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Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS

ACTION: Semiannual Regulatory Agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the following inventory of the rulemaking actions under development by the Department. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration. Members of the public wishing to communicate to the Department their views on the potential rulemakings 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 these planned rulemakings. Comments may be directed to the Agency officials cited in each of the summaries, or, if early attention at the Secretary's level is seen as required, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

Dated: March 27, 2007.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
774	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
775	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
776	Safe Harbor for Waiver of Beneficiary Co-insurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
777	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23
778	Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Under the Anti-Kickback Statute	0991–AB38

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
779	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
780	Debt Collection	0991–AB18
781	Salary Offset	0991–AB19

HHS

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
782	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
783	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
784	Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations	0920–AA14
785	Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices	0920–AA16

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
786	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04
787	Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices	0920–AA10
788	Amendments to Requirements for Coal Mine Dust Personal Sampler Units	0920–AA18
789	Medical Examination of Aliens	0920–AA20

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
790	Control of Communicable Diseases, Interstate and Foreign Quarantine	0920–AA12
791	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
792	Interstate Shipment of Etiologic Agents	0920–AA19

Centers for Disease Control and Prevention—Long-Term Actions

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

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
794	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
795	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
796	Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use: Required Alcohol Warning **(Section 610 Review)**	0910–AF74
797	Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients **(Section 610 Review)**	0910–AF75
798	Medical Devices: Classification/Reclassification; Restricted Devices; Analyte Specific Reagents **(Section 610 Review)**	0910–AF76
799	Amended Economic Impact Analysis of Final Rule on User Labeling on Natural Rubber-Containing Medical Device **(Section 610 Review)**	0910–AF77
800	Financial Disclosure by Clinical Investigators **(Section 610 Review)**	0910–AF79
801	Beverages: Bottled Water **(Section 610 Review)**	0910–AF80
802	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
803	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen and Separate Classification of Oxygen Conserving Devices	0910–AC30
804	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
805	Reporting Information Regarding Falsification of Data	0910–AC59
806	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
807	Blood Initiative—Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
808	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
809	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
810	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
811	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
812	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
813	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
814	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
815	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
816	Import Tolerances for Unapproved New Animal Drugs	0910–AF78
817	Current Good Manufacturing Practice for Combination Products	0910–AF81
818	Postmarket Safety Reporting for Combination Products	0910–AF82
819	Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma	0910–AF84
820	Revision of the Requirements for Live Vaccine Processing	0910–AF85
821	Medical Device Reporting; Electronic Submission Requirements	0910–AF86
822	Laser Products; Amendment to Performance Standard	0910–AF87
823	Electronic Registration and Listing for Devices	0910–AF88
824	Regulations on Fixed-Combination Drug Products	0910–AF89
825	Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Epinephrine]	0910–AF92
826	Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn, and Nedocromil]	0910–AF93
827	Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients	0910–AF95
828	Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements	0910–AF96
829	Proposed Revisions to 21 CFR Parts 314 and 320 To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes	0910–AF97

HHS

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
830	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
831	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
832	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications	0910–AB34
833	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
834	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88
835	Additional Safeguards for Children in Clinical Investigations	0910–AC07
836	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
837	Institutional Review Boards: Registration Requirements	0910–AC17
838	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
839	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
840	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
841	Charging for Investigational Drugs	0910–AF13
842	Expanded Access to Investigational Drugs for Treatment Use	0910–AF14
843	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
844	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
845	Blood Initiative—Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment	0910–AF26
846	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
847	Infant Formula Quality Factors	0910–AF28
848	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
849	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
850	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
851	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
852	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
853	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
854	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
855	Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy	0910–AF46
856	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
857	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
858	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
859	Designation of New Animal Drugs for Minor Uses or Minor Species	0910–AF60
860	Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	0910–AF67
861	Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile	0910–AF90
862	Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling	0910–AF98
863	Over-the-Counter (OTC) Drug Review—Acne Drug Products Containing Benzoyl Peroxide	0910–AG00

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
864	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
865	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
866	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
867	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
868	Food Standards: General Principles and Food Standards Modernization	0910–AC54

HHS

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

Sequence Number	Title	Regulation Identifier Number
869	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
870	Health Claims	0910–AF09
871	Cochineal Extract and Carmine Label Declaration	0910–AF12
872	Obstetrical and Gynecological Devices; Designation of Special Control for Condoms and Condoms With Spermicidal Lubricant	0910–AF21
873	Food Labeling; Prominence of Calories	0910–AF22
874	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
875	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
876	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
877	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
878	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
879	Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants	0910–AF54
880	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
881	Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin **(Section 610 Review)**	0910–AF99

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
882	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
883	Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria	0910–AC32
884	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
885	Over-the-Counter (OTC) Drug Review—Dandruff, Seborrheic Dermatitis, and Psoriasis Products	0910–AF49
886	Supplements and Other Changes to Approved New Animal Drug Applications	0910–AF59
887	Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation	0910–AF65
888	Over-the-Counter (OTC) Drug Review—Multiple Drug Products	0910–AG01

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
889	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
890	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57
891	Requirements Establishing a Limitation on Administrative Expenses; Ryan White CARE Act Title IV Grants for Coordinated Services and Access to Research	0906–AA65
892	National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy	0906–AA68

HHS

Health Resources and Services Administration—Long-Term Actions

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

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
895	Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA62
896	Healthy Tomorrow's Partnership for Children (HTPC) Program	0906–AA70

Indian Health Service—Final Rule Stage

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

Agency for Healthcare Research and Quality—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
898	Patient Safety and Quality Improvement Act of 2005 Rules	0919–AA01

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
899	Grants for Research Projects	0925–AA42
900	National Institutes of Health Loan Repayment Programs	0925–AA43
901	National Library of Medicine Training Grants	0925–AA44
902	Minority Biomedical Research Support Program	0925–AA45
903	National Institute of Environmental Health Sciences Hazardous Substances Basic Research and Training Grants	0925–AA46
904	Endowment Program	0925–AA47
905	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health	0925–AA48
906	NIH Training Grants	0925–AA49
907	NIH Center Grants	0925–AA50

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
908	Standards for a National Chimpanzee Sanctuary System	0925–AA31

HHS

National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identifier Number
909	NIH Construction Grant	0925–AA51

Office of Public Health and Science—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
910	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
911	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940–AA01
912	Human Subjects Protection Regulations: Training and Ed. Requirements for Institutional Officials, Institutional Review Board Members and Staff, Human Protections Administrators, and Investigators	0940–AA08
913	Human Subjects Protection Regulations: Additional Protections for Adult Individuals With Impaired Decision-making Capacity	0940–AA11

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
914	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
915	Appeals of CMS or Contractor Determinations When a Provider or Supplier Fails To Meet the Requirements for Medicare Billing (CMS-6003-P2)	0938–AI49
916	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)	0938–AJ17
917	Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938–AL26
918	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938–AL80
919	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938–AM50
920	Revisions to HIPAA Code Sets (CMS-0013-P)	0938–AN25
921	National Plan and Provider Enumeration System (NPPES) Data Dissemination (CMS-6060-NC)	0938–AN71
922	Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (CMS-3156-P)	0938–AN73
923	Payments for Service Provided Without Charge (CMS-2489-P)	0938–AO07
924	Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)	0938–AO10
925	Outpatient Hospital Services and Rural Health Clinic Services Amendment (CMS-2213-P)	0938–AO17
926	Redistribution of Unexpended State Children's Health Insurance Program (SCHIP) Funds From the Appropriation for Fiscal Year 2004 (CMS-2241-NC)	0938–AO28
927	Home Health Prospective Payment System Refinements and Rate Update for Calendar Year 2008 (CMS-1541-P)	0938–AO32
928	Gynecological Cytology Proficiency Testing Requirements for Laboratories, Individuals, and Proficiency Testing Program Approvals (CMS-2252-P)	0938–AO34
929	State Option To Establish Non-Emergency Medical Transportation Program (CMS-2234-P)	0938–AO45
930	Premiums and Cost Sharing (CMS-2244-P)	0938–AO47
931	State Flexibility for Medicaid Benefit Packages (CMS-2232-P)	0938–AO48
932	Self-Directed Personal Assistance Services State Plan Option (CMS-2229-P)	0938–AO52
933	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-P)	0938–AO53
934	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2008 (CMS-1551-P)	0938–AO63
935	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2008 (CMS-1545-P)	0938–AO64
936	Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Payment Under Part B for CY 2008 (CMS-1385-P)	0938–AO65
937	Standards for E-Prescribing Under Medicare Part D (CMS-0016-P)	0938–AO66

HHS

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

Sequence Number	Title	Regulation Identifier Number
938	Exemption of Privacy Act Disclosure of Certain Investigative Materials (CMS-0029-P)	0938–AO69
939	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates (CMS-1533-P)	0938–AO70
940	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Calendar Year 2008 Payment Rates (CMS-1392-P)	0938–AO71
941	Hospice Wage Index for FY 2008 (CMS-1539-P)	0938–AO72
942	Policy and Technical Changes to the Medicare Prescription Drug Benefit (CMS-4130-P)	0938–AO74
943	Special Enrollment Period and Medicare Premium Changes (CMS-4129-P)	0938–AO77
944	Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes (CMS-4124-P)	0938–AO78
945	Rehabilitation Services: State Plan Option (CMS-2261-P)	0938–AO81
946	Waiver of Disapproval of Nurse Aide Training Program in Certain Cases and Nurse Aide Petition for Removal of Information for Singular Finding of Neglect (CMS-2266-P)	0938–AO82
947	Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-P)	0938–AO84
948	Children of State Employees: Premium Assistance (CMS-2148-P)	0938–AO86
949	Application of Certain Part 405 Appeals Provisions to the Part 423 Medicare Prescription Drug Appeals Process (CMS-4127-P)	0938–AO87
950	Limitation on Contractor Liability (CMS-2264-P)	0938–AO88
951	Health Insurance Reform: Remote Security Standards (CMS-0020-P)	0938–AO89
952	Establishing Additional Provider and Supplier Requirements for Enrollment Standards and Related Issues (CMS-6036-P)	0938–AO90
953	Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS-3178-P)	0938–AO91
954	Inpatient Psychiatric Facility Prospective Payment System—Update for Rate Year Beginning July 1, 2008 (RY 2009) (CMS-1401-P)	0938–AO92
955	Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-P)	0938–AO94

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
956	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) **(Section 610 Review)**	0938–AG82
957	Hospital Conditions of Participation: Laboratory Services (CMS-3014-IFC) **(Section 610 Review)**	0938–AJ29
958	Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938–AJ96
959	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (CMS-1810-RCN)	0938–AK67
960	Provider Reimbursement Determinations and Appeals (CMS-1727-F)	0938–AL54
961	Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)	0938–AM73
962	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-F)	0938–AM98
963	Enhanced DSH Treatment for Certain Hospitals (CMS-2198-F)	0938–AN09
964	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-F)	0938–AN14
965	Medicaid Prescription Drugs—Average Manufacturer Price (CMS-2238-F)	0938–AO20
966	Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates and Policy Changes(CMS-1529-F)	0938–AO30
967	Inpatient Psychiatric Facility Prospective Payment System—Update for Rate Year 2008 (CMS-1479-N)	0938–AO40
968	Group Health Plans and Health Insurance Issues Under the Newborns and Mothers Health Protection Act (CMS-4116-F)	0938–AO43
969	High Risk Pools (CMS-2260-IFC)	0938–AO46
970	Targeted Case Management (CMS-2237-IFC)	0938–AO50
971	Citizenship Documentation Requirements (CMS-2257-F)	0938–AO51
972	Cost Limits for Governmentally-Operated Providers (CMS-2258-F) **(Section 610 Review)**	0938–AO57
973	Inpatient Hospital Deductible and Hospital and Extended Care Services Co-insurance Amounts for CY 2008 (CMS-8032-N)	0938–AO61
974	Part A Premiums for CY 2008 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8031-N)	0938–AO62
975	Part B Monthly Actuarial Rates and Premium Rates Beginning January 1, 2008 (CMS-8033-N)	0938–AO68

HHS

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

Sequence Number	Title	Regulation Identifier Number
976	Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-F)	0938–AO73
977	Fiscal Year 2008 SCHIP Allotments (CMS-2262-N)	0938–AO76
978	Health Care-Related Tax Revisions (CMS-2275-P)	0938–AO80
979	Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F5)	0938–AO83
980	Fee Schedule for Payment of Ambulance Services—Update for CY 2008 (CMS-1552-N)	0938–AO85

