Federal Register

Monday,
May 16, 2005

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require this semiannual publication that inventories all rulemaking actions under development or review 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 the planned rulemakings referenced below. Comments may be directed to the agency officials cited in each of the summaries. Or, if early attention at the Secretary's level is seen as required, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

Dated: April 6, 2005.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
821	Safe Harbor for Electronic Prescribing Information Technology	0991–AB39

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
822	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
823	Amending the Regulations Governing Nondiscrimination on the Basis of Race, Color, National Origin, Handicap, Sex, and Age To Conform to the Civil Rights Restoration Act of 1987	0991–AB10
824	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
825	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23
826	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
827	Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments	0991–AB03
828	Claims Collection	0991–AB18
829	Salary Offset	0991–AB19
830	Health Insurance Portability and Accountability Act—Enforcement	0991–AB29
831	Revisions to the Waiver Provisions of the Office of Inspector General's (OIG)Exclusion Authorities	0991–AB33

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Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
832	Office of Inspector General (OIG) Civil Money Penalties Under the Medicare Prescription Drug Discount Card Program	0991–AB40

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
833	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
834	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
835	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04
836	Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices	0920–AA10
837	Control of Communicable Diseases, Interstate and Foreign Quarantine	0920–AA12

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
838	Possession, Use, and Transfer of Select Agents and Toxins	0920–AA09
839	Establishment of Vaccination Clinics; User Fees for Investigational New Drug (IND) Influenza Vaccine Services and Vaccines	0920–AA11

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
840	Food Labeling; Prominence of Calories	0910–AF22
841	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
842	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
843	Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Certain Biological Drugs, and Animal Drugs	0910–AA49

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Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
844	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
845	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52
846	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
847	Food Standards: General Principles and Food Standards Modernization	0910–AC54
848	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
849	Reporting Information Regarding Falsification of Data	0910–AC59
850	Health Claims	0910–AF09
851	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation	0910–AF11
852	Cochineal Extract and Carmine Label Declaration	0910–AF12
853	Charging for Investigational Drugs	0910–AF13
854	Treatment Use of Investigational Drugs	0910–AF14
855	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
856	Revocation of the Status of Specific Products; Group A Streptococcus	0910–AF20
857	Obstetrical and Gynecological Devices; Designation of Special Control for Condoms and Condoms With Spermicidal Lubricant	0910–AF21
858	Blood Initiative—Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
859	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
860	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
861	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
862	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
863	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
864	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
865	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
866	Substances Prohibited From Use in Animal Food or Feed	0910–AF46
867	Over-the-Counter (OTC) Drug Review—Dandruff, Seborrheic Dermatitis, and Psoriasis Products	0910–AF49
868	Over-the-Counter (OTC) Drug Review—Skin Bleaching Prodcuts	0910–AF53
869	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
870	Designation of New Animal Drugs for Minor Use and Minor Species	0910–AF60

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
871	Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products	0910–AA94
872	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
873	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
874	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
875	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88
876	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
877	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
878	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
879	Institutional Review Boards: Registration Requirements	0910–AC17
880	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
881	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
882	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
883	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
884	Registration of Food and Animal Feed Facilities	0910–AC40
885	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
886	Quality Standard Regulation Establishing an Allowable Level for Arsenic in Bottled Water	0910–AF10

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Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
887	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
888	Blood Initiative—Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma	0910–AF26
889	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
890	Infant Formula Quality Factors	0910–AF28
891	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
892	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
893	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
894	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
895	Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle	0910–AF48
896	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
897	Supplements and Other Changes to Approved New Animal Drug Applications	0910–AF59
898	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AF62

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
899	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
900	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
901	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
902	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
903	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
904	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
905	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
906	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
907	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
908	Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants	0910–AF54
909	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
910	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement	0910–AB28
911	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Completion of a Section 610 Review)**	0910–AC39
912	Food Labeling: Food Allergen Ingredient Labeling	0910–AF07
913	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol	0910–AF18
914	Requirements for Human and Animal Medical Products Manufactured From, Processed With, or Otherwise Containing Material From Cattle	0910–AF55

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Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
915	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906–AA41
916	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44
917	Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA62
918	National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy	0906–AA68
919	Revision to 42 CFR Subpart D—Public Health Service (PHS) Grant Appeals Procedure	0906–AA69
920	Healthy Tomorrow's Partnership for Children (HTPC) Program	0906–AA70

