Federal Register

Monday,
April 24, 2006

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 agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require this semi-annual publication inventorying all 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 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, DC 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 the planned rulemakings referenced below. 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: March 20, 2006.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
833	Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments	0991–AB03

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
834	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
835	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
836	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23
837	Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Under the Anti-Kickback Statute	0991–AB38
838	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—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
839	Debt Collection	0991–AB18
840	Salary Offset	0991–AB19
841	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
842	Health Insurance Portability and Accountability Act—Enforcement	0991–AB29

HHS

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
843	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
844	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

Centers for Disease Control and Prevention—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
845	Foreign Quarantine Regulations, Proposed Revision of CDC Animal Importation Regulations	0920–AA14
846	Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices	0920–AA16
847	Amendments to Performance Requirements for Chemical Biological, Radiological, and Nuclear (CBRN) Approval of Respiratory Protection Devices	0920–AA17

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
848	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04
849	Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices	0920–AA10
850	Control of Communicable Diseases, Interstate and Foreign Quarantine	0920–AA12
851	Amendments to Requirements for Coal Mine Dust Personal Sampler Units	0920–AA18

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
852	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

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
853	Control of Communicable Diseases	0920–AA15

Food and Drug Administration—Prerule Stage

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

HHS

Food and Drug Administration—Prerule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
855	Package Size Limitation for Sodium Phosphates Oral Solution and Warning and Direction Statements for Oral and Rectal Sodium Phosphates for Over-the-Counter Laxative Use **(Section 610 Review)**	0910–AF73
856	Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use: Required Alcohol Warning **(Section 610 Review)**	0910–AF74
857	Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients **(Section 610 Review)**	0910–AF75
858	Medical Devices: Classification/Reclassification; Restricted Devices; Analyte Specific Reagents **(Section 610 Review)**	0910–AF76
859	Amended Economic Impact Analysis of Final Rule on User Labeling on Natural Rubber-Containing Medical Device **(Section 610 Review)**	0910–AF77
860	Financial Disclosure by Clinical Investigators **(Section 610 Review)**	0910–AF79
861	Beverages: Bottled Water **(Section 610 Review)**	0910–AF80
862	Food Labeling; Nutrient Content Claims: Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods **(Section 610 Review)**	0910–AF83

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
863	Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs	0910–AA49
864	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
865	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
866	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
867	Reporting Information Regarding Falsification of Data	0910–AC59
868	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
869	Cochineal Extract and Carmine Label Declaration	0910–AF12
870	Charging for Investigational Drugs	0910–AF13
871	Expanded Access to Investigational Drugs for Treatment Use	0910–AF14
872	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
873	Blood Initiative—Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
874	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
875	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
876	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
877	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
878	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
879	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
880	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
881	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
882	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
883	Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation	0910–AF65
884	Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	0910–AF67
885	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
886	Import Tolerances for Animal Drugs	0910–AF78
887	Current Good Manufacturing Practice for Combination Products	0910–AF81
888	Postmarket Safety Reporting for Combination Products	0910–AF82

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
889	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
890	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications	0910–AB34
891	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
892	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88
893	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
894	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
895	Institutional Review Boards: Registration Requirements	0910–AC17
896	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
897	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
898	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
899	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
900	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
901	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
902	Revocation of the Status of Specific Products; Group A Streptococcus	0910–AF20
903	Obstetrical and Gynecological Devices; Designation of Special Control for Condoms and Condoms With Spermicidal Lubricant	0910–AF21
904	Blood Initiative—Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment	0910–AF26
905	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
906	Infant Formula Quality Factors	0910–AF28
907	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
908	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
909	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
910	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
911	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
912	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
913	Substances Prohibited From Use in Animal Food or Feed	0910–AF46
914	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
915	Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle	0910–AF48
916	Over-the-Counter (OTC) Drug Review—Dandruff, Seborrheic Dermatitis, and Psoriasis Products	0910–AF49
917	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
918	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
919	Supplements and Other Changes to Approved New Animal Drug Applications	0910–AF59
920	Designation of New Animal Drugs for Minor Uses or Minor Species	0910–AF60

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
921	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
922	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
923	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
924	Food Standards: General Principles and Food Standards Modernization	0910–AC54
925	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
926	Health Claims	0910–AF09
927	Food Labeling; Prominence of Calories	0910–AF22
928	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
929	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31

HHS

Food and Drug Administration—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
930	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
931	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
932	Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants	0910–AF54
933	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
934	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
935	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
936	Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products	0910–AA94
937	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AF62
938	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

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
939	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44
940	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57
941	National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy	0906–AA68

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
942	Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
943	Smallpox Vaccine Injury Compensation Program: Administrative Implementation	0906–AA61
944	Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA62
945	Requirements Establishing a Limitation on Administrative Expenses; Ryan White CARE Act Title IV Grants for Coordinated Services and Access to Research	0906–AA65
946	Healthy Tomorrow's Partnership for Children (HTPC) Program	0906–AA70

Health Resources and Services Administration—Long-Term Actions

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

HHS

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
949	Public Health Service (PHS) Grant Appeals Procedure	0906–AA69

Indian Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
950	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
951	Grants for Research Projects	0925–AA42
952	National Institutes of Health Loan Repayment Programs	0925–AA43
953	National Library of Medicine Training Grants	0925–AA44
954	Minority Biomedical Research Support Program	0925–AA45
955	National Institute of Environmental Health Sciences Hazardous Substances Basic Research and Training Grants	0925–AA46
956	Endowment Program	0925–AA47
957	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health	0925–AA48

National Institutes of Health—Final Rule Stage

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

Office of Public Health and Science—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
960	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
961	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940–AA06

Office of Public Health and Science—Long-Term Actions

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

HHS

Office of Public Health and Science—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
963	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
964	Federal Policy for the Protection of Human Subjects Technical Amendment	0940–AA10

Centers for Medicare & Medicaid Services—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
965	Innovations in Fee-for-Service Payment Systems to Improve Quality and Outcomes (CMS-1298-ANPR)	0938–AN91

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
966	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
967	Appeals of CMS or Contractor Determinations When a Provider or Supplier Fails To Meet or Maintain the Requirements for Medicare Billing Privileges (CMS-6003-P2)	0938–AI49
968	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)	0938–AJ17
969	Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938–AL26
970	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938–AL80
971	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938–AM50
972	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938–AM87
973	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-P)	0938–AN14
974	Revisions to HIPAA Code Sets (CMS-0013-P)	0938–AN25
975	Limitation on Recoupment of Overpayments (CMS-6025-P)	0938–AN42
976	Revisions to the Oversight and Validation Program for Accrediting Organizations Approved for Deeming Authority (CMS-2255-P)	0938–AN62
977	Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (CMS-3156-P)	0938–AN73
978	Home Health Payment System Rate Update for Calendar Year 2007 (CMS-1304-P)	0938–AN76
979	Fire Safety Requirements for Long-Term Care Facilities: Sprinkler Systems (CMS-3191-P)	0938–AN79
980	Payments for Service Provided Without Charge (CMS-2489-P)	0938–AO07
981	Quality Standards for Genetic Testing (CMS-2121-P)	0938–AO09
982	Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)	0938–AO10
983	Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services (CMS-1317-P)	0938–AO11
984	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates (CMS-1488-P)	0938–AO12
985	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates (CMS-1506-P)	0938–AO15
986	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2007 (CMS-1540-P)	0938–AO16
987	Outpatient Hospital Services and Rural Health Clinic Services Amendment (CMS-2213-P)	0938–AO17
988	Best Price Requirements for Authorized Generic Drugs (CMS-2238-P)	0938–AO20
989	Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule (CMS-1512-PN)	0938–AO22
990	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 (CMS-1321-P)	0938–AO24
991	Use of Repayment Plans (CMS-6032-P)	0938–AO27

HHS

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

Sequence Number	Title	Regulation Identifier Number
992	Redistribution of Unexpended State Children's Health Insurance Program (SCHIP) Funds From the Appropriation for Fiscal Year 2004 (CMS-2241-NC)	0938–AO28
993	Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates (CMS-1529-P)	0938–AO30
994	Home Health Prospective Payment System Rate Update for Calendar Year 2008 (CMS-1541-P)	0938–AO32
995	Provider Nomination Provision (CMS-1331-P)	0938–AO33
996	Gynecological Cytology Proficiency Testing Requirements for Laboratories, Individuals, and Proficiency Testing Program Approvals (CMS-2252-P)	0938–AO34
997	Special Medicare GME Affillations for a Teaching Hospital Affected by a Disaster (CMS-1531-IFC)	0938–AO35
998	State Children's Health Insurance Program (SCHIP) Redistribution of Unexpended SCHIP Funds From the Appropriation for Fiscal Year 2003 (CMS-2235-NC)	0938–AO38
999	Inpatient Psychiatric Facility Prospective Payment System—Update for Rate Year Beginning July 1, 2007 (FY 2008) (CMS-1479-P)	0938–AO40
1000	Notification Procedures for Hospital Discharges (CMS-4105-F)	0938–AO41
1001	State Option To Establish Non-Emergency Medical Transportation Program (CMS-2234-P)	0938–AO45
1002	High Risk Pools (CMS-2260-P)	0938–AO46
1003	Cost Sharing Options (CMS-2244-P)	0938–AO47
1004	Benchmark Benefit Package (CMS-2232-P)	0938–AO48
1005	Improved Enforcement of Documentation Requirements (CMS-2257-P)	0938–AO51
1006	Self-Directed Personal Assistance Services State Plan Option (CMS-2229-P)	0938–AO52

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1007	Requirements for Providers and Suppliers To Establish and Maintain Medicare Enrollment (CMS-6002-F)	0938–AH73
1008	Hospital Conditions of Participation: Laboratory Services (CMS-3014-IFC) **(Section 610 Review)**	0938–AJ29
1009	Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938–AJ96
1010	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (CMS-1810-F)	0938–AK67
1011	Enhanced DSH Treatment for Certain Hospitals (CMS-2198-F)	0938–AN09
1012	Nondiscrimination in Health Coverage in the Group Market (CMS-4081-F)	0938–AN29
1013	Hospital Conditions of Participation: Patients' Rights (CMS-3018-F)	0938–AN30
1014	National Plan and Provider Enumeration System (NPPES) Data Dissemination (CMS-6060-NC)	0938–AN71
1015	Payment Error Rate Measurement (PERM) Program (CMS-6026-IFC2)	0938–AN77
1016	Inpatient Psychiatric Facility Prospective Payment System—Update for RY 2006 (CMS-1306-F)	0938–AN82
1017	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-F)	0938–AN83
1018	Prospective Payment System for Long-Term Care Hospitals RY 2007: Annual Payment Rate Updates (CMS-1485-F)	0938–AO06
1019	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
1020	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2007 (CMS-8029-N)	0938–AO19
1021	Fiscal Year 2007 SCHIP Allotments (CMS-2251-N)	0938–AO21
1022	Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2007 (CMS-8030-N)	0938–AO23
1023	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2007 (CMS-1530-N)	0938–AO25
1024	Hospice Wage Index for FY 2007 (CMS-1535-N)	0938–AO26
1025	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Fiscal Year 2006 (CMS-2231-IFC)	0938–AO31
1026	State Health Insurance Assistance Program (SHIP) (CMS-4005-F)	0938–AO37
1027	Fee Schedule for Payment of Ambulance Services—Update for CY 2007 (CMS-1532-N)	0938–AO39
1028	Adoption of Standards for the E-Prescribing and the Medicare Prescription Drug Program (CMS-0018-N)	0938–AO42
1029	Group Health Plans and Health Insurance Issues Under the Newborns and Mothers Health Protection Act (CMS-4116-F)	0938–AO43
1030	Targeted Case Management (CMS-2237-IFC)	0938–AO50

HHS

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

Sequence Number	Title	Regulation Identifier Number
1031	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-IFC)	0938–AO53