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
981	Hospice Care Conditions of Participation (CMS-3844-F) **(Section 610 Review)**	0938–AH27
982	Electronic Claims Attachments Standards (CMS-0050-F)	0938–AK62
983	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)	0938–AL88
984	Prior Determination Process for Certain Items and Services (CMS-6024-F)	0938–AN10
985	Medicare Secondary Payer Amendments (CMS-6272-F)	0938–AN27
986	Termination of Non-Random Prepayment Review (CMS-6022-F)	0938–AN31
987	Limitation on Recoupment of Provider and Supplier Overpayments (CMS-6025-F)	0938–AN42
988	Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F)	0938–AN58
989	Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements (CMS-6030-F)	0938–AN72
990	Payment Error Rate Measurement (PERM) Program (CMS-6026-F)	0938–AN77
991	Fire Safety Requirements for Long-Term Care Facilities: Sprinkler Systems (CMS-3191-F)	0938–AN79
992	Use of Repayment Plans (CMS-6032-F)	0938–AO27
993	Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1) (CMS-0018-F)	0938–AO42
994	Prohibition of Mid-Year Benefit Enhancements for Medicare Advantage Organizations Offering Plans in Calendar Year 2007 and Subsequent Calendar Years (CMS-4121-F)	0938–AO54
995	Medicare Part D Data (CMS-4119-F)	0938–AO58

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
996	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-F)	0938–AH17
997	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938–AM87
998	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
999	Nondiscrimination in Health Coverage in the Group Market (CMS-4081-F)	0938–AN29
1000	Hospital Conditions of Participation: Patients' Rights (CMS-3018-F)	0938–AN30
1001	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-F)	0938–AN83
1002	Medicare Graduate Medical Education Affiliation Provisions for Teaching Hospitals in Certain Emergency Situations (CMS-1531-F2)	0938–AO35
1003	Notification Procedures for Hospital Discharges (CMS-4105-F)	0938–AO41

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1004	Developmental Disabilities and Bill of Rights Act	0970–AC07
1005	Care and Placement of Unaccompanied Alien Children	0970–AC20

HHS

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

Sequence Number	Title	Regulation Identifier Number
1006	Adoption and Foster Care Analysis and Reporting System	0970–AC23
1007	Privatizing Functions	0970–AC25
1008	Limitation on Use of Funds Made Available To Monitor and Combat Trafficking in Persons	0970–AC28
1009	Child Care and Development Fund Error Rate Reporting	0970–AC29
1010	Abstinence Education	0970–AC30

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1011	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01
1012	Cost Allocation Methodology Applicable to the Temporary Assistance for Needy Families Program	0970–AC15
1013	Child Care and Development Fund State Match Provisions	0970–AC18
1014	Chafee National Youth in Transition Database	0970–AC21
1015	Medical Support	0970–AC22
1016	Child Support Provisions of the Deficit Reduction Act	0970–AC24
1017	TANF Work Provisions of the Deficit Reduction Act	0970–AC27

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1018	Head Start Transportation	0970–AC26

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

Proposed Rule Stage

774. 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''; date various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e-mail communications.

Timetable:

Action	Date	FR Cite
NPRM	10/00/07	
NPRM Comment Period End	12/00/07	

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)

775. 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	10/00/07	

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

776. SAFE HARBOR FOR WAIVER OF BENEFICIARY CO–INSURANCE 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	10/00/07	

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

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule would amend the Office of Inspector General's exclusion regulations at 42 CFR part 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	10/00/07	

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

778. 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 exists.

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	09/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

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

RIN: 0991–AB38

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

Long-Term Actions

779. 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
Final Action	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

780. DEBT COLLECTION

Priority: Other Significant

CFR Citation: 45 CFR 30

Completed:

Reason	Date	FR Cite
Final Action	03/08/07	72 FR 10404

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jeffrey S. Davis
Phone: 202 619–0150

RIN: 0991–AB18

781. SALARY OFFSET

Priority: Other Significant

CFR Citation: 5 CFR 550; 45 CFR 33

Completed:

Reason	Date	FR Cite
Final Action	03/08/07	72 FR 10419

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jeffrey S. Davis
Phone: 202 619–0150

RIN: 0991–AB19

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

Proposed Rule Stage

782. 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, 42 USC 290jj to 290jj–2

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	07/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

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

RIN: 0930–AA10

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

783. 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	07/00/07	

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)

784. FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF HHS/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: 42 CFR 71

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 parts 71.51 and 71.56).

The input received from stakeholders via the ANPRM will guide CDC in drafting a rule proposal with the aim of improving CDC's ability to prevent importation of communicable diseases. The scope of this ANPRM does not include the nonhuman primate regulations.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Federalism: Undetermined

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

RIN: 0920–AA14

785. 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	03/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Frank Palya, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochran Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200
Fax: 412 386–4089
Email: fpalya@cdc.gov

Bill Hoffman, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochran Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200
Fax: 412 386–4089
Email: whoffman@cdc.gov

RIN: 0920–AA16

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

Proposed Rule Stage

786. 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	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bill Hoffman, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochran Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200
Fax: 412 386–4089
Email: whoffman@cdc.gov

RIN: 0920–AA04

787. 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	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tim Rehak, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochran Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200
Fax: 412 386–4089
Email: trehak@cdc.gov

RIN: 0920–AA10

788. 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 of 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 1970s. 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	09/00/07	

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

789. ● MEDICAL EXAMINATION OF ALIENS

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 34

Legal Deadline: None

Abstract: CDC is changing the definition of ''communicable disease of public health significance'' in 42 CFR part 34.2(b). We are taking this action to afford CDC the maximum flexibility it needs to identify and respond to newly emerging and reemerging diseases. The existing definition is outdated, and immediate changes are urgently needed to improve the U.S. Government's ability to prevent the importation of infectious diseases that are currently causing severe illness and death in regions of the world where large numbers of U.S.-bound immigrants and refugees reside. Annually, approximately 500,000 immigrants and refugees enter the United States to reside permanently. The majority arrive from Asia, Africa, and Central and South America, regions with recently reported outbreaks of emerging infectious diseases.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

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 (NE E–03), 1600 Clifton Road NE., Atlanta, GA 30333
Phone: 404 639–7048

RIN: 0920–AA20

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

Centers for Disease Control and Prevention (CDC)

790. 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 to 71

Legal Deadline: None

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. 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 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	11/30/05	70 FR 71892
Final Action	07/00/07	

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

791. 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 to 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	
Final Action	07/00/07	

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

RIN: 0920–AA13

792. INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 72

Legal Deadline: None

Abstract: HHS/CDC proposes to rescind part 72 of title 42, Code of Federal Regulations, which governs the interstate shipment of etiologic agents, because the U.S. Department of Transportation (DOT) already has in effect a more comprehensive set of regulations applicable to the transport in commerce of infectious substances. DOT harmonizes its transport requirements with international standards adopted by the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods for the classification, packaging, and transport of infectious substances. Rescinding the rule will eliminate duplication of the more current DOT regulations that cover intrastate and international, as well as interstate, transport. HHS/CDC replaced those sections of part 72 that deal with select biological agents and toxins with a new set of regulations found in part 73 of title 42. HHS/CDC anticipates that rescission of part 72 will alleviate confusion and reduce the regulatory burden with no adverse impact on public health and safety.

Timetable:

Action	Date	FR Cite
NPRM	01/02/07	72 FR 92
Interim Final Rule	07/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Janet K. Nicholson, Associate Director, Lab Science, Department of Health and Human Services, Centers for Disease Control and Prevention, Room 5131, Clifton Building 16, Atlanta, GA 30329–4018
Phone: 404 639–3945

RIN: 0920–AA19

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

Long-Term Actions

793. 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

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	03/00/09	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Bill Hoffman, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochran Mill Road, Pittsburgh, PA 15236
Phone: 412 386–5200
Fax: 412 386–4089
Email: whoffman@cdc.gov

RIN: 0920–AA17

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

Prerule Stage

794. 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 is soliciting 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	04/00/07	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0910–AF71

795. 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 sec. 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	12/01/06	
End Review	12/00/07	

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

796. 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 that 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 proposed to remove section 201.322 in the Federal Register on December 26, 2006, (71 FR 77314). FDA will consider the comments received in response to that proposal and, in addition, 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	12/01/06	
End Review	12/00/07	

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

797. 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 part 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 product 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	12/01/06	
End Review	12/00/07	

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

798. 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 two regulations in part 809. The purpose of this review is to determine if 21 CFR part 809.10 and 809.30 should be continued without change, or should be amended or rescinded, to minimize adverse economic impact on small entities. FDA is soliciting and will consider comments on the following: 1) The continued need for 21 CFR part 809.10 and 809.30; 2) the nature of complaints or comments received concerning 21 CFR part 809.10 and 809.30; 3) the complexity of 21 CFR part 809.10 and 809.30; 4) the extent to which 21 CFR part 809.10 and 809.30 overlap, duplicate, or conflict 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 21 CFR part 809.10 and 809.30.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF76

799. 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 of the regulations in part 801 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine, consistent with stated objectives and applicable statutes, whether the regulations in part 801 should be continued without change, amended, or rescinded in order 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 regulation; 2) the nature of complaints or comments received concerning the regulation; 3) the complexity of the regulation; 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 the regulation.

Timetable:

Action	Date	FR Cite
Final Action	09/30/97	62 FR 51021
Final Action Effective	09/30/98	
End Review of Current Regulation	12/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF77

800. 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 360; 21 USC 360c to 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 54

Legal Deadline: Other, Statutory, February 2, 2006, Planned section 610 review.

Abstract: FDA is undertaking a review of 21 CFR part 54, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 54 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 part 54; (2) the nature of complaints or comments received concerning the regulations in part 54; (3) the complexity of the regulations in part 54, (4) the extent to which the regulations in part 54 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 54.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	12/01/06	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF79

801. 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 part 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	03/01/07	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AF80

802. 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 part 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 part 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	12/01/06	
End Review	09/00/07	

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

803. MEDICAL DEVICES; ANESTHESIOLOGY DEVICES; PROPOSED RECLASSIFICATION OF PRESSURE REGULATORS FOR USE WITH MEDICAL OXYGEN AND SEPARATE CLASSIFICATION OF OXYGEN CONSERVING DEVICES

Priority: Routine and Frequent

Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360(c); 21 USC 360e; 21 USC 360j; 21 USC 371

CFR Citation: 21 CFR 868.2700; 21 CFR 868.2750; 21 CFR 868.5905; 21 CFR 5910

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

Timetable:

Action	Date	FR Cite
NPRM	02/27/07	72 FR 8643
NPRM Comment Period End	05/29/07	
Final Action	01/00/09	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC30

804. 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; 21 CFR 314.96

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	11/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC52

805. 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 16.1; 21 CFR 58.11; 21 CFR 58.12; 21 CFR 71.1; 21 CFR 101.69; 21 CFR 101.70; 21 CFR 170.101; 21 CFR 171.1; 21 CFR 190.6; 21 CFR 312.56; 21 CFR 511.1; 21 CFR 571.1; 21 CFR 812.46

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	04/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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Related RIN: Previously reported as 0910–AC02

RIN: 0910–AC59

806. 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 part 201.56, 201.57, and 201.80).

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

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–AF11

807. 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	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AB26

RIN: 0910–AF25

808. 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; 21 USC 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)	12/26/06	71 FR 77314
NPRM Comment Period End	05/25/07	
NPRM (Amendment) (Overindulgence/ Hangover)	10/00/07	
NPRM (Amendment) (Pediatric)	12/00/07	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	12/00/07	
NPRM (Amendment) (Safety)	12/00/07	
Final Action (Internal Analgesics)	06/00/08	

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

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

Priority: Other Significant

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
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
NPRM (Sunscreen and Insect Repellent)	04/00/07	
NPRM (UVA/UVB)	04/00/07	
ANPRM Comment Period End	05/23/07	

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 (HFD–560), 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF43

810. 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 phenyl propanolamine, and the other action addresses the ingredient benzocaine.

Timetable:

Action	Date	FR Cite
NPRM (Phenyl propanolamine)	12/22/05	70 FR 75988
NPRM (Benzocaine)	12/00/07	
Final Action (Phenyl propanolamine)	12/00/08	

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF45

811. 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)	10/00/07	

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 (HFD–560), 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF56

812. 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 342; 21 USC 343; 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	02/00/08	

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), Room 14C–17, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF61

813. 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	12/00/07	

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 Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Related to 0910–AC82

RIN: 0910–AF63

814. 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)	12/00/07	

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–AF68

815. 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 health care, food handlers, and health care antiseptic products.

Timetable:

Action	Date	FR Cite
NPRM (Food Handlers)	12/00/07	
Final Action	12/00/08	

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

816. IMPORT TOLERANCES FOR UNAPPROVED NEW ANIMAL DRUGS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b(a)(6); 21 USC 371

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: FDA plans to publish a proposed rule and a direct final 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 United States.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	
Direct Final Rule	08/00/07	

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, Rm. 169 (MPN–4, HFV–6), 7519 Standish Place, Rockville, MD 20855
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RIN: 0910–AF78

817. 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: 21 CFR 4, subchapter A

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 parts 210 and 211 will generally meet the requirements of the device quality system regulations in 21 CFR part 820). It would allow manufacturers the flexibility to select either the cGMP or quality system regulation to apply for the manufacture of their combination product, provided that their system incorporates select, key provisions from the regulations pertaining to the other part of their combination product. It would avoid the necessity to fully implement both sets of cGMP regulations when manufacturing combination products. The proposed rule is intended to

ensure consistency and appropriateness in the regulation of combination products.

