 final rule (61 FR 58991) removed standards of identity for sweetened condensed skim milk, lowfat dry milk, evaporated skim milk, lowfat milk, acidified lowfat milk, skim (nonfat) milk, cultured skim (nonfat) milk, sour half-and-half, acidified sour half-and-half, and lowfat cottage cheese. The final rule amended the standard of identity for dry cream by removing the reference to the lowfat milk standard. The regulation also amended the nutrient content claims regulations for fat, fatty acids, and cholesterol (part 101.62) to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products. The purpose of this review is to determine whether the regulations in parts 131 and 133 should be continued without change, or whether they should be further 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 parts 131 and 133; (2) the nature of complaints or comments received concerning the regulations in parts 131 and 133; (3) the complexity of the regulations in parts 131 and 133; (4) the extent to which the regulations in parts 131 and 133 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the food standard regulations in parts 131 and 133.

The section 610 review will be carried out along with a regulatory 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 greater alignment with the President's priorities and the principles set forth in the Executive order. The combined effect of the two reviews will be to determine if it is possible to redesign milk and cheese food standards of identity in ways that will maintain or increase the effectiveness of food labeling in providing useful information to consumers, and, at the same time, reduce compliance and other costs associated with the regulations.

Timetable:

Action	Date	FR Cite
Begin Review	08/01/05	
End Review	12/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Richard A. Williams, Director, Division of Market Studies, OSAS, CFSAN, Department of Health and Human Services, Food and Drug Administration, HFS–725, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1989
Fax: 301 436–2626
Email: richard.williams@cfsan.fda.gov

RIN: 0910–AF64

1075. ● OVER–THE–COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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 phenazopyridine.

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Walter Ellenberg, Regulatory Health Project Manager, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, CRP2 RMS214, HFD–560, Rockville, MD 20850
Phone: 301 827–2279
Fax: 301–827–2316
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF70

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

Completed Actions

1076. REQUIREMENTS PERTAINING TO SAMPLING SERVICES AND PRIVATE LABORATORIES USED IN CONNECTION WITH IMPORTED FOOD

Priority: Routine and Frequent

CFR Citation: 21 CFR 59

Completed:

Reason	Date	FR Cite
Withdrawn	08/05/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Philip L. Chao
Phone: 301 827–0587
Fax: 301 827–4774
Email: philip.chao@fda.hhs.gov

RIN: 0910–AB96

1077. AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X–RAY SYSTEMS AND THEIR MAJOR COMPONENTS

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 1020.30; 21 CFR 1020.31; 21 CFR 1020.32; 21 CFR 1020.33

Completed:

Reason	Date	FR Cite
Final Action	06/10/05	70 FR 33998

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Myrna Hanna
Phone: 301 827–2971
Fax: 301 594–4765
Email: myh@fda.hhs.gov

RIN: 0910–AC34

1078. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority: Other Significant

CFR Citation: 21 CFR 1; 21 CFR 20

Completed:

Reason	Date	FR Cite
Final Rule	10/03/05	70 FR 57505

Regulatory Flexibility Analysis Required: No

HHS—FDA

Completed Actions

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Catherine Copp
Phone: 301 436–1589
Fax: 301 436–2637
Email: catherine.copp@cfsan.fda.gov

RIN: 0910–AC40

1079. QUALITY STANDARD REGULATION ESTABLISHING AN ALLOWABLE LEVEL FOR ARSENIC IN BOTTLED WATER

Priority: Other Significant

CFR Citation: 21 CFR 165.110(b)

Completed:

Reason	Date	FR Cite
Final Rule	06/09/05	70 FR 33694

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Henry Kim
Phone: 301 436–2023
Fax: 301 436–2651
Email: hkim@cfsan.fda.gov

RIN: 0910–AF10

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)

Proposed Rule Stage

1080. DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 254b; 42 USC 254e

CFR Citation: 42 CFR 5; 42 CFR 51c

Legal Deadline: None

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. This notice of proposed rulemaking (NPRM) will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
Second NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Andy Jordan, Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C–26, Rockville, MD 20857
Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

1081. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: REPORTING ADVERSE AND NEGATIVE ACTIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396r–2

CFR Citation: 45 CFR 60

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Mark S. Pincus, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 8–103, Rockville, MD 20857
Phone: 301 443–2300

RIN: 0906–AA57

1082. INTESTINES ADDED TO THE DEFINITION OF ORGANS COVERED BY THE RULES GOVERNING THE OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

Priority: Other Significant

Legal Authority: 42 USC 274e, sec 301; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138

CFR Citation: 42 CFR 121

Legal Deadline: None

Abstract: The Department of Health and Human Services proposes to add intestines to the definition of organs covered by the rules governing the operation of the OPTN. After a review of intestinal transplants, HHS believes that intestines should now be included within the definition. The notice of proposed rulemaking provides the history of intestinal transplants, the factors that have persuaded HHS of the advisability of including intestines within the scope of the regulations governing the operation of the OPTN, and the anticipated consequences of this proposal.

As the field of intestinal transplantation evolves, it becomes more critical that intestinal organ allocation policies keep pace with the advances in the field; that policy development include performance indicators to assess how well the policies achieve the goals of

an equitable transplant system; that those policies are enforceable; and that patients and physicians have timely access to accurate data that will assist them in making decisions regarding intestinal transplantation.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Laura St. Martin, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C–04, Parklawn Bldg., Rockville, MD 20857
Phone: 301 443–4423
Email: lstmartin@hrsa.gov

RIN: 0906–AA62

1083. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: CALCULATION OF AVERAGE COST OF A HEALTH INSURANCE POLICY

Priority: Info./Admin./Other

Legal Authority: Section 2115 of the Public Health Service Act, 42 USC, 300aa–15

CFR Citation: 42 CFR 100, sec 100.2

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) is proposing to revise the current method for calculating the average cost of a health insurance policy, which is an amount deducted from the award of compensation in certain cases. According to the Final Rule published on June 24, 1992, which established the current calculation, ''lf, over time, the average cost of health insurance, as calculated by the method described above, significantly differs from subsequent HIAA survey results or other authoritative sources then available, the Secretary of HHS will consider appropriate revisions of this rule.'' 57 FR 28098 (June 24, 1992). When the latest average monthly of an individual health insurance policy was calculated based on the current methodology, it was significantly different from the Kaiser Family Foundation/Health Research and Educational Trust average monthly cost of an individual health insurance policy for the same time period. Therefore, the Secretary is proposing a new methodology to calculate the average cost of a health insurance policy.

Subtitle 2 of title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act of 1986, as amended, governs the National Vaccine Injury Compensation Program (VICP). The VICP, administered by the Secretary of Health and Human Services (the Secretary) provides that a proceeding for compensation for a vaccine-related injury or death shall be initiated by service upon the Secretary, and the filing of a petition with the United States Court of Federal Claims. In some cases, the injured individual may receive compensation for future lost earnings, less appropriate taxes and the ''average cost of a health insurance policy, as determined by the Secretary.'' The elements of compensation that may be awarded to a successful petitioner are set out in section 2115 of the Public Service Act, 42 U.S.C. section 300aa-15. Subsection (a)(3)(B) specifically provides for compensation for lost earnings for a person who has sustained a vaccine-related injury at age 18 and beyond. The injured person would be eligible to receive compensation for loss of earnings, after the age of 18, which are calculated on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the ''average cost of a health insurance policy, as determined by the Secretary.'' The wage data are taken from the Employment and Earnings survey done by the Department of Labor, Bureau of Labor Statistics.

Subsection (a)(3)(A) specifically provides for payment of actual and anticipated lost earnings for individuals injured after reaching age 18 and does not include deductions for taxes and the cost of health insurance. This new methodology is expected to result in a more accurate reflection of the actual average cost of a health insurance policy as compared to the figure reached under the methodology that is currently used which results in a number that is too high. Because the amount of compensation for lost wages is reduced by this figure for some petitioners receiving compensation under the VICP, such petitioners are likely to receive a greater amount of compensation if the amendment is adopted.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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
Email: gevansr@hrsa.gov

RIN: 0906–AA68

1084. HEALTHY TOMORROW'S PARTNERSHIP FOR CHILDREN (HTPC) PROGRAM

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: Social Security Act, title V, sec 501(a)(2); Social Security Act, title V, sec 502(a)(1); 42 USC 701

CFR Citation: 42 CFR 51(a)

Legal Deadline: None

Abstract: In this rule, the HTPC is proposing to formally add a cost participation component to its grant program. This would require the grantees to have non-Federal matching funds and/or in-kind resources that are equal to or greater than $100,000 in years 2 through 5 of the 5-year project period. For example, in years 2-5, a project awarded $50,000 (i.e. the maximum annual award) of HTPC funds yearly would be expected to have, at a minimum, $100,000 in non-Federal matching funds each funding year. In this example, the $100,000 must come from alternate non-Federal funds, including, but not limited to, individuals, corporations, foundations, in-kind resources, or State and local agencies. Documentation of matching funds would be required (i.e., specific sources, funding level, in-kind contributions).

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

HHS—HRSA **Proposed Rule Stage**

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jose Belardo, Director, Healthy Tomorrow's Partnership for Children Program, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 18A–55, Rockville, MD 20857
Phone: 301 443–0757
Email: jbelardo@hrsa.gov

RIN: 0906–AA70

Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) — Final Rule Stage

1085. INTERIM FINAL RULE FOR THE SMALLPOX EMERGENCY PERSONNEL PROTECTION PROGRAM: SMALLPOX (VACCINIA) VACCINE INJURY TABLE

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

Abstract: To establish a table identifying adverse effects (including injuries, disabilities, conditions, and deaths) that shall be presumed to result from the administration of, or exposure to, the smallpox vaccine, and the time interval in which the first symptom or manifestation of each listed injury must manifest in order for such presumption to apply.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/27/03	68 FR 51492
Final Action	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Mr. Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Department of Health and Human Services, Health Resources and Services Administration, 11th Floor, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–5255
Email: smallpox@hrsa.gov

Related RIN: Related to 0906–AA61

RIN: 0906–AA60

1086. SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

Abstract: To provide benefits to certain persons harmed as a result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a result of contracting vaccinia through accidental exposure to certain persons. The Secretary may also provide death benefits to certain survivors of people who died as a direct result of these injuries.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/16/03	68 FR 70080
Final Action	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Mr. Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Department of Health and Human Services, Health Resources and Services Administration, 11th Floor, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–5255
Email: smallpox@hrsa.gov

Related RIN: Related to 0906–AA60

RIN: 0906–AA61

1087. REQUIREMENTS ESTABLISHING A LIMITATION ON ADMINISTRATIVE EXPENSES; RYAN WHITE CARE ACT TITLE IV GRANTS FOR COORDINATED SERVICES AND ACCESS TO RESEARCH

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 300ff–71

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule finalizes the determination to establish a limitation on administrative expenses for Ryan White Comprehensive AIDS Resources Emergency (CARE) Act title IV Grants for Coordinated Services and Access to Research for Women, Infants, Children, and Youth. The rule establishes the limitation on administrative expenses as a percentage of the grant award, provides guidance on the procedures and processes for implementation of the limitation on administrative expenses, and clarifies the individual expenses that shall be categorized as administrative. The rule specifies the date for implementation as grants funded using fiscal year 2005 grant dollars.

Timetable:

Action	Date	FR Cite
NPRM	08/12/03	68 FR 47923
NPRM Comment Period End	09/11/03	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jose Rafael Morales, Acting Director, Division of Community Based Programs, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 7A–21, Rockville, MD 20857
Phone: 301 443–3650

HHS—HRSA **Final Rule Stage**

Email: jmorales@hrsa.gov

RIN: 0906–AA65

1088. REVISION TO 42 CFR SUBPART D—PUBLIC HEALTH SERVICE (PHS) GRANT APPEALS PROCEDURE

Priority: Other Significant

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 50.402

Legal Deadline: None

Abstract: The Health Resources and Services Administration (HRSA), an operating division under the U.S. Department of Health and Human Services, is proposing to no longer require its grantees to appeal certain adverse agency decisions to an ''informal'' appeals board (as outlined in 42 CFR part 50, subpart D—Public Health Service Grant Appeals Procedure) before exercising the right to appeal to the Departmental Appeals Board. In doing so, HRSA will join other PHS agencies (Substance Abuse and Mental Health Services Administration and the Indian Health Service) which no longer require the use of an informal appeal procedure.