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1032	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) **(Section 610 Review)**	0938–AG82
1033	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-F)	0938–AH17
1034	Hospice Care Conditions of Participation (CMS-3844-F) **(Section 610 Review)**	0938–AH27
1035	Electronic Claims Attachments Standards (CMS-0050-F)	0938–AK62
1036	Organ Procurement Organization Conditions for Coverage and Recertification (CMS-3064-F) **(Section 610 Review)**	0938–AK81
1037	Provider Reimbursement Determinations and Appeals (CMS-1727-F)	0938–AL54
1038	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)	0938–AL88
1039	Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)	0938–AM73
1040	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
1041	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-F)	0938–AM98
1042	Prior Determination Process for Certain Items and Services (CMS-6024-F)	0938–AN10
1043	Medicare Secondary Payer Amendments (CMS-6272-F)	0938–AN27
1044	Random Prepayment Review (CMS-6022-F)	0938–AN31
1045	Fire Safety Requirements for Certain Health Care Facilities; Alcohol-Based Hand Sanitizer Amendment (CMS-3145-F)	0938–AN36
1046	Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F)	0938–AN58
1047	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; E-Prescribing Exceptions (CMS-1303-F)	0938–AN69
1048	Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements (CMS-6030-F)	0938–AN72
1049	Health Care Infrastructure Improvement Program; Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care (CMS-1287-F)	0938–AO03
1050	Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F4)	0938–AO36

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1051	Standard Unique National Health Plan Identifier (CMS-6017-P)	0938–AH87
1052	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)	0938–AJ10
1053	Hospice Care Amendments (CMS-1022-F)	0938–AJ36
1054	Electronic Medicare Claims Submission (CMS-0008-F)	0938–AM22
1055	Requirements for Long-Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information (CMS-3121-F)	0938–AM55
1056	Conditions for Coverage for Payment of Power Mobility Devices, Including Powered Wheelchairs and Power-Operated Vehicles (CMS-3017-F)	0938–AM74
1057	Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS-1167-F)	0938–AN02
1058	Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-F)	0938–AN23
1059	Payment for Clinical Laboratory Tests (CMS-1494-P)	0938–AN26
1060	Federal Enforcement in Group and Individual Health Insurance Markets (CMS-4091-F)	0938–AN35
1061	Home Health Prospective Payment System Rate Update for Calendar Year 2006 (CMS-1301-F)	0938–AN44
1062	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-FC)	0938–AN46
1063	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6019-F)	0938–AN48
1064	Electronic Prescribing Standards (CMS-0011-F)	0938–AN49

HHS

Centers for Medicare & Medicaid Services—Completed Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
1065	Group Market Health Insurance Reform: Guaranteed Availability, Guaranteed Renewability, Disclosures to Small Employers (CMS-4102-F)	0938–AN60
1066	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
1067	All Provider Bad Debt Payment (CMS-1126-F)	0938–AN75
1068	Application of Inherent Reasonableness to All Medicare Part B Services (Other Than Physician Services) (CMS-1908-F)	0938–AN81
1069	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-FC)	0938–AN84
1070	Electronic Submission of Cost Reports (CMS-1199-F)	0938–AN87
1071	Loan Forgiveness Criteria for the Health Care Infrastructure Loan Program (CMS-1320-F)	0938–AN93
1072	Fee Schedule for Payment of Ambulance Services—Update for CY 2006 (CMS-1294-N)	0938–AN99
1073	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals (CMS-2210-F)	0938–AO04
1074	Federal Government's Adoption of Twenty (20) Healthcare Messaging and Vocabulary Standards Recommended by the Consolidated Health Informatics Initiative (CMS-0015-N)	0938–AO05
1075	Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-P)	0938–AO13
1076	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

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1077	Developmental Disabilities and Bill of Rights Act	0970–AC07
1078	Administrative Cost Sharing Under TANF	0970–AC15
1079	Care and Placement of Unaccompanied Alien Children	0970–AC20
1080	Chafee National Youth in Transition Database	0970–AC21
1081	Medical Support	0970–AC22
1082	Adoption and Foster Care Analysis and Reporting System	0970–AC23
1083	Child Support Provisions of the Deficit Reduction Act	0970–AC24
1084	Privatizing Functions	0970–AC25
1085	Head Start Transportation	0970–AC26

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1086	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01
1087	Child Care and Development Fund State Match Provisions	0970–AC18
1088	Reasonable Quantitative Standard for Review and Adjustment of Child Support Orders	0970–AC19
1089	TANF Work Provisions of the Deficit Reduction Act	0970–AC27

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1090	Administrative Costs for Children in Title IV-E Foster Care	0970–AC14
1091	Head Start Transportation	0970–AC16

Department of Health and Human Services (HHS) — Proposed Rule Stage
Office of the Secretary (OS)

833. 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	09/00/06	
NPRM Comment Period End	11/00/06	

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

Department of Health and Human Services (HHS) — Final Rule Stage
Office of the Secretary (OS)

834. 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	10/00/06	

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

835. 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	10/00/06	

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

836. 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

HHS—OS

Final Rule Stage

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	10/00/06	

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

837. 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	10/00/06	

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

838. 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	10/00/06	

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)
Office of the Secretary (OS)

Long-Term Actions

839. DEBT 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, HHS Cohen Building,

Room 4760, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0150

RIN: 0991–AB18

840. SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 5514

CFR Citation: 5 CFR 550; 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, HHS Cohen Building, Room 4760, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0150

RIN: 0991–AB19

841. 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 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)
Office of the Secretary (OS)

Completed Actions

842. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

Priority: Other Significant

CFR Citation: 45 CFR 160, subparts C to E

Completed:

Reason	Date	FR Cite
Final Action	02/16/06	71 FR 8390
Final Action Effective	03/16/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Conrad
Phone: 202 690–1840

RIN: 0991–AB29

Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Proposed Rule Stage

843. 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	09/00/06	

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: Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental

HHS—SAMHSA **Proposed Rule Stage**

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)

844. 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	09/00/06	

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, 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) **Prerule Stage**
Centers for Disease Control and Prevention (CDC)

845. • FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF CDC ANIMAL IMPORTATION REGULATIONS

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: The Centers for Disease Control and Prevention (CDC) is issuing this Advance Notice of Proposed Rulemaking (ANPRM) to begin the process of revising the regulations for importation of dogs, cats and other animals into the United States (42 CFR 71.51 and 71.56).

The input received from stakeholders via the ANPRM with the aim of improving CDC's ability to prevent importation of communicable diseases. The scope of this ANPRM does not include the nonhuman primate regulations (42 CFR 71.53).

Timetable:

Action	Date	FR Cite
ANPRM	05/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jennifer Brooks, Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Infectious Diseases, 1600 Clifton Road NE., NE E–03, Atlanta, GA 30333
Phone: 404 639–7048

RIN: 0920–AA14

846. • AMENDMENTS TO POWERED AIR–PURIFYING RESPIRATOR REQUIREMENTS FOR APPROVAL OF RESPIRATORY PROTECTION DEVICES

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

Unfunded Mandates: Undetermined

Legal Authority: 28 USC 651; 30 USC 3; 30 USC 7; 30 USC 11; 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 powered air-purifying respirators. These respirators are used in a variety of workplace applications, including emergency response activities.

Timetable:

Action	Date	FR Cite
ANPRM	03/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Federalism: Undetermined

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, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200

RIN: 0920–AA16

847. • AMENDMENTS TO PERFORMANCE REQUIREMENTS FOR CHEMICAL BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR (CBRN) APPROVAL OF RESPIRATORY PROTECTION DEVICES

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

Legal Authority: 29 USC 651; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 11; 30 USC 842l; 30 USC 844

CFR Citation: 42 CFR 84

Legal Deadline: None

HHS—CDC **Prerule Stage**

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

Timetable:

Action	Date	FR Cite
ANPRM	03/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200

RIN: 0920–AA17

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

Proposed Rule Stage

848. 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, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200

RIN: 0920–AA04

849. 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, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200

RIN: 0920–AA10

850. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 70; 42 CFR 71

Legal Deadline: None

Abstract: By statute, the Secretary of Health and Human Services (HHS) has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. Interstate authority is split between CDC and the Food and Drug Administration (FDA), with CDC delegated interstate authority as it pertains to humans. CDC maintains quarantine stations at eight major airports with quarantine inspectors who respond to reports of diseases from carriers. According to the statutory scheme, the President of the United States determines through Executive order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and Severe Acute Respiratory Syndrome (SARS) and influenza caused by novel or reemergent influenza virus that are

causing, or have the potential to cause, a pandemic.

Timetable:

Action	Date	FR Cite
NPRM	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ram Koppaka M.D., Ph.D, Department of Health and Human Services, Centers for Disease Control and Prevention, MS–E–03, 1600 Clifton Road, Atlanta, GA 30333
Phone: 404 498–2308

RIN: 0920–AA12

851. • AMENDMENTS TO REQUIREMENTS FOR COAL MINE DUST PERSONAL SAMPLER UNITS

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: NIOSH and MSHA jointly plan to modify 30 CFR part 74, which provides requirements for the approval by NIOSH and MSHA or coal mine dust personal sampler units that are worn by miners to determine the concentrations of respirable dust in coal mine atmospheres. The existing requirements are design-specific for a particular monitoring technology that has been available since the 1970's. The amendments would establish requirements that would promote the development and govern the testing and approval of new coal mine dust sampler designs and technology for use in coal mines.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: John Breslin, Director, Science, Pittsburgh Research Laboratory, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–6873

RIN: 0920–AA18

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

Long-Term Actions

852. 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, Public Law No. 108-375 (codified as amended in scattered sections of 42 U.S.C.).

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/22/05	70 FR 75949
Interim Final Rule Comment Period End	02/21/06	
Next Action Undetermined		

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, 4676 Columbia Pkwy, MS C–46, Cincinnati, OH 45226
Phone: 513 533–6825

RIN: 0920–AA13

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

Completed Actions

853. • CONTROL OF COMMUNICABLE DISEASES

Priority: Other Significant

Legal Authority: 25 USC 198, 231, and 1661; 42 U.S.C. 243, 248, 249, 264–272, and 2001

CFR Citation: 42 CFR 70 and 71

Legal Deadline: None

Abstract: CDC is committed to protecting the health and safety of the American public by preventing the introduction of communicable disease into the United States. Having updated regulations in place is an important measure to ensure swift response to public health threats. CDC proposes to update existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. and from one State or possession into another.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/30/05	70 FR 71892

Regulatory Flexibility Analysis Required: No

HHS—CDC **Completed Actions**

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0920–AA15

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

854. 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 local 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	04/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AF71

855. ● PACKAGE SIZE LIMITATION FOR SODIUM PHOSPHATES ORAL SOLUTION AND WARNING AND DIRECTION STATEMENTS FOR ORAL AND RECTAL SODIUM PHOSPHATES FOR OVER–THE–COUNTER LAXATIVE USE (SECTION 610 REVIEW)

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

Legal Authority: 5 USC 610

CFR Citation: 21 CFR 201.307

Legal Deadline: None

Abstract: Section 201.307 (21 CFR section 201.307) describes a final rule to limit the container size for sodium phosphates oral solution (dibasic sodium phosphate/monobasic sodium phosphate oral solution) to not greater than 90 milliliters (mL) (3 ounces (oz)) when used as an over-the-counter (OTC) laxative drug product. FDA limited the container size due to reports of deaths associated with an overdosage of sodium phosphates when packaged in a larger size container and a larger than intended dose was ingested inadvertently. In addition, this final rule required warning and direction statements to inform consumers that exceeding the recommended dose of oral and rectal sodium phosphates products in a 24 hour period could be harmful.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.307. The purpose of this review is to determine whether the regulation in section 201.307 should be continued without change, or whether it 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 regulation in section 201.307; (2) the nature of the complaints or comments received concerning the regulation in section 201.307; (3) the complexity of the regulation in section 201.307; (4) the extent to which the regulation in section 201.307 overlaps, duplicates, or conflicts 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 package size and labeling regulation in section 201.307.