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
921	Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
922	Smallpox Vaccine Injury Compensation Program: Administrative Implementation	0906–AA61
923	Requirements Establishing a Limitation on Administrative Expenses; Ryan White CARE Act Title IV Grants for Coordinated Services and Access to Research	0906–AA65

Health Resources and Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
924	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57
925	Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA63

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
926	National Vaccine Injury Compensation Program; Revisions and Additions to the Vaccine Injury Table	0906–AA66

Indian Health Service—Proposed Rule Stage

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

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
928	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925–AA10
929	National Institutes of Health AIDS Research Loan Repayment Program	0925–AA32
930	National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers	0925–AA33
931	National Institutes of Health Pediatric Research Loan Repayment Program	0925–AA34
932	National Institutes of Health Loan Repayment Program for Health Disparities Research	0925–AA35

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National Institutes of Health—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
933	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925–AA36
934	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925–AA41

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
935	National Institutes of Health Loan Repayment Program for Research Generally	0925–AA18
936	National Institutes of Health Training Grants	0925–AA28
937	Standards for a National Chimpanzee Sanctuary System	0925–AA31

Office of Public Health and Science—Prerule Stage

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

Office of Public Health and Science—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
939	Public Health Service Policies on Research Misconduct	0940–AA04
940	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940–AA06
941	Federal Policy for the Protection of Human Subjects Technical Amendment	0940–AA10

Office of Public Health and Science—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
942	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940–AA01
943	Human Subjects Protection Regulations: Training and Ed. Requirements for Institutional Officials, Institutional Review Board Members and Staff, Human Protections Administrators, and Investigators	0940–AA08

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
944	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)	0938–AG81
945	Hospice Care—Conditions of Participation (CMS-3844-P)	0938–AH27
946	Standard Unique National Health Plan Identifier (CMS-6017-P)	0938–AH87
947	Appeals of Carrier Determinations That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS-6003-P2)	0938–AI49
948	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)	0938–AJ17
949	Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS-6010-P)	0938–AJ98
950	Standards for Electronic Health Care Claim Attachments (CMS-0050-P)	0938–AK62

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

Sequence Number	Title	Regulation Identifier Number
951	Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938–AL26
952	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938–AL80
953	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938–AM50
954	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938–AM87
955	Enhanced DSH Treatment for Certain Hospitals (CMS-2198-P)	0938–AN09
956	Prior Determination Process for Certain Items and Services (CMS-6024-P)	0938–AN10
957	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-P)	0938–AN14
958	Revisions to HIPAA Code Sets (CMS-0013-P)	0938–AN25
959	Payment for Clinical Laboratory Tests (CMS-1494-P)	0938–AN26
960	Termination of Non-Random Prepayment Medical Review (CMS-6022-P)	0938–AN31
961	Limitation on Recoupment of Overpayments (CMS-6025-P)	0938–AN42
962	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2006 (CMS-1290-P)	0938–AN43
963	Home Health Prospective Payment System Rate Update for Calendar Year 2006 (CMS-1301-P)	0938–AN44
964	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-P)	0938–AN46
965	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6019-P)	0938–AN48
966	Changes to the Hospital Inpatient Prospective Payment System and FY 2006 Rates (CMS-1500-P)	0938–AN57
967	Special Payment Provisions and Standards for Suppliers of Custom Fabricated Orthotics and Prosthetics (CMS-6012-P)	0938–AN63
968	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2006 (CMS-1282-P)	0938–AN65
969	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Communitywide Health Information Systems and Electronic Prescribling Exception (CMS-1303-P)	0938–AN69
970	National Plan and Provider Enumeration System (NPPES) Data Dissemination (CMS-6060-N)	0938–AN71
971	Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements (CMS-6030-P2)	0938–AN72
972	Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (CMS-3156-P)	0938–AN73
973	Home Health Payment System Rate Update for Calendar Year 2007 (CMS-1304-P)	0938–AN76
974	Inpatient Psychiatric Facility Prospective Payment System—Update for 2006 (CMS-1306-P)	0938–AN82
975	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-P)	0938–AN84