Timetable:

Action	Date	FR Cite
NPRM	06/07/05	70 FR 33053
NPRM Comment Period End	08/08/05	
Final Rule	06/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Agency Contact: Gail Ellen Lipton, Director, Division of Grants Policy, Department of Health and Human Services, Health Resources and Services Administration, Room 11A–55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–6509
Email: glipton@hrsa.gov

RIN: 0906–AA69

Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) — Long-Term Actions

1089. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: MEDICAL MALPRACTICE PAYMENTS REPORTING REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 11131

CFR Citation: 45 CFR 60.7

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	12/24/98	63 FR 71255
Second NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Mark S. Pincus, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 8–103, Rockville, MD 20857
Phone: 301 443–2300

RIN: 0906–AA41

1090. OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 274e, sec 301, 1984; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138

CFR Citation: 42 CFR 121

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) proposes to amend the final rule governing the operation of the OPTN.

This notice of proposed rulemaking provides the legislative and regulatory history of the current rule, the factors that persuaded HHS of the advisability of amending the final rule governing the operation of the OPTN, and the anticipated consequences of this proposal. As required rapid changes in response to better understanding of the clinical scientific issues have become evident, HHS has determined that the current process for approving and enforcing policies must be amended.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Hui—Hsing Wong, Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857
Phone: 301 443–8104
Fax: 301 594–6095
Email: hwong@hrsa.gov

RIN: 0906–AA63

Department of Health and Human Services (HHS)
Indian Health Service (IHS)

Proposed Rule Stage

1091. SECTION 506—LIMITATION ON CHARGES FOR SERVICES FURNISHED BY MEDICARE PARTICIPATING INPATIENT HOSPITAL TO INDIANS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: MMA, sec 506; PL 108–173

CFR Citation: 42 CFR 135, subpart D; 42 CFR 489, subpart B

Legal Deadline: None

Abstract: This provision requires that as a condition of participation in the Medicare Program, providers accept payment at rates established by the Secretary in regulations as payment in full for services provided in an inpatient hospital to American Indians/Alaskan Natives (AI/AN) beneficiaries referred or authorized by the Indian Health Service, Tribes or Tribal organizations, or Urban Indian Organization (I/T/U).

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	
NPRM Comment Period End	02/00/06	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Betty Z. Gould, Regulations Officer, Department of Health and Human Services, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852
Phone: 301 443–1116
Email: bgould@hqe.ihs.gov

RIN: 0917–AA07

Department of Health and Human Services (HHS)
National Institutes of Health (NIH)

Proposed Rule Stage

1092. ● GRANTS FOR RESEARCH PROJECTS — 42 CFR PART 52–NPRM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 52

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA42

1093. ● NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216 42 USC 288–5a; 42 USC 287c–33 USC 288–6; 42 USC 288–1 42 USC 288–3 42 USC 288–5; 42 USC 288–5a 42 USC 288–6

CFR Citation: 42 CFR 68

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA43

1094. ● NATIONAL LIBRARY OF MEDICINE TRAINING GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216 42 USC 286b–3

CFR Citation: 42 CFR 64

Legal Deadline: None

Abstract: NIH proposes to amend the regulations governing National Library of Medicine training grants by revising the definition of Project Director 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 the project director to one single individual when that more accurately reflects the management needs of a research project.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852

HHS—NIH **Proposed Rule Stage**

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA44

1095. • MINORITY BIOMEDICAL RESEARCH SUPPORT PROGRAM

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 216 42 USC 241(a) (3)

CFR Citation: 42 CFR 52c

Legal Deadline: None

Abstract: NIH proposes to amend the regulations governing Minority Biomedical Research Support Program grants by revising the definition of Program Director to mean one or more individuals designated by the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the program, rather than limiting the role of the program director to one single individual when that more accurately reflects the management needs of a research program.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA45

1096. • NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 286b–3

CFR Citation: 42 CFR 65a

Legal Deadline: None

Abstract: NIH proposes to amend the regulations governing National Institute of Environmental Health Sciences Hazardous Substances Basic Research and Training grants by revising the definition of Program Director 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 the program director to one single individual when that more accurately reflects the management needs of a research project.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA46

Department of Health and Human Services (HHS) National Institutes of Health (NIH) — Final Rule Stage

1097. NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 285g–10

CFR Citation: 42 CFR 63a

Legal Deadline: None

Abstract: NIH proposes to amend the training grants regulations to implement the new authority under section 452G of the Public Health Service (PHS) Act. This action is necessitated by enactment of the Children's Health Act of 2000. Section 1002 of this Act adds a new section 452G to the PHS Act that authorizes the Director of the National Institute of Child Health and Human Development, in consultation with the Administrator of the Health Resources and Services Administration, to support activities to provide for an increase in the number and size of institutional training grants supporting pediatric training.

Timetable:

Action	Date	FR Cite
NPRM	01/28/05	70 FR 4080
Final Action	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA28

1098. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Other Significant

Legal Authority: 42 USC 287a–3a

CFR Citation: 42 CFR 9

Legal Deadline: NPRM, Statutory, June 18, 2001.

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

Timetable:

Action	Date	FR Cite
NPRM	01/11/05	70 FR 1843
Final Action	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

HHS—NIH

Final Rule Stage

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA31

Department of Health and Human Services (HHS)
National Institutes of Health (NIH)

Completed Actions

1099. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH (NIH)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68b

Completed:

Reason	Date	FR Cite
Withdrawn	10/20/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA10

1100. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68d

Completed:

Reason	Date	FR Cite
Withdrawn	08/05/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA18

1101. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68

Completed:

Reason	Date	FR Cite
Withdrawn	08/05/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA32

1102. NATIONAL INSTITUTES OF HEALTH EXTRAMURAL LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68g

Completed:

Reason	Date	FR Cite
Withdrawn	10/20/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA33

1103. NATIONAL INSTITUTES OF HEALTH PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68e

Completed:

Reason	Date	FR Cite
Withdrawn	10/20/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA34

1104. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR HEALTH DISPARITIES RESEARCH

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68f

Completed:

Reason	Date	FR Cite
Withdrawn	10/20/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA35

1105. NATIONAL INSTITUTES OF HEALTH CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68a

Completed:

Reason	Date	FR Cite
Withdrawn	10/20/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore

HHS—NIH **Completed Actions**

Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA36

1106. NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 68c

Completed:

Reason	Date	FR Cite
Withdrawn	10/20/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA41

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)

Prerule Stage

1107. HUMAN SUBJECTS PROTECTION REGULATIONS: ADDITIONAL PROTECTIONS FOR ADULT INDIVIDUALS WITH IMPAIRED DECISIONMAKING CAPACITY

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: Through this advance notice of proposed rulemaking (ANPRM), the Office for Human Research Protections (OHRP), Office of Public Health and Science, and the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) are seeking comment on whether it is necessary to develop additional safeguards to help protect adult individuals with impaired decisionmaking capacity who are potential subjects in research, and if so, suggestions for appropriate safeguards. This ANPRM stems from the recommendation of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission entitled ''Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity'' (December 1998), and from subsequent recommendations by the National Human Research Protections Advisory Committee. The goal of these efforts is to maximize the safety and welfare of adult subjects with impaired decisionmaking capacity who participate in research supported, conducted, or regulated by HHS.

Timetable:

Action	Date	FR Cite
ANPRM	06/00/06	
ANPRM Comment Period End	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Irene Stith–Coleman Ph.D, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071

RIN: 0940–AA11

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)

Final Rule Stage

1108. PUBLIC HEALTH SERVICE STANDARDS FOR THE PROTECTION OF RESEARCH MISCONDUCT WHISTLEBLOWERS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 289b

CFR Citation: 42 CFR 94

Legal Deadline: None

Abstract: To implement section 493(e) of the Public Health Service Act (added by section 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.

Timetable:

Action	Date	FR Cite
NPRM	11/28/00	65 FR 70830
NPRM Comment Period End	01/29/01	
Final Action	08/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Suite 750, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–8200

HHS—OPHS

Final Rule Stage

Fax: 301 443–5351

Related RIN: Related to 0940–AA04

RIN: 0940–AA01

1109. HUMAN SUBJECTS PROTECTION REGULATIONS: INSTITUTIONAL REVIEW BOARDS REGISTRATION REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	07/04/04	69 FR 40584
NPRM Comment Period End	10/04/04	
Final Action	03/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Irene Stith–Coleman Ph.D, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071

RIN: 0940–AA06

1110. FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS TECHNICAL AMENDMENT

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289; 42 USC 300v–1(b)

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This final rule amends the Department of Health and Human Services (HHS) regulations for the protection of human subjects by changing all references to the Office for Protection from Research Risks (OPRR) to the Office for Human Research Protections (OHRP) and revising the footnote at the end of 45 CFR 46.101(i) by deleting the references to research involving fetuses, pregnant women, or human in vitro fertilization and subpart B of 45 CFR part 46. This technical amendment is being made in conjunction with the other federal departments and agencies that have promulgated the Federal Policy for the Protection of Human Subjects.

Timetable:

Action	Date	FR Cite
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071

RIN: 0940–AA10

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)

Long-Term Actions

1111. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND ED. REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATORS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart E to the Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, and would require that institutions engaged in human subjects research covered by an assurance of compliance filed with the Office for Human Research Protections ensure that institutional officials, institutional review board (IRB) chairpersons, and human protection administrators receive appropriate training and education about the institution's assurance and that IRB chairpersons and members, IRB staff, investigators, and other personnel involved in the conduct or oversight of human subjects research receive appropriate training and education about relevant human subjects protection requirements. The proposed training and education requirements will help to ensure that responsible individuals at assured institutions understand and meet their regulatory responsibilities for human subjects protection.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

HHS—OPHS **Long-Term Actions**

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071

RIN: 0940–AA08

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)

Completed Actions

1112. PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Priority: Other Significant

CFR Citation: 42 CFR 93

Completed:

Reason	Date	FR Cite
Final Action	05/17/05	70 FR 28370

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Chris Pascal
Phone: 240 453–8200
Fax: 301 443–5351

Related RIN: Related to 0940–AA01

RIN: 0940–AA04

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Prerule Stage

1113. • INNOVATIONS IN FEE–FOR–SERVICE PAYMENT SYSTEMS TO IMPROVE QUALITY AND OUTCOMES (CMS–1298–ANPR)

Regulatory Plan: This entry is Seq. No. 50 in part II of this issue of the **Federal Register**.

RIN: 0938–AN91

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

1114. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P) (SECTION 610 REVIEW)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb

CFR Citation: 42 CFR 484

Legal Deadline: None

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 the Administration's 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.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Scott Cooper, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–05–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9465
Email: scott.cooper@cms.hhs.gov

Mercedes Benitez–McCray, 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
Email: mercedes.benitezmccra@cms.hhs.gov

RIN: 0938–AG81

1115. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIER (CMS–6017–P)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect State, local or tribal governments.

Legal Authority: 42 USC 1320d to 1320d–8

CFR Citation: 45 CFR 160; 45 CFR 162

Legal Deadline: Final, Statutory, February 21, 1998.

Abstract: This proposed rule would implement a standard identifier to identify health plans that process and pay certain electronic health care transactions. It would implement one of the requirements for administrative simplification that have a national scope beyond Medicare and Medicaid.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Helen Dietrick, 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: 410 786–7448

RIN: 0938–AH87

1116. APPEALS OF CARRIER DETERMINATIONS THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS–6003–P2)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b)

CFR Citation: 42 CFR 405.874

Legal Deadline: None

Abstract: This proposed rule would extend 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. The rule would also extend appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. This rule would incorporate provisions from section 936 of the Medicare Modernization Act.