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.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	06/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

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

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RIN: 0910–AF73

856. ● OVER–THE–COUNTER DRUG PRODUCTS CONTAINING ANALGESIC/ANTIPYRETIC ACTIVE INGREDIENTS FOR INTERNAL USE: REQUIRED ALCOHOL WARNING (SECTION 610 REVIEW)

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

Legal Authority: 5 USC 610

CFR Citation: 21 CFR 201.322

Legal Deadline: None

Abstract: Section 201.322 describes a regulation which requires an alcohol warning for all over-the-counter (OTC) drug products, labeled for adult use, containing internal analgesic/antipyretic active ingredients. The required warning statements advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. FDA issued the final rule after considering comments on the Agency's proposed regulation for OTC internal analgesic, antipyretic, and antirheumatic drug products: a proposed regulation to establish an alcohol warning; recommendations from its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC); and data submitted to the agency.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.322. The purpose of this review is to determine whether the regulation in section 201.322 should be continued without change, or whether it 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 regulation in section 201.322; (2) the nature of the complaints or comments received concerning the regulation in section 201.322; (3) the complexity of the regulation in section 201.322; (4) the extent to which the regulation in section 201.322 overlaps, duplicates, or conflicts 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 labeling regulation in section 201.322.

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.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	06/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

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

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RIN: 0910–AF74

857. ● STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG CATEGORY II AND III ACTIVE INGREDIENTS (SECTION 610 REVIEW)

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

Legal Authority: 5 USC 610

CFR Citation: 21 CFR 310.545

Legal Deadline: None

Abstract: Section 310.545 (21 CFR 310.545) codifies a final rule that was issued stating certain first aid antiseptic, vaginal contraceptive, and antimicrobial diaper rash ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective and are misbranded. This rule took into consideration the reports and recommendations of various OTC drug advisory review panels and public comment on proposed Agency regulations. Based on the absence of substantive comments in opposition to the Agency's proposed nonmonograph status for various ingredients, as well as the failure of interested parties to submit new data or information to FDA, the Agency determined that the presence of the subject ingredients in an OTC drug products would result in that product not being generally recognized as safe and effective and would result in misbranding.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 310.545. The purpose of this review is to determine whether the regulation in section 310.545 should be continued without change, or whether it 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 regulation in section 310.545; (2) the nature of the complaints or comments received concerning the regulation in section 310.545; (3) the complexity of the regulations in section 310.545; (4) the extent to which the regulation in section 310.545 overlaps, duplicates, or conflicts 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 regulation in section 310.545.

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.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	06/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

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

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RIN: 0910–AF75

858. ● MEDICAL DEVICES: CLASSIFICATION/ RECLASSIFICATION; RESTRICTED DEVICES; ANALYTE SPECIFIC REAGENTS (SECTION 610 REVIEW)

Priority: Other Significant

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360j

CFR Citation: 21 CFR 809.10; 21 CFR 809.30

Legal Deadline: None

Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 809. The purpose of this review is to determine if any of the regulations in part 809 should be continued without change, or should be amended or rescinded, to minimize adverse economic impact on small entities. FDA will consider and solicit comments on the following: 1) The continued need for a regulation in part 809; 2) the nature of complaints or comments received concerning a regulation in part 809; 3) the complexity of a regulation in part 809; 4) the extent to which a regulation in part 809 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 809.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	04/00/06	
End Review of Current Regulation	11/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF76

859. ● AMENDED ECONOMIC IMPACT ANALYSIS OF FINAL RULE ON USER LABELING ON NATURAL RUBBER–CONTAINING MEDICAL DEVICE (SECTION 610 REVIEW)

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 357; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 801.437

Legal Deadline: Other, Statutory, September 30, 2007, Planned Section 610 Review.

Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 801. The purpose of this review is to determine if any of the regulations in part 801 should be continued without change, or should be amended or rescinded, consistent with stated objectives and applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider and solicit comments on the following: 1) The continued need for a regulation in part 801; 2) the nature of complaints or comments received concerning a regulation in part 801; 3) the complexity of a regulation in part 801; 4) the extent to which a regulation in part 801 overlaps, duplicates, or conflicts with other Federal rules, and to the extent feasible, with State and local government rules; and 5) the degree to which technology, economic conditions or other factors have changed in the area affected by a regulation in part 801.

Timetable:

Action	Date	FR Cite
Final Action	09/30/97	62 FR 51021
Final Action Effective	09/30/98	
End Review of Current Regulation	12/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF77

860. ● FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (SECTION 610 REVIEW)

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 360; 21 USC 360c – 360j; 21 USC 371; 21 USC 372; 21 USC 373; 21 USC 374; 21 USC 375; 21 USC 376; 21 USC 379; 42 USC 262

CFR Citation: 21 CFR Part 54; 21 CFR 312.53; 21 CFR 312.57; 21 CFR 312.64; 21 CFR 314.50; 21 CFR 314.60; 21 CFR 314.94; 21 CFR 314.200; 21 CFR 314.300; 21 CFR 320.36; 21 CFR 330.10; 21 CFR 601.2; 21 CFR 807.31; 21 CFR 807.87; 21 CFR 807.100; 21 CFR 812.43; 21 CFR 812.110; 21 CFR 812.140; 21 CFR 814.20; 21 CFR 814.42; 21 CFR 814.112; 21 CFR 860.123

Legal Deadline: Other, Statutory, February 2, 2006, Planned Section 610 Review.

Abstract: FDA is undertaking a review of 21 CFR sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123 should be continued without change, or whether they should be amended or rescinded,

consistent with the stated objectives of applicable statues, 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 sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123; (2) the nature of complaints or comments received concerning the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123; (3) the complexity of the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123; (4) the extent to which the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123 overlap, duplicate, or conflict with other regulations with other Federal, State, or governmental rules, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 54, 312.53, 312.47, 312.64, 314.50, 314.60, 314.94, 314.200, 314.300, 320.36, 330.10, 601.2, 807.31, 807.87, 807.100, 812.43, 812.110, 812.140, 814.20, 814.42, 814.112 and 860.123.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	04/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF79

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861. • BEVERAGES: BOTTLED WATER (SECTION 610 REVIEW)

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 343–1; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 379e

CFR Citation: 21 CFR 165.110

Legal Deadline: Other, Statutory, November 13, 2005, Planned Section 610 Review.

Abstract: Section 165.110 (21 CFR 165.110) describes requirements for identity and quality standards for bottled water. FDA is undertaking a review of section 165.110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in section 165.110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) the continued need for the regulations in section 165.110; (2) the nature of complaints or comments received concerning the regulations in section 165.110; (3) the complexity of the regulations; (4) the extent to which the regulations in section 165.110 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in section 165.110.

Timetable:

Action	Date	FR Cite
Begin Review	03/00/07	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AF80

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862. • FOOD LABELING; NUTRIENT CONTENT CLAIMS: DEFINITION FOR ''HIGH POTENCY'' AND DEFINITION OF ''ANTIOXIDANT'' FOR USE IN NUTRIENT CONTENT CLAIMS FOR DIETARY SUPPLEMENTS AND CONVENTIONAL FOODS (SECTION 610 REVIEW)

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

Legal Authority: 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

CFR Citation: 21 CFR 101.54; 21 CFR 101.60

Legal Deadline: Other, Statutory, September 23, 2007, Deadline for 610(c) Review.

Abstract: Section 101.54 (21 CFR 101.54) describes the requirements for when the terms ''high potency'' and ''antioxidant'' may be used on the label or in the labeling of foods, including dietary supplements. Section 101.60 (21 CFR 101.60) describes the requirements for when the terms ''low calorie'' or ''reduced calorie'' may be used on the label or in the labeling of such foods. FDA is undertaking a review of sections 101.54 and 101.60 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine

whether the regulations should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in sections 101.54 and 101.60; (2) the nature of complaints or comments received concerning the regulations; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.54 and 101.60 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.54 and 101.60.

Timetable:

Action	Date	FR Cite
Begin Review	04/00/06	
End Review	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal, Local, State, Tribal

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

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RIN: 0910–AF83

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

Proposed Rule Stage

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

Priority: Other Significant

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

CFR Citation: 21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 330; 21 CFR 514; 21 CFR 515; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 1271

Legal Deadline: None

Abstract: The proposed rule would reorganize, consolidate, clarify, and modify current regulations at 21 CFR part 207 concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted for initial registration and listing and for changes to registration and listing. The proposed rule would require that this information be submitted via the Internet into the FDA registration and listing database, instead of the current requirement to submit the information to FDA on paper forms. The proposed rule would also require that the NDC number appear on certain drug labels. In addition, FDA would assign the NDC number to newly listed drugs and take other steps to minimize the use of inaccurate NDC numbers on drug labels.

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AA49

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

Priority: Routine and Frequent

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	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC30

865. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

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

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

CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94

Legal Deadline: None

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which study data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments be provided in an electronic format that FDA can process, review, and archive. The proposal would also require the use of standardized data structure, terminology, and code sets to allow for more efficient and comprehensive data review.

Timetable:

Action	Date	FR Cite
NPRM	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC52

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

Priority: Other Significant

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

CFR Citation: 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125

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	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	04/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AC53

867. 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	10/00/06	

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
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Related RIN: Previously reported as 0910–AC02

RIN: 0910–AC59

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

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b;

21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

CFR Citation: 21 CFR 201.56; 21 CFR 201.57; 21 CFR 201.80

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

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, Center for Drug Evaluation and Research, 5515 Security Lane, Rockville, MD 20852
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RIN: 0910–AF11

869. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

Priority: Other Significant

Legal Authority: 21 USC 379e(b)

CFR Citation: 21 CFR 73.100(d); 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	01/30/06	71 FR 4839
NPRM Comment Period End	05/01/06	

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
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RIN: 0910–AF12

870. 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 expanded access to investigational drugs for treatment use, 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	08/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF13

871. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Priority: Other Significant

Legal Authority: 21 USC 355; 21 USC 360bbb; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 312.42; 21 CFR 312.300; 21 CFR 312.305; 21 CFR 312.310; 21 CFR 312.315; 21 CFR 312.320

Legal Deadline: None

Abstract: To amend the regulations governing investigational new drugs to describe the ways patients may obtain investigational drugs for treatment use under expanded access programs. Such use of investigational drugs would be available to: (1) Individual patients, including in emergencies; (2) intermediate size patient populations; and (3) larger populations under a treatment protocol or IND.

Timetable:

Action	Date	FR Cite
NPRM	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

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RIN: 0910–AF14

872. 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	02/01/06	71 FR 5200
NPRM Comment Period End	05/02/06	
Final Action	12/00/06	

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
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RIN: 0910–AF16

873. 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	12/00/06	

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, Center for Biologics Evaluation and Research, HFM–17, 1401 Rockville Pike, Rockville, MD 20852–1448
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Related RIN: Split from 0910–AB26

RIN: 0910–AF25

874. 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 2 years old and weight- and age-based dosing for children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The Stevens Johnson and Cardiovascular Warnings Documents address new proposed product warnings.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	06/00/06	
NPRM (Amendment) (Pediatric)	08/00/06	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	10/00/06	
NPRM (Amendment) (Overindulgence/ Hangover)	05/00/07	
NPRM (Amendment) (Stevens Johnson Warnings)	06/00/06	
NPRM (Amendment) (Cardiovascular Warnings)	06/00/06	
Final Action (Internal Analgesics)	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF36

875. 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)	06/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF37

876. 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)	01/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF39

877. 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 sunscreen 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
NPRM (UVA/UVB)	05/00/06	
ANPRM (Sunscreen and Insect Repellent)	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF43

878. 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)	12/22/05	70 FR 75988
NPRM (Benzocaine)	08/00/06	
Final Action (Phenyl propanolamine)	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF45

879. 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 skin bleaching drug products containing hydroquinone.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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
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RIN: 0910–AF53

880. 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)	06/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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
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RIN: 0910–AF56

881. 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	02/00/07	

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, Office of Policy and Planning (HF–23), 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
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RIN: 0910–AF61

882. 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 ingredients.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Related to 0910–AC82

RIN: 0910–AF63

883. 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	06/00/06	
Direct Final Rule	06/00/06	

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, Center for Biologics Evaluation and Research, HFM–17, 1401 Rockville Pike, Rockville, MD 20852–1448
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RIN: 0910–AF65

884. 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 target animal safety and effectiveness of a new animal drug proposed for indexing.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Action	Date	FR Cite
NPRM Comment Period End	08/00/06	

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
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RIN: 0910–AF67