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
976	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-F)	0938–AH73
977	Hospital Conditions of Participation: Laboratory Services (CMS-3014-IFC)	0938–AJ29
978	Medicare Hospice Care Amendments (CMS-1022-F)	0938–AJ36
979	Conditions for Coverage of Power Mobility Devices, Including Powered Wheelchairs and Power-Operated Vehicles Scooter (CMS-3017-IFC)	0938–AM74
980	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)	0938–AN19
981	Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-IFC)	0938–AN23
982	Medicare Secondary Payer Amendments (CMS-6272-IFC)	0938–AN27
983	Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-F)	0938–AN28
984	Development of New Standards for Medigap Policies (CMS-4087-FN)	0938–AN50
985	Fiscal Year 2006 SCHIP Allotments (CMS-2219-N)	0938–AN56
986	All Provider Bad Debt Payment (CMS-1126-F)	0938–AN75
987	State Children's Health Insurance Program (SCHIP); Redistribution of Unexpended SCHIP Funds From the Appropriation for Fiscal Year (FY) 2002 (CMS-2230-FN)	0938–AN78
988	Extending Sunset Date for the Interim Final Regulation on Mental Health Parity (CMS-4094-F3)	0938–AN80
989	Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services) (CMS-1908-F)	0938–AN81
990	Electronic Submission of Cost Reports: Revision to Cost Reporting Period (CMS-1199-IFC)	0938–AN87

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Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
991	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) **(Section 610 Review)**	0938–AG82
992	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-F)	0938–AH17
993	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)	0938–AJ10
994	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938–AJ96
995	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (CMS-1810-F)	0938–AK67
996	Organ Procurement Organization Conditions for Coverage (CMS-3064-F)	0938–AK81
997	Provider Reimbursement Determinations and Appeals (CMS-1727-F)	0938–AL54
998	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)	0938–AL88
999	Electronic Medicare Claims Submission (CMS-0008-F)	0938–AM22
1000	Requirements for Long-Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information (CMS-3121-F)	0938–AM55
1001	Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-IFC)	0938–AM73
1002	Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Post-Anesthesia Evaluations (CMS-3122-P2)	0938–AM88
1003	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-F)	0938–AM98
1004	Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS-1167-F)	0938–AN02
1005	Evaluation Criteria and Standards for Quality Improvement Program Contracts (CMS-3142-FN)	0938–AN13
1006	Medicare Ambulance Fee Schedule Update (CMS-1492-F)	0938–AN24
1007	Nondiscrimination in Health Coverage and Wellness Plans in the Group Market (CMS-4081-F)	0938–AN29
1008	Hospital Conditions of Participation: Patients' Rights (CMS-3018-F)	0938–AN30
1009	Federal Enforcement in Group and Individual Health Insurance Markets (CMS-4091-F)	0938–AN35
1010	Fire Safety Requirements for Certain Health Care Facilities; Alcohol-Based Hand Sanitizer Amendment (CMS-3145-IFC)	0938–AN36
1011	Medicare Modernization Act; Electronic Prescribing (CMS-0011-F)	0938–AN49
1012	Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F)	0938–AN58
1013	Group Market Health Insurance Reform: Guaranteed Availability, Guaranteed Renewability, Disclosures to Small Employers (CMS-4102-F)	0938–AN60
1014	Individual Market Health Insurance Reform: Portability From Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules (CMS-4103-F)	0938–AN61
1015	Revisions to the Oversight and Validation Program for Accrediting Organizations Approved for Deeming Authority (CMS-2255-P)	0938–AN62
1016	Payment Error Rate Measurement (PERM) Program (CMS-6026-F)	0938–AN77
1017	Fire Safety Requirements for Long-Term Care Facilities: Sprinkler Systems (CMS-3191-P)	0938–AN79
1018	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-F)	0938–AN83

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1019	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS-2151-F)	0938–AL43
1020	Prospective Payment System for Inpatient Psychiatric Facilities for FY 2004 (CMS-1213-F)	0938–AL50
1021	Request for Information on Benefit-Specific Waiting Periods (CMS-2150-NC)	0938–AL64
1022	Revisions to the Medicare Appeals Process (CMS-4004-FC)	0938–AL67
1023	DMERC Service Areas and Related Matters (CMS-1219-F)	0938–AL76
1024	Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services (CMS-3119-FN)	0938–AM36
1025	Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS-1427-FC)	0938–AM75
1026	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS-1429-FC)	0938–AM90
1027	Physician Referral for Nuclear Medicine Services and Supplies (CMS-1261-P)	0938–AN04
1028	Medicare Advantage Program—Title II (CMS-4069-F)	0938–AN06
1029	Medicare Drug Benefit Effective Calendar Year 2006—Title I (CMS-4068-F)	0938–AN08
1030	Schedule for Publishing Medicare Final Regulations After a Proposed or Interim Final Regulation (CMS-9026-N)	0938–AN12
1031	Modifications to Managed Care Rules (CMS-4041-IFC)	0938–AN38
1032	Furnishing Hospitals With Information To Compute the Disproportionate Share Hospital Formula (CMS-1283-P)	0938–AN52