Timetable:

Action	Date	FR Cite
NPRM	11/00/07	

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 Administration, Office of Combination Products, Suite 200 (HFG–3), 15800 Crabbs Branch Way, Rockville, MD 20855
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RIN: 0910–AF81

818. 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: 21 CFR 4, subchapter B

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. 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	11/00/07	

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, Suite 200 (HFG–3), 15800 Crabbs Branch Way, Rockville, MD 20855
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RIN: 0910–AF82

819. REVISIONS TO THE REQUIREMENTS APPLICABLE TO BLOOD, BLOOD COMPONENTS, AND SOURCE PLASMA

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 606.3; 21 CFR 607.65; 21 CFR 610.53; 21 CFR 640.4; 21 CFR 640.21; 21 CFR 640.22; 21 CFR 640.24; 21 CFR 640.25; 21 CFR 640.30; 21 CFR 640.32; 21 CFR 640.34; 21 CFR 640.64

Legal Deadline: None

Abstract: FDA is issuing this rulemaking to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. Some examples of the amendments include revisions to the dating period for Platelets, Red Blood Cells Deglycerolized, and Red Blood Cells Frozen; storage temperatures for blood; and pooling and pH level of Platelets. FDA is also removing two obsolete provisions.

Timetable:

Action	Date	FR Cite
NPRM—Companion to Direct Final Rule	06/00/07	
Direct Final Rule	06/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Stephen M. Ripley, Team Leader, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM–17), 1401 Rockville Pike, Rockville, MD 20852–1448
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RIN: 0910–AF84

820. REVISION OF THE REQUIREMENTS FOR LIVE VACCINE PROCESSING

Priority: Other Significant

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

CFR Citation: 21 CFR 600.11

Legal Deadline: None

Abstract: This rulemaking is being issued to provide options to the existing requirement for processing live vaccines. FDA is amending the regulations due to advances in facility, system, and equipment design, and in sterilization technologies that will allow live vaccine processing to be performed in multiproduct manufacturing areas. We are amending this regulation to permit manufacturers greater flexibility in the use of their buildings and equipment for processing live vaccines when appropriate controls exist and have been demonstrated to be effective in preventing cross contamination of other products and areas. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection.

Timetable:

Action	Date	FR Cite
NPRM—Companion to Direct Final Rule	08/00/07	
Direct Final Rule	08/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Nathaniel L. Geary, Consumer Safety Officer, 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–AF85

821. MEDICAL DEVICE REPORTING; ELECTRONIC SUBMISSION REQUIREMENTS

Priority: Other Significant

Legal Authority: 21 USC 352; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 803

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its postmarket medical device reporting regulations to require that reports submitted to the Agency by persons subject to mandatory reporting requirements be transmitted electronically in a form that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AF86

822. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360hh–ss

CFR Citation: 21 CFR 1010; 21 CFR 1040

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AF87

823. ELECTRONIC REGISTRATION AND LISTING FOR DEVICES

Priority: Other Significant

Legal Authority: PL 107–188, sec 321; 21 USC 360(p)

CFR Citation: 21 CFR 807

Legal Deadline: None

Abstract: FDA is proposing to amend the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the new requirements in section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) and section 510(p) of the Federal Food, Drug, and Cosmetic Act, which was added by section 207 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This proposed rule would require domestic and foreign device establishments to submit registration and listing data electronically via the Internet using FDA's Unified Registration and Listing System. This proposed rule would convert the registration and listing process to a paperless process. For those companies that do not have access to the web, FDA would offer an avenue by which they can register, list, and update information with a paper submission.

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AF88

824. REGULATIONS ON FIXED–COMBINATION DRUG PRODUCTS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 300.50

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations on fixed-combination prescription and OTC

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101 (HFD–7), 5515 Security Lane, Rockville, MD 20852
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RIN: 0910–AF89

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825. USE OF OZONE–DEPLETING SUBSTANCES; REMOVAL OF ESSENTIAL USE DESIGNATIONS [EPINEPHRINE]

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 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 355; 42 USC 7671 et seq

CFR Citation: 21 CFR 1.25 (Revision); 40 CFR 82.4; 40 CFR 82.64; 40 CFR 82.66

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Martha Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Regulatory Policy, Suite 1101 (HFD–7), 5515 Security Lane, Rockville, MD 20852
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RIN: 0910–AF92

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826. USE OF OZONE–DEPLETING SUBSTANCES; REMOVAL OF ESSENTIAL USE DESIGNATIONS [FLUNISOLIDE, TRIAMCINOLONE, METAPROTERENOL, PIRBUTEROL, ALBUTEROL AND IPRATROPIUM IN COMBINATION, CROMOLYN, AND NEDOCROMIL]

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 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 355; 42 USC 7671 et seq

CFR Citation: 21 CFR 1.25 (Revision); 40 CFR 82.4; 40 CFR 82.64; 40 CFR 82.66

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF93

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827. ● STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG CATEGORY II ACTIVE INGREDIENTS

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/07	

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.

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RIN: 0910–AF95

828. ● POSTMARKETING SAFETY REPORTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS: ELECTRONIC SUBMISSION REQUIREMENTS

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 355a; 21 USC 356; 21 USC 356a; 21 USC 356b; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375

CFR Citation: 21 CFR 310.305; 21 CFR 314.80; 21 CFR 314.98; 21 CFR 600.80; 21 CFR 600.81

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
ANPRM	11/05/98	63 FR 59746
ANPRM Comment Period End	02/03/99	
NPRM	11/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Federalism: Undetermined

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RIN: 0910–AF96

829. ● PROPOSED REVISIONS TO 21 CFR PARTS 314 AND 320 TO IMPLEMENT PORTIONS OF TITLE XI OF THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 AND OTHER CHANGES

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

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

CFR Citation: 21 CFR 314.3; 21 CFR 314.50; 21 CFR 314.52; 21 CFR 314.53; 21 CFR 314.60; 21 CFR 314.70; 21 CFR 314.94; 21 CFR 314.95; 21 CFR 314.96; 21 CFR 314.97; 21 CFR 314.101; 21 CFR 314.105; 21 CFR 314.107; 21 CFR 314.108; 21 CFR 320.1; 21 CFR 320.23

Legal Deadline: None

Abstract: Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) (MMA) amended provisions of the Federal Food, Drug, and Cosmetic Act (the act) that govern the approval of new drug applications (NDAs) described by section 505(b)(2) of the act (505(b)(2) applications) and abbreviated new drug applications (ANDAs) described by section 505(j) of the act. This proposed rule would implement portions of Title XI of the MMA. These provisions are those: 1) That require applicants to notify drug sponsors who have patents listed in the FDA' Orange Book of the application; 2) that apply to the period of delay (a 30-month stay) before approval of certain applications; 3) that control the submission of amendments and supplements to certain applications, and, 4) define the types of bioavailability and bioequivalence data that can be used to support these applications. This proposed rule also would amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the Act.

Timetable:

Action	Date	FR Cite
NPRM	03/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AF97

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

Food and Drug Administration (FDA)

830. 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 rule will reorganize, consolidate, clarify, and modify current regulations at 21 CFR part 207 concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted for initial registration and listing and for changes to registration and listing. The rule will require that this information be submitted 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 rule will also require that the NDC number appear on certain drug labels. In addition, FDA will 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	08/29/06	71 FR 51276
NPRM Comment Period End	02/26/07	72 FR 5944
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AA49

831. 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 to 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	04/00/07	
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AA97

832. 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	10/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AB34

833. 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 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, 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	06/00/07	

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

834. 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	12/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AB88

835. ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS

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	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AC07

836. 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 five-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	12/00/07	

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

837. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS

Priority: Info./Admin./Other

Legal Authority: 21 USC 321; 21 USC 346 to 346a; 21 USC 348; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n

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	03/00/08	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AC17

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

Priority: Other Significant

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 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n

CFR Citation: 21 CFR 50.23

Legal Deadline: None

Abstract: This final rule will add an exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/07/06	71 FR 32827
Final Action	04/00/07	

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

839. 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	01/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AC53

840. 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	08/00/07	

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

841. CHARGING FOR INVESTIGATIONAL DRUGS

Priority: Other Significant

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 rule will amend FDA's investigational new drug regulation

concerning charging for investigational drugs. The rule will clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of treatment uses described in the Agency's rule on expanded access to investigational drugs for treatment use, and clarify what costs can be recovered for an investigational drug. The rule is intended to permit charging for a broader range of investigational uses than is explicitly permitted in current regulations.

Timetable:

Action	Date	FR Cite
NPRM	12/14/06	71 FR 75168
NPRM Comment Period End	03/14/07	
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF13

842. 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 treatment IND.

Timetable:

Action	Date	FR Cite
NPRM	12/14/06	71 FR 75147
NPRM Comment Period End	03/14/07	
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

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RIN: 0910–AF14

843. 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 part 312.120 that non-IND foreign clinical studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki or with the laws and regulations of the country that is the research site, whichever provide greater protection to subjects. We 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	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF15

844. 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 amending 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), would not allow registered blood establishments or hemophilia treatment centers that provide health care services to concurrently distribute drugs, including blood derivatives. The effective date of those provisions of that rule is delayed until December 1, 2008,

as published on November 13, 2006 (71 FR 66108)—final rule; the applicability date was delayed in order to consider comments on the proposed rule published in the Federal Register February 1, 2006 (71 FR 5200). FDA is amending the final rule to allow registered blood establishments that provide health care services related to their activities as blood establishments and certain hemophilia treatment centers to also distribute certain products, including blood derivatives.

Timetable:

Action	Date	FR Cite
NPRM	02/01/06	71 FR 5200
NPRM Comment Period End	05/02/06	
Delay of Applicability	11/13/06	71 FR 66108
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF16

845. 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 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360d; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264

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	10/00/07	

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

846. 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. On August 1, 2006, FDA reopened the comment period on selected topics. The comment period closed on September 15, 2006.

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	
NPRM Comment Period Reopened	08/01/06	71 FR 43392
NPRM Comment Period End	09/15/06	
Final Action	02/00/08	

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

847. 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. The comment period was reopened on August 1, 2006, to end on September 15, 2006.

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	
NPRM Comment Period Reopened	08/01/06	71 FR 43392
NPRM Comment Period End	09/15/06	
Final Action	02/00/08	

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

848. 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; 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 combination products containing an oral bronchodilator.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40232
Final Action (Technical Amendment)	04/00/07	
Final Action	06/00/07	

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–AF33

849. 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 phenyl propanolamine.

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)	08/01/06	71 FR 83358
Final Action (Phenyl propanolamine)	12/00/07	

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

850. 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; 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 external analgesic drug products.

Timetable:

Action	Date	FR Cite
Final Action	12/00/07	

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–AF35

851. 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; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 371; 21 USC 358; 21 USC 360gg to 360ss; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/06	71 FR 74474
Final Action	12/00/07	

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–AF37

852. 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; 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 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 (Granular Psyllium)	03/29/07	72 FR 14669
Final Action (Laxative Drug Products)	12/00/07	
NPRM (Professional Labeling)	06/00/08	

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

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses labeling for products formulated and marketed as lip protectants. The second action addresses skin protectant products to protect and treat fever blisters and cold sores.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	12/00/07	
Final Action (Fever Blisters/Cold Sores)	06/00/07	
Final Action (Diaper Rash)	12/00/07	
Final Action (Aluminum Acetate) (Technical Amendment)	06/00/07	

HHS—FDA **Final Rule Stage**

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

854. 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)	04/00/07	
NPRM (Vaginal Contraceptive Drug Products)	12/00/07	

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–AF44

855. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED TO PREVENT THE TRANSMISSION OF BOVINE SPONGIFORM ENCEPHALOPATHY

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 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	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF46

856. 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	12/00/07	

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–AF51

857. 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)	12/00/07	
Final Action (Sodium Bicarbonate Labeling)	12/00/07	

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–AF52

858. 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	08/29/06	71 FR 51146
NPRM Comment Period End	12/27/06	
Final Action	12/00/07	

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–AF53

859. 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, 2008.
Final, Statutory, August 2, 2009.

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 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 7 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 comments received. This is a voluntary program for animal drug sponsors. 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	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bernadette Dunham, Director, Office of Minor Use and Minor Species Animal Drug Development, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV–50, MPN–4), Room 180, 7519 Standish Place, Rockville, MD 20855
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HHS—FDA **Final Rule Stage**

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RIN: 0910–AF60

860. 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, 2009.
Final, Statutory, August 2, 2010.