885. 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)	12/00/06	
NPRM (Food Handlers)	12/00/06	
NPRM (Healthcare Antiseptics)	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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RIN: 0910–AF69

886. • IMPORT TOLERANCES FOR ANIMAL DRUGS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b(a)(6)

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: FDA plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerances will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act (the Act) and may be imported into the U.S.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: George Kenneth Haibel, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, 7519 Standish Place, Rm. 169, MPN–4, HFV–6, Rockville, MD 20855
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RIN: 0910–AF78

887. • CURRENT GOOD MANUFACTURING PRACTICE FOR COMBINATION PRODUCTS

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: James S. Cohen, Senior Counsel, Department of Health and Human Services, Food and Drug

HHS—FDA **Proposed Rule Stage**

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RIN: 0910–AF81

888. ● POSTMARKET SAFETY REPORTING FOR COMBINATION PRODUCTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The proposed rule would clarify the postmarket safety reporting requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a framework for the reporting of adverse events for combination products and specify sponsors' reporting requirements for each type of combination product. The proposed rule would clarify the circumstances in which following one set of postmarket safety reporting regulations generally would meet the requirements of another set, and the circumstances in which these requirements would be supplemented with specific reporting provisions applicable to the other constituent part of the combination product. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Leigh Hayes, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Office of Combination Products, 15800 Crabbs Branch Way, Suite 200 (HFG–3), Rockville, MD 20855
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RIN: 0910–AF82

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

Final Rule Stage

889. 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	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AA97

890. 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 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 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	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AB34

891. 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 263 to 42 USC 263a; 42 USC 264; 21 USC 372; 21 USC 381

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	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Related to 0910–AB26

RIN: 0910–AB76

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

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 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

CFR Citation: 21 CFR 111

Legal Deadline: None

Abstract: The Food and Drug Administration proposed in the Federal Register of March 13, 2003 (68 FR 12158), current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. The proposed rule was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, they do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. FDA also proposed to require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule also responds to concerns that such regulations are necessary to ensure that consumers are provided with dietary supplement products which have not been adulterated as a result of manufacturing, packing, or holding, e.g., which have the identity and provide the quantity of dietary ingredients declared in labeling.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AB88

893. 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	10/00/06	

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
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RIN: 0910–AC07

894. 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	12/00/06	

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.

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RIN: 0910–AC14

895. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS

Priority: Info./Admin./Other

Legal Authority: 21 USC 321; 21 USC 346 to 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 the Department of Health and Human Services. The registration information would include the name of the IRB, the name of the institution operating the IRB, and names, addresses, phone numbers, facsimile (fax) numbers, and electronic mail (e-mail) addresses of the senior officer of the institution and IRB chair or contact, the number of active protocols involving FDA-regulated products reviewed in the previous calendar year, and a description of the types of FDA-regulated products reviewed. The final rule would make it easier for FDA to inspect IRBs and to convey information to IRBs.

Timetable:

Action	Date	FR Cite
NPRM	07/06/04	69 FR 40556
Final Action	01/00/07	

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, Office of Policy and Planning (HF–23), 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
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RIN: 0910–AC17

896. 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: State

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

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RIN: 0910–AC25

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

Priority: Routine and Frequent

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	06/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC32

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

Priority: Other Significant

Legal Authority: 21 USC 355b

CFR Citation: 21 CFR 201; 21 CFR 208; 21 CFR 209

Legal Deadline: Final, Statutory, January 4, 2003.

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

Timetable:

Action	Date	FR Cite
NPRM	04/22/04	69 FR 21778
NPRM Comment Period End	07/21/04	
Final Action	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC35

899. 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	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

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RIN: 0910–AC41

900. 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

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Related RIN: Previously reported as 0910–AB63

RIN: 0910–AC55

901. 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	11/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF15

902. 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 issued 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	12/02/05	70 FR 72257
Direct Final Rule	12/02/05	70 FR 72197
Final Action	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF20

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

Priority: Other Significant

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	11/14/05	70 FR 69102
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF21

904. 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 human blood and blood components, including source plasma to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the 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	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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Related RIN: Split from 0910–AB26

RIN: 0910–AF26

905. 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	
NPRM Comment Period Reopened	04/28/03	68 FR 22341
NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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Related RIN: Split from 0910–AA04

RIN: 0910–AF27

906. 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	
NPRM Comment Period Reopened	04/28/03	68 FR 22341
NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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Related RIN: Split from 0910–AA04

RIN: 0910–AF28

907. 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	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF32

908. 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	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF33

909. 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)	12/22/05	70 FR 75988
Final Action (Amendment) (Sinusitis Claim)	10/31/05	70 FR 58974
Final Action (Phenylephrine Bitartrate)	08/00/06	
Final Action (Phenyl propanolamine)	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF34

910. 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. One action will address laxative drug products. The other action will address psyllium laxative drug products in a granular dosage form.

Timetable:

Action	Date	FR Cite
Final Action (Laxative Drug Products)	08/00/06	
Final Action (Granular Psyllium)	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF38

911. 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)	06/00/06	
Final Action (Fever Blisters/Cold Sores)	10/00/06	
Final Action (Diaper Rash)	12/00/06	
NPRM (Amendment) (Diaper Rash Drug Product)	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF42

912. 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. One action will address labeling warning statements for products containing Nonoxynol 9. The other action addresses vaginal contraceptive drug products.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	05/00/06	
NPRM (Vaginal Contraceptive Drug Products)	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF44

913. 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: On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE which resulted in this rulemaking.

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

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RIN: 0910–AF46

914. 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 (IFR), 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 under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) (Beef). Specified risk materials are the brain, skull, eyes,

trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. After reviewing comments received to the interim final rule, FDA intends to issue a final rule.

On September 7, 2005, FDA amended the IFR to permit the use of small intestine in human food and cosmetics if it is effectively removed from the distal ileum. The amendment also clarified that milk and milk products, hides, and tallow derivatives are not prohibited for use in human food and cosmetics.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF47

915. 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	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF48

916. 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)	12/09/05	70 FR 73178
Final Action	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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RIN: 0910–AF49

917. 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	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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RIN: 0910–AF51

918. 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

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 (Overindulgence Labeling)	08/00/06	
Final Action (Sodium Bicarbonate Labeling)	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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RIN: 0910–AF52

919. 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	11/00/06	
Final Action Effective	01/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF59

920. DESIGNATION OF NEW ANIMAL DRUGS FOR MINOR USES OR MINOR SPECIES

Priority: Other Significant

Legal Authority: 21 USC 360ccc–2

CFR Citation: 21 CFR 516

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

Abstract: The proposed rule was published on September 27, 2005, in response to the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The proposed rule would implement section 573 of the MUMS Act which sets forth the requirements for drug sponsors requesting MUMS designation for proposed new animal drugs. MUMS designation of a new animal drug allows 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 would define content and format requirements for designation, requests changing designation ownership, and annual reporting requirements. This rule would also describe the criteria CVM will use for granting or denying these requests. Specific sections of the rule

are dedicated to documentation of MUMS status in a request, granting MUMS designation, and revocation of MUMS designation. FDA intends to finalize this proposal after reviewing any comments received. 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
NPRM Comment Period End	12/12/05	
Final Rule	10/00/06	

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
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RIN: 0910–AF60

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

Long-Term Actions

921. 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: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC21

922. 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, Center for Drug

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RIN: 0910–AC23

923. 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

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Related RIN: Related to 0910–AB66

RIN: 0910–AC50

924. 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

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Related RIN: Related to 0583–AC72

RIN: 0910–AC54

925. 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
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RIN: 0910–AF08

926. 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

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RIN: 0910–AF09

927. 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
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RIN: 0910–AF22

928. 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

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RIN: 0910–AF23

929. 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)	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF31

930. 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: Local, State

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF35

931. 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 used to reduce or prevent dental plaque and gingivitis.

Timetable:

Action	Date	FR Cite
NPRM (Plaque Gingivitis)	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF40

932. 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 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 360f; 21 USC 360i; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 262; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 211.116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500.200; 21 CFR 530; 21 CFR 600.16; 21 CFR 895.102; 21 CFR 1271.465; 21 CFR 1271.470

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
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Related RIN: Merged with 0910–AF55

RIN: 0910–AF54

933. 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)	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

Agency Contact: Walter Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, WO22 RM 5489, HFD–569, Rockville, MD 20850
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RIN: 0910–AF68

934. 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 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 products used for urinary pain relief.

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	08/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

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

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RIN: 0910–AF70

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

Completed Actions

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

Priority: Other Significant

CFR Citation: 21 CFR 312.110

Completed:

Reason	Date	FR Cite
Final Action	11/23/05	70 FR 70720

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao
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RIN: 0910–AA61

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

Priority: Other Significant

CFR Citation: 21 CFR 201

Completed:

Reason	Date	FR Cite
Final Action	01/24/06	71 FR 3922

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Elizabeth J. Sadove
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RIN: 0910–AA94

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

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 610.21

Completed:

Reason	Date	FR Cite
Final Action	12/19/05	70 FR 75018
Final Order	12/19/05	70 FR 75180

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Astrid L. Szeto
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RIN: 0910–AF62

938. 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

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

Completed:

Reason	Date	FR Cite
Withdrawn	02/27/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Richard A. Williams
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RIN: 0910–AF64

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

Proposed Rule Stage

939. 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	06/00/06	

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
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RIN: 0906–AA44

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

Priority: Other Significant

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	06/00/06	

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

941. 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 cost 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	06/00/06	

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

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

942. 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 Rule	06/00/06	

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

943. 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 Rule	06/00/06	

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

944. 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	11/23/05	70 FR 70765—70768
NPRM Comment Period End	01/23/06	
Final Rule	06/00/06	

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

945. 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.

HHS—HRSA

Final Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	08/12/03	68 FR 47923
NPRM Comment Period End	09/11/03	
Final Rule	06/00/06	

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
Email: jmorales@hrsa.gov

RIN: 0906–AA65

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

Priority: Other Significant

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	12/27/05	70 FR 76435—76436
NPRM Comment Period End	02/27/06	
Final Rule	06/00/06	

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)

Long-Term Actions

947. 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

948. 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) Health Resources and Services Administration (HRSA) — Completed Actions

949. PUBLIC HEALTH SERVICE (PHS) GRANT APPEALS PROCEDURE

Priority: Other Significant

CFR Citation: 42 CFR 50.402

Completed:

Reason	Date	FR Cite
Final Rule	12/23/05	70 FR 76174

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Gail Ellen Lipton
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Email: glipton@hrsa.gov

RIN: 0906–AA69

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

950. 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	04/00/06	
NPRM Comment Period End	06/00/06	
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

951. GRANTS FOR RESEARCH PROJECTS

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	05/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169

Email: jm40z@nih.gov

RIN: 0925–AA42

952. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–5a; 42 USC 287c–33; 42 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 (LRP) authorities. This action will include rescinding the current regulations at 42 CFR 68a and at 42 CFR 68c replaced by the new consolidated set of LRP regulations. This action will also include withdrawing the previously announced planned actions concerning NIH LRP authorities.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA43

953. 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	07/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
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RIN: 0925–AA44

954. 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	07/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA45

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 9660(a)

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	07/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA46

956. • ENDOWMENT PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 287c–31

CFR Citation: Not Yet Determined

Legal Deadline: None

HHS—NIH **Proposed Rule Stage**

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
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RIN: 0925–AA47

957. • UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH

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

Legal Authority: 42 USC 216; 42 USC 288–4

CFR Citation: 42 CFR 68b

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
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Email: jm40z@nih.gov

RIN: 0925–AA48

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

958. 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	05/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA28

959. 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	05/00/06	

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, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496–4606
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Email: jm40z@nih.gov

RIN: 0925–AA31

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

960. 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	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Julie A. Kaneshiro, Department of Health and Human Services, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852
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Fax: 301 402–2071
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RIN: 0940–AA11

Department of Health and Human Services (HHS) — Final Rule Stage
Office of Public Health and Science (OPHS)

961. 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	01/00/07	

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, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–6900
Fax: 301 402–2071

RIN: 0940–AA06

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

Long-Term Actions

962. 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 sec 163 of the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: 1) Persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to an allegation of research misconduct; and 2) persons who cooperate in good faith with an investigation of research misconduct.