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

Sequence Number	Title	Regulation Identifier Number
1033	End Stage Renal Disease (ESRD) Composite Rate Exception (CMS-1278-P)	0938–AN53
1034	Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program (CMS-2175-F)	0938–AN55
1035	Recognition of NAIC Standards for Regulation of Medicare Supplemental Insurance (CMS-4080-N)	0938–AN66
1036	Quality Improvement Organizations Contracts: Solicitation of Statements of Interest From In-State Organizations—Alaska, Hawaii, Idaho, Maine, South Carolina, Vermont, and Wyoming (CMS-3155-N)	0938–AN67
1037	Procedures for the Submission of Non-Privacy Administrative Simplification Complaints Under the Health Insurance Portability and Accountability Act of 1996 (CMS-0014-N)	0938–AN68
1038	Clinical Laboratory Improvement Amendments of 1988; Continuance of Exemption of Laboratories Licensed by the State of Washington (CMS-2207-N)	0938–AN70

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1039	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01
1040	Developmental Disabilities and Bill of Rights Act	0970–AC07
1041	Administrative Cost Sharing Under TANF	0970–AC15
1042	Care and Placement of Unaccompanied Alien Children	0970–AC20
1043	Chafee National Youth in Transition Database	0970–AC21
1044	Medical Support	0970–AC22

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1045	Administrative Costs for Children in Title IV-E Foster Care	0970–AC14
1046	Head Start Transportation	0970–AC16
1047	Child Care and Development Fund State Match Provisions	0970–AC18
1048	Reasonable Quantitative Standard for Review and Adjustment of Child Support Orders	0970–AC19

Administration on Aging—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1049	Grants for State and Community Programs on Aging, Training, Research, and Discretionary Programs; Vulnerable Elder Rights; Grants to Indians and Native Hawaiians	0985–AA00

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

Office of the Secretary (OS)

821. ● SAFE HARBOR FOR ELECTRONIC PRESCRIBING INFORMATION TECHNOLOGY

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

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	
NPRM Comment Period End	10/00/05	

HHS—OS **Proposed Rule Stage**

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0991–AB39

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

Final Rule Stage

822. 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	10/00/05	

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

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

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

Legal Authority: PL 100–259, Civil Rights Restoration Act of 1987

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

Legal Deadline: None

Abstract: The Secretary proposes to amend the Department's regulations implementing title VI of the Civil Rights Act of 1964, as amended, section 504 of the Rehabilitation Act of 1973, as amended, title IX of the Education Amendments of 1972, and the Age Discrimination Act of 1975, as amended. The principal proposed conforming change is to amend the regulations to add the definitions of ''program or activity'' or ''program'' that correspond to the statutory definitions enacted under the Civil Rights Restoration Act of 1987.

Timetable:

Action	Date	FR Cite
NPRM	12/06/00	65 FR 76460
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Agency Contact: Robinsue Frohboese, Principal Deputy Director, Office for Civil Rights, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW., Washington, DC 20202
Phone: 202 619–0403

RIN: 0991–AB10

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

Priority: Substantive, Nonsignificant

Legal Authority: PL 100–93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This final rule will expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will protect waivers of coinsurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver.

Timetable:

Action	Date	FR Cite
NPRM	09/25/02	67 FR 60202
NPRM Comment Period End	10/25/02	
Final Action	10/00/05	

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

HHS—OS **Final Rule Stage**

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/15/03	68 FR 53939
NPRM Comment Period End	11/14/03	
Final Action	10/00/05	

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

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

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

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

CFR Citation: 42 CFR 1001

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

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/00/05	
Interim Final Rule Comment Period End	08/00/05	

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

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would revise part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments, by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; modify the current definition for the term ''claim;'' update various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e-mail communications.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