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Second NPRM	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Michael Collett, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–6121
Email: michael.collett@cms.hhs.gov

RIN: 0938–AI49

1117. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS–1910–P2)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405; 42 CFR 491

Legal Deadline: None

Abstract: This rule proposes to amend the Medicare certification and payment requirements for rural health clinics (RHCs), as required by Section 4205 of the Balanced Budget Act of 1997. It proposes to change the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establish 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 as medically underserved; and limit nonphysician practitioner staffing requirements. This rule proposes to impose payment limits on provider-based RHCs and prohibit the use of RHC space, professional staff, equipment, and other RHC resources by another Medicare entity. The rule also proposes to require RHCs to establish a quality assessment and performance improvement program.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74792
Second NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: David Worgo, Health Insurance Specialist, Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory, Mailstop C4–15–18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5919
Email: david.worgo@cms.hhs.gov

RIN: 0938–AJ17

1118. USE OF RESTRAINTS AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS–2130–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: PL 106–554, (BIPA 2000 of the Children's Health Act)

CFR Citation: 42 CFR 101; 42 CFR 418; 42 CFR 482; 42 CFR 483; 42 CFR 485

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Carla McGregor, Health Insurance Specialist, Survey and

Certification Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–11–27, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–0663
Email: carla.mcgregor@cms.hhs.gov

RIN: 0938–AL26

1119. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (CMS–3887–P)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Joan Brooks, 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
Email: joan.brooks@cms.hhs.gov

Jacqueline Morgan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards and Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4282
Email: jmorgan@cms.hhs.gov

RIN: 0938–AL80

1120. MODIFICATIONS TO ELECTRONIC TRANSACTIONS AND CODE SETS (CMS–0009–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Sec 1171 to 1179 of the Social Security Act

CFR Citation: 42 CFR 162.1002; 42 CFR 162.1802

Legal Deadline: None

Abstract: This proposed rule would revise some of the electronic transactions and code set standards mandated by the Health Insurance Portability and Accountability Act of 1966.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Federalism: This action may have federalism implications as defined in EO 13132.

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, Mail Stop S2–24–18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0273
Email: gladys.wheeler@cms.hhs.gov

RIN: 0938–AM50

1121. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P)

Priority: Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1395i–3; 42 USC 1396r

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This proposed rule establishes requirements that hospice agencies and long term care (LTC) facilities must meet 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.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anita Panicker, 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: 410 786–5646
Fax: 410 786–8532
Email: anita.panicker@cms.hhs.gov

RIN: 0938–AM87

1122. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES AND RESIDUAL ISSUES (CMS–1270–P)

Regulatory Plan: This entry is Seq. No. 51 in part II of this issue of the **Federal Register**.

RIN: 0938–AN14

1123. REVISIONS TO HIPAA CODE SETS (CMS–0013–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: PL 104–191

CFR Citation: 45 CFR 162

Legal Deadline: None

Abstract: This proposed rule would revise some of the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003.

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Federalism: This action may have federalism implications as defined in EO 13132.

Energy Effects: Statement of Energy Effects planned as required by Executive Order 13211.

Agency Contact: Gladys Wheeler, 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 21244–1850
Phone: 410 786–0273
Email: gladys.wheeler@cms.hhs.gov

RIN: 0938–AN25

1124. PAYMENT FOR CLINICAL LABORATORY TESTS (CMS–1494–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1833(h)(8) of the MMA; Sec 416 of the MMA; PL 108–173

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, July 1, 2004.

Abstract: The Medicare Modernization Act of 2003 (MMA), requires codification of the payment basis for determining Medicare payments for new clinical laboratory tests under the clinical laboratory fee schedule. Also, section 416 of the MMA eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the two-year period beginning on July 1, 2004. Section 1833(h) of the Social Security Act mandates payment for outpatient clinical laboratory tests under a clinical laboratory fee schedule.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anita Greenberg, Health Insurance Specialist, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4601
Email: anita.greenberg@cms.hhs.gov

RIN: 0938–AN26

1125. TERMINATION OF NON–RANDOM PREPAYMENT MEDICAL REVIEW (CMS–6022–F)

Priority: Other Significant

Legal Authority: Sec 934 of the MMA

CFR Citation: Not Yet Determined

Legal Deadline: NPRM, Statutory, December 8, 2004.

Abstract: This rule implements the statutory requirements regarding the termination of non-random prepayment review under section 934 of the Medicare Modernization Act beginning December 8, 2004. This rule provides guidelines for terminating a provider of services or supplier from non-random payment review.

Timetable:

Action	Date	FR Cite
NPRM	10/07/05	70 FR 58649
Final Action	10/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Marie Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7861
Email: marie.casey2@cms.hhs.gov

RIN: 0938–AN31

1126. LIMITATION ON RECOUPMENT OF OVERPAYMENTS (CMS–6025–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: Section 935 of the MMA

CFR Citation: None

Legal Deadline: Final, Statutory, December 8, 2003.

Abstract: This proposed rule would implement one provision of section 935 of the Medicare Modernization Act which added a new subsection to section 1893 of the Social Security Act. It would prohibit recoupment where a provider or supplier has appealed an overpayment determination until the reconsideration-level appeal is decided.

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Nancy Braymer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4323
Email: nancy.braymer@cms.hhs.gov

RIN: 0938–AN42

1127. REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1864; Social Security Act, sec 1865; Social Security Act, sec 1875

CFR Citation: 42 CFR 488.1 to 488.9

Legal Deadline: None

Abstract: This proposed rule would respond to the recommendations in the GAO Report, ''CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals'' (GAO-04-850). With respect to the oversight and validation of hospital accreditation programs, a rate of disparity calculation is specified in Federal regulations at 42 CFR, 488.8. This rule proposes to consider additional alternative measures to assess the performance of the accreditation organizations.

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

Regulatory Flexibility Analysis Required: No

HHS—CMS **Proposed Rule Stage**

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Amber L. Wolfe, Health Insurance Specialist, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Survey and Certification Group, Mailstop S2–12–25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6773
Email: amber.wolfe@cms.hhs.gov

RIN: 0938–AN62

1128. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; EXCEPTIONS FOR CERTAIN ELECTRONIC PRESCRIBING AND ELECTRONIC HEALTH RECORDS ARRANGEMENTS (CMS–1303–F)

Priority: Other Significant

Legal Authority: 1827(b)(4)–(b)(5); 1860D–4(e)(6); 1860D–42(e)(8)(B)

CFR Citation: 42 CFR 411.357

Legal Deadline: Final, Statutory, January 1, 2006.

Abstract: This rule proposes an exception to the physician self-referral prohibition for certain nonmonetary remuneration related to electronic prescribing (section 1860D-4 of the Medicare Modernization Act).

Timetable:

Action	Date	FR Cite
NPRM	10/07/05	70 FR 59181
Final Action	10/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Linda Howard, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–13–08, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–5255
Email: linda.howard@cms.hhs.gov

RIN: 0938–AN69

1129. NATIONAL PLAN AND PROVIDER ENUMERATION SYSTEM (NPPES) DATA DISSEMINATION (CMS–6060–PN)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: HIPAA of 1996, secs 1171 to 1179 of the Social Security Act (42 USC 1329d to 1320d–8); NPI final rule (01/23/2004); NPS System of Records (07/28/1998)

CFR Citation: 45 CFR 163

Legal Deadline: None

Abstract: The National Provider Identifier final rule, published January 23, 2004, stated that CMS would publish a follow-up notice to describe the data dissemination processes and any applicable charges for data. This notice describes the data that would be available from the National Plan and Provider Enumeration System (NPPES), in compliance with the provisions of the Privacy Act, the Freedom of Information Act, the Electronic Freedom of Information Act (FOIA) Amendments of 1996, and other applicable regulations and authorities, and must be consistent with the National Provider System of Records Notice, published on July 28, 1998. The notice would describe the data dissemination strategy, processes, and any applicable charges for data.

Timetable:

Action	Date	FR Cite
Notice	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Helen Dietrick, 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: 410 786–7448
Email: helen.dietrick@cms.hhs.gov

RIN: 0938–AN71

1130. CHANGES TO THE DISCLOSURE OF INFORMATION REQUIREMENTS FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS–3156–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: sec 1154 to 1160 of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Maria L. Hammel, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Improvement Group, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1775
Email: maria.hammel@cms.hhs.gov

RIN: 0938–AN73

1131. HOME HEALTH PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2007 (CMS–1304–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1895

CFR Citation: 42 CFR 484

Legal Deadline: Final, None, January 1, 2007, effective date.

Abstract: The proposed rule would set forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies, effective on January 1, 2007.

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Randy Throndset, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–07–28, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0131
Email: rthrondset@ cms.hhs.gov

RIN: 0938–AN76

1132. FIRE SAFETY REQUIREMENTS FOR LONG–TERM CARE FACILITIES: SPRINKLER SYSTEMS (CMS–3191–P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: On July 16, 2004, GAO published a report on Federal fire safety standards and procedures in nursing facilities. The GAO Report recommended that CMS explore requiring sprinkler systems in all nursing facilities. This proposed rule would implement this regulation. We propose to require sprinkler systems in all long-term care facilities and solicit public comment regarding an appropriate and feasible phase-in period for this regulation.

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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
Email: danielle.shearer@cms.hhs.gov

RIN: 0938–AN79

1133. INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR 2006 (CMS–1306–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: PL 106–113, sec 124 BBRA

CFR Citation: 42 CFR 412.400, subpart N

Legal Deadline: None

Abstract: This rule would update the Inpatient Psychiatric Facility Prospective Payment System for 2006. This rule would update and revise the market basket and the use of new market area definitions.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local

Federalism: Undetermined

Agency Contact: Paul Olenick, Director, Division of Technical Payment Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4533
Email: paul.olenick@cms.hhs.gov

Janet Samen, Chronic Care Management and the Chronic Care Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9161
Email: janet.samen@cms.hhs.gov

RIN: 0938–AN82

1134. • PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS FY 2007: ANNUAL PAYMENT RATE UPDATES (CMS–1485–P)

Priority: Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: sec 123 PL 106–113; sec 307(b), PL 106–554

CFR Citation: 42 CFR 412

Legal Deadline: Final, Statutory, May 1, 2005, To be effective July 1, 2005.

Abstract: This rule proposes the payment rate update for the 2007 prospective payment system for Medicare long-term care hospitals. The new rates will be based on cost reports from the first LTC PPS rate year. (The proposed and final rules must be published by 5/1/06 to be effective 7/1/06.)

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judith Richter, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AO06

1135. • PAYMENTS FOR SERVICE PROVIDED WITHOUT CHARGE (CMS–2489–P)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would increase States' accountability for Federal Financial participation (FFP) provided for certain services furnished without charge to (but not limited to) the following groups: children residing in various foster care settings; juvenile offenders residing in detention, correctional, or shelter facilities; and others. The rule would clarify circumstances under which Federal financial participation (FFP) will or will not be made available to States on behalf of Medicaid beneficiaries in instances where the services are provided free of charge to all users in the community. The regulation would specify the criteria for determining when a service is free.

Timetable:

Action	Date	FR Cite
NPRM	08/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Ellen W. Blackwell, Disability & Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S2–26–12, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4498
Fax: 410 786–3262
Email: ellen.blackwell@cms.hhs.gov

RIN: 0938–AO07

1136. ● REVISIONS TO PAYMENT OF AMBULANCE SERVICES UNDER MEDICARE (CMS–1317–P)

Priority: Substantive, Nonsignificant

Legal Authority: Section 1834(1) of the Social Security Act (the Act).

CFR Citation: 42 CFR 414.605; 42 CFR 412.64; 42 CFR 410.40

Legal Deadline: None

Abstract: This rule would revise the fee schedule for payment of ambulance services specifically with respect to the definition of Specialty Care Transport (SCT) and the Metropolitan Statistical Area (MSA) geographic breakdown in relation to payment of ambulance services under Medicare. In addition, this proposed rule, discusses the conversion factor and the effect of low billers.

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anne Elizabeth Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–06–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4546
Email: anne.tayloe@cms.hhs.gov

RIN: 0938–AO11

1137. ● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2007 RATES (CMS–1488–P)

Regulatory Plan: This entry is Seq. No. 52 in part II of this issue of the **Federal Register**.