Timetable:

Action	Date	FR Cite
NPRM	11/28/00	65 FR 70830
NPRM Comment Period End	01/29/01	
Final Action	08/00/07	

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, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 240 453–8200
Fax: 301 443–5351

Related RIN: Related to 0940–AA04

RIN: 0940–AA01

963. 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

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, 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

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

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 46

Completed:

Reason	Date	FR Cite
Technical Amendment	06/23/05	70 FR 36325

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome
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Fax: 301 402–2071

RIN: 0940–AA10

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

Prerule Stage

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

Priority: Other Significant

Legal Authority: None

CFR Citation: None

Legal Deadline: None

Abstract: This advance notice of proposed rulemaking explores the concept of ''paying for performance'' as a means of promoting better quality of care in Medicare fee-for-service payment systems. It explains the concept in general and reports on a number of activities of the Center for Medicare and Medicaid Services measuring and reporting and possible ways these results could be used to create financial incentives for high quality care. The notice seeks public comments on these ideas.

Timetable:

Action	Date	FR Cite
ANPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Gay W. Burton, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
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Teresa Clark, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
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RIN: 0938–AN91

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

Proposed Rule Stage

966. 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 our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

Timetable:

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

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
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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
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RIN: 0938–AG81

967. APPEALS OF CMS OR CONTRACTOR DETERMINATIONS WHEN A PROVIDER OR SUPPLIER FAILS TO MEET OR MAINTAIN 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	07/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: August Nemec, 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: 410 786–0612
Email: august.nemec@cms.hhs.gov

RIN: 0938–AI49

HHS—CMS **Proposed Rule Stage**

968. 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. In light of the fact that section 902 of MMA of 2003 requires the Secretary to issue regulations within 3 years, CMS is republishing the provisions of the final RHC rule as a proposed rule to provide the public with an opportunity to formally comment on the new policies established under the December 24, 2003 rule. In addition, we are proposing new policy revisions to the RHC and FQHC program to improve and strengthen this rural safety net benefit.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74792
Second NPRM	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: David Worgo, Health Insurance Specialist, Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–15–18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5919
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RIN: 0938–AJ17

969. 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 to 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	10/00/06	

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
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RIN: 0938–AL26

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

Priority: Other Significant. Major under 5 USC 801.

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	09/00/06	

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
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RIN: 0938–AL80

971. 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: Not Yet Determined

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 1996.

Timetable:

Action	Date	FR Cite
NPRM	01/00/07	

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

972. 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	10/00/06	

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
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RIN: 0938–AM87

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 108–173, MMA; Deficit Reduction Act of 2005, PL 109–171, sec 5101

CFR Citation: 42 CFR 414.200; 42 CFR 405.502(g); 42 CFR 424.57; 42 CFR 410.38

Legal Deadline: Final, Statutory, December 31, 2007.

Abstract: Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will also create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. This rule also incorporates provisions from section 5105 of the DRA of 2005, which concerns beneficiary ownership of certain DMEs. (The statute requires competitive bidding be implemented by 2007).

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, State

Agency Contact: Michael Keane, Health Policy Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4495
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RIN: 0938–AN14

974. 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	02/00/07	

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
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RIN: 0938–AN25

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

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

Legal Authority: Section 1893 (f) (2) of the Social Security Act added by Section 935 of the MMA

CFR Citation: 42 CFR 405

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 limit recoupment where a provider or supplier has appealed an overpayment determination until the reconsideration-level appeal is decided. The proposed rule also changes how interest is to be paid to a provider or supplier whose overpayment is reversed at the third or subsequent levels of administrative appeal or through judicial review.

Timetable:

Action	Date	FR Cite
NPRM	08/00/06	

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
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RIN: 0938–AN42

976. 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	12/00/06	

Regulatory Flexibility Analysis Required: No

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

977. 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	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Captain Arnold C. Farley, 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
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RIN: 0938–AN73

978. 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; Deficit Reduction Act of 2005, PL 109–171, sec 5101 to 5201

CFR Citation: 42 CFR 484

Legal Deadline: Final, Statutory, January 1, 2007, Effective Date.

Abstract: This notice sets 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. This rule would also incorporate provisions from the Deficit Reduction Act of 2005, which affects Home Health payments.

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Randy Throndset, Technical Advisor,, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C5–07–28, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AN76

979. 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: This proposed rule would require all long-term care facilities to be equipped with sprinkler systems. This proposed rule requests public comment, including comment on the duration of a phase-in period, to allow long-term care facilities to install such systems.

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

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
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RIN: 0938–AN79

980. 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: The proposed rule would clarify that Federal Financial Participation (FFP) is not available to States on behalf of Medicaid beneficiaries for Medicaid-covered services provided without charge (that is, free care) to individuals receiving the services. Free care means a particular service is available without charge to an individual who receives the service or to any third party on behalf of the individual.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

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
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RIN: 0938–AO07

981. • QUALITY STANDARDS FOR GENETIC TESTING (CMS–2121–P)

Priority: Other Significant

Legal Authority: Sec. 353 of Public Health Service Act (42 USC 263a)

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule would add to the Clinical Laboratory Improvement Amendment (CLIA) regulations a new specialty of genetic testing that will address recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC) and the Secretary's advisory committee for genetic testing.

Timetable:

Action	Date	FR Cite
NPRM	11/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Cecelia Hinkel, Health Insurance Specialist, Division of Laboratory Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid State Operations, Mailstop S2–12–25, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO09

982. 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	12/00/06	

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
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RIN: 0938–AO10

983. REVISIONS TO THE PAYMENT POLICIES OF AMBULANCE SERVICES UNDER THE FEE SCHEDULE FOR AMBULANCE SERVICES (CMS–1317–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sections 1834(1), and 1861 (s) (7) of the Social Security Act (the Act).

CFR Citation: 42 CFR 414.605; 42 CFR 412.64; 42 CFR 410.40; 42 CFR 410.12; 42 CFR 414.610; 42 CFR 414.615

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	06/00/06	

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

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 1886(d) of the Social Security Act;; Deficit Reduction Act of 2005, (PL 109–171), sec 5001 and 5003

CFR Citation: 42 CFR 405; 42 CFR 412; 42 CFR 413; 42 CFR 415; 42 CFR 419; 42 CFR 422; 42 CFR 485

Legal Deadline: NPRM, Statutory, April 1, 2006.
Final, Statutory, August 1, 2006.

Abstract: This rule proposes to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. The Addendum to this proposed rule proposes changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These proposed changes would apply to discharges occurring on or after 10/1/06. It also proposes rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits. This rule also incorporates provisions from sections 5001 and 5003 of the Deficit Reduction Act of 2005, which allows for hospital quality improvement and improvement to the Medicare dependent hospital program.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Tziv Hefter, Director, Division of Acute Care Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4487
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RIN: 0938–AO12

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: BBA; BBRA; BIPA; MMA; Deficit Reduction Act of 2005; (PL 109–171), sec 5103 and 5105

CFR Citation: 42 CFR 419 to 485

Legal Deadline: Final, Statutory, 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 Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2007. In addition, this rule would also propose additions to and deletions from the list of covered procedures for ASCs effective July 1, 2007. Further, this rule would also propose to revise the method by which Medicare sets payment rates for ASC facility services, and the list of covered ASC procedures effective January 1, 2008. This rule would incorporate provisions from the DRA of 2005, which limits payments for procedures in ASCs, and includes a 3-year phase-out of hold harmless for small rural hospitals under the prospective payment system for hospital outpatient department services.

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
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Email: rebecca.kane@cms.hhs.gov

Related RIN: Related to 0938–AO13, Related to 0938–AN23

RIN: 0938–AO15

986. 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;; Deficit Reduction Act of 2005; (PL 109–171), sec 5005

CFR Citation: 42 CFR 412

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

Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2007. This rule would also incorporate provisions from section 5055 of the Deficit Reduction Act of 2005, which extends the phase-in of the inpatient rehabilitation facility classification criteria.

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Bill Ullman, Center for Medicare Management, Chronic Care Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–06–24, 7500 Security Boulevard, Baltimore, MD 21244–1850
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Email: bill.ullman@cms.hhs.gov

RIN: 0938–AO16

987. 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	12/00/06	

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
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RIN: 0938–AO17

988. • BEST PRICE REQUIREMENTS FOR AUTHORIZED GENERIC DRUGS (CMS–2238–P)

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

Legal Authority: 42 USC 1396r.8; Deficit Reduction Act of 2005, PL 109–171, sec 6001 to 6003

CFR Citation: 42 CFR 447.535

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

Abstract: This proposed rule would require manufacturers to include best price in the calculation of rebates for authorized generic drugs, when such drugs are transferred or sold to a subsidiary or another unit within a company or to another entity that has been authorized (cross-licensed) to market and/or distribute authorized generic drug products. The proposed rule would define authorized generics as drugs marketed under the brand manufacturer's new drug application (NDA) and transferred or sold to a subsidiary or another unit within the brand company or to another entity that has been authorized (cross-licensed) to market and/or distribute authorized generic drug products. In addition, the rule would provide guidance to manufacturers regarding the appropriate treatment of authorized generic drugs under the Medicaid Drug Rebate program and would clarify CMS' policy on the issue.

Timetable:

Action	Date	FR Cite
NPRM	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Yolanda Lashawn Reese, Health Insurance Specialist, Division of Benefits and Coverage Policy Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop S2–06–15, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO20

989. 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: Final, Statutory, November 1, 2006, Comments to be addressed as part of final physician fee.

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	05/00/06	

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, Center for Medicare Management, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO22

990. 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; Deficit Reduction Act of 2005; (PL 109–171), sec 5102, 5104, 5106, 5107, 5112, 5113

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

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

Abstract: This rule would make changes affecting Medicare Part B payment.

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 & Medicaid Services, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
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Related RIN: Related to 0938–AN26, Related to 0938–AN05

RIN: 0938–AO24

991. 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 401.601, 42 CFR 401.607

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

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

Timetable:

Action	Date	FR Cite
NPRM	08/00/06	

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
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RIN: 0938–AO27

992. ● REDISTRIBUTION OF UNEXPENDED STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR 2004 (CMS–2241–NC)

Priority: Other Significant

Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); secs 2104(e) & (f) of the Social Security Act

CFR Citation: 42 CFR 457.600–630

Legal Deadline: None

Abstract: This notice announces the procedure for redistribution of States' unexpended FY 2004 allotments that remained at the end of FY 2004 to those States that fully expended the FY 2004 SCHIP allotment. These redistributed allotments will be available through the end of FY 2007.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Richard Strauss, Technical Director of Finance Systems & Budget Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid and State Operations, Mailstop, S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO28

993. ● PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2008: ANNUAL PAYMENT RATE UPDATES (CMS–1529–P)

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

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

CFR Citation: 42 CFR 412

Legal Deadline: Final, Statutory, Effective 07/01/2007.

Abstract: This rule proposes the annual payment rate update for the 2008

prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions on LTCH PPS policy for public comment.

Timetable:

Action	Date	FR Cite
NPRM	01/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Linda McKenna, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO30

994. ● HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2008 (CMS–1541–P)

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

Legal Authority: Social Security Act, sec 1895

CFR Citation: 42 CFR 484

Legal Deadline: Final, Statutory, January 1, 2008, Effective 01/01/08.

Abstract: This proposed rule would update the 60-day national episode rate and the national per-visit rate amounts under the Medicare Prospective Payment System for home health agencies, effective 1/1/08. This rule would also propose the first major refinement to the HH PPS since its implementation on 10/1/01.