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

828. CLAIMS COLLECTION

Priority: Substantive, Nonsignificant

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

CFR Citation: 45 CFR 30

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991–AB18

829. SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 5514; 5 CFR 550

CFR Citation: 45 CFR 33

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991–AB19

830. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

Priority: Other Significant

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

CFR Citation: 45 CFR 160, subparts C to E

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	04/18/05	70 FR 20224
Final Action	08/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0991–AB29

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: In accordance with section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, this rule would revise the OIG's exclusion authority to permit any Federal health care program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), 1128(a)(3), or 1128(a)(4) of the Social Security Act.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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

RIN: 0991–AB33

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

Completed Actions

832. ● OFFICE OF INSPECTOR GENERAL (OIG) CIVIL MONEY PENALTIES UNDER THE MEDICARE PRESCRIPTION DRUG DISCOUNT CARD PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: PL 108–173, sec 101; Social Security Act, sec 1860D–31

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This rule sets forth the OIG's new authority for imposing civil money penalties against endorsed sponsors that knowingly engage in false or misleading marketing practices, overcharge program enrollees or misuse transitional assistance funds under the Medicare prescription drug discount card program.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/19/04	69 FR 28842
Interim Final Rule Comment Period End	07/19/04	
Final Rule	12/14/04	69 FR 74451

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

HHS—OS **Completed Actions**

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–AB40

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

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

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

Legal Authority: PL 106–310

CFR Citation: Not Yet Determined

Legal Deadline: NPRM, Statutory, April 2001.

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

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

RIN: 0930–AA10

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

834. 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	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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

RIN: 0930–AA12

Department of Health and Human Services (HHS) — Proposed Rule Stage
Centers for Disease Control and Prevention (CDC)

835. 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	08/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

HHS—CDC **Proposed Rule Stage**

Agency Contact: Roland Berry Ann, Acting Chief, Respirator Branch, National Personal Protection Technology Laboratory, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–4000

RIN: 0920–AA04

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

Priority: Other Significant

Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842; 30 USC 844

CFR Citation: 42 CFR 84

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Roland Berry Ann, Acting Chief, Respirator Branch, National Personal Protection Technology Laboratory, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–4000

RIN: 0920–AA10

837. ● CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 70; 42 CFR 71

Legal Deadline: None

Abstract: By statute, the Secretary of Health and Human Services (HHS) has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. Interstate authority is split between CDC and the Food and Drug Administration (FDA), with CDC delegated interstate authority as it pertains to humans. CDC maintains quarantine stations at 8 major airports with quarantine inspectors who respond to reports of diseases from carriers. According to the statutory scheme, the President of the United States determines through Executive order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2003, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and Severe Acute Respiratory Syndrome (SARS).

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

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

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

838. POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Priority: Other Significant

CFR Citation: 42 CFR 72; 42 CFR 72.6

Completed:

Reason	Date	FR Cite
Final Action	03/18/05	70 FR 13294

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Mark Hemphill
Phone: 404 498–2255

Related RIN: Previously reported as 0920–AA08

RIN: 0920–AA09

839. ● ESTABLISHMENT OF VACCINATION CLINICS; USER FEES FOR INVESTIGATIONAL NEW DRUG (IND) INFLUENZA VACCINE SERVICES AND VACCINES

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 70

Legal Deadline: None

Abstract: We are amending 42 CFR part 70 to establish vaccination clinics and a user fee connection with the administration of vaccination services and vaccine. The Secretary of HHS announced the purchase of 1.2 million doses of GlaxoSmithKline (GSK) influenza vaccine, Fluarix, for distribution to areas most in need as determined by State public health authorities. The Fluartix vaccine has been approved in seventy-eight foreign countries, and FDA has recently reviewed extensive manufacturing and summary clinical information and conducted an inspection of the GSK manufacturing facility in Germany to determine that this vaccine, although not licensed in the United States, is suitable for use under an

HHS—CDC **Completed Actions**

Investigational New Drug application (IND).