RIN: 0938–AO12

1138. ● REVISED PAYMENT SYSTEM FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS (ASCS) EFFECTIVE JANUARY 1, 2008 (CMS–1517–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: 42 CFR 416, Social Security Act 1832(2)(F) and 1833(i), as amended by section 626 of the Medicare Modernization Act

CFR Citation: 42 FR 416

Legal Deadline: Final, Statutory, November 1, 2007.

Abstract: This rule, proposes to revise the method by which Medicare sets payment rates for ASC facility services, and will propose new payment rates for ASC services in accordance with that methodology. (Effective January 1, 2008).

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: Federal

Federalism: Undetermined

Agency Contact: Joan H. Sanow, Deputy Director, Division of Outpatient Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C4–03–18, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–9739
Fax: 410 786–4490
Email: joan.sanow@cms.hhs.gov

RIN: 0938–AO13

1139. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2007 PAYMENT RATES (CMS–1506–P)

Priority: Substantive, Nonsignificant

Legal Authority: BBA; BBRA; BIPA; MMA

CFR Citation: 42 CFR 419 and 485

Legal Deadline: Final, None, November 1, 2006.

Abstract: This proposed 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 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. These changes would be applicable to services furnished on or after January 1, 2007.

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Rebecca Kane, Health Insurance Specialist, Center for Medicare Management, Hospital & Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division Group of Outpatient Care, Mailstop C5–01–28, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1589
Email: rebecca.kane@cms.hhs.gov

RIN: 0938–AO15

1140. ● PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2007 (CMS–1540–P)

Priority: Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Section 1866(l) of the Social Security Act; ; PL 105–33; PL 106–554; PL 106–113

CFR Citation: 42 CFR 412

Legal Deadline: Final, None, August 1, 2006.

Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2007. (Effective October 1, 2006).

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Robert Kuhl, Division Director of Center for Medicaid and Medicare, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–06–24, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4597
Email: bkuhl@cms.hhs.gov

RIN: 0938–AO16

1141. ● OUTPATIENT HOSPITAL SERVICES AND RURAL HEALTH CLINIC SERVICES AMENDMENT (CMS–2213–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Section 1102 of the Social Security Act

CFR Citation: 42 CFR 440.20

Legal Deadline: None

Abstract: This rule would amend 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.

Timetable:

Action	Date	FR Cite
NPRM	08/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Jeremy Silanskis, Health Insurance Specialist, Center for Medicaid Services, 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 21244–1850
Phone: 410 786–1592
Fax: 410 786–8533
Email: jeremy.silanskis@cms.hhs.gov

RIN: 0938–AO17

1142. ● FIVE YEAR REVIEW OF WORK RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE (CMS–1512–PN)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act sec 1848

CFR Citation: Not Yet Determined

Legal Deadline: Other, Statutory, April 2006, Proposed notice. Comments to be addressed as part of final physician fee. Final, Statutory, November 1, 2006.

Abstract: This notice discusses changes to work relative value units (RVUs) affecting payment for physician services. Comments on this notice will be addressed as part of the final physician fee schedule rule required to be published by 11/01/06.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Diane Milstead, Health Insurance Specialist, Center of Medicare and Medicaid, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3355
Email: diane.milstead@cms.hhs.gov

RIN: 0938–AO22

1143. ● REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2007 (CMS–1321–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 405; 42 CFR 410; 42 CFR 411; 42 CFR 413; 42 CFR 414; 42 CFR 426

Legal Deadline: Final, Statutory, November 1, 2006.

Abstract: This rule would make several changes affecting Medicare Part B payment. (The statute requires the final rule be published by 11/01/06.)

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Diane Milstead, Health Insurance Specialist, Center for Medicare and Medicaid Services, Department of Health and Human Services, Centers for Medicare &

HHS—CMS **Proposed Rule Stage**

Medicaid Services, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3355
Email: diane.milstead@cms.hhs.gov

RIN: 0938–AO24

1144. ● USE OF REPAYMENT PLANS (CMS–6032–P)

Priority: Other Significant

Legal Authority: Section 1893(i)(1) of the Social Security Act as amended by sec. 935(i)(1) of Medicare Modernization Act (MMA)

CFR Citation: 42 CFR 401.607, 42 CFR 401.601

Legal Deadline: Final, Statutory, December 9, 2003.

Abstract: This rule would implement a provision of section 935 of the MMA and adds a new subsection to section 1893 (42 U.S.C. 1395ddd) of the Social Security Act. The provision, ''Use of Repayment Plans,'' requires CMS to enter into a repayment plan with a provider or supplier when repaying a Medicare overpayment would be a hardship for the provider or supplier absent specific exceptions. The rule would establish criteria and procedures to apply this requirement to include the concepts of extreme hardship and the discretionary right to accelerate upon default.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Thomas A. Noplock, Health Insurance Specialist, Division of Medicare Overpayments, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Financial Services Group, Mailstop C3–15–01, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3378
Fax: 410 786–7030
Email: thomas.noplock@cms.hhs.gov

RIN: 0938–AO27

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

1145. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (CMS–6002–F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 424

Legal Deadline: Final, Statutory, April 25, 2006, MMA 902.

Abstract: This final rule requires that all providers and suppliers (other than physicians who have elected to ''opt-out'' of the Medicare program) complete an enrollment form and submit specific information to CMS. This rule will requires that all providers and suppliers periodically update and certify the accuracy of their enrollment information to receive and maintain billing privileges in the Medicare program. In addition, this final rule will implement provisions in the Medicare statute that require CMS to ensure that all Medicare providers and suppliers are qualified to provide the appropriate health care services. These statutory provisions include requirements meant to protect beneficiaries and the Medicare Trust Funds by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or billing the Medicare program or its beneficiaries.

Timetable:

Action	Date	FR Cite
NPRM	04/25/03	68 FR 22064
Final Action	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Michael Collett, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, Division of Provider/Supplier Enrollment, N3–22–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6121

RIN: 0938–AH73

1146. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–IFC) (SECTION 610 REVIEW)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This interim final rule with comment period requires hospitals that transfuse blood and blood products 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.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Interim Final Rule With Comment	03/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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
Email: mary.collins@cms.hhs.gov

RIN: 0938–AJ29

1147. MEDICARE HOSPICE CARE AMENDMENTS (CMS–1022–F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 105–33, sec 1961(dd); PL 105–33, sec 1814(i); PL 105–33, sec 4441 to 4444; PL 105–33, sec 4448; PL 106–113, sec 131; PL 106–554, sec 321; PL 106–554, sec 322; PL 105–33, sec 4449

CFR Citation: 42 CFR 418

Legal Deadline: Final, Statutory, November 22, 2005, MMA 902.

Abstract: This final rule revises certain regulations governing coverage and payments for hospice care under the Medicare program as required by the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	11/22/02	67 FR 70363
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Linda Smith, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Chronic Care Policy Group, Mailstop C5–02–24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5650

Related RIN: Previously reported as 0938–AH73

RIN: 0938–AJ36

1148. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS–2065–F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1396d

CFR Citation: 42 CFR 441; 42 CFR 442; 42 CFR 483

Legal Deadline: None

Abstract: This 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.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/22/01	66 FR 7148
60–Day Delay of Effective Date To 05/22/2001	03/21/01	66 FR 15800
Interim Final Rule Comment Period End	03/23/01	
Interim Final Rule Effective	03/23/01	
Interim Final Rule Amendment with Clarification	05/22/01	66 FR 28110
Interim Final Rule Comment Period End	07/23/01	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Mary Clarkson, Health Insurance Specialist, Disabled & Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Benefits & Coverage Policy, Mailstop S2–12–11, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–5918
Email: mary.clarkson@cms.hhs.gov

RIN: 0938–AJ96

1149. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–IFR) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 53 in part II of this issue of the **Federal Register**.

RIN: 0938–AK81

1150. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

Priority: Other Significant

Legal Authority: 42 USC 1395(m)(3)

CFR Citation: 42 CFR 414.222(a)(1)

Legal Deadline: Final, Statutory, August 22, 2006, MMA, section 902.

Abstract: This final rule clarifies that respiratory assist devices with bi-level capability and a back-up rate must be classified as capped rental durable medical equipment (DME) in accordance with section 1834(a)(3) of the Social Security Act (42 U.S.C. 1395(m)(3)).

Timetable:

Action	Date	FR Cite
NPRM	08/22/03	68 FR 50735
Final Action	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joel Kaiser, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4499
Email: joel.kaiser@cms.hhs.gov

Related RIN: Related to 0938–AL27

RIN: 0938–AN02

1151. ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–F)

Priority: Other Significant

Legal Authority: Section 1923(i) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule implements section 1001(d) of the Medicare Modernization Act which requires States to report additional information about their disproportionate share hospital (DSH) programs to their annual report. This section also requires States to independently audit and submit these certified audits annually to the Secretary (effective December 8, 2003).

Timetable:

Action	Date	FR Cite
NPRM	08/26/05	70 FR 50262
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: James Frizzera, Director, National Institutional Payment Policy Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–3263
Email: james.frizzera@cms.hhs.gov

RIN: 0938–AN09

1152. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–IFC)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: Final, Statutory, July 1, 2005.

Abstract: This final rule updates the list of Medicare-covered ASC procedures.

Timetable:

Action	Date	FR Cite
NPRM	11/26/04	69 FR 69178
Interim Final Rule	05/04/05	70 FR 23690
Final Action	01/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Dana Burley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Hospital and Ambulatory Policy Group, Mailstop C4–05–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4547
Email: dana.burley@cms.hhs.gov

RIN: 0938–AN23

1153. MEDICARE SECONDARY PAYER AMENDMENTS (CMS–6272–IFC)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: Sec 301 of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 411; 42 CFR 489

Legal Deadline: Final, Statutory, December 8, 2003.

Abstract: Section 301 of the Medicare Modernization Act clarifies when CMS may make a conditional Medicare payment when other insurance cannot reasonably be expected to make a prompt payment (effective December 8, 2003).

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment	02/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Agency Contact: Jeremy Silanskis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid Services Office, Mail Stop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1592
Fax: 410 786–8533
Email: jeremy.silanskis@cms.hhs.gov

RIN: 0938–AN27

1154. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2006 (CMS–1301–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 1895 of the Social Security Act

CFR Citation: 42 CFR 484

Legal Deadline: Final, Statutory, November 1, 2005.

Abstract: This rule updates the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies.

Timetable:

Action	Date	FR Cite
NPRM	07/14/05	70 FR 40788
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Randy Throndset, Health Insurance Specialist, Division of Community Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C5–09–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0131
Email: randy.throndset@cms.hhs.gov

RIN: 0938–AN44

1155. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2006 PAYMENT RATES (CMS–1501–FC)

Regulatory Plan: This entry is Seq. No. 54 in part II of this issue of the **Federal Register**.

RIN: 0938–AN46

1156. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)

Priority: Other Significant

Legal Authority: SSA, sec 1834

CFR Citation: 42 CFR 412; 42 CFR 413; 42 CFR 1902

Legal Deadline: Final, Statutory, February 10, 2006, MMA sec. 902.

Abstract: This final rule will achieve a consistent bad debt reimbursement policy for all providers currently eligible to receive payments from Medicare for bad debt. It implements a court settlement agreement and removes the cap on End Stage Renal Disease (ESRD) bad debt reimbursement, which limits payment of allowable bad debts to the facility's unrecovered costs.

Timetable:

Action	Date	FR Cite
NPRM	02/10/03	68 FR 6682
Final Action	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Katie Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center of Medicare Management, Mailstop C5–03–03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7278
Email: katie.walker@cms.hhs.gov

Related RIN: Related to 0938–AK02

RIN: 0938–AN75

1157. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–F)

Priority: Other Significant

Legal Authority: Improper Payment Information Act of 2002

CFR Citation: 42 CFR 431; 42 CFR 457

Legal Deadline: Final, Statutory, October 1, 2005.