Timetable:

Action	Date	FR Cite
NPRM	11/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Randy L. Throndset, Technical Advisor; Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–02–03, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO32

995. ● PROVIDER NOMINATION PROVISION (CMS–1331–P)

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

Legal Authority: Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), sec 911(d)(2)(A)

CFR Citation: 42 CFR 421.103 to 42 CFR 421.106 ; 42 CFR 421.114

Legal Deadline: None

Abstract: This regulation will allow the provider to utilize an intermediary to process submitted claims and bills. Groups and associations of providers may nominate organizations or agencies to serve as the intermediary for their group. If the provider would like to submit claims to an intermediary outside of the provider's service area, the provider has the right to nominate this outside intermediary to act on their behalf. CMS must approve these nominations based on a set of standards. If CMS determines an assignment or reassignment of a provider's intermediary will result in a more effective and efficient administration of the Medicare program, CMS can assign any intermediary to any provider. Effective 9/30/05, the provider nomination provision contained under title XVIII of the Social Security Act, section 1816, will expired. These provisions have been amended by the MMA. Section 911 (d) (2) (A) of the MMA requires the Secretary to enter into new agreements under section 1816 without regard to the provider nomination provisions and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 139u).

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Local

Agency Contact: Scott Sturiale, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S1–14–17, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO33

996. ● GYNECOLOGICAL CYTOLOGY PROFICIENCY TESTING REQUIREMENTS FOR LABORATORIES, INDIVIDUALS, AND PROFICIENCY TESTING PROGRAM APPROVALS (CMS–2252–P)

Priority: Other Significant

Legal Authority: 42 USC 263a, Clinical Laboratory Improvement Amendments of 1988; 42 USC 1395x secs 1861s(15) through 1861s(17)

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This proposed rule would revise certain participation requirements for clinical laboratories offering cytology services and individuals examining gynecological cytology specimens; and CMS-approval requirements for programs offering proficiency testing for gynecologic cytology under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 program. Evaluating the competency of each individual who examines gynecologic cytology specimens (pap smears) is required by Federal law and regulations. The cytology community, through professional organizations, is lobbying Congress to request a change in the statute to eliminate proficiency testing of individuals (pathologists and cytotechnologists) who examine pap smears. Failure to publish this rule timely could result in the failure to identify individuals who cannot competently and accurately examine pap smears, or failure to demonstrate a need for continual education. Identifying these individuals is essential in providing quality patient care.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Cheryl B Wiseman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare & Medicare Services, Mailstop, S2–12–25, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO34

997. ● SPECIAL MEDICARE GME AFFILLATIONS FOR A TEACHING HOSPITAL AFFECTED BY A DISASTER (CMS–1531–IFC)

Priority: Other Significant

Legal Authority: sec 1886(h)(d) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule will amend the current closed program regulations and Medicare affiliation agreement regulations to ameliorate the disruption in residency training caused by Hurricane Katrina and future emergency situations. Amendments to current closed program and Medicare affiliation agreement regulations will allow hospitals in areas affected by Hurricane Katrina and those hospitals adopting displaced residents, greater flexibility in maintaining Medicare funding during emergency situations. The amended regulations would go into effect during emergency situations as defined by the section 1135 emergency waiver invoked by the Secretary. Without changes to current regulations, adopting hospitals may be financially incapable of accepting displaced residents, home hospitals may have increased difficulty reopening residency training programs, and residents may be unable to continue with their planned residency training.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–07–07, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO35

998. ● STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) REDISTRIBUTION OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR 2003 (CMS–2235–NC)

Priority: Other Significant

Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); 2104 (e) & (f) of the Social Security Act, sec 6101 of DRA

CFR Citation: 42 CFR 457.600.630

Legal Deadline: None

Abstract: This notice announces the procedure for redistribution of States, unexpended FY 2003 allotments that remained at the end of FY 2005 to those States that fully expended the FY 2003 SCHIP allotment. It also announces the implementation of the section 6101 of the Deficit Reduction Act of 2006, which provides for additional allotments to eliminate States. SCHIP funding shortfalls in FY 2006. These redistributed allotments will be available through the end of FY 2006 (September 30, 2006).

Timetable:

Action	Date	FR Cite
Notice	05/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss, Senior Financial Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–13–07, 7500 Security Boulevard, Baltimore, MD 21244–1850
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Email: richard.strauss@cms.hhs.gov

RIN: 0938–AO38

999. ● INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR RATE YEAR BEGINNING JULY 1, 2007 (FY 2008) (CMS–1479–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: Final, Statutory, July 1, 2007, Effective 07/01/2007.

Abstract: This proposed 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	01/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Local

Federalism: Undetermined

Agency Contact: Janet Samen, Acting 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 21244–1850
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RIN: 0938–AO40

1000. ● NOTIFICATION PROCEDURES FOR HOSPITAL DISCHARGES (CMS–4105–F)

Priority: Other Significant

Legal Authority: 42 USC 1396ff

CFR Citation: 42 CFR 405; 42 CFR 412; 42 CFR 422; 42 CFR 489

Legal Deadline: Final, Judicial, November 28, 2006, Based on language in settlement agreement.

Abstract: This rule sets forth new requirements for hospital discharge notices under both original Medicare and the Medicare Advantage (MA) program. Notably, this rule requires hospitals to comply with a two-step notice process when discharging hospital inpatients that is similar to the notice requirements applicable to home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

Timetable:

Action	Date	FR Cite
NPRM	04/05/06	71 FR 17052

Action	Date	FR Cite
NPRM Comment Period End	06/05/06	
Final Action	04/00/09	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Eileen Zerhusen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Department of Health and Human Services, Mailstop S3–23–03, 7500 Security Boulevard, Baltimore, MD 21244
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Related RIN: Merged with 0938–AK48, Merged with 0938–AL67

RIN: 0938–AO41

1001. ● STATE OPTION TO ESTABLISH NON–EMERGENCY MEDICAL TRANSPORTATION PROGRAM (CMS–2234–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005 (PL 109–171), sec 6083

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, February 8, 2006.

Abstract: Enactment of section 6083 of the Deficit Reduction Act of 2005 (DRA amends section 1902(a)of the Social Security Act (the Act) by adding a new section 1902(a)(70) that provides States with the ability to establish, under the State plan, a non-emergency medical transportation (NEMT) brokerage program. Such a program may be managed through a contract with a broker(s), as a method of assuring NEMT services for beneficiaries who need access to medical care, but have no other means of transportation. A regulation is needed in order to implement this provision of the DRA.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jean Sheil, Director, Family and Children's Health Programs Group, CMSO, CMS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid Services Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO45

1002. ● HIGH RISK POOLS (CMS–2260–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005; (PL 109–171), sec 6202

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, March 31, 2006.

Abstract: Section 6202 of the Deficit Reduction Act of 2005 extends the funding and authorizes (H.R. 4519) and appropriates for FY 2006 $75 million for grants to help fund existing qualified State high risk pools and $15 million for grants to assist States to create and initially fund qualified high risk pools. The bill also authorizes appropriations of $75 million for each year FY 2007 through 2010. The section 6202 provision amendment to section 2745 establishes: (1) Seed grants to States for the creation and initial operation of a qualified high-risk pool for those States that do not have one, (2) grants to States to reimburse them for a percentage of losses incurred based on a methodology that allocates funding by 40 percent among all states, 30 percent to states based on their number of uninsured residents and 30 percent based on the number of people in State risk pools operating as an existing qualified high-risk pools during specified years and (3) bonus grants for supplemental consumer benefits. A regulation is needed in order to implement this provision of the DRA.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jean Sheil, Director, Family and Children's Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C2–01–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO46

1003. ● COST SHARING OPTIONS (CMS–2244–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005, PL 109–171

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, March 31, 2006, sec 6041 & 6042.
Final, Statutory, January 1, 2007, sec 6043.

Abstract: This rule would incorporate sections 6041, 6042, and 6043 of the Deficit Reduction Act of 2005 (DRA), which provides State Medicaid agencies with increased flexibility to implement premium and cost sharing requirements for certain Medicaid recipients. This authority is in addition to the current authority States already had under section 1916 of the Social Security Act to implement premiums and cost sharing. Sections 6041, 6042, and 6043 of the DRA provide States with additional State plan flexibility to implement alternative premiums for certain recipients and to implement alternative cost sharing for certain medical services, particularly non-preferred drugs and non-emergency care furnished in a hospital emergency department.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jean Sheil, Director, Family and Childrens Health Programs Group, Department of Health and

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RIN: 0938–AO47

1004. • BENCHMARK BENEFIT PACKAGE (CMS–2232–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005 ; sec 6044

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, March 31, 2006.

Abstract: Enactment of section 6044 of the Deficit Reduction Act of 2005 (DRA) responds to State requests for additional flexibility by providing States with new options. For non-disabled, non-elderly persons who are eligible for Medicaid, the DRA allows States to follow the lead established by SCHIP and provide more flexible benefit packages that are more comparable to those in the private sector. Benchmark coverage is one four types of coverage: Blue Cross/Blue Shield standard FEHBP coverage; State employee coverage; coverage of the largest commercial HMO in the states; and Secretary approved coverage. Children under age 19 enrolled in a benchmark plan will continue to receive EPSDT benefits through wrap-around coverage. A regulation is needed in order to implement this provision of the DRA.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jean Sheil, Director, Family and Children's Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, MailStop S2–01–16, 7500 Security Boulevard, Balitimore, MD 21244
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RIN: 0938–AO48

1005. • IMPROVED ENFORCEMENT OF DOCUMENTATION REQUIREMENTS (CMS–2257–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005 (PL 109–171), sec 6036

CFR Citation: Not Yet Determined

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

Abstract: Enactment of section 6036 of the Deficit Reduction Act of 2005 (DRA) requires that, effective July 1, 2006, all new applicants for Medicaid must, in addition to declaring that they are a citizen or national of the U.S. or an alien in a satisfactory immigration status, if claiming to be a citizen or national submit to the State evidence of citizenship. Since 1987, aliens claiming to be in a satisfactory immigration status have had to provide evidence of the claimed status and have that status verified with the Department of Homeland Security (previously the Immigration and Naturalization Service). A regulation is needed in order to implement this provision of the DRA.

Timetable:

Action	Date	FR Cite
NPRM	02/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jean Sheil, Director, Family and Children's Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid States Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–5957
Fax: 410 786–8534
Email: jean.sheil@cms.hhs.gov

RIN: 0938–AO51

1006. • SELF–DIRECTED PERSONAL ASSISTANCE SERVICES STATE PLAN OPTION (CMS–2229–P)

Priority: Other Significant

Legal Authority: Deficit Reduction Act of 2005; (PL 109–171), sec 6087

CFR Citation: Not Yet Determined

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

Abstract: The regulation is in support of the Deficit Reduction Act. Section 6087 allows a State to offer self-directed personal assistance services as a State Plan option and is intended to offer guidance to States on implementing the statutory provision.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, State

Agency Contact: Theresa Pratt, Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9499
Email: theresa.pratt@cms.hhs.gov

RIN: 0938–AO52

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

Final Rule Stage

1007. REQUIREMENTS FOR PROVIDERS AND SUPPLIERS TO ESTABLISH AND MAINTAIN MEDICARE ENROLLMENT (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 Sec 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 require 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

1008. 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	08/00/06	

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

1009. USE OF RESTRAINTS 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, and 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	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Thomas Shenk, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Benefits & Coverage Policy, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3295
Email: thomas.shenk@cms.hhs.gov

RIN: 0938–AJ96

1010. 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

1011. ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–F)

Priority: Other Significant

Legal Authority: Section 1923(a)(2)(D)of the Social Security Act

CFR Citation: 42 CFR 447; 42 CFR 455

Legal Deadline: Final, Statutory, December 8, 2003, Sec 1001(d) of MMA.

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

Timetable:

Action	Date	FR Cite
NPRM	08/26/05	70 FR 50262
Final Action	01/00/07	

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

1012. NONDISCRIMINATION IN HEALTH COVERAGE 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.

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	09/00/06	

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: david.mlawsky@cms.hhs.gov

Related RIN: Previously reported as 0938–AK19

RIN: 0938–AN29

1013. 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

Small Entities Affected: No

Government Levels Affected: None

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–AN30

1014. NATIONAL PLAN AND PROVIDER ENUMERATION SYSTEM (NPPES) DATA DISSEMINATION (CMS–6060–NC)

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 with comment period 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 describes the data dissemination strategy, processes, and any applicable charges for data.