Abstract: This rule is being issued in response to the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The 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 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	08/22/06	71 FR 48840
NPRM Comment Period Extended	10/02/06	71 FR 57892
NPRM Comment Period End	12/20/06	
Final Action	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF67

861. EXCEPTIONS OR ALTERNATIVES TO LABELING REQUIREMENTS FOR PRODUCTS HELD BY THE STRATEGIC NATIONAL STOCKPILE

Priority: Other Significant

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

CFR Citation: 21 CFR 201; 21 CFR 312; 21 CFR 314; 21 CFR 601; 21 CFR 610; 21 CFR 801; 21 CFR 807; 21 CFR 809; 21 CFR 812; 21 CFR 814

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AF90

862. ● HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS; DONOR SCREENING AND TESTING, AND RELATED LABELING

Priority: Other Significant

Legal Authority: 42 USC 264

CFR Citation: 21 CFR 1271.55; 21 CFR 1271.80; 21 CFR 1271.90; 21 CFR 1271.290; 21 CFR 1271.370

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is issuing a final rule, after issuing an interim final rule that amended certain regulations regarding the screening and testing of donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps); and related labeling. FDA is taking this action to complete the rulemaking initiated with the interim final rule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/25/05	70 FR 29949
Final Action	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Brenda Friend, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM–17), 1410 Rockville Pike, Rockville, MD 20852–1448
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RIN: 0910–AF98

HHS—FDA

Final Rule Stage

863. ● OVER–THE–COUNTER (OTC) DRUG REVIEW—ACNE DRUG PRODUCTS CONTAINING BENZOYL PEROXIDE

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 will address acne drug products containing benzoyl peroxide.

Timetable:

Action	Date	FR Cite
Final Action	12/00/07	

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.

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RIN: 0910–AG00

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

Long-Term Actions

864. 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

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RIN: 0910–AC23

865. 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	06/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC35

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

Priority: Other Significant

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 (the act), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), requires notification to FDA prior to the entry of imported food. The regulation explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided.

Section 307 authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. FDA and the Bureau of Customs and Border Protection (CBP) issued an interim final rule (IFR) on October 10, 2003 (68 FR 58974). The IFR originally provided a 75-day comment period to ensure that those that comment on the IFR have the benefit of our outreach and educational efforts and have the experience with the systems, timeframes, and data elements. We reopened the comment period for an additional 90 days in April through July 2004, to allow for additional comment on the industry's experience with the prior notice system, and comment on the Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes. The final rule currently is under development, and it will confirm or amend the IFR, as appropriate. This final rule is not expected to have a significant impact on a substantial number of small entities.

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	09/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

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RIN: 0910–AC41

867. 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

868. 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

869. 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

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RIN: 0910–AF08

870. 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

871. 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 Agency published a proposed rule on January 30, 2006, to require the label declaration of all foods and cosmetics containing the color additives cochineal extract and carmine in order to protect consumers with allergies to these additives. This proposal was issued in response to adverse event reports received by FDA and to a citizen petition submitted to FDA. The comment period ended on May 1, 2006. FDA intends to issue a final rule after reviewing comments.

Timetable:

Action	Date	FR Cite
NPRM	01/30/06	71 FR 4839
NPRM Comment Period End	05/01/06	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF12

872. 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 part 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
NPRM Comment Period End	02/13/06	
Final Action	01/00/09	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF21

873. 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

Federalism: Undetermined

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RIN: 0910–AF22

874. 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

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

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AF23

875. 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)	06/00/08	

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–AF31

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)	12/00/08	

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—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)	06/00/08	
Final Action	06/00/08	

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–AF40

878. 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 and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. 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 (Amendments)	09/07/05	70 FR 53063
Interim Final Rule (Amendments) Comment Period End	11/07/05	
Final Action	04/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF47

879. 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	01/12/07	72 FR 1582
NPRM Comment Period End	03/13/07	
NPRM Comment Period Reopened	03/30/07	
Final Action	10/00/08	

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, Room 14C–17, HF–23, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Merged with 0910–AF55

RIN: 0910–AF54

880. 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)	06/00/08	

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

RIN: 0910–AF70

881. ● FOOD LABELING; SERVING SIZES; REFERENCE AMOUNT FOR BAKING POWDER, BAKING SODA, AND PECTIN (SECTION 610 REVIEW)

Priority: Routine and Frequent

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

Legal Deadline: Other, Statutory, March 16, 2009, Planned section 610 review.

Abstract: Section 101.9 (21 CFR part 101.9) describes the nutrition labeling regulations for the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin.'' Section 101.12 (21 CFR part 101.12) includes 1/8 teaspoon (tsp) as an additional allowable household measure. FDA is undertaking a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.9 and 101.12 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulations in sections 101.9 and 101.12; (2) the nature of complaints or comments received concerning the regulations in sections 101.9 and 101.12; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.9 and 101.12 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.9 and 101.12.

Timetable:

Action	Date	FR Cite
Begin Review	12/00/08	
End Review	03/00/09	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: David Zorn, Lead Economist, Department of Health and Human Services, Food and Drug Administration, HFS–020, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1825
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Email: david.zorn@fda.hhs.gov

RIN: 0910–AF99

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

Completed Actions

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

Priority: Other Significant

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Withdrawn	03/23/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rebecca Buckner
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RIN: 0910–AC21

883. MEDICAL DEVICES; PATIENT EXAMINATION AND SURGEONS' GLOVES; TEST PROCEDURES AND ACCEPTANCE CRITERIA

Priority: Routine and Frequent

CFR Citation: 21 CFR 800.20

Completed:

Reason	Date	FR Cite
Final Action	12/19/06	71 FR 75865

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Myrna Hanna
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RIN: 0910–AC32

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

Priority: Routine and Frequent

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

Completed:

Reason	Date	FR Cite
Final Action (Technical Amendment)	03/19/07	72 FR 12730

HHS—FDA **Completed Actions**

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF32

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

Priority: Routine and Frequent

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

Completed:

Reason	Date	FR Cite
Final Action	03/06/07	72 FR 9849

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
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RIN: 0910–AF49

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

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Final Action	12/13/06	71 FR 74766

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Dennis Bensley
Phone: 301 827–6956
Email: dennis.bensley@fda.hhs.gov

RIN: 0910–AF59

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

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 1271; 42 CFR 121

Completed:

Reason	Date	FR Cite
Final Action	03/12/07	72 FR 10922

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Denise Sanchez
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AF65

888. • OVER–THE–COUNTER (OTC) DRUG REVIEW—MULTIPLE 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: Amendments to the Federal Food, Drug, and Cosmetic Act (the act) necessitate several changes to the citations used in Food and Drug Administration (FDA) regulations regarding the prescription-exemption procedure and the list of new drugs that are exempted from the prescription-dispensing requirements. These changes are editorial, pertaining only to citations, and do not constitute a change in FDA regulation.

Timetable:

Action	Date	FR Cite
Final Action–Technical Amendment	03/30/07	72 FR 15043

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.

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

RIN: 0910–AG01

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

Proposed Rule Stage

889. 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.

HHS—HRSA **Proposed Rule Stage**

Timetable:

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
NPRM	07/00/07	

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, Room 8C–26, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

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

890. 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	03/21/06	71 FR 14135
NPRM Comment Period End	05/22/06	
Final Action	07/00/07	

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, Room 8–103, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2300

RIN: 0906–AA57

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

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

Legal Authority: 42 USC 300ff–71

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/12/03	68 FR 47923
NPRM Comment Period End	09/11/03	
Final Rule	07/00/07	

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, Room 7A–21, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–3650
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RIN: 0906–AA65

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

Priority: Other Significant

Legal Authority: sec 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, ''If, 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

HHS—HRSA **Final Rule Stage**

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	06/09/06	71 FR 33420
Final Action	07/00/07	

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
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RIN: 0906–AA68

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

Long-Term Actions

893. 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, Room 8–103, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2300

RIN: 0906–AA41

894. 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.

HHS—HRSA **Long-Term Actions**

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, Mail Stop 16C–17, 5600 Fishers Lane, Parklawn Building, Rockville, MD 20857
Phone: 301 443–8104
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Email: hwong@hrsa.gov

RIN: 0906–AA63

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

895. 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

CFR Citation: 42 CFR 121

Completed:

Reason	Date	FR Cite
Final Rule	03/09/07	72 FR 10616

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Laura St. Martin
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RIN: 0906–AA62

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

Priority: Other Significant

CFR Citation: 42 CFR 51(a)

Completed:

Reason	Date	FR Cite
Final Rule	01/24/07	72 FR 3079

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jose Belardo
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RIN: 0906–AA70

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

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

Priority: Other Significant

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	04/28/06	71 FR 25124
NPRM Comment Period End	06/27/06	
Final Action	08/00/07	

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, Suite 450, 12300 Twinbrook Parkway, Rockville, MD 20852
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Email: bgould@hqe.ihs.gov

RIN: 0917–AA07

Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ) — Proposed Rule Stage

898. ● PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005 RULES

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

Legal Authority: 42 USO 299b–12 to 299b–26; PL 109–41

CFR Citation: 42 CFR 3

Legal Deadline: None

Abstract: The proposed rules to implement the Patient Safety and Quality Improvement Act of 2005 establish a framework in which hospitals, doctors, and other health care providers may voluntarily contract with Patient Safety Organizations (PSOs) to report and analyze health care errors. Providers contract with PSOs for expertise in the collection of patient safety event reports and analysis of the cause of adverse events. The proposed rules outline the requirements that entities must meet and certify to the Secretary for acceptance as a PSO. The

HHS—AHRQ **Proposed Rule Stage**

proposed rules establish legal boundaries of privilege and confidentiality within which reporting and analysis occurs, and sets forth procedures for the imposition of civil money penalties for the knowing or reckless disclosure of patient safety work product.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: William Munier, Department of Health and Human Services, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850
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RIN: 0919–AA01

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

899. GRANTS FOR RESEARCH PROJECTS

Priority: Other Significant

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	06/00/07	

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–AA42

900. 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 part 68a and at 42 CFR part 68c replaced by the new consolidated set of LRP regulations. This action will also include withdrawing the previously announced planned actions concerning NIH LRP authorities.

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	

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
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Fax: 301 402–0169
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RIN: 0925–AA43

901. 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	08/00/07	

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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RIN: 0925–AA44

902. 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	08/00/07	

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
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RIN: 0925–AA45

903. 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	08/00/07	

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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RIN: 0925–AA46

904. ENDOWMENT PROGRAM

Priority: Substantive, Nonsignificant

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

CFR Citation: Not Yet Determined

Legal Deadline: None

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	09/00/07	

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–AA47

905. 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	07/00/07	

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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RIN: 0925–AA48

906. NIH TRAINING GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 285q–1; 42 USC 287c–32

HHS—NIH **Proposed Rule Stage**

CFR Citation: 42 CFR 63a

Legal Deadline: None

Abstract: NIH plans to amend the Agency's existing training grants regulations to (1) reflect their applicability to the training authorities set forth in PHS's ACT sections 464W and 485F, (2) reflect their applicability to the National Center on Minority Health and Health Disparities (NCMHD) and Fogarty International Center (FIC) Minority Health and Health Disparities International Research Training (MHIRT) awards, and (3) revise the definition of program director to mean one or more individuals named by the grantee in the grant application, and approved by the Secretary, who is responsible for the management and conduct of the training program, rather than limiting the role of program director to a single individual when that more accurately reflects the management needs of a training program.

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	

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
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RIN: 0925–AA49

907. NIH CENTER GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 287c–21h; 42 USC 241

CFR Citation: 42 CFR 57a

Legal Deadline: None

Abstract: NIH plans to amend the Agency's existing center grant regulations by revising section 52a.1 to reflect the applicability of the regulations to (1) the program of research centers on complementary and alternative medicine administered by the National Center for Complementary and Alternative Medicine (NCCAM) and (2) the regional centers of excellence for biodefense and emerging infectious diseases research administered by the National Institute of Allergy and Infectious Diseases (NIAID).

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	

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
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RIN: 0925–AA50

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

908. 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	08/00/07	

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
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RIN: 0925–AA31

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

909. NIH CONSTRUCTION GRANT

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 52b

Completed:

Reason	Date	FR Cite
Withdrawn	04/02/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0925–AA51

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

Final Rule Stage

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

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart F to Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, to require registration of institutional review boards (IRBs) with HHS. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for the Office for Human Research Protections (OHRP) to convey information to IRBs, and will support the current IRB registration operated by OHRP. Under the current OHRP IRB registration system, the submission of certain registration information is required by human subjects protection regulations, and certain other information may be submitted voluntarily. This proposed information collection was submitted to the Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single, HHS IRB Registration system. FDA simultaneously published a proposed rule regarding FDA IRB registration requirements.

Timetable:

Action	Date	FR Cite
NPRM	07/04/04	69 FR 40584
NPRM Comment Period End	10/04/04	
Final Action	03/00/08	

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
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Fax: 301 402–2071
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RIN: 0940–AA06

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

Long-Term Actions

911. 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	06/00/08	

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

912. 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: Through this advance notice of proposed rulemaking (ANPRM), the Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services is seeking comment on whether it is necessary to require institutions engaged in human subjects research covered by Federalwide Assurance filed with OHRP to ensure that institutional officials and institutional review board (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.