Abstract: This rule requires States to estimate improper payments in the Medicaid program and the State Children's Health Insurance Program. The State level estimates will be used to produce estimates of improper payments for both Medicaid and SCHIP at the national level. These national level estimates will enable us to comply with the Improper Payments Information Act of 2002. The intended effect of this regulation is for States to produce estimates of improper payments for their Medicaid and SCHIP programs and identify existing and emerging vulnerabilities that can be effectively targeted for corrective actions by the States.

Timetable:

Action	Date	FR Cite
NPRM	08/27/04	69 FR 52620
Interim Final Rule	10/05/05	70 FR 58260
Final Action	10/00/08	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Chrstine Jones, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mail stop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3722
Email: christine.jones@cms.hhs.gov

Related RIN: Related to 0938–AM86

RIN: 0938–AN77

1158. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006 (CMS–1502–FC)

Regulatory Plan: This entry is Seq. No. 55 in part II of this issue of the **Federal Register**.

RIN: 0938–AN84

1159. ● FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES — UPDATE FOR CY 2006 (CMS–1294–N)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Sec 1834(1) of the Social Security Act

CFR Citation: 42 CFR 410

Legal Deadline: None

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(1) of the Social Security Act. (effective January 1, 2006)

Timetable:

Action	Date	FR Cite
Notice	11/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Anne Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4546
Email: anne.tayloe@cms.hhs.gov

RIN: 0938–AN99

1160. ● STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS (CMS–2210–F)

Priority: Other Significant

Legal Authority: Section 4732 of the Balanced Budget Act of 1997 (PL 105–33)

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: Section 4732 of the Balanced Budget Act amended the Social Security Act to provide for certain low income Medicare Beneficiaries (also known as Qualified Individuals, or QIs) for whom Medicaid payment can be made for Medicare Part B premiums. Section 1933(c) of the Act limits the total amount of Federal funds available for payment of Part B premiums each fiscal year and specifies the formula to be used to determine an allotment for each State from this total amount. States must limit the number of QIs so that the amount of assistance provided during the fiscal year is approximately equal to the allotment for that year. For FY 2005 some States have experienced a deficit in their allotments which has necessitated denial of benefits to applicants after a certain date, while other States project that they will not utilize their full allotments. To fully utilize the authorized funding and to prevent denial of benefits to eligible applicants, the FY 2005 funds will be reallocated based on current data available from States. This interim final rule with comment period announces the reallocation of funds available to States for FY 2005 and describes the methodology used to determine each State's allotment.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/26/05	70 FR 50214
Comment Period End	10/25/05	
Final Action	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss, Technical Director Finance Systems & Budget Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare State Operations, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

RIN: 0938–AO04

1161. ● FEDERAL GOVERNMENT'S ADOPTION OF TWENTY (20) HEALTHCARE MESSAGING AND VOCABULARY STANDARDS RECOMMENDED BY THE CONSOLIDATED HEALTH INFORMATICS INITIATIVE (CMS–0015–N)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: This notice identifies the 20 messaging and vocabulary standards adopted for use by the Federal government health information technology systems. The first set of 5 standards were adopted on 3/21/03, and the second set of 15 standards were adopted on 5/6/04, which completed the initial portfolio of the Consolidated Health Informatics initiative.

Timetable:

Action	Date	FR Cite
Notice	12/00/05	

HHS—CMS **Final Rule Stage**

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Alicia Bradford, Office of HIPAA Standards, Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C5–25–04, Baltimore, MD 21244–1850
Phone: 410 786–4160

RIN: 0938–AO05

1162. ● FIRE SAFETY REQUIREMENTS FOR RELIGIOUS NON–MEDICAL HEALTH CARE INSTITUTIONS: CORRECTION TO ADD WRITTEN FIRE CONTROL PLANS & MAINTENANCE OF DOCUMENTATION (CMS–3183–IFC)

Priority: Other Significant

Legal Authority: 42 USC.1395hh; 42 USC 1302

CFR Citation: 42 CFR 403

Legal Deadline: None

Abstract: On January 10, 2003, CMS issued a final rule amending the fire safety standards for religious non-medical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long-term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals. This final rule adopted, with certain exceptions, the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Assoc. (NFPA). On August 11, 2004, the final Inpatient PPS rule was published. The LSC provisions in the August rule were meant to clarify the effective date of the roller latch prohibition. The clarifying regulatory language was accidentally deleted. These requirements will be restored by this regulation.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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
Email: janice.graham@cms.hhs.gov

RIN: 0938–AO14

1163. ● PART A PREMIUMS FOR CALENDAR YEAR 2007 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8028–N)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395i–2(d)(2); 42 USC 1395i–2a(d)(2); Social Security Act, Section 1818(d)(2); Social Security Act, section 1818 A(d)(2)

CFR Citation: None

Legal Deadline: Final, Statutory, September 30, 2006.

Abstract: This notice announces the hospital insurance premium for Calendar Year 2007 under Medicare's Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

Action	Date	FR Cite
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Division 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 21244–1850
Phone: 410 786–6390
Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO18

1164. ● INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2007 (CMS–8029–N)

Priority: Other Significant. Major under 5 USC 801.

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

CFR Citation: None

Legal Deadline: Final, Statutory, September 15, 2006.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in Calendar Year 2007 under Medicare's Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

Timetable:

Action	Date	FR Cite
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–6390
Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO19

1165. ● FISCAL YEAR 2007 SCHIP ALLOTMENTS (CMS–2251–N)

Priority: Other Significant

Legal Authority: Title XXI of the Social Security Act, sec 2104

CFR Citation: 42 CFR 457

Legal Deadline: Final, Statutory, September 30, 2006.

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 2007.

Timetable:

Action	Date	FR Cite
Final Notice	06/00/06	

HHS—CMS **Final Rule Stage**

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

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 21244–1850
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

RIN: 0938–AO21

1166. • PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2007 (CMS–8030–N)

Priority: Other Significant

Legal Authority: 42 USC 1395r; Social Security Act, section 1839; MMA, section 629; MMA, section 811

CFR Citation: None

Legal Deadline: Final, Statutory, September 30, 2006.

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 2007. It also announces the monthly Part B premium to be paid by all enrollees, and the Part B deductible, during 2007.

Timetable:

Action	Date	FR Cite
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Suzanne Codespote, Division Director of Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7737
Email: suzanne.codespote@cms.hhs.gov

RIN: 0938–AO23

1167. • PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2007 (CMS–1530–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1888(e)

CFR Citation: 42 CFR 424

Legal Deadline: Other, Statutory, July 30, 2005, Notice must be published before August 1, 2006.

Abstract: This notice updates the payment rates used under the SNF PPS beginning 10/1/06.

Timetable:

Action	Date	FR Cite
Final Action	07/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Bill Ullman, Health Insurance Specialist, Division of Institutional Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Chronic Care Policy Group, Mailstop C5–07–08, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–5667
Email: bill.ullman@cms.hhs.gov

RIN: 0938–AO25

1168. • HOSPICE WAGE INDEX FOR FY 2007 (CMS–1535–N)

Priority: Other Significant

Legal Authority: 1824 (i)(2)(D) of the Act; 1814 (i)(1)(A); 1814 (i)(C)(ii)

CFR Citation: 42 CFR 418.306 (c)

Legal Deadline: Final, Statutory, September 1, 2006.

Abstract: This notice announces the annual update to the hospice wage index for FY 2007. 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 8/8/97.

Timetable:

Action	Date	FR Cite
Final Action	08/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Terri Deutsch, Health Insurance Specialist, Division of Community Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mailstop C5–08–18, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–9462
Email: terri.deutsch@cms.hhs.gov

RIN: 0938–AO26

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

1169. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–F) (SECTION 610 REVIEW)

Priority: Other Significant

Legal Authority: 42 USC 1395rr et al

CFR Citation: 42 CFR 400; 42 CFR 405; 42 CFR 410; 42 CFR 412 to 414; 42 CFR 488; 42 CRR 494

Legal Deadline: Final, Statutory, February 4, 2008, MMA sec. 902.

Abstract: This final rule revises the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	02/04/05	70 FR 6184
Final Action	02/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Teresa Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7215
Email: mary.casey@cms.hhs.gov

Robert Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–04–25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6797
Email: robert.miller@cms.hhs.gov

Rebecca Donnay, 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: 410 786–1428
Email: rebecca.donnay@hhs.cms

RIN: 0938–AG82

1170. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND RE–APPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 USC 405; 42 USC 482; 42 USC 488

Legal Deadline: Final, Statutory, February 4, 2008, MMA sec. 902.

Abstract: This rule establishes conditions of participation for Medicare-covered transplant centers.

Timetable:

Action	Date	FR Cite
NPRM	02/04/05	70 FR 6140
Final Action	02/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Eva Fung, 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: 410 786–7539
Email: eva.fung@cms.hhs.gov

RIN: 0938–AH17

1171. HOSPICE CARE—CONDITIONS OF PARTICIPATION (CMS–3844–F) (SECTION 610 REVIEW)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 418

Legal Deadline: Final, Statutory, May 27, 2008, MMA sec. 902.

Abstract: This final rule is a regulatory reform initiative that would revise existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The proposed 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, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

Timetable:

Action	Date	FR Cite
NPRM	05/27/05	70 FR 30840
Final Action	05/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

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
Email: mary .rossicoajou@cms.hhs.gov

RIN: 0938–AH27

1172. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (CMS–3006–F)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect State, local or tribal governments and the private sector.

Legal Authority: 42 USC 1302; 42 USC 1395(hh)

CFR Citation: 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 202.

Abstract: This final rule requires home health agencies to electronically report OASIS data as a condition of participation in the Medicare program.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/25/99	64 FR 3748
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Local, State, Tribal

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Rebecca Donnay, 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: 410 786–1428
Email: rebecca.donnay@cms.hhs.gov

RIN: 0938–AJ10

1173. STANDARDS FOR ELECTRONIC HEALTH CARE CLAIM ATTACHMENTS (CMS–0050–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: This action may affect State, local or tribal governments.

Legal Authority: 42 USC 1320d–2(a)(2)(B)

CFR Citation: 45 CFR 162

Legal Deadline: Final, Statutory, February 21, 1999.

Abstract: This rule finalizes an electronic standard for claims

attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It will be used to transmit clinical data, in addition to the data contained in the claims standard, to help establish medical necessity for coverage and payment.

Timetable:

Action	Date	FR Cite
NPRM	09/23/05	70 FR 55989
Final Action	09/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal, Local, State, Tribal

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Lorraine Doo, Health Insurance Specialist, Office of E–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S–25–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6597
Email: lorraine.doo@cms.hhs.gov

RIN: 0938–AK62

1174. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS (CMS–1810–F)

Priority: Other Significant

Legal Authority: 42 USC 1877

CFR Citation: 42 CFR 411; 42 CFR 424

Legal Deadline: Final, Statutory, March 26, 2007, MMA sec. 902.

Abstract: This final rule incorporates into regulation certain statutory provisions that preclude payment for services under Medicare if a physician makes a referral to a facility in which he or she has a financial interest. It addresses comments from the January 9, 1998 proposed rule concerning the ownership, investment, and compensation exceptions. It also addresses comments from the January 4, 2001 final rule with comment period.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/26/04	69 FR 16054
Interim Final Rule Comment Period End	06/24/04	
Correction Notice	04/06/04	69 FR 17933
Second Correction Notice	09/24/04	69 FR 57226
Final Action	03/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Linda P. Howard, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5255
Email: linda.howard@cms.hhs.gov

RIN: 0938–AK67

1175. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–F)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1878 of the Social Security Act

CFR Citation: 42 CFR 405

Legal Deadline: Final, Statutory, June 25, 2007, MMA sec. 902.