Timetable:

Action	Date	FR Cite
Notice	08/00/06	

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

1015. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–IFC2)

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 interim final rule sets forth the State requirements to provide information to us for purposes of estimating improper payments in Medicaid and SCHIP. The Improper Payments Information Act of 2002 (IPIA) requires heads of Federal agencies to annually estimate and report to the Congress these estimates of improper payments for the programs they oversee and submit a report on actions the Agency is taking to reduce erroneous payments.

This interim final rule responds to the public comments on the October 5, 2005 interim final rule and sets forth State requirements for submitting claims and policies to the Federal contractor for purposes of conducting FFS and managed care reviews. This interim final rule also solicits comments on the State requirements for conducting eligibility reviews and estimating payment error rates due to errors in eligibility determinations.

Timetable:

Action	Date	FR Cite
NPRM	08/27/04	69 FR 52620
Interim Final Rule	10/05/05	70 FR 58260
Interim Final Rule	08/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Christine Jones, Division Director, 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: 410 786–3722
Email: christine.jones@cms.hhs.gov

Related RIN: Related to 0938–AM86

RIN: 0938–AN77

1016. INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR RY 2006 (CMS–1306–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 106–113, sec 124 BBRA

CFR Citation: 42 CFR 412

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

Abstract: This rule will update the Prospective Payment Rate for Medicare Inpatient Psychiatric Facilities for discharges occurring during the rate year beginning 7/1/06 to 6/30/07. This rule will update and revise the market basket and the use of new market area definitions.

Timetable:

Action	Date	FR Cite
NPRM	01/23/06	71 FR 3616
Final Action	05/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local

Agency Contact: Janet Samen, Acting 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: 410 786–9161
Email: janet.samen@cms.hhs.gov

RIN: 0938–AN82

1017. 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 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

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

1018. PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2007: ANNUAL PAYMENT RATE UPDATES (CMS–1485–F)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 412

Legal Deadline: Final, Statutory, Effective July 1, 2006.

Abstract: This rule proposes the annual payment rate update for the RY 2007 prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions in LTCH PPS policy for public comment.

Timetable:

Action	Date	FR Cite
NPRM	01/27/06	71 FR 4647
Final Action	05/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Linda McKenna, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4537
Email: linda.mckenna@cms.hhs.gov

RIN: 0938–AO06

1019. 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

Legal Authority: 42 USC 1395i–2(d)(2); 42 USC 1395i–2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 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
Notice	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–6390
Email: clare.mcfarland@cms.hhs.gov

RIN: 0938–AO18

1020. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2007 (CMS–8029–N)

Priority: Other Significant

Legal Authority: 42 USC 1395e–2(b)(2); Social Security Act, sec 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
Notice	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office the 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–AO19

1021. 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 State Children's Health Insurance Program (SCHIP) 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	08/00/06	

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

1022. 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, sec 1839; MMA, sec 629; MMA, sec 811; Deficit Reduction Act of 2005, PL 109–171, sec 5111

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. This notice will also incorporate provisions from section 5111 of the Deficit Reduction Act of 2005, which affects implementation of income income-related change in part B premium subsidy.

Timetable:

Action	Date	FR Cite
Notice	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Suzanne Codespote, Deputy Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Actuary, Mailstop N3–26–00, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7737
Email: suzanne.codespote@cms.hhs.gov

RIN: 0938–AO23

1023. 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 31, 2006, Notice must be published before 08/01/2006.

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

1024. HOSPICE WAGE INDEX FOR FY 2007 (CMS–1535–N)

Priority: Other Significant

Legal Authority: 1814(i) (1) of the Act; 1814(i) (2)

CFR Citation: 42 CFR 418

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, Chronic Care Policy Group, Mailstop C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–9462
Email: terri.deutsch@cms.hhs.gov

RIN: 0938–AO26

1025. ● STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS: FISCAL YEAR 2006 (CMS–2231–IFC)

Priority: Other Significant

Legal Authority: QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005, sec 101

CFR Citation: 42 CFR 433.10

Legal Deadline: Final, Statutory, September 30, 2006.

Abstract: On August 26, 2005 CMS published in the FR an interim final rule for determining the revised FY 2005 allotments, CMS-2210-IFC. When CMS published this in the FR, we did not reference the allotments for fiscal years after FY 2005, since the funding for the program ended with FY 2005. However, on October 20, 2005, Pub. L. 109-91 was enacted; section 101 of that law extended the QI program to FY 2006 and FY 2007. In particular, section 101 extended the qualifying individual program through September 30, 2007 with no change in funding; that is, under this legislation, $400 million per fiscal year is appropriated for each of FY 2006 and FY 2007. We are publishing this rule as an IFC

because of the need to notify individual States of the limitations on Federal funds for their Medicaid expenditures for payment of Medicare Part B premiums for QIs. Some States have experienced deficits in their current allotments that have caused them to deny benefits to eligible applicants, while other States project a surplus in their allotments. This rule permits redistribution of funds and will allow all eligible applicants to receive QI benefits during this calendar year.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Richard Strauss, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–22–25, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–2019
Email: richard.strauss@cms.hhs.gov

Related RIN: Related to 0938–AO04

RIN: 0938–AO31

1026. ● STATE HEALTH INSURANCE ASSISTANCE PROGRAM (SHIP) (CMS–4005–F)

Priority: Other Significant

Legal Authority: sec 4360 of OBRA 1990 (PL 101–508)

CFR Citation: 42 CFR 403

Legal Deadline: Final, Statutory, December 8, 2006, MMA Section 902.

Abstract: This rule adopts as final the provisions in the interim final regulation that published June 1, 2000, which explain the terms and conditions that apply to State grants for counseling and assistance to Medicare beneficiaries, and makes several minor technical clarifications.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Robert Adams, Director, Division of Community–Based Education and Assistance, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S1–20–21, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–8695
Fax: 410 786–8004
Email: robert.adams1 @ cms.hhs.gov

Related RIN: Related to 0938–AJ67

RIN: 0938–AO37

1027. ● FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2007 (CMS–1532–N)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 410

Legal Deadline: Final, Statutory, Effective 01/01/2007.

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(1) of the Social Security Act (effective 1/1/07).

Timetable:

Action	Date	FR Cite
Final Action	10/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Anne Tayloe, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AO39

1028. ● ADOPTION OF STANDARDS FOR THE E–PRESCRIBING AND THE MEDICARE PRESCRIPTION DRUG PROGRAM (CMS–0018–N)

Priority: Info./Admin./Other

Legal Authority: 42 USC 1395

CFR Citation: 42 CFR 423

Legal Deadline: None

Abstract: This notice permits the use of Version 8.1 of the NCPDP SCRIPT standard for e-prescribing transactions. Use of the standard is voluntary at this time. Version 5.0 of the NCPDP SCRIPT was adopted as an e-prescribing foundation standard 11/7/05. Voluntary use of Version 8.1 will be pilot tested with other available e-prescribing standards during the 2006 e-prescribing pilot project.

Timetable:

Action	Date	FR Cite
Final Action	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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Related RIN: Related to 0938–AN49

RIN: 0938–AO42

1029. ● GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUES UNDER THE NEWBORNS AND MOTHERS HEALTH PROTECTION ACT (CMS–4116–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 300gg to 300gg–63; 300gg–91 to 300gg–92

CFR Citation: 45 CFR 144; 45 CFR 146; 45 CFR 148

Legal Deadline: None

Abstract: This final rule sets forth the post-childbirth hospitalization length of stay requirements for group health plans and health insurance issuers that cover such length of stays.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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

HHS—CMS **Final Rule Stage**

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Related RIN: Related to 0938–AI17

RIN: 0938–AO43

1030. ● TARGETED CASE MANAGEMENT (CMS–2237–IFC)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005; (PL 109–171), sec 6052

CFR Citation: Not Yet Determined

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

Abstract: This regulation is required by the Deficit Reduction Act. Section 6052 clarifies what is reimbursable under the Medicaid case management and targeted case management benefit and is intended to offer guidance to States on implementing the statutory provision.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Theresa Pratt, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Secruity Boulevard, Baltimore, MD 21244
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RIN: 0938–AO50

1031. ● HOME AND COMMUNITY–BASED SERVICES (HCBS) STATE PLAN OPTION (CMS–2249–IFC)

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

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005; (PL 109–171), sec 6086

CFR Citation: Not Yet Determined

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

Abstract: The regulation would offer guidance to States on implementing the statutory provisions of sec 6086 of the Deficit Reduction Act

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Theresa Pratt, Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO53

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

Long-Term Actions

1032. 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 413, 42 CFR 414; 42 CFR 488 and CFR 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

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RIN: 0938–AG82

1033. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405, ; 42 CFR 482, and 42 CFR 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

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RIN: 0938–AH17

1034. 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 revises existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, and allow hospices greater flexibility in meeting quality standards. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

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

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RIN: 0938–AH27

1035. ELECTRONIC CLAIMS ATTACHMENTS STANDARDS (CMS–0050–F)

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 health care claims attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It will be used to transmit clinical or administrative data, in addition to the data contained in the claims standard, to help establish medical necessity or policy compliance 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 S2–25–17, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AK62

1036. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE AND RECERTIFICATION (CMS–3064–F) (SECTION 610 REVIEW)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1302 et al

CFR Citation: 42 CFR 413; 42 CFR 441; 42 CFR 486; 42 CFR 498

Legal Deadline: Final, Statutory, February 4, 2008, MMA sec 902.

Abstract: This rule establishes conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from Medicare and Medicaid for organ procurement costs, and to be designated by the Secretary for a specific geographic service area. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from two years to four years and to promulgate new performance standards for OPOs.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/01	66 FR 67109
NPRM	02/04/05	70 FR 6086
Final Rule	02/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director, Division of Acute Care Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare and Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850
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RIN: 0938–AK81

1037. 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

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RIN: 0938–AL54

1038. 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.

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RIN: 0938–AL88

1039. 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, August 26, 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
Interim Final Rule	08/26/05	70 FR 50214
Final Action	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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Related RIN: Related to 0938–AK69

RIN: 0938–AM73

1040. 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 must meet these final requirements to participate in Medicare and Medicaid programs. They must establish and maintain policies and procedures that will ensure their hospital will 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.

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RIN: 0938–AM88

1041. 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, July 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. This rule also finalizes an August 4, 2005, rule that outlines the process for health care providers to follow if they wish CMS to request a waiver of exclusion on their behalf.

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
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Related RIN: Related to 0938–AN48

RIN: 0938–AM98

1042. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES (CMS–6024–F)

Priority: Other Significant

Legal Authority: Sec 938 of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 410

Legal Deadline: Final, Statutory, June 8, 2005.

Abstract: Section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary to establish a process for Medicare contractors to provide eligible participating physicians and beneficiaries with a determination of coverage relating to medical necessity for certain physicians' services before the services are furnished. This rule is intended to afford the physician and beneficiary the opportunity to know the financial liability for a service before expenses are incurred. This final rule establishes reasonable limits on physicians' services for which a prior determination of coverage may be requested and discusses generally our plans for establishing the procedures by which those determinations may be obtained.

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

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RIN: 0938–AN10

1043. MEDICARE SECONDARY PAYER AMENDMENTS (CMS–6272–F)

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: This final rule implements amendments to the Medicare Secondary Payer (MSP) provisions under Title III of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The MMA amendments clarify the MSP provisions regarding the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare.

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/24/06	71 FR 9466
Final Action	02/00/09	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0938–AN27

1044. RANDOM PREPAYMENT REVIEW (CMS–6022–F)

Priority: Other Significant

Legal Authority: Sec 934 of the MMA

CFR Citation: 42 CFR 421

Legal Deadline: Final, Statutory, October 7, 2008, MMA sec. 902.

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, 2003. 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

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RIN: 0938–AN31

1045. 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 to 42 CFR 483; 42 CFR 485

Legal Deadline: Final, Statutory, March 25, 2008, MMA sec. 902.

Abstract: This final rule amends the fire safety standards 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). The LSC change allows facilities to place alcohol-based hand rub dispensers in exit corridors under certain conditions. 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 Comment	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.