Timetable:

Action	Date	FR Cite
ANPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Elyse Summers, Department of Health and Human Services, Office of Public Health and

HHS—OPHS **Long-Term Actions**

Science, The Tower Building, 1101 Wootten Parking, Rockville, MD 20852
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Email: elyse.summers@hhs.gov

RIN: 0940–AA08

913. 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.

Timetable:

Action	Date	FR Cite
ANPRM	To Be Determined	

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, Suite 200, 1101 Wootton Parkway, Rockville, MD 20852
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RIN: 0940–AA11

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

Proposed Rule Stage

914. 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 409, 42 CFR 418, 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	11/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

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

RIN: 0938–AG81

915. APPEALS OF CMS OR CONTRACTOR DETERMINATIONS WHEN A PROVIDER OR SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING (CMS–6003–P2)

Priority: Other Significant

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

CFR Citation: 42 CFR 405.874; 42 CFR 424.525; 42 CFR 424.535; 42 CFR 424.545; 42 CFR 498.1; 42 CFR 498.2; 42 CFR 498.5; 42 CFR 498.22; 42 CFR 498.40; 42 CFR 498.44; 42 CFR 498.56; 42 CFR 498.78; 42 CFR 498.79; 42 CFR 498.86; 42 CFR 498.88; 42 CFR 405.802; 42 CFR 424.510;

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	03/02/07	72 FR 9479

Action	Date	FR Cite
Second NPRM Comment Period End	05/02/07	

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, Office of Financial Management, Program Integrity Group, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0612
Email: august.nemec@cms.hhs.gov

RIN: 0938–AI49

916. 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; Deficit Reduction Act of 2005 (PL 109–171), sec 6083

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 which addresses section 5114 of the DRA.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74792
Interim Final Rule	09/22/06	71 FR 55341
Interim Final Rule Comment Period End	11/21/06	
Second NPRM	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: John Warren, Centers for Medicare Management,, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Ambulatory Services, Mailstop C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3633
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RIN: 0938–AJ17

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

Priority: Other Significant

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

CFR Citation: 45 CFR 101; 42 CFR 418; 42 CFR 482; 42 CFR 483; 42 CFR 485

Legal Deadline: None

Abstract: This proposed rule would implement provisions of the Children's Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Carla McGregor, Technical Director, Survey and Certification Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S2–12–25, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AL26

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

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: sec 1102 and 1871 of the Social Security Act

CFR Citation: 42 CFR 416

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	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Joan Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5526

Email: joan.brooks@cms.hhs.gov

Commander Jacqueline Morgan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards and Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AL80

919. 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; Deficit Reduction Act of 2005, PL 109–171, sec 6035

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would adopt new versions of the X12 suite of HIPAA Transactions and allow the industry to use the most up-to-date versions of the HIPAA transactions for claims and remittance advice.

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

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

920. 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	08/00/07	

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
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RIN: 0938–AN25

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

Priority: Other Significant

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 (FOIA), 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	05/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Patrica Peyton, Technical Advisor, 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
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RIN: 0938–AN71

922. 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	12/00/07	

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, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
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Email: arnold.farley@cms.hhs.gov

RIN: 0938–AN73

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

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: None

CFR Citation: 42 CFR 435

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	11/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Melissa L. Harris, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Disability and Elderly Health Programs Group, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3397
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RIN: 0938–AO07

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

Additionally, this proposed rule would give States offering Medicaid buy-in programs for employed individuals with disabilities the option of applying a minimum work standard to two Medicaid buy-in groups.

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Carey Appold, Technical Director, Disabled and 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
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RIN: 0938–AO10

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: sec 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	10/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Jeremy Silanskis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AO17

926. 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) and (f) of the Social Security Act; National Institutes of Health Reform Act of 2006 (PL 109–432), sec 201(b)

CFR Citation: 42 CFR 457.600 to 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
Notice With Comment	06/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0938–AO28

927. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM REFINEMENTS AND RATE UPDATE FOR CALENDAR YEAR 2008 (CMS–1541–P)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 484

Legal Deadline: Final, Statutory, January 1, 2008.

Abstract: This major proposed rule would set forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health services, effective on January 1, 2008. As part of this proposed rule, we are also proposing to rebase and revise the home health market basket to ensure it continues to adequately reflect the price changes of efficiently providing home health services. In addition, we are proposing to revise the fixed dollar loss ratio, which is used in the calculation of outlier payments. This proposed rule also would set forth the refinements to the payment system. In addition, this proposed rule would establish new quality of care data collection requirements.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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

928. 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); of the Social Security Act.

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This proposed rule would revise certain proficiency testing 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. Identifying these individuals is essential in providing quality patient care.

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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RIN: 0938–AO34

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

Priority: Other Significant

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	08/00/07	

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, Center for Medicaid State Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO45

930. PREMIUMS AND COST SHARING (CMS–2244–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Deficit Reduction Act of 2005; PL 109–171; secs 6041 to 6043; Tax Relief and Health Care Act of 2006; PL 109–432, sec 405(a)

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, March 31, 2006, secs 6041 and 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 provide State Medicaid agencies with increased flexibility to implement premium and cost sharing requirements for certain Medicaid recipients. This authority is in addition to the current authority States already had under section 1916 of the Social Security Act to implement premiums and cost sharing. 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	08/00/07	

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 Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid State Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO47

931. STATE FLEXIBILITY FOR MEDICAID BENEFIT PACKAGES (CMS–2232–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Deficit Reduction Act of 2005; sec 6044; sec 1102 of the Social Security Act

CFR Citation: 42 CFR 440.300; 440.385

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

Abstract: This proposed rule would implement provisions of section 6044 of the Deficit Reduction Act of 2005, which amends the Social Security Act by adding a new section related to the coverage of medical assistance under approved State plans. Under this new section, States have increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid recipients.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

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, Center for Medicaid State Operations, MailStop S2–01–16, 7500 Security Boulevard, Balitimore, MD 21244
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RIN: 0938–AO48

932. 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	08/00/07	

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, Center for Medicaid State Operations, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO52

933. HOME AND COMMUNITY–BASED SERVICES (HCBS) STATE PLAN OPTION (CMS–2249–P)

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

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

CFR Citation: 42 CFR 431; 42 CFR 440; 42 CFR 441

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

Abstract: This proposed rule would amend the Medicaid regulations to define and describe the home and community-based State plan services implementing new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

Timetable:

Action	Date	FR Cite
NPRM	10/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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, Center for Medicaid State Operations, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO53

934. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2008 (CMS–1551–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: SSA, sec 1886(i); PL 105–33; PL 106–554; PL 106–113

CFR Citation: 42 CFR 412

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

Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2008.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: William Ullman, Health Insurance Specialist, Centers for Medicare Management, 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
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RIN: 0938–AO63

935. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2008 (CMS–1545–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1888(e)

CFR Citation: 42 CFR 424

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

Abstract: This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs), for fiscal year (FY) 2008. In addition, this proposed rule would revise and rebase the SNF market basket.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: William Ullman, Health Insurance Specialist, Centers for Medicare Management, 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
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RIN: 0938–AO64

936. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER CHANGES TO PAYMENT UNDER PART B FOR CY 2008 (CMS–1385–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871; Social Security Act, sec 1848;; Tax Relief and Health Care Act of 2006 (Pub L 109–432), Sec 101(a), 102, 108, and 110

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

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

Abstract: This rule would make several changes affecting Medicare Part B payment to physicians and other Part B providers and suppliers.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Diane S. Milstead, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid Management, Mailstop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO65

937. STANDARDS FOR E–PRESCRIBING UNDER MEDICARE PART D (CMS–0016–P)

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

Unfunded Mandates: This action may affect State, local or tribal governments and the private sector.

Legal Authority: 42 USC 1395

CFR Citation: 42 CFR 423

Legal Deadline: Final, Statutory, April 1, 2008.

Abstract: This rule proposes standards for electronic prescribing (e-prescribing) under Medicare Part D. This rule would require Medicare Part D and Medicare Advantage plans to support electronic transmission of basic prescription data to and from doctors and pharmacies and to adopt final standards for e-prescribing as required by section 101 of the MMA.

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

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

Agency Contact: Denise Buenning, Senior Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO66

938. EXEMPTION OF PRIVACY ACT DISCLOSURE OF CERTAIN INVESTIGATIVE MATERIALS (CMS–0029–P)

Priority: Info./Admin./Other

Legal Authority: 5 USC 301; 5 USC 552a

CFR Citation: 45 CFR 5b

Legal Deadline: None

Abstract: Unrestricted disclosure of confidential information in CMS files can impede ongoing investigations, invade the personal privacy of individuals, reveal the identities of confidential sources, or otherwise impair the ability of CMS to conduct investigations. For these reasons this rule proposes to exempt the ASPEN Complaint/Incident Tracking System (ACTS), Organ Procurement Organizations Systems (OPOS), Fraud Investigation Database (FID), and HIPAA Information Tracking System (HITS) from the notification, access, correction, and amendment provisions of the Privacy Act concerning records compiled for law enforcement purposes.

Timetable:

Action	Date	FR Cite
NPRM	05/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Katherine Marie Brewer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop N2–04–27, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO69

939. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2008 RATES (CMS–1533–P)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 412; 413; 424; 485; 489

Legal Deadline: NPRM, Statutory, April 1, 2007.
Final, Statutory, August 1, 2007.

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.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Marc Hartstein, Deputy Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–25–11, 7500 Security Boulevard, Baltimore, MD 21244
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Related RIN: Related to 0938–AO35

RIN: 0938–AO70

940. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM CALENDAR YEAR 2008 PAYMENT RATES (CMS–1392–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: BBA; BBRA; BIPA; MMA; DRA of 2005; 1833(i)(2)(D)(iii);

CFR Citation: 42 CFR 410, 42 CFR 416, 42 CFR 419; 42 CFR 421, 42 CFR 485, 42 CFR 488

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

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. The rule also proposes changes to the Ambulatory Surgical Center Payment System list and rates. These changes would be applicable to services furnished on or after January 1, 2008.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal

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

Agency Contact: Alberta Dwivedi, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3–24–23, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO71

941. HOSPICE WAGE INDEX FOR FY 2008 (CMS–1539–P)

Priority: Other Significant

Legal Authority: 42 USC 1814(i)(1) and 1814(i)(2)

CFR Citation: 42 CFR 418

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

Abstract: This rule proposes the annual update to the hospice wage index for FY 2008. The wage index is used to reflect local differences in wage levels.

The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

Timetable:

Action	Date	FR Cite
NPRM	05/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Terri Deutsch, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Community Post Acute Care, Hospital and Ambulatory Policy Group, Mailstop C5–08–18, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO72

942. ● POLICY AND TECHNICAL CHANGES TO THE MEDICARE PRESCRIPTION DRUG BENEFIT (CMS–4130–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395w 101 through 1395w 152; 42 USC 1302

CFR Citation: 42 CFR 423.50; 42 CFR 423.56; 42 CFR 423.100; 42 CFR 423.120; 42 CFR 423.293; 42 CFR 423.308; 42 CFR 423.350 42 CFR 423.458; 42 CFR 423.464; 42 CFR 423.504; 42 CFR 423.505; 42 CFR 423.509; 42 CFR 423.560; 42 CFR 423.570; 42 CFR 423.584; 42 CFR 423.610; 42 CFR 423.780; 42 CFR 423.884; 42 CFR 423.902; 42 CFR 423.906; 42 CFR 423.910;

Legal Deadline: None

Abstract: This proposed rule both clarifies existing policy that is outlined in the final rule published in the Federal Register on January 28, 2005 entitled ''Medicare Program; Medicare Prescription Drug Benefit,'' as well as offers several proposed clarifications of policy for which we seek public comment. These proposed clarifications address our expectations of Part D sponsors in providing adequate access to home infusion pharmacies for infused covered Part D drugs and supplies associated with the ''inhalation of insulin''; the appropriate drug costs Part D sponsors should use as the basis for (1) Calculating beneficiary cost sharing, (2) reporting drug costs to CMS for the purposes of reconciliation and risk sharing, (3) developing bids submitted to CMS, and (4) retiree subsidy provisions related to the actuarial equivalence test. This proposed rule also addresses the exclusion from the definition of ''a Part D drug'' when used for the treatment of sexual or erectile dysfunction, in accordance with an October 26, 2005 statutory amendment to the Social Security Act.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Alissa M. Deboy, Acting Division Director, Center for Beneficiary Choices, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Drug Plan Policy and Analysis Division, Mailstop C1–26–16, 7500 Secruity Boulevard, Balitmore, MD 21244
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Related RIN: Related to 0938–AN08

RIN: 0938–AO74

943. SPECIAL ENROLLMENT PERIOD AND MEDICARE PREMIUM CHANGES (CMS–4129–P)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: PL 109–171, sec 5115; PL 108–173, sec 811

CFR Citation: 42 CFR 406 to 408

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

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

Timetable:

Action	Date	FR Cite
NPRM	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0938–AO77

944. REVISIONS TO THE MEDICARE ADVANTAGE AND PART D PRESCRIPTION DRUG CONTRACT DETERMINATIONS, APPEALS, AND INTERMEDIATE SANCTIONS PROCESSES (CMS–4124–P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395(hh); 42 USC 1395(w–101) to 1395(w–152)

CFR Citation: 42 CFR 422, and 42 CFR 423

Legal Deadline: None

Abstract: This proposed rule would clarify and modify the Medicare Advantage (MA) program provisions relating to disclosure of information, and contract determinations by MA organizations and Part D prescription drug plan sponsors. This proposed rule would also revise requirements

concerning the reconsideration of determinations and clarify the schedule for MA organizations and Part D plan sponsors to complete corrective action plans. In addition, it would clarify the intermediate sanction and civil money penalty (CMP) provisions relating to MA organizations and Medicare Part D prescription drug plan sponsors.