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

Timetable:

Action	Date	FR Cite
NPRM	06/25/04	69 FR 35716
NPRM Comment Period End	08/24/04	
Final Action	06/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Morton Marcus, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4477

RIN: 0938–AL54

1176. HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS–2158–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg; PL 104–191

CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	12/30/04	69 FR 78800
Final	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal, Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Mailstop S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: david.mlawsky@cms.hhs.gov

RIN: 0938–AL88

1177. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS–0008–F)

Priority: Other Significant

Legal Authority: PL 107–105

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This final rule implements the requirements for electronic submission of Medicare claims, submitted on or after October 16, 2003. In addition, this rule also implements the conditions upon which a waiver could be granted for these requirements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/15/03	68 FR 48805
Interim Final Rule Comment Period End	10/16/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Stewart Streimer, Director, Provider Billing Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–10–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9318
Email: stewart.streimer@cms.hhs.gov

RIN: 0938–AM22

1178. REQUIREMENTS FOR LONG–TERM CARE FACILITIES; NURSING SERVICES; POSTING OF NURSE STAFFING INFORMATION (CMS–3121–F)

Priority: Other Significant

Legal Authority: Sec 1819(b) of the Social Security Act; 42 USC 1395i–3(b)

CFR Citation: 42 CFR 483

Legal Deadline: Final, Statutory, February 27, 2007, MMA sec. 902.

Abstract: This final rule implements section 941 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and requires nursing homes to post daily, for each shift, the number of registered nurses, licensed practical nurses, licensed vocational nurses, and certified nurse aides who are directly responsible for resident care.

Timetable:

Action	Date	FR Cite
NPRM	02/27/04	69 FR 9282
NPRM Comment Period End	04/27/04	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5646
Fax: 410 786–8532
Email: anita.panicker@cms.hhs.gov

RIN: 0938–AM55

1179. REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 401 and 405

Legal Deadline: Final, Statutory, June 30, 2008, MMA sec. 902.

Abstract: This final rule will revise 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).

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/08/05	70 FR 11419
Interim Final Rule	06/30/05	70 FR 37700
Final Action	06/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Arrah Tabe–Bedward, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S1–05–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–7129
Email: arrah.tabe-bedward@cms.hhs.gov

Related RIN: Related to 0938–AK69

RIN: 0938–AM73

1180. CONDITIONS FOR COVERAGE OF POWER MOBILITY DEVICES, INCLUDING POWERED WHEELCHAIRS AND POWER–OPERATED VEHICLES SCOOTER (CMS–3017–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 1102 of the Social Security Act; Sec 1871 of the Social Security Act; 42 USC 1302 ; 42 USC 1359 hh

CFR Citation: 42 CFR 410.38

Legal Deadline: Final, Statutory, August 26, 2008, MMA sec. 902.

Abstract: This rule will make the requirements to purchase power operated vehicles, functioning as wheelchairs, less stringent. It expands who can order a Powered Operated Vehicle. It also requires a face-to-face examination of the beneficiary before ordering a device.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/26/05	70 FR 50939
Final Rule	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Karen Daily, Health Insurance Specialist Coverage & Analysis Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare and Medicaid Services, Mailstop C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0189
Email: karen.daily@cms.hhs.gov

RIN: 0938–AM74

1181. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS; SECURING MEDICATIONS; AND POST–ANESTHESIA EVALUATIONS (CMS–3122–F)

Priority: Other Significant

Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482

Legal Deadline: Final, Statutory, March 25, 2008, MMA sec. 902.

Abstract: This rule will reduce the burden on hospitals and allow hospitals to conform to current standards of practice. Hospitals would meet these final requirements to participate in Medicare and Medicaid. They must establish and maintain policies and procedures that would ensure their hospital would meet these requirements by using standard practices for history and physical examinations, securing medications, authenticating verbal orders, and completing post-anesthesia evaluations.

Timetable:

Action	Date	FR Cite
NPRM	03/25/05	70 FR 15266
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: Decreases burden for hospitals and clinicians.

Agency Contact: Patricia Chmielewski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards and Quality Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6899
Email: patricia.chmielewski@cms.hhs.gov

RIN: 0938–AM88

1182. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–F)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 402

Legal Deadline: Final, Statutory, August 23, 2007, MMA sec. 902.

Abstract: This final rule proposes revisions to the CMS civil money penalty authorities. These proposed revisions are intended to add the specific exclusion sanction authorities as established in the procedures for imposing civil money penalties, assessments, and exclusions for certain violations of the Medicare and Medicaid programs.

Timetable:

Action	Date	FR Cite
NPRM	07/23/04	69 FR 43956
Final Action	07/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joel Cohen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, C3–04–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3349

RIN: 0938–AM98

1183. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES (CMS–6024–P)

Priority: Other Significant

Legal Authority: Sec 938 of the Medicare Modernization Act of 2003

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, June 8, 2005.

Abstract: Section 938 of the Medicare Modernization Act requires that physicians and beneficiaries be able to receive a prior determination regarding coverage of certain items and physicians' services (effective June 8, 2005).

Timetable:

Action	Date	FR Cite
NPRM	08/30/05	70 FR 51321
Final Action	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Misty D. Whitaker, Health Insurance Specialist, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Program Integrity Group, Office of Financial Management, Mail Stop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3087
Email: misty.whitaker@cms.hhs.gov

RIN: 0938–AN10

1184. NONDISCRIMINATION IN HEALTH COVERAGE AND WELLNESS PLANS IN THE GROUP MARKET (CMS–4081–F)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 300gg

CFR Citation: 45 CFR 146.121

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This final rule governs the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996. It also addresses comments we received on the Bonafide Wellness Plan proposed rule (CMS-2078-P).

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/17/97	
Interim Final Rule Effective	07/17/97	
Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Effective	03/09/01	
Interim Final Rule Comment Period End	04/09/01	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: dmlawsky@cms.hhs.gov

RIN: 0938–AN29

1185. HOSPITAL CONDITIONS OF PARTICIPATION: PATIENTS' RIGHTS (CMS–3018–F)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This final rule sets forth standards for the use of restraints and seclusion in Medicare- and Medicaid-participating hospitals as part of the Patients' Rights Condition of Participation (CoP) and finalizes other patients' rights afforded by that CoP. It finalizes six standards that ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to: notification of his or her rights; the exercise of his or her rights in regard to his or her care; privacy and safety; confidentiality of patient records; freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and freedom from seclusion and restraint for behavior management unless clinically necessary.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/02/99	64 FR 36069
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Janice Graham, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–05–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–8020
Email: janice.graham@cms.hhs.gov

RIN: 0938–AN30

1186. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–4091–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg–22; 42 USC 300gg–31

CFR Citation: 45 CFR 150.101 to 150.465

Legal Deadline: None

Abstract: This rule finalizes, without any substantive changes, an interim final regulation (HCFA-2019-IFC) that sets forth the process by which CMS enforces the HIPAA title I requirements with regard to State and local governmental group health plans. It also finalizes the process by which CMS assumes direct enforcement responsibility in a State with regard to group and individual market health insurance issues.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/20/99	64 FR 1999
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Mailstop S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: david.mlawsky@cms.hhs.gov

RIN: 0938–AN35

1187. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES; ALCOHOL–BASED HAND SANITIZER AMENDMENT (CMS–3145–F)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 403; 42 CFR 416; 42 CFR 418; 42 CFR 460; 42 CFR 482; 42 CFR 483; 42 CFR 485

Legal Deadline: Final, Statutory, March 25, 2008, MMA sec. 902.

Abstract: This final rule amends the fire safety standard for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long-term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals that participate in Medicare and Medicaid. The rule adopts a change made to the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). We adopted the 2000 edition of the LSC in January 2003. The LSC change will allow facilities to place alcohol-based hand sanitizer dispensers in exit corridors under certain conditions. These sanitizers have proven to be effective in increasing hand hygiene and have the potential to improve infection control practice. Adopting the LSC change will increase a provider's flexibility in meeting infection control goals while minimizing potential fire safety concerns. Additionally, this rule includes a requirement for placement of battery operated smoke alarms in resident rooms in non-sprinkled SNFs.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comments	03/25/05	70 FR 15229
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Providers requesting publication of this regulation.

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
Email: danielle.shearer@cms.hhs.gov

RIN: 0938–AN36

1188. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6019–F)

Priority: Other Significant

Legal Authority: PL 108–173, sec 949 of MMA

CFR Citation: 42 CFR 402.400

Legal Deadline: Final, Statutory, December 8, 2003.

Abstract: Section 949 of the Medicare Modernization Act changed the designation of authority to request waiver of a program exclusion under the Social Security Act from the State to the Administrator of a Federal health

care program. This rule proposes to outline a process for health care providers to follow if they wish CMS to request a waiver of exclusion on their behalf (effective December 8, 2003).

Timetable:

Action	Date	FR Cite
NPRM	08/04/05	70 FR 44879
Final Action	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Cohen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3349
Email: jcohen@cms.hhs.gov

Related RIN: Merged with 0938–AM98

RIN: 0938–AN48

1189. ELECTRONIC PRESCRIBING STANDARDS (CMS–0011–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395

CFR Citation: None

Legal Deadline: Final, Statutory, September 1, 2005, Required e–prescribing before outset of January 1, 2006, Medicare part D drug benefit.

Abstract: This final rule requires Medicare part D plans and Medicare Advantage Plans to support electronic transmission of basic prescription data to, and from, doctors and pharmacies, and to adopt a number of the initial standards required for electronic prescribing by section 1860(d) of the Medicare Modernization Act.

Timetable:

Action	Date	FR Cite
NPRM	02/04/05	70 FR 6255
Final Action	02/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal, Local, State, Tribal

Federalism: This action may have federalism implications as defined in EO 13132.

Agency Contact: Gladys Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0273
Email: gwheeler@cms.hhs.gov

RIN: 0938–AN49

1190. MEDICARE PART B COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: MMA of 2003, sec 303(d)

CFR Citation: 42 CFR 414

Legal Deadline: Final, Statutory, January 1, 2006, MMA of 2003, section 303(d) or section 1847(B)(a)(1) of the Social Security Act.

Abstract: Section 303(d) of the Medicare Modernization Act requires the implementation of a competitive bidding program for Medicare part B drugs not paid on a cost or prospective payment system basis. Beginning January 1, 2006, physicians will be given a choice between purchasing these drugs and being paid by Medicare under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. If the physician elects to obtain drugs from a competitive vendor, the vendor will bill Medicare for the drug.

Timetable:

Action	Date	FR Cite
NPRM	03/04/05	70 FR 10745
Interim Final Rule	07/06/05	70 FR 39022
Final Action	07/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Edmund E. Kasaitis, Health Insurance Specialist, Hospital & Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0477
Email: edmund.kasaitis@cms.hhs.gov

RIN: 0938–AN58

1191. GROUP MARKET HEALTH INSURANCE REFORM: GUARANTEED AVAILABILITY, GUARANTEED RENEWABILITY, DISCLOSURES TO SMALL EMPLOYERS (CMS–4102–F)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 300gg–92

CFR Citation: 45 CFR 146.150; 45 CFR 146.152; 45 CFR 146.160

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This regulation finalizes the interim final regulation (BPD-890-IFC) guaranteeing the availability of health insurance coverage to small employers, and guaranteeing the renewability of health insurance coverage to small and large employers.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky, Health Insurance Specialist, Center for Beneficiary Choices, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Plan Policy Group, Mailstop S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 877 267–2323
Email: david.mlawsky@cms.hhs.gov

Related RIN: Related to 0938–AI08

RIN: 0938–AN60

1192. INDIVIDUAL MARKET HEALTH INSURANCE REFORM: PORTABILITY FROM GROUP TO INDIVIDUAL COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIVIDUAL MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (CMS–4103–F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 300gg–92

CFR Citation: 42 CFR 148.11; 42 CFR 148.102; 42 CFR 148.103; 42 CFR 148.122; 42 CFR 148.1

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This regulation finalizes the interim final rule (BPD-890-IFC) that

guarantees availability of health coverage to certain individuals, guarantees renewability of coverage in the individual market, and sets standards for State alternative mechanisms for guaranteeing coverage to certain individuals.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Mailstop S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 877 267–2323
Email: david.mlawsky@cms.hhs.gov

Related RIN: Related to 0938–AI08

RIN: 0938–AN61

1193. MEDICARE INTEGRITY PROGRAM, FISCAL INTERMEDIARY AND CARRIER FUNCTIONS, AND CONFLICT OF INTEREST REQUIREMENTS (CMS–6030–F)

Priority: Other Significant

Legal Authority: Sec 902 of the MMA

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, June 17, 2008, MMA sec. 902.