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/25/05	70 FR 3490

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Lisa Rotz, Department of Health and Human Services, Centers for Disease Control and Prevention, MS–C–19, 1600 Clifton Road, Atlanta, GA 30333
Phone: 404 639–0153

RIN: 0920–AA11

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

Prerule Stage

840. FOOD LABELING; PROMINENCE OF CALORIES

Priority: Other Significant

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

CFR Citation: 21 CFR 101.9

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0910–AF22

841. 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(b); 21 CFR 101.12; 21 CFR 101.60(b)

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0910–AF23

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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

HHS—FDA **Prerule Stage**

Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov
Related RIN: Split from 0910–AA01
RIN: 0910–AF43

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

843. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR HUMAN DRUGS, CERTAIN BIOLOGICAL DRUGS, AND ANIMAL DRUGS

Priority: Other Significant

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AA49

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360c(e)(1); 21 USC 371

CFR Citation: 21 CFR 868.2700

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC30

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

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

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

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

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend the regulations governing the format in which clinical study data (CSD) 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 CSD submitted for NDAs, ANDAs, BLAs, and their supplements and amendments be provided in electronic format and require the use of standard data structure, terminology, and code sets. The proposal would improve the efficiency of the exchange of information from clinical studies through the adoption of standards for study data submitted in an electronic form that FDA can process, review, and archive.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Nicole K. Mueller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Room 3037, (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AC52

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

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

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Elaine H. Tseng, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AC53

847. 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 are now proposing a set of general principles that define how modern food standards should be structured. 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	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Ritu Nalubola, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, HFS–820, Center for Food Safety and Applied Nutrition, Harvey Wiley Building, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Related to 0583–AC72

RIN: 0910–AC54

848. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

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

Unfunded Mandates: Undetermined

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	05/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Federal, State

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

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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Related RIN: Previously reported as 0910–AB63

RIN: 0910–AC55

849. REPORTING INFORMATION REGARDING FALSIFICATION OF DATA

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

Unfunded Mandates: Undetermined

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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Related RIN: Previously reported as 0910–AC02

RIN: 0910–AC59

850. 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	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Nancy Crane, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AF09

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

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360(b); 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 201.57

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations concerning the format and content of the ''Pregnancy,'' ''Labor and Delivery,'' and ''Nursing Mothers'' subsections of the ''Use in Specific Populations'' section of the labeling for human prescription drugs. The proposal would require that labeling include a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF11

852. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

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

Legal Authority: 21 USC 379e(b)

CFR Citation: 21 CFR 73.100(d); 21 CFR 73.1100(c); 21 CFR 73.2087(c); 21 CFR 101.22(k); 21 CFR 201.100(b); 21 CFR 201.324

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Mical E Honigfort, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–265, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AF12

853. CHARGING FOR INVESTIGATIONAL DRUGS

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

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

CFR Citation: 21 CFR 312.7; 21 CFR 312.8

Legal Deadline: None

Abstract: The proposed rule would amend FDA's investigational new drug exemption regulations concerning charging for investigational drugs. The proposed rule describes the types of investigational uses for which a sponsor may be able to charge, including uses for which charging was not previously expressly permitted, and the criteria for allowing charging for the identified investigational uses. The proposed rule would also describe the types of costs that can be recovered when charging for an investigational drug.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF13

854. TREATMENT USE OF INVESTIGATIONAL DRUGS

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

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

CFR Citation: 21 CFR 312.42; 21 CFR 312.400; 21 CFR 312.405; 21 CFR 312.410; 21 CFR 312.415; 21 CFR 312.420; 21 CFR 312.425; 21 CFR 312.430; 21 CFR 312.435

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations governing investigational new drugs (INDs) to describe the way patients may obtain investigational drugs for treatment use. Treatment use of investigational drugs would be available to: 1) individual patients, including in emergencies; 2) intermediate size patient populations; and 3) larger populations under a treatment protocol or IND.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF14

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

Priority: Substantive, Nonsignificant

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

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

Legal Deadline: None

Abstract: FDA is proposing to amend certain limited provisions of the implementing regulations of the Prescription Drug Marketing Act (PDMA) of 1987, as modified by the Prescription Drug Amendments (PDA) of 1992 and the FDA Modernization Act of 1997. Certain provisions of that final rule that published on December 3, 1999, (64 FR 67720), do not allow a registered blood establishment that

provides health care services related to its activities as a blood establishment to concurrently distribute blood derivatives. The effective date of those provisions of that rule is December 1, 2006, as published on February 23, 2004, (69 FR 8105). FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute blood derivatives.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

Agency Contact: Kathleen E. Swisher, Supervisory Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, (HFM–17), Rockville, MD 20852
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RIN: 0910–AF16

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

Priority: Info./Admin./Other

Legal Authority: 42 USC 262

CFR Citation: 21 CFR 610.19

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM – Companion to Direct