Timetable:

Action	Date	FR Cite
NPRM	04/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Christine Perenich, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–23–07, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO78

945. • REHABILITATION SERVICES: STATE PLAN OPTION (CMS–2261–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: sec 1905 (a)(13) of the Social Security Act

CFR Citation: 42 CFR 440.130(d)

Legal Deadline: None

Abstract: This proposed rule would amend the definition of Medicaid rehabilitative services in order to provide for important beneficiary protections such as a person-centered written rehabilitation plan and maintenance of case records. The proposed rule would also ensure the fiscal integrity of claimed Medicaid expenditures by clarifying the service definition and providing that Medicaid rehabilitative services must be coordinated with, but do not include services furnished by, other programs that are focused on social or educational development goals and are available as part of other services or programs. These services and programs include, but are not limited to, foster care, child welfare, education, child care, prevocational and vocational services, housing, parole and probation, juvenile justice, public guardianship, and any other non-Medicaid services from Federal, State, or local programs.

Timetable:

Action	Date	FR Cite
NPRM	06/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Linda Peltz, Director, Divison of Integrated Health Systems, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Disabled and Elderly Health Programs Group, Center for Medicaid State Operations, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO81

946. • WAIVER OF DISAPPROVAL OF NURSE AIDE TRAINING PROGRAM IN CERTAIN CASES AND NURSE AIDE PETITION FOR REMOVAL OF INFORMATION FOR SINGULAR FINDING OF NEGLECT (CMS–2266–P)

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

Unfunded Mandates: Undetermined

Legal Authority: sec 932 (c) (2) MMA; secs 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	11/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Patricia Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mailstop S2–19–14, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO82

947. • SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) (CMS–6006–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: sec 4312(a) of BBA of 1997

CFR Citation: 42 CFR 424.57

Legal Deadline: None

Abstract: This proposed rule would implement section 4312(a) of the Balanced Budget Act of 1997, which requires a Medicare supplier of durable medical equipment (DME) to furnish CMS with a surety bond.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: August Nemec, Department of Health and Human Services, Centers for Medicare &

Medicaid Services, Mailstop C3–08–07, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO84

948. ● CHILDREN OF STATE EMPLOYEES: PREMIUM ASSISTANCE (CMS–2148–P)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 457.1010; 42 CFR 457.310

Legal Deadline: None

Abstract: This proposed rule would amend Medicaid regulations by revising the definition of ''optional targeted low-income child'' to exclude children eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency, children who are inmates of a public institution, and children who are patients in an institution for mental diseases. This proposed rule also addresses the requirements for SCHIP family coverage through premium assistance.

Timetable:

Action	Date	FR Cite
NPRM	10/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Kathleen Farrell, Director, State Children's Health Insurance Program, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers of Medicaid State Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21224
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RIN: 0938–AO86

949. ● APPLICATION OF CERTAIN PART 405 APPEALS PROVISIONS TO THE PART 423 MEDICARE PRESCRIPTION DRUG APPEALS PROCESS (CMS–4127–P)

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

Unfunded Mandates: Undetermined

Legal Authority: sec 1102, 1860D–1 to 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 to 1395w–152, and 1395hh)

CFR Citation: 42 CFR 560 to 638

Legal Deadline: None

Abstract: The voluntary prescription drug benefit program was enacted into law by section 101 of title 1 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). The implementing regulations for the Part D program were published in a final rule on January 28, 2005, and became effective March 22, 2005. These regulations provide that the Medicare Advantage (MA) rules regarding appeals and reopenings will apply to the Part D appeals process to the extent they are appropriate. The MA regulations in turn apply the fee-for-service (FFS) appeals regulations (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) to the extent they are appropriate.

Based on this regulatory framework, we noted in the January 28, 2005, rule that differences in the appeals procedures for Part D enrollees would be addressed in a future Part D rulemaking document. The purpose of the proposed rule is to provide additional guidance on the differences in appeals procedures for Part D enrollees by proposing more detailed regulations governing Part D appeals at the ALJ, MAC, and Federal district court levels and reopenings of determinations and decisions that follow the Part A and Part B procedures set forth in the part 405 rule, as appropriate.

Timetable:

Action	Date	FR Cite
NPRM	02/00/08	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Anthony Culotta, Director, Medicare Enrollment & Appeals Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C2–12–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO87

950. ● LIMITATION ON CONTRACTOR LIABILITY (CMS–2264–P)

Priority: Other Significant

Legal Authority: Deficit Reduction Act of 2005 (PL 109–171), sec 6034; sec 1157 of the Social Security Act

CFR Citation: 42 CFR 45

Legal Deadline: None

Abstract: Section 6034 of the Deficit Reduction Act of 2005 established the Medicaid Integrity Program to promote the integrity of the Medicaid program by authorizing the Centers for Medicare and Medicaid Services (CMS) to enter into contracts with contractors that will (1) Review the actions of individuals or entities furnishing items or services (whether fee-for-service, risk, or other basis) for which payment may be made under an approved State plan and/or any waiver of the plan approved under section 1115 of the Social Security Act; (2) audit claims for payment of items or services furnished, or administrative services furnished, under a State plan; (3) identify overpayment of individuals or entities receiving Federal funds; and (4) educate providers of services, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care. This proposed rule would set forth limitations on a contractor's liability while performing these services under the Medicaid Integrity Program.

This proposed rule would provide for limitation of a contractor's liability for actions taken to carry out a contract under the Medicaid Integrity Program. The proposed rule would, to the extent possible, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1157 of the Social Security Act.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Barbara Rufo, Director, Division of Medicaid Integrity Contracts, Medicaid Integrity Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop B2–02–24, 7111 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AO88

951. ● HEALTH INSURANCE REFORM: REMOTE SECURITY STANDARDS (CMS–0020–P)

Priority: Other Significant

Legal Authority: HIPAA

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would further address the existing compliance requirements of the HIPAA Security regulations specific to covered entities that allow offsite access to, or use of, electronic protected health information. The proposed rule is necessitated by several recent security incidents related to the use of laptops other portable and mobile devices and external handware that store, contain, or are used to access electronic protected health information. It is intended to provide a more prescriptive set of remote security requirements designed to reduce the likelihood of unauthorized uses and disclosures of sensitive health information.

Timetable:

Action	Date	FR Cite
NPRM	07/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Michael T. Phillips, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Electronic Health E–Standards & Services, Mailstop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21224
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RIN: 0938–AO89

952. ● ESTABLISHING ADDITIONAL PROVIDER AND SUPPLIER REQUIREMENTS FOR ENROLLMENT STANDARDS AND RELATED ISSUES (CMS–6036–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 numbers of providers and suppliers enrolling and maintaining enrollment within the Medicare Program are of such a large magnitude that CMS must be able to ensure that quality care is given to beneficiaries while at the same time guaranteeing the protection of the Medicare Trust Fund. This rule proposes new standards to help to maintain an acceptable level of care for the beneficiaries without adding increased risk of loss to the Medicare Trust Fund.

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: August Rudolph Nemec III, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop C3–07–08, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO90

953. ● EMERGENCY PREPAREDNESS REQUIREMENTS FOR MEDICARE PARTICIPATING PROVIDERS AND SUPPLIERS (CMS–3178–P)

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

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule proposes emergency preparedness requirements for a variety of Medicare providers and suppliers who participate in the Medicare and Medicaid programs. Medicare beneficiaries rely on health care facilities to safely and effectively plan for and execute appropriate evacuation procedures during times of disaster.

Timetable:

Action	Date	FR Cite
NPRM	02/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Monique S. Howard, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S3–02 01, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO91

954. ● INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR RATE YEAR BEGINNING JULY 1, 2008 (RY 2009) (CMS–1401–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

Legal Deadline: Final, Statutory, July 1, 2008.

Abstract: This rule proposes updates to the Inpatient Psychiatric Facility Prospective Payment System for RY 2009.

Timetable:

Action	Date	FR Cite
NPRM	01/00/08	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Federalism: Undetermined

Agency Contact: Janet Samen, Director, Division of Chronic Care Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–07, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO92

HHS—CMS **Proposed Rule Stage**

955. ● PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2009: ANNUAL PAYMENT RATE UPDATES (CMS–1393–P)

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, July 1, 2008.

Abstract: This rule proposes the payment rate update for the rate year 2009 prospective payment system (PPS) for Medicare long-term care hospitals (LTCH) and also presents proposed changes or revisions on LTCH PPS policy for public comment.

Timetable:

Action	Date	FR Cite
NPRM	01/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judith Richter, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–16–07, 7500 Security Boulevard, Baltimore
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RIN: 0938–AO94

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

956. 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 405; 42 CFR 410; 42 CFR 413 to 414; 42 CFR 488; 42 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

Agency Contact: Teresa Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AG82

957. 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 components to: Prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospital received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Interim Final Rule	07/00/07	

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
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RIN: 0938–AJ29

958. 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 final rule addresses standards of practice that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints (including psychoactive drugs) and seclusion.

Timetable:

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

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 and Coverage Policy, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AJ96

959. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS (CMS–1810–RCN)

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 rule finalizes certain statutory provisions that prevent payment for services and impose penalties when a physician makes a referral to an entity in which that physician has a financial interest, unless an exception applies. It also addresses comments received on the ''Phase II'' Stark regulation published in the Federal Register on March 26, 2004.

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
Notice	03/23/07	72 FR 13710
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Lisa Ohrin, Deputy Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, Divison of Technical Payment Policy, Mailstop C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AK67

960. 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, 413, and 417

Legal Deadline: Final, Statutory, June 25, 2007, MMA sec. 902.

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

Timetable:

Action	Date	FR Cite
NPRM	06/25/04	69 FR 35716
NPRM Comment Period End	08/24/04	
Final Action	06/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Morton Marcus, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AL54

961. REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: sec 1869 (b) of the Act, as amended by sec 521 of BIPA

CFR Citation: 42 CFR 401 and 405

Legal Deadline: Final, Statutory, March 8, 2008, MMA sec 902.

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/08/05	70 FR 11419
Second Interim Final Rule	06/30/05	70 FR 37700
Third Interim Final Rule	08/26/05	70 FR 50214
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Katherine L. Hosna, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C2–12–16, 7500 Security Boulevard, Baltimore, MD 21244
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Related RIN: Related to 0938–AK69

RIN: 0938–AM73

962. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–F)

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: sec 1128a of the Social Security Act

CFR Citation: 42 CFR 402

Legal Deadline: Final, Statutory, July 23, 2007, MMA sec. 902.

Abstract: This final rule revises the CMS civil money penalty authorities. These 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	

HHS—CMS **Final Rule Stage**

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, Program Integrity Group, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
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Related RIN: Related to 0938–AN48

RIN: 0938–AM98

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

Priority: Other Significant

Legal Authority: sec 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	11/00/07	

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
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RIN: 0938–AN09

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

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 411; 42 CFR 414;

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 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.

Timetable:

Action	Date	FR Cite
NPRM	05/01/06	71 FR 25654
Notice	04/10/07	72 FR 16794
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, State

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RIN: 0938–AN14

965. MEDICAID PRESCRIPTION DRUGS—AVERAGE MANUFACTURER PRICE (CMS–2238–F)

Priority: Other Significant. Major under 5 USC 801.

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 final rule implements sections 6001, 6002, and 6003 of the Deficit Reduction Act of 2005. This rule sets the Federal upper reimbursement limit (FUL) as 250 percent of the average manufacturer price (AMP) for drugs on the FUL list, and will clarify the requirements and manner in which AMPs are determined for multiple-source drugs and other drug payment revisions. This rule also lists the physician administered multiple-source drugs that the Secretary determines have the highest dollar volume of dispensing in Medicaid and will require manufacturers to include authorized generics when they report their AMP and best price for covered outpatient drugs to the Secretary.