Abstract: This rule finalizes certain sections of the Medicare regulations concerning fiscal intermediaries and carriers and brings them into conformity with the Medicare statute. The rule would distinguish between those functions that the statute requires to be included in agreements with fiscal intermediaries and those that may be included in the agreements. It would also provide that some or all of the functions may be included in carrier contracts. Currently all these functions are mandatory for carrier contracts.

Timetable:

Action	Date	FR Cite
NPRM	06/17/05	70 FR 35204
Final Action	06/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Lauren Haley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare and Medicaid Services, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–1730
Email: lauren.haley@cms.hhs.gov

Related RIN: Related to 0938–AI09

RIN: 0938–AN72

1194. APPLICATION OF INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES (OTHER THAN PHYSICIAN SERVICES) (CMS–1908–F)

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: BBA; BBRA

CFR Citation: 42 CFR 405

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This rule finalizes the December 13, 2002, interim final rule and sets forth the process for establishing realistic and equitable payment amounts for all Medicare part B items and services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. The rule describes the factors CMS (or its carriers) will consider, and the procedures that will be followed in establishing realistic and equitable payment amounts. This rule implements section 4316 of the BBA, and section 223 of the BBRA that required CMS to publish this subsequent final rule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/13/02	67 FR 76684
Interim Final Rule Comment Period End	02/11/03	
Final Rule	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bill Long, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5655
Email: bill.long@cms.hhs.gov

RIN: 0938–AN81

1195. PROGRAM FOR ALL–INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS–1201–F)

Priority: Other Significant

Legal Authority: PL 108–173, sec 902 of MMA; BIPA, sec 903

CFR Citation: 42 CFR 460

Legal Deadline: Final, Statutory, December 8, 2006, MMA sec. 902.

Abstract: This rule finalizes two interim final rules with comment periods. The November 24, 1999, rule established requirements for Programs of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs and the October 1, 2002, rule that implemented section 903 of BIPA. These are pre-paid, capitated programs for beneficiaries who meet special eligibility requirements and who elect to enroll.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/24/99	64 FR 66234
Interim Final Rule	10/01/02	67 FR 61496
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Federalism: Undetermined

Agency Contact: Janet Harris, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Mailstop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3137
Email: janet.harris@cms.hhs.gov

Related RIN: Previously reported as 0938–AL59

RIN: 0938–AN83

1196. ELECTRONIC SUBMISSION OF COST REPORTS: REVISION TO COST REPORTING PERIOD (CMS–1199–F)

Priority: Substantive, Nonsignificant

Legal Authority: None

CFR Citation: None

Legal Deadline: Final, Statutory, May 27, 2008, MMA sec. 902.

Abstract: This final rule follows a August 26, 2003, final rule that requires ESRD facilities, hospices, rural health clinics, federally qualified health centers, and community mental health centers to file cost reports in a standardized electronic format. It provided a delay or waiver of this requirement if implementation would result in financial hardship. Because the software packages for accepting the cost reports are not available yet, this final rule changes the cost report ending date from December 31, 2004, to March 31, 2005.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/27/05	70 FR 30640
Final Action	05/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Darryl E. Simms, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–03–30, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4524
Email: dsimms@cms.hhs.gov

Related RIN: Related to 0938–AL51

RIN: 0938–AN87

1197. ● LOAN FORGIVENESS CRITERIA FOR THE HEALTH CARE INFRASTRUCTURE LOAN PROGRAM (CMS–1320–F)

Priority: Other Significant

Legal Authority: sec 1016 of PL 108–173

CFR Citation: 42 CFR 505

Legal Deadline: NPRM, Statutory, July 1, 2004.

Abstract: The Secretary is authorized to forgive such loans awarded in the Health Care Infrastructure Improvement Program if the hospital establishes an outreach program for cancer prevention, early diagnosis, and treatment for a substantial majority of the residents of the state, a similar program for multiple Indian tribes, and either unique research resources or an affiliation with an entity that has unique research resources.

Timetable:

Action	Date	FR Cite
NPRM	09/30/05	70 FR 57376
Final Action	09/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director of the Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mailstop C4–01–17, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4487
Email: tzvi.hefter@cms.hhs.gov

RIN: 0938–AN93

1198. ● HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM; SELECTION CRITERIA OF LOAN PROGRAM FOR QUALIFYING HOSPITALS ENGAGED IN CANCER–RELATED HEALTH CARE (CMS–1287–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Section 1016 of Public Law 108–173

CFR Citation: 42 CFR 505

Legal Deadline: Final, Statutory, July 1, 2004.

Abstract: This rule would establish a loan program to improve certain hospital infrastructure, including capital improvement. To receive assistance, the applicant would be required to: 1) Engage in cancer research; and 2) be designated by the National Cancer Institute (NCI) as a cancer center or by the State as the official cancer institute. No later than 4 years after enactment, the Secretary must submit a report to Congress summarizing the financial performance of the projects that have received assistance under the loan program.

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/30/05	70 FR 57368
Final Action	09/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Melinda Jones, Health Insurance Specialist, Quality Measurement & Health Assessment Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–7069
Email: melinda.jones@cms.hhs.gov

Tzvi Hefter, Director of the Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–01–17, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4487
Email: tzvi.hefter@cms.hhs.gov

Related RIN: Related to 0938–AN93

RIN: 0938–AO03

1199. ● MEDICAL IMPROVEMENT ELIGIBILITY GROUP AND DEFINITION OF WORK (CMS–2143–P)

Priority: Other Significant

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

CFR Citation: 42 CFR 435 238; 42 CFR 436–232

Legal Deadline: None

Abstract: In order to provide health services to employed individuals whose medical conditions have improved to the point where they are no longer eligible for disability benefits, this proposed rule would provide a definition of ''medically determinable severe impairment'' under the Ticket to Work and Work Incentives Improvement Act of 1999 (Ticket to Work). Under this definition, States can determine eligibility standards for the Medical Improvement Group authorized under the Ticket to Work law, thereby permitting individuals to retain their Medicaid coverage. Additionally, this proposed rule would

give States offering Medicaid buy-in programs for employed individuals with disabilities the option of selecting a minimum work standard for participation.

Timetable:

Action	Date	FR Cite
NPRM	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Carey Appold, Technical Director, Disabled & Elderly Health Programs 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 Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–2117
Fax: 410 786–9004
Email: carey.appold@cms.hhs.gov

RIN: 0938–AO10

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Completed Actions

1200. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 424.57

Completed:

Reason	Date	FR Cite
Withdrawn	06/28/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ralph Goldberg
Phone: 410 786–4870

RIN: 0938–AJ98

1201. EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–FN)

Priority: Info./Admin./Other

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	07/22/05	70 FR 42331

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Maria L. Hammel
Phone: 410 786–1775
Email: maria.hammel@cms.hhs.gov

RIN: 0938–AN13

1202. NONDISCRIMINATION IN POST–HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 482

Completed:

Reason	Date	FR Cite
Withdrawn	08/15/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Sarah Shipey
Phone: 410 786–0187

RIN: 0938–AN19

1203. MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–IFC)

Priority: Other Significant

CFR Citation: 42 CFR 414, subpart H

Completed:

Reason	Date	FR Cite
Withdrawn	08/29/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local

Agency Contact: Robert Niemann
Phone: 410 786–4596
Email: rnieman@cms.hhs.gov

Related RIN: Related to 0938–AO11

RIN: 0938–AN24

1204. PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	05/06/05	70 FR 24168

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judy Richter
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AN28

1205. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2006 (CMS–1290–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
NPRM	05/25/05	70 FR 30187
Final Action	08/15/05	70 FR 47879

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Robert Kuhl
Phone: 410 786–4597
Email: bob.kuhl@cms.hhs.gov

RIN: 0938–AN43

1206. DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES (CMS–4087–FN)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	05/27/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Julie Walton
Phone: 410 786–4622
Email: jwalton@cms.hhs.gov

Related RIN: Related to 0938–AN08

RIN: 0938–AN50

1207. FISCAL YEAR 2006 SCHIP ALLOTMENTS (CMS–2219–N)

Priority: Other Significant

CFR Citation: 42 CFR 457

Completed:

Reason	Date	FR Cite
Notice	06/24/05	70 FR 36615

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

RIN: 0938–AN56

1208. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2006 RATES (CMS–1500–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 412; 42 CFR 413; 42 CFR 485; 42 CFR 489

Completed:

Reason	Date	FR Cite
NPRM	05/04/05	70 FR 23306
Final Action	08/12/05	70 FR 47277

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Marc Hartstein
Phone: 410 786–6192
Email: marc.hartstein@cms.hhs.gov

RIN: 0938–AN57

1209. SPECIAL PAYMENT PROVISIONS AND STANDARDS FOR SUPPLIERS OF CUSTOM FABRICATED ORTHOTICS AND PROSTHETICS (CMS–6012–P)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 410; 42 CFR 414; 42 CFR 424

Completed:

Reason	Date	FR Cite
Withdrawn	06/28/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Theresa Linkowich
Phone: 410 786–9249
Email: tlinkowich@cms.hhs.gov

Ralph Goldberg
Phone: 410 786–8864

RIN: 0938–AN63

1210. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2006 (CMS–1282–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 409; 42 CFR 411; 42 CFR 424; 42 CFR 489

Completed:

Reason	Date	FR Cite
NPRM	05/19/05	70 FR 29069
Final Action	08/04/05	70 FR 45025

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Bill Ullman
Phone: 401 786–5667
Email: bill.ullman@cms.hhs.gov

RIN: 0938–AN65

1211. STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP); REDISTRIBUTION OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR (FY) 2002 (CMS–2230–FN)

Priority: Other Significant

CFR Citation: 42 CFR 457.600 to 457.630

Completed:

Reason	Date	FR Cite
Final Action	09/29/05	70 FR 56901

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

RIN: 0938–AN78

1212. EXTENDING SUNSET DATE FOR THE INTERIM FINAL REGULATION ON MENTAL HEALTH PARITY (CMS–4094–F3)

Priority: Other Significant

CFR Citation: 42 CFR 146

Completed:

Reason	Date	FR Cite
Final Action	07/22/05	70 FR 42276

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David Mlawsky
Phone: 410 786–6851
Email: david.mlawsky@cms.hhs.gov

Related RIN: Related to 0938–AN22

RIN: 0938–AN80

1213. • DISPROPORTIONATE SHARE HOSPITAL PAYMENTS—INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2062–N2)

Timetable:

Action	Date	FR Cite
Duplicate of 0938-AN96	05/24/05	

RIN: 0938–AN88

1214. ● HOSPICE WAGE INDEX FOR FY 2006 (CMS–1286–F)

Priority: Other Significant

Legal Authority: Sec. 408 and 946 of the MMA of 2003;; Sec. 1861(dd) of the Social Security Act

CFR Citation: 42 CFR 418.306c

Legal Deadline: Final, None, August 2005, Rates are updated October 1st of each year–need at least 3 months to implement.

Abstract: This rule announces the annual update to the hospice wage index for FY 2006. 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 8/8/97.

Timetable:

Action	Date	FR Cite
NPRM	04/29/05	70 FR 22393
Final Action	08/04/05	70 FR 45129

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Terri Deutsch, Health Insurance Specialist, Division of Community Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mailstop C5–08–28, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9462
Email: terri.deutsch@cms.hhs.gov

RIN: 0938–AN89

1215. ● INPATIENT REHABILITATION FACILITY CLASSIFICATION RULE COMPLIANCE (CMS–1480–N)

Priority: Other Significant

Legal Authority: Public Law 108–477, In accordance with the Consolidated Appropriations Act of 2005

CFR Citation: 420CFR 412.23(b)(2)

Legal Deadline: None

Abstract: In accordance with the provisions of the Consolidated Appropriations Act of 2005, the notice announces the Secretary's determination that the requirements for classification as an inpatient rehabilitation facility (IRF) specified in section 412.23(b)(2) were inconsistent with a report that the Government Accountability Office (GAO) issued concerning classification of a facility as an IRF.