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RIN: 0938–AN36

1046. MEDICARE PART B COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–F)

Priority: Other Significant

Legal Authority: MMA of 2003, sec 303(d)

CFR Citation: 42 CFR 414

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

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 July 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

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RIN: 0938–AN58

1047. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; E–PRESCRIBING EXCEPTIONS (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
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RIN: 0938–AN69

1048. 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: 42 CFR 400 and 421

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

HHS—CMS **Long-Term Actions**

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Related to 0938–AI09

RIN: 0938–AN72

1049. HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM; LOAN PROGRAM FOR QUALIFYING HOSPITALS ENGAGED IN CANCER–RELATED HEALTH CARE (CMS–1287–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 108–173 sec 1016

CFR Citation: 42 CFR 505

Legal Deadline: Final, Statutory, September 30, 2008, MMA sec 902.

Abstract: This rule will establish a loan program to improve certain hospital infrastructure, including capital improvement. To receive assistance, the applicant will 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. This rule will also establish the conditions under which these loans may be forgiven. No later than 4 years after enactment, the Secretary must submit a report to the 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
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Related RIN: Related to 0938–AN93

RIN: 0938–AO03

1050. • EXTENDING SUNSET DATE FOR THE INTERIM FINAL REGULATION ON MENTAL HEALTH PARITY (CMS–4094–F4)

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

Legal Authority: 42 USC 300gg to 300gg63; 300gg–91 to 300gg–92

CFR Citation: 45 CFR 146

Legal Deadline: None

Abstract: This amendment extends the sunset date of the regulation to December 31, 2006, consistent with a recent extension of the sunset date of the statute this regulation implements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/22/05	70 FR 42276
Final Rule	07/00/08	

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, C3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
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Email: david.mlawsky@cms.hhs.gov

Related RIN: Related to 0938–AN80

RIN: 0938–AO36

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

Completed Actions

1051. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIER (CMS–6017–P)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 160; 45 CFR 162

Completed:

Reason	Date	FR Cite
Withdrawn	02/22/06	

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
Phone: 410 786–7448

RIN: 0938–AH87

1052. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (CMS–3006–F)

Priority: Other Significant

CFR Citation: 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68

Completed:

Reason	Date	FR Cite
Final Rule	12/23/05	70 FR 76199

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Local, State, Tribal

Agency Contact: Rebecca Donnay
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RIN: 0938–AJ10

1053. HOSPICE CARE AMENDMENTS (CMS–1022–F)

Priority: Other Significant

CFR Citation: 42 CFR 418

Completed:

Reason	Date	FR Cite
Final Rule	11/22/05	70 FR 70532

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Linda Smith
Phone: 410 786–5650

Related RIN: Previously reported as 0938–AH73

RIN: 0938–AJ36

1054. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS–0008–F)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Rule	11/25/05	70 FR 71008

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Stewart Streimer
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RIN: 0938–AM22

1055. REQUIREMENTS FOR LONG–TERM CARE FACILITIES; NURSING SERVICES; POSTING OF NURSE STAFFING INFORMATION (CMS–3121–F)

Priority: Other Significant

CFR Citation: 42 CFR 483

Completed:

Reason	Date	FR Cite
Final Rule	10/28/05	70 FR 62065

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker
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RIN: 0938–AM55

1056. CONDITIONS FOR COVERAGE FOR PAYMENT OF POWER MOBILITY DEVICES, INCLUDING POWERED WHEELCHAIRS AND POWER–OPERATED VEHICLES (CMS–3017–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 410.38

Completed:

Reason	Date	FR Cite
Final Rule	04/05/06	71 FR 17021

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Karen Daily
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RIN: 0938–AM74

1057. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

Priority: Other Significant

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

Completed:

Reason	Date	FR Cite
Final Rule	01/27/06	71 FR 4518

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joel Kaiser
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Related RIN: Related to 0938–AL27

RIN: 0938–AN02

1058. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–F)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	02/09/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dana Burley
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Related RIN: Merged with 0938–AO15

RIN: 0938–AN23

1059. PAYMENT FOR CLINICAL LABORATORY TESTS (CMS–1494–P)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	02/08/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anita Greenberg
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Related RIN: Merged with 0938–AO24

RIN: 0938–AN26

1060. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–4091–F)

Priority: Other Significant

CFR Citation: 45 CFR 150.101 to 150.465

Completed:

Reason	Date	FR Cite
Final Rule	11/25/05	70 FR 71020

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: David Mlawsky
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Email: david.mlawsky@cms.hhs.gov

RIN: 0938–AN35

1061. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR CALENDAR YEAR 2006 (CMS–1301–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 484

Completed:

Reason	Date	FR Cite
Final Rule	11/09/05	70 FR 68131

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Randy Throndset
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RIN: 0938–AN44

1062. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2006 PAYMENT RATES (CMS–1501–FC)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 419; 42 CFR 485

Completed:

Reason	Date	FR Cite
Final Action	11/10/05	70 FR 68515

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Rebecca Kane
Phone: 410 786–1589
Email: rebecca.kane@cms.hhs.gov

RIN: 0938–AN46

1063. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6019–F)

Priority: Other Significant

CFR Citation: 42 CFR 402.400

Completed:

Reason	Date	FR Cite
Withdrawn	02/06/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Cohen
Phone: 410 786–3349
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Related RIN: Merged with 0938–AM98

RIN: 0938–AN48

1064. ELECTRONIC PRESCRIBING STANDARDS (CMS–0011–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Rule	11/07/05	70 FR 67567

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
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RIN: 0938–AN49

1065. GROUP MARKET HEALTH INSURANCE REFORM: GUARANTEED AVAILABILITY, GUARANTEED RENEWABILITY, DISCLOSURES TO SMALL EMPLOYERS (CMS–4102–F)

Priority: Other Significant

CFR Citation: 45 CFR 146.150; 45 CFR 146.152; 45 CFR 146.160

Completed:

Reason	Date	FR Cite
Withdrawn	02/08/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky
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Related RIN: Related to 0938–AI08

RIN: 0938–AN60

1066. 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.

CFR Citation: 42 CFR 148.11; 42 CFR 148.102; 42 CFR 148.103; 42 CFR 148.122; 42 CFR 148.1

Completed:

Reason	Date	FR Cite
Withdrawn	02/08/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky
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Related RIN: Related to 0938–AI08

RIN: 0938–AN61

1067. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)

Priority: Other Significant

CFR Citation: 42 CFR 412 to 413; 42 CFR 1902

Completed:

Reason	Date	FR Cite
Notice	02/10/06	71 FR 6991

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Jill Keplinger
Phone: 410 786–4550
Email: jill.keplinger@cms.hhs.gov

Related RIN: Related to 0938–AK02

RIN: 0938–AN75

1068. APPLICATION OF INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES (OTHER THAN PHYSICIAN SERVICES) (CMS–1908–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 405

Completed:

Reason	Date	FR Cite
Final Rule	12/13/05	70 FR 73623

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bill Long
Phone: 410 786–5655
Email: bill.long@cms.hhs.gov

RIN: 0938–AN81

1069. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006 (CMS–1502–FC)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 410; 42 CFR 414

Completed:

Reason	Date	FR Cite
Final Rule	11/21/05	70 FR 70116
Comment Period End	01/03/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal

Agency Contact: Diane Milstead
Phone: 410 786–3355

Related RIN: Related to 0938–AN04

RIN: 0938–AN84

1070. ELECTRONIC SUBMISSION OF COST REPORTS (CMS–1199–F)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	02/10/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Darryl E. Simms
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Related RIN: Related to 0938–AL51

RIN: 0938–AN87

1071. LOAN FORGIVENESS CRITERIA FOR THE HEALTH CARE INFRASTRUCTURE LOAN PROGRAM (CMS–1320–F)

Priority: Other Significant

CFR Citation: 42 CFR 505

Completed:

Reason	Date	FR Cite
Withdrawn	02/08/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter
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Related RIN: Merged with 0938–AO03

RIN: 0938–AN93

1072. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2006 (CMS–1294–N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 410

Completed:

Reason	Date	FR Cite
Notice	11/25/05	70 FR 71163

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anne Tayloe
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RIN: 0938–AN99

1073. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS (CMS–2210–F)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Comment Period End	10/25/05	
Withdrawn	02/08/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss
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Related RIN: Related to 0938–AO31

RIN: 0938–AO04

1074. 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

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	12/23/05	70 FR 76287

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Cheryl Ford
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RIN: 0938–AO05

1075. 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.

CFR Citation: 42 FR 416

Completed:

Reason	Date	FR Cite
Withdrawn	02/10/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: Federal

Agency Contact: Joan H. Sanow
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Related RIN: Merged with 0938–AO15

RIN: 0938–AO13

1076. 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

CFR Citation: 42 CFR 403

Completed:

Reason	Date	FR Cite
Withdrawn	02/08/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Janice A. Graham
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Related RIN: Related to 0938–AM90

RIN: 0938–AO14

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

Proposed Rule Stage

1077. 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	09/00/06	

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, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 690–5841

RIN: 0970–AC07

1078. 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	09/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Grant Collins, Deputy Director, Office of Family Assistance, 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

1079. 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	07/00/06	

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
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RIN: 0970–AC20

1080. 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	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Director, Division of Policy, Children's Bureau, ACYF/ACF/HHS, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW, Washington, DC 20447
Phone: 202 401–5789
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov

RIN: 0970–AC21

1081. MEDICAL SUPPORT

Priority: Other Significant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 302 to 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	07/00/06	

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
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RIN: 0970–AC22

HHS—ACF

Proposed Rule Stage

1082. 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 (Pub. L. 108-145).

Timetable:

Action	Date	FR Cite
NPRM	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Director, Division of Policy, Children's Bureau, ACYF/ACF/HHS, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW, Washington, DC 20447
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RIN: 0970–AC23

1083. • CHILD SUPPORT PROVISIONS OF THE DEFICIT REDUCTION ACT

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The proposed rule would implement provisions of the Deficit Reduction Act of 2005 related to review and adjustment of child support orders, Federal financial participation in the program, and fees for program services.

Timetable:

Action	Date	FR Cite
NPRM	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Federal, 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.hhs.gov

RIN: 0970–AC24

1084. • PRIVATIZING FUNCTIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 1355 to 1356

Legal Deadline: None

Abstract: Proposed rule would address States' ability to delegate decision-making authority to private agencies performing administration functions and the availability of funding for training funds under the Foster Care program.

Timetable:

Action	Date	FR Cite
NPRM	07/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Director, Division of Policy, Children's Bureau, ACYF/ACF/HHS, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW, Washington, DC 20447
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RIN: 0970–AC25

1085. • HEAD START TRANSPORTATION

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1310

Legal Deadline: None

Abstract: This proposed rule will address waiver for Head Start grantees from certain transportation requirements related to child safety restraint systems and bus monitors.

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Craig Turner, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
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RIN: 0970–AC26

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

Final Rule Stage

1086. 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

HHS—ACF **Final Rule Stage**

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	10/14/05	70 FR 60038
NPRM Comment Period End	12/13/05	
Final Action	11/00/06	

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
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RIN: 0970–AC01

1087. 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	10/00/06	

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

1088. 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 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 of review.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/04	69 FR 77659
Final Action	07/00/06	

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
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RIN: 0970–AC19

1089. ● TANF WORK PROVISIONS OF THE DEFICIT REDUCTION ACT

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: Not Yet Determined

Legal Deadline: Other, Statutory, June 30, 2006, Interim Final Rule.

Abstract: Interim final rule will be issued to address new work requirements associated with the Deficit Reduction Act of 2005, including what counts as work activities, reporting and verifying hours of work and who should be included in the work participation rate.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State, Tribal

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RIN: 0970–AC27

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

Completed Actions

1090. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

Priority: Other Significant

CFR Citation: 45 CFR 1356.60(c)

Completed:

Reason	Date	FR Cite
Withdrawn	02/17/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

HHS—ACF

Completed Actions

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RIN: 0970–AC14

1091. HEAD START TRANSPORTATION

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

CFR Citation: 45 CFR 1310

Completed:

Reason	Date	FR Cite
Withdrawn	02/17/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0970–AC16

[FR Doc. 06–2942 Filed 04–21–06; 8:45 am]
BILLING CODE 4150–24–S