Timetable:

Action	Date	FR Cite
NPRM	12/22/06	71 FR 77174
NPRM Comment Period End	02/20/07	
Final Action	07/00/07	

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
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RIN: 0938–AO20

966. PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2008: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES(CMS–1529–F)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 412

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

Abstract: This rule finalizes the annual payment rate update for the Rate Year (RY) 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	02/01/07	72 FR 4776
NPRM Comment Period End	03/26/07	
Final Action	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0938–AO30

967. INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR RATE YEAR 2008 (CMS–1479–N)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: PL 106–113, sec 124 BBRA

CFR Citation: 42 CFR 412.400, subpart N

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

Abstract: This notice updates the Inpatient Psychiatric Facility Prospective Payment System for RY 2008. These changes are applicable for discharges occuring on or before July 1, 2007 through June 30, 2008.

Timetable:

Action	Date	FR Cite
Notice	05/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Agency Contact: Janet Samen, 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
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RIN: 0938–AO40

968. 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	11/00/07	

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.

Agency Contact: Adam Shaw, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Employer & Policy Operations Group, Mailstop C5–14–15, 7500 Security Boulevard, Baltimore, MD 21244
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Related RIN: Related to 0938–AI17

RIN: 0938–AO43

969. HIGH RISK POOLS (CMS–2260–IFC)

Priority: Other Significant. Major under 5 USC 801.

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 (HR 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 pool 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
Interim Final Rule	09/00/07	

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 Services Operations, Mailstop C2–01–16, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AO46

970. TARGETED CASE MANAGEMENT (CMS–2237–IFC)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 431, 42 CFR 440 to 441

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

Abstract: This interim final rule with comment period revises current Medicaid regulations to incorporate changes made by section 6052 of the Deficit Reduction Act of 2005. In addition, it incorporates provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, the Omnibus Budget Reconciliation Act of 1986, the Tax Reform Act of 1986, the Omnibus Budget Reconciliation Act of 1987, and the Technical and Miscellaneous Revenue Act of 1988, concerning case managment and targeted case management services. This interim final rule with comment period will provide for optional coverage of case management services or targeted case management services furnished according to section 1905 (a)(19) and section 1915 (g) of the Social Security Act. This interim final rule with comment period clarifies the situations in which Medicaid will pay for case management activities and also clarifies when payment will not be consistent with proper and efficient operation of the Medicaid program, and is not available.

Timetable:

Action	Date	FR Cite
Final Action	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Theresa A. Pratt, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO50

971. CITIZENSHIP DOCUMENTATION REQUIREMENTS (CMS–2257–F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Deficit Reduction Act of 2005 (PL 109–171), sec 6036; sec 1102 of Social Security Act; Tax Relief and Health Care Act of 2006 (PL 109–432,) sec 405(c)

CFR Citation: 42 CFR 435.403; 42 CFR 435.1009; 42 CFR 435.1010; 42 CFR 435.406 to 435.408; 42 CFR 435.1002; 42 CFR 435.1008; 42 CFR 435.1011; 42 CFR 436.406; 42 CFR 436.403; 42 CFR 436.407; 42 CFR 436.408; 42 CFR 436.1004; 42 CFR 436.1005; 42 CFR 440.2; 42 CFR 435.1009; 42 CFR 435.1010; 42 CFR 440.140; 42 CFR 440.180; 42 CFR 440.185; 42 CFR 441.13; 42 CFR 457.310; 42 CFR 483.5; 42 CFR 483.20; 42 CFR 483.102; 42 CFR 483.136;

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 United States 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
Interim Final Rule Comment Period	07/12/06	71 FR 39214
Interim Final Rule Comment Period End	08/11/06	
Final Action	05/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: 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
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Fax: 410 786–8534
Email: jean.sheil@cms.hhs.gov

RIN: 0938–AO51

972. ● COST LIMITS FOR GOVERNMENTALLY–OPERATED PROVIDERS (CMS–2258–F) (SECTION 610 REVIEW)

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: sec 1102 of the Social Security Act (42 U.S.C. 1302)

CFR Citation: 42 CFR 447.321; 42 CFR 433.51; 42 CFR 447.271; 42 CFR 447.272; 42 CFR 447.34; 42 CFR 457.220; 42 CFR 457.628; 42 CFR 447.206, 447.207;

Legal Deadline: None

Abstract: The final rule will: (1) clarify that only units of government are able to participate in the financing of the non-Federal share; (2) establish minimum requirements for documenting cost when using a certified public expenditure; (3) limit providers operated by units of government to reimbursement that does not exceed the cost of providing covered services to eligible Medicaid recipients; and (4) establish a new regulatory provision explicitly requiring that provders receive and retain the total computable amount of their Medicaid payments

Timetable:

Action	Date	FR Cite
NPRM	01/18/07	72 FR 2236
NPRM Comment Period End	03/19/07	
Final Action	05/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal, Local, State

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

Agency Contact: Aaron Blight, Technical Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO57

973. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES CO–INSURANCE AMOUNTS FOR CY 2008 (CMS–8032–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, 2007.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2008 under Medicare's Hospital Insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

Timetable:

Action	Date	FR Cite
Final Action	09/00/07	

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
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RIN: 0938–AO61

974. PART A PREMIUMS FOR CY 2008 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8031–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 1818A (d)(2)

CFR Citation: None

Legal Deadline: Final, Statutory, September 30, 2007.

Abstract: This notice announces the hospital insurance premium for calendar year 2008 under Medicare's Hospital Insurance program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

Action	Date	FR Cite
Final Action	09/00/07	

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
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RIN: 0938–AO62

975. PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATES BEGINNING JANUARY 1, 2008 (CMS–8033–N)

Priority: Other Significant

Legal Authority: 42 USC 1395; Social Security Act, sec 1839; MMA, sec 629; MMA, sec 811; DRA, sec 5111

CFR Citation: None

Legal Deadline: Final, Statutory, September 30, 2007.

Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in Part B of Medicare for CY 2008. It also announces the monthly Part B premiums and the Part B deductible for CY 2008.

Timetable:

Action	Date	FR Cite
Final Action	09/00/07	

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
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RIN: 0938–AO68

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

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1833(i)(2)(D)(iii)

CFR Citation: 42 CFR 416

Legal Deadline: Final, Statutory, January 1, 2008.

Abstract: This rule revises the method by which Medicare sets payment rates for ASC facility services and includes illustrative new payment rates for ASC services in accordance with that methodology. This rule finalizes policies proposed as part of the August 23, 2006, CY 2007 Outpatient Prospective Payment System rule.

Timetable:

Action	Date	FR Cite
Final Action	11/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Joan Sanow, Deputy Director, Division of Outpatient Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

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Email: joan.sanow@cms.hhs.gov

Related RIN: Split from 0938–AO15

RIN: 0938–AO73

977. FISCAL YEAR 2008 SCHIP ALLOTMENTS (CMS–2262–N)

Priority: Other Significant

Legal Authority: title XXI of the Social Security Act, sec 2104

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, September 30, 2007.

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 2008.

Timetable:

Action	Date	FR Cite
Notice	08/00/07	

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, Centers for Medicaid State Operations, Mailstop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO76

978. ● HEALTH CARE–RELATED TAX REVISIONS (CMS–2275–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: President's 2007 Budget; PL 109–432, sec 403

CFR Citation: 42 CFR 433.66(1)(3)(i); 42 CFR 433.56(a)(4); 42 CFR 433.56(a)(8); 42 CFR 433.58; 42 CFR 433.60;

Legal Deadline: None

Abstract: This proposed rule would revise the threshold under the indirect guarantee hold harmless arrangement test to reflect the provisions of the Tax Relief and Health Care Act of 2006 by providing that, when determining whether there is an indirect guarantee under the two-prong test for any part of a fiscal year on or after January 1, 2008, through September 30, 2011, the allowable amount that can be collected from a health care-related tax is reduced from 6 to 5.5 percent of net patient revenues received by the taxpayers. This proposed rule would also clarify the standard for determining the existence of a hold harmless arrangement under the positive correlation test, Medicaid payment test, and the guarantee test (with conforming changes to parallel provisions concerning hold harmless arrangements with respect to provider-related donations); codify descriptions for two classes of health care services permissible under Federal statute for purposes of taxes on health care providers; and remove obsolete transition period regulatory language.

Timetable:

Action	Date	FR Cite
NPRM	03/23/07	72 FR 13726
Final Action	07/00/07	

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.

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

Agency Contact: James Frizzera, Director, Division of Reimbursement and State Financing, 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
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RIN: 0938–AO80

979. ● EXTENDING SUNSET DATE FOR THE INTERIM FINAL REGULATION ON MENTAL HEALTH PARITY (CMS–4094–F5)

Priority: Routine and Frequent

Legal Authority: sec 2705 of the Public Health Service Act (as amended by the Mental Health Parity Act of 1996); sec 115(c) of the Tax Relief and Health Care Act of 2006 PL 109–432

CFR Citation: 45 CFR 146.136

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

Abstract: In section 115(c) of the Tax Relief and Health Care Act of 2006, legislation was enacted that extended the PHS Act provisions of the Mental Health Parity Act (MHPA) to services furnished through December 31, 2007. As a result of this most recently enacted legislation, it is now necessary to again publish conforming changes to the interim final regulation published June 27, 2003. These changes would conform the regulatory sunset date to the new statutory sunset date December 31, 2007, and would extend the duration of the increased cost exemption to be consistent with the new sunset date. The conforming changes would make absolutely no substantive changes to the existing regulation.

Timetable:

Action	Date	FR Cite
Final Action	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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Related RIN: Related to 0938–AO36

RIN: 0938–AO83

980. ● FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2008 (CMS–1552–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: sec 1834 (e) of the Social Security Act

CFR Citation: 42 CFR 410

Legal Deadline: Final, Statutory, January 1, 2008.

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing

section 1834(e) of the Social Security Act (effective January 1, 2008).

Timetable:

Action	Date	FR Cite
Final Action	11/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Anne Tayloe, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO85

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

Long-Term Actions

981. 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

Agency Contact: Mary Rossi–Coajou, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AH27

982. 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 for claims adjudication purposes.

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, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of E–Health Standards and Services, Mailstop S2–25–17, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AK62

983. 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 Action	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal, Local, State

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

Agency Contact: Adam Shaw, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Employer and Policy Operations Group, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AL88

984. 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 Modernization Act requires that physicians and beneficiaries be able to receive a prior determination regarding coverage of certain items and physicians' services beginning June 8, 2005. Full knowledge regarding financial liability for these services will be available to physicians and beneficiaries before expenses are incurred, although prior determination of coverage is not required for submission of a claim.

Timetable:

Action	Date	FR Cite
NPRM	08/30/05	70 FR 51321
Final Action	08/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Debbie Skinner, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Program Integrity Goup, Office of Financial Management, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AN10

985. 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, November 27, 2009, MMA sec. 902.

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

Agency Contact: Suzanne Ripley, Health Insurance Specialist, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3–14–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AN27

986. TERMINATION OF NON–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 Prescription Drug Improvement and Modernization Act beginning December 8, 2003. This rule provides guidelines for terminating a provider of services or supplier from non-random payment review.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Daniel Schwartz, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Intergrity Group, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AN31

987. LIMITATION ON RECOUPMENT OF PROVIDER AND SUPPLIER OVERPAYMENTS (CMS–6025–F)

Priority: Other Significant

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

CFR Citation: 42 CFR 405

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

Abstract: This rule implements one provision of section 935 of the Medicare Prescription Drug Improvement and Modernization Act which added a new subsection to section 1893 of the Social Security Act. It adjusts Medicare's ability to recover an overpayment when the Qualified Independent Contractor (QIC) receives a valid appeal from the provider or supplier. This rule defines the overpayments to which the limitation applies, how the limitation works in concert with the appeals process, and the change in Medicare's obligation to pay interest to a provider or supplier whose appeal is successful at levels above the QIC.

Timetable:

Action	Date	FR Cite
NPRM	09/22/06	71 FR 55404
NPRM Comment Period End	11/21/06	
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0938–AN42

988. 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
Second Interim Final Rule	09/06/05	70 FR 52930
Third Interim Final Rule	11/21/05	70 FR 70478
Fourth Interim Final Rule	08/18/06	71 FR 47870
Fourth Interim Final Rule Comment Period End	10/02/06	
Final Action	07/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Corinne Axelrod, Health Insurance Specialist, Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AN58

989. MEDICARE INTEGRITY PROGRAM, FISCAL INTERMEDIARY AND CARRIER FUNCTIONS, AND CONFLICT OF INTEREST REQUIREMENTS (CMS–6030–F)

Priority: Other Significant

Legal Authority: sec 1124, 1816, 1842, and 1893 of the Social Security Act

CFR Citation: 42 CFR 400 and 42 CFR 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 distinguishes between those functions that the statute requires to be included in agreements with fiscal intermediaries and those that may be included in the agreements. It would also provide that some or all of the functions may be included in carrier contracts. Currently all these functions are mandatory for carrier contracts.