Timetable:

Action	Date	FR Cite
Notice	06/24/05	70 FR 36640

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal, Local, State

Agency Contact: Robert Kuhl, Division Director, Chronic Care Policy Group, Division of Institutional Post Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, Mailstop C5–26–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4597
Email: bob.kuhl@cms.hhs.gov

RIN: 0938–AN92

1216. ● WITHDRAWAL OF AMBULANCE FEE SCHEDULE ISSUED IN ACCORDANCE WITH FEDERAL DISTRICT COURT ORDER IN LIFESTAR AMBULANCE, INC. V. U.S.—MEDICARE COVERED AMBULANCE SERVICES (CMS–1308–)

Priority: Info./Admin./Other

Legal Authority: None

CFR Citation: None

Legal Deadline: None

Abstract: This notice would withdraw the fee schedule that was put in place to effect compliance with the Court Order in Lifestar Ambulance, Inc. v. United States. That Order was vacated by the U.S. Court of Appeals for the Eleventh Circuit in Lifestar Ambulance Service, Inc. v. United States and, accordingly, is no longer in force.

Timetable:

Action	Date	FR Cite
Notice	09/01/05	70 FR 52105

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Ann Tayloe, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–7452
Email: atayloe@cms.hhs.gov

RIN: 0938–AN94

1217. ● IMMUNIZATION STANDARD FOR LONG TERM CARE FACILITIES (CMS–3198–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395i–3; SSA 1819 ; 42 USC 1396r; SSA 1919

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This rule would mandate nursing facilities to immunize each resident for influenza and pneumonia and would reinforces the residents' rights to receive the immunizations for vaccine-preventable diseases. The residents will have the right to refuse the immunizations, if they choose to or if contraindication exist.

Timetable:

Action	Date	FR Cite
NPRM	08/15/05	70 FR 47759
Final Action	10/07/05	70 FR 58834

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker, 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: 410 786–5646
Fax: 410 786–8532
Email: anita.panicker@cms.hhs.gov

RIN: 0938–AN95

1218. ● DISPROPORTIONATE SHARE HOSPITAL PAYMENTS — INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2209–N)

Priority: Other Significant

Legal Authority: 42 USC 1396r–4; PL 108–173, Sec 1001(a)

CFR Citation: None

Legal Deadline: None

Abstract: Section 1001(a) of the MMA amended the Act to revise the methodology for calculating States Disproportionate Share Hospital (DSH) allotments. CMS published a notice describing this methodology and States' preliminary FY 2003, and 2004 DSH allotments and preliminary FY 2003 and 2004 IMD DSH limits in the Federal Register on 3/26/04. This notice announces the final Federal DSH allotments for Federal fiscal years (FFYs) 2003 and 2004, and the preliminary Federal share DSH allotments for FFY 2005. It also announces the final FFYs 2003 and 2004, and the preliminary FFY 2005, limitations on aggregate DSH payments that States may make to institutions for mental disease and other mental health facilities. This notice also includes a background describing the methodology for determining the amounts of States' FFY DSH allotments for FFY 1998 and thereafter.

Timetable:

Action	Date	FR Cite
Notice	08/26/05	70 FR 50358

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Richard Strauss, Technical Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid Operations Services, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

Related RIN: Previously reported as 0938–AN88

RIN: 0938–AN96

1219. ● MEDICARE PRESCRIPTION DRUG DISCOUNT CARD (CMS–4063–F)

Priority: Other Significant

Legal Authority: SSA 1851(d)(1) ; SSA 1860D–1(c); SSA 1860D–31(h)(7)(B); SSA 1860D–31(h)(8)

CFR Citation: 42 CFR 403; 42 CFR 408

Legal Deadline: None

Abstract: The regulation will finalize the marketing rules for the drug card program; specifically it will provide current drug card sponsors who become prescription drug plans (PDPs) the ability to market their PDP offerings to their current Medicare members. CMS is making the change because the current regulation provides that an endorsed sponsor's information and outreach materials may describe only those products or services within the scope of the Medicare endorsement for the drug card. The intended effect is to increase Medicare beneficiaries' awareness and knowledge of PDP offerings for Part D enrollment effective in 2006. The current draft of the marketing section in the interim final rule contradicts the intention of the Medicare Modernization Act to facilitate efficient enrollment into Part D. The revised final rule will reflect the actual intention of the law.

Timetable:

Action	Date	FR Cite
Final Action	09/01/05	70 FR 52019

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jessica Shapiro, Acting Director, of the Division of Drug Card Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7407
Fax: 410 786–1048

Related RIN: Related to 0938–AM71

RIN: 0938–AN97

1220. ● INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2006 (CMS–8026–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395e–2(b)(2); Sec 1813(b)(2) of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 15, 2005.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2006 under Medicare's Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

Timetable:

Action	Date	FR Cite
Notice	09/23/05	70 FR 55885

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0938–AO00

1221. ● PART A PREMIUMS FOR CALENDAR YEAR 2006 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8025–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395i–2(d)(2); 42 USC 1395i thru 2a(d)(2); Sec 1818(d)(2) of the Social Security Act; Sec 1818A(d)(2) of the Social Security Act

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the hospital insurance premium for Calendar Year 2006 under Medicare's Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

Action	Date	FR Cite
Notice	09/23/05	70 FR 55896

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human

HHS—CMS **Completed Actions**

Services, Centers for Medicare & Medicaid Services, Office of the Actuary, 7500 Security Boulevard, Mailstop N3–26–00, Baltimore, MD 21244
Phone: 410 786–6390
Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO01

1222. • MEDICARE PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2006 (CMS–8027–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395r; Sec 1839 of the Social Security Act; Sec 629 of MMA; Sec 811 of MMA

CFR Citation: None

Legal Deadline: None

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 2006. It also announces the monthly Part B premium to be paid by all enrollees, and the Part B deductible, during 2006. Section 629 of the Medicare Modernization Act requires indexing the Part B deductible to the increase in the Part B aged actuarial rate beginning 1/1/06.

Timetable:

Action	Date	FR Cite
Notice	09/23/05	70 FR 55897

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Suzanne Codespote, Division Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Actuary, 7500 Security Boulevard, Mailstop N3–26–00, Baltimore, MD 21244
Phone: 410 786–7737
Email: suzanne.codespote@cms.hhs.gov

RIN: 0938–AO02

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

Proposed Rule Stage

1223. SAFEGUARDING CHILD SUPPORT AND EXPANDED FEDERAL PARENT LOCATOR SERVICES (FPLS) INFORMATION

Priority: Other Significant

Legal Authority: 42 USC 652 to 654A; 42 USC 663; 42 USC 1302

CFR Citation: 45 CFR 303.3; 45 CFR 303.21; 45 CFR 303.70

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State, Tribal

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
Email: bmatheson@acf.dhhs.gov

RIN: 0970–AC01

1224. DEVELOPMENTAL DISABILITIES AND BILL OF RIGHTS ACT

Priority: Substantive, Nonsignificant

Legal Authority: PL 106–402; 42 USC 15001 et seq

CFR Citation: 45 CFR 1385 to 1388

Legal Deadline: Final, Statutory, October 30, 2001.

Abstract: A notice of proposed rulemaking to amend current regulations and to implement changes made by the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, State, Tribal

Agency Contact: Elsbeth Wyatt, Program Specialist, Department of Health and Human Services, Administration for Children and Families, ADD HHH–300F, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 690–5841

RIN: 0970–AC07

1225. ADMINISTRATIVE COST SHARING UNDER TANF

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 263; 45 CFR 263.14

Legal Deadline: None

Abstract: This proposed rule will require States (including the District of Columbia) and territories to use the ''benefiting'' cost allocation methodology in allocating the common administrative costs of determining eligibility in the Temporary Assistance for Needy Families (TANF) program,

the Medicaid program, and the Food Stamp programs.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Grant Collins, Deputy Director, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–6953
Email: gcollins@acf.hhs.gov

RIN: 0970–AC15

1226. CARE AND PLACEMENT OF UNACCOMPANIED ALIEN CHILDREN

Priority: Other Significant

Legal Authority: 6 USC 279

CFR Citation: 45 CFR 410

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM	11/01/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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
Email: mdunn@acf.hhs.gov

RIN: 0970–AC20

1227. CHAFEE NATIONAL YOUTH IN TRANSITION DATABASE

Priority: Other Significant

Legal Authority: 42 USC 677

CFR Citation: 45 CFR 1356

Legal Deadline: None

Abstract: This rule would require States to collect and report data on youth who are receiving independent living services and the outcomes of certain youth who are in foster care or who age-out of foster care.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
Phone: 202 401–5789
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov

RIN: 0970–AC21

1228. MEDICAL SUPPORT

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 302; 45 CFR 303; 45 CFR 304; 45 CFR 305

Legal Deadline: None

Abstract: These rules would 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.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Local, State

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
Email: bmatheson@acf.dhhs.gov

RIN: 0970–AC22

1229. • ADOPTION AND FOSTER CARE ANALYSIS AND REPORTING SYSTEM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 679

CFR Citation: 45 CFR 1355

Legal Deadline: None

Abstract: This NPRM amends the Adoption and Foster Care Analysis and Reporting System (AFCARS) regulations at 45 CFR 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 (P.L. 108-145).

Timetable:

Action	Date	FR Cite
NPRM	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
Phone: 202 401–5789
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov

RIN: 0970–AC23

Department of Health and Human Services (HHS) **Final Rule Stage**

Administration for Children and Families (ACF)

1230. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

Priority: Other Significant

Legal Authority: 42 USC 672; 42 USC 674; 42 USC 1302

CFR Citation: 45 CFR 1356.60(c)

Legal Deadline: None

Abstract: This notice of proposed rulemaking implements the title IV-E foster care eligibility and administrative cost provisions in sections 472 and 474 of the Social Security Act. We propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unlicensed foster family homes, with the exception of children in relative foster family homes while the State is in the process of licensing the home. We also propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unallowable facilities, with the exception of the month prior to a child's transition into an allowable facility.

Timetable:

Action	Date	FR Cite
NPRM	01/31/05	70 FR 4803
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
Phone: 202 401–5789
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov

RIN: 0970–AC14

1231. HEAD START TRANSPORTATION

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1310

Legal Deadline: None

Abstract: This final rule will extend for 150 days those parts of the Head Start transportation regulation that deal with the requirement that each vehicle used to transport children is equipped for use of child safety restraint systems and the requirement that each bus have a bus monitor. Additionally, these rules will provide Head Start grantees the opportunity to request further extension of the effective date when such an extension is in the best interest of the children they serve.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/16/04	69 FR 2513
Final Action	01/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Windy Hill, Associate Commissioner, Head Start Bureau, Department of Health and Human Services, 330 C Street SW., Washington, DC 20447
Phone: 202 205–8573
Email: whill@acf.hhs.gov

RIN: 0970–AC16

1232. CHILD CARE AND DEVELOPMENT FUND STATE MATCH PROVISIONS

Priority: Other Significant

Legal Authority: 42 USC 9858C

CFR Citation: 45 CFR 98.16

Legal Deadline: None

Abstract: This proposed rule revises the Child Care and Development Fund (CCDF) regulations to permit States to designate multiple public and/or private entities as eligible to receive private donations that may be certified as child care expenditures for purposes of receiving Federal CCDF matching funds.

Timetable:

Action	Date	FR Cite
NPRM	11/09/04	69 FR 64881
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Karen Tvedt, Policy Director, Child Care Bureau, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Room 2046, Washington, DC 20447
Phone: 202 401–5130
Email: ktvedt@acf.hhs.gov

RIN: 0970–AC18

1233. REASONABLE QUANTITATIVE STANDARD FOR REVIEW AND ADJUSTMENT OF CHILD SUPPORT ORDERS

Priority: Other Significant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 303

Legal Deadline: None

Abstract: This interim final rule permits States to use reasonable quantitative standards in adjusting an existing child support award amount after conducting review of the order, regardless of the method review.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/04	69 FR 77659
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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
Email: bmatheson@acf.dhhs.gov

RIN: 0970–AC19

[FR Doc. 05–21044 Filed 10–28–05; 8:45 am]

BILLING CODE 4150–24–S