Timetable:

Action	Date	FR Cite
NPRM	06/17/05	70 FR 35204
Final Action	06/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gary D. Williams, 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 21244–1850
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Related RIN: Related to 0938–AI09

RIN: 0938–AN72

990. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–F)

Priority: Other Significant

Legal Authority: Improper Payment Information Act of 2002

CFR Citation: 42 CFR 431; 42 CFR 457

Legal Deadline: Final, Statutory, October 1, 2005.

Abstract: This rule sets forth the State requirements to provide information for purposes of estimating improper payments under Medicaid and SCHIP. The Improper Payments Information Act of 2002 (IPIA) requires heads of Federal agencies to annually estimate and report to 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 rule also responds to the public comments on the August 28, 2006, interim final rule and sets forth State requirements for submitting claims and policies to the Federal contractor for purposes of conducting fee-for-service and managed care reviews. This rule also responds to public 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
Second Interim Final Rule	08/28/06	71 FR 51049
Final Action	08/00/09	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Janet Reichert, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program

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Related RIN: Related to 0938–AM86

RIN: 0938–AN77

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 483

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	10/27/06	71 FR 62957
NPRM Comment Period End	12/26/06	
Final Action	10/00/09	

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

992. USE OF REPAYMENT PLANS (CMS–6032–F)

Priority: Other Significant

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

Timetable:

Action	Date	FR Cite
NPRM	11/27/06	71 FR 68519
NPRM Comment Period End	01/26/07	
Final Action	11/00/09	

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
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RIN: 0938–AO27

993. IDENTIFICATION OF BACKWARD COMPATIBLE VERSION OF ADOPTED STANDARD FOR E–PRESCRIBING AND THE MEDICARE PRESCRIPTION DRUG PROGRAM (VERSION 8.1) (CMS–0018–F)

Priority: Other Significant

Legal Authority: 42 USC 1395

CFR Citation: 42 CFR 423

Legal Deadline: Final, Statutory, June 23, 2009, MMA sec. 902.

Abstract: This final rule identifies version 8.1 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard as a backward compatible update of the adopted version 5.0. This rule also permits the voluntary use of version 8.1 of the NCPDP SCRIPT Standard for conducting certain e-prescribing transactions for the electronic prescription drug program under title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/23/06	71 FR 36020
Interim Final Rule Comment Period End	08/22/06	
Final Action	06/00/09	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Gladys C. Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Electronic Standards and Services, Mailstop S2–16–17, 7500 Security Boulevard, Baltimore, MD 21244
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Related RIN: Related to 0938–AN49

RIN: 0938–AO42

994. PROHIBITION OF MID–YEAR BENEFIT ENHANCEMENTS FOR MEDICARE ADVANTAGE ORGANIZATIONS OFFERING PLANS IN CALENDAR YEAR 2007 AND SUBSEQUENT CALENDAR YEARS (CMS–4121–F)

Priority: Other Significant

Legal Authority: 42 USC 1302, 1395hh

CFR Citation: 42 CFR 422.2; 42 CFR 422.254

Legal Deadline: None

Abstract: This rule implements new policy to prohibit Medicare Advantage (MA) organizations from offering mid-year benefit enhancements (MYBEs). The policy is based on our experience during the first year of the new Medicare Advantage program and our belief that, in order to fully comply with the statute (MMA), we can no longer permit MYBEs as these threaten the integrity of the competitive bidding process established by the statute.

Timetable:

Action	Date	FR Cite
NPRM	09/01/06	71 FR 52014
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Christopher McClintick, Health Insurance Specialist, Center for Beneficiary Choices, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Advantage Group, Division of Plan Policy, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO54

995. MEDICARE PART D DATA (CMS–4119–F)

Priority: Other Significant

Legal Authority: sec 1860 D–12 of the Social Security Act

CFR Citation: 42 CFR 423

Legal Deadline: Final, Statutory, October 18, 2009, MMA sec. 902.

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

Timetable:

Action	Date	FR Cite
NPRM	10/18/06	71 FR 61445
NPRM Comment Period End	12/18/06	
Final Action	10/00/09	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Organizations

Government Levels Affected: None

Agency Contact: Alissa M. Deboy, Acting Division Director, Center for Beneficiary Choices, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Drug Plan Policy and Analysis Division, Mailstop C1–26–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO58

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

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

Priority: Other Significant

CFR Citation: 42 CFR 405; 42 CFR 482; 42 CFR 488; 42 CFR 498

Completed:

Reason	Date	FR Cite
Final Action	03/30/07	72 FR 15198

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

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RIN: 0938–AH17

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

Priority: Other Significant

CFR Citation: 42 CFR 483

Completed:

Reason	Date	FR Cite
Withdrawn	01/30/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0938–AM87

998. 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

CFR Citation: 42 CFR 482

Completed:

Reason	Date	FR Cite
Final Rule	11/27/06	71 FR 68672

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

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RIN: 0938–AM88

HHS—CMS **Completed Actions**

999. NONDISCRIMINATION IN HEALTH COVERAGE IN THE GROUP MARKET (CMS–4081–F)

Priority: Other Significant

CFR Citation: 45 CFR 146.121

Completed:

Reason	Date	FR Cite
Final Action	12/13/06	71 FR 75014

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local, State

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Related RIN: Previously reported as 0938–AK19

RIN: 0938–AN29

1000. HOSPITAL CONDITIONS OF PARTICIPATION: PATIENTS' RIGHTS (CMS–3018–F)

Priority: Other Significant

CFR Citation: 42 CFR 482

Completed:

Reason	Date	FR Cite
Final Action	12/08/06	71 FR 71378

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Patricia Chmielewski
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RIN: 0938–AN30

1001. PROGRAM FOR ALL–INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS–1201–F)

Priority: Other Significant

CFR Citation: 42 CFR 460

Completed:

Reason	Date	FR Cite
Final Action	12/08/06	71 FR 71244

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Agency Contact: Janet Harris
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Related RIN: Previously reported as 0938–AL59

RIN: 0938–AN83

1002. MEDICARE GRADUATE MEDICAL EDUCATION AFFILIATION PROVISIONS FOR TEACHING HOSPITALS IN CERTAIN EMERGENCY SITUATIONS (CMS–1531–F2)

Priority: Other Significant

CFR Citation: 42 CFR 413

Completed:

Reason	Date	FR Cite
Withdrawn	02/05/07	

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–AO70

RIN: 0938–AO35

1003. NOTIFICATION PROCEDURES FOR HOSPITAL DISCHARGES (CMS–4105–F)

Priority: Other Significant

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

Completed:

Reason	Date	FR Cite
Final Rule	11/27/06	71 FR 68708

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Eileen Zerhusen
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Related RIN: Merged with 0938–AK48, Merged with 0938–AL67

RIN: 0938–AO41

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

Proposed Rule Stage

1004. 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	09/00/07	

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

1005. 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	09/00/07	

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
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RIN: 0970–AC20

1006. 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 part 1355.40 and the appendices to part 1355 to modify the requirements for States to collect and report data to ACF on children in foster care and in subsidized adoption or guardianship arrangements with the State. The rule also implements the AFCARS penalty requirements of the Adoption Promotion Act of 2003 (Pub. L. 108-145).

Timetable:

Action	Date	FR Cite
NPRM	12/00/07	

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

1007. 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 decisionmaking 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	12/00/07	

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

1008. LIMITATION ON USE OF FUNDS MADE AVAILABLE TO MONITOR AND COMBAT TRAFFICKING IN PERSONS

Priority: Other Significant

Legal Authority: 22 USC chapter 78 Trafficking Victims Protection Act

CFR Citation: 45 CFR 404

Legal Deadline: None

Abstract: This rule will implement provisions of the Trafficking Victims Protection Act which prohibit programs from using trafficking funds to promote, support, or advocate the legalization or practice of prostitution and make organizations ineligible to receive such funds that promotes, supports, or advocates the legalization or the practice of prostitution if the program operates a program that targets several forms of trafficking unless the organization provides services to individuals solely after they are no longer engaged in activities that resulted from such activities being trafficked.

Timetable:

Action	Date	FR Cite
NPRM	09/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Kenneth Tota, Chief of Operations—Office of Refugee Resettlement, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
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RIN: 0970–AC28

1009. CHILD CARE AND DEVELOPMENT FUND ERROR RATE REPORTING

Priority: Other Significant

Legal Authority: Improper Payments Information Act (PL 107–300)

CFR Citation: 45 CFR 98

Legal Deadline: None

Abstract: This rule will require States and selected territories to employ a case review process every 4 years in calculating a CCDF error rate.

Timetable:

Action	Date	FR Cite
NPRM	03/02/07	72 FR 9491
NPRM Comment Period End	05/01/07	
Final Action	08/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Local, State, Tribal

Agency Contact: Jeffrey J. Polich, Child Care Program Specialist, Department of Health and Human Services, Administration for Children and Families, 8th Floor, 1250 Maryland Avenue SW., Washington, DC 20447
Phone: 202 205–8696

HHS—ACF **Proposed Rule Stage**

Email: jeffrey.polich@acf.hhs.gov

RIN: 0970–AC29

1010. ABSTINENCE EDUCATION

Priority: Other Significant

Unfunded Mandates: This action may affect State, local or tribal governments and the private sector.

Legal Authority: sec 510 of the Social Security Act

CFR Citation: 45 CFR 1352

Legal Deadline: None

Abstract: This rule will provide guidance on the general requirements for abstinence education curricula, clarify the treatment of section 510(b)(2)(A) through (H), clarify appropriate target age groups for title V State Abstinence Education Grants, and clarify appropriate application of additional activities used by title V State Abstinence Education grantees.

Timetable:

Action	Date	FR Cite
NPRM	03/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Organizations

Government Levels Affected: State

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

Agency Contact: David Siegel, Family and Youth Services Bureau, Department of Health and Human Services, Administration for Children and Families, 8th Floor, 1250 Maryland Avenue SW., Washington, DC 20447
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RIN: 0970–AC30

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

Final Rule Stage

1011. SAFEGUARDING CHILD SUPPORT AND EXPANDED FEDERAL PARENT LOCATOR SERVICES (FPLS) INFORMATION

Priority: Other Significant

Legal Authority: 42 USC 652 to 654A; 42 USC 663; 42 USC 1302

CFR Citation: 45 CFR 303.3; 45 CFR 303.21; 45 CFR 303.70

Legal Deadline: None

Abstract: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 made far-reaching amendments to title IV-D of the Social Security Act, which governs the child support enforcement program. The Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997, and the Child Support Performance and Incentive Act of 1998 further amended title IV-D. A significant result of this legislation is an expansion in the scope of information available to State IV-D child support enforcement agencies. The legislation has rendered obsolete or inconsistent several regulations at 45 CFR chapter III, Office of Child Support Enforcement, including the regulations on the Federal Parent Locator Service, the State Parent Locator Services, the offset of Federal payments for purposes of collecting child support, and the safeguarding of information. This regulation would update various sections in 45 CFR chapter III to reflect the statutory changes.

Timetable:

Action	Date	FR Cite
NPRM	10/14/05	70 FR 60038
NPRM Comment Period End	12/13/05	
Final Action	06/00/07	

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
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RIN: 0970–AC01

1012. COST ALLOCATION METHODOLOGY APPLICABLE TO THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES PROGRAM

Priority: Other Significant

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	09/27/06	71 FR 56440
NPRM Comment Period End	11/27/06	
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Robert Shelbourne, Deputy Director, Office of Family Assistance, Office of Policy, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
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RIN: 0970–AC15

1013. 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 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	05/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Christine Calpin, Associate Director, Child Care—Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 8th Floor, 1250 Maryland Avenue SW., Washington, DC 20447
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RIN: 0970–AC18

1014. 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	07/14/06	71 FR 40345
Final Action	03/00/08	

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–AC21

1015. 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	09/20/06	71 FR 54965
Final Action	09/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Local, State

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RIN: 0970–AC22

1016. CHILD SUPPORT PROVISIONS OF THE DEFICIT REDUCTION ACT

Priority: Economically Significant. Major under 5 USC 801.

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	01/24/07	72 FR 3093
Final Action	01/00/08	

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
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RIN: 0970–AC24

1017. TANF WORK PROVISIONS OF THE DEFICIT REDUCTION ACT

Priority: Other Significant

Legal Authority: 42 USC 1302

CFR Citation: 261, et seq

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

Abstract: This rule will 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	06/29/06	71 FR 37454
Final Action	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State, Tribal

Agency Contact: Robert Shelbourne, Director of Policy, OFA/ACF/HHS, Department of Health and Human Services, Administration for Children and Families, 901 D Street SW., Washington, DC 20447
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RIN: 0970–AC27

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

Completed Actions

1018. HEAD START TRANSPORTATION

Priority: Other Significant

CFR Citation: 45 CFR 1310

Completed:

Reason	Date	FR Cite
Final Action	10/04/06	71 FR 58533

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0970–AC26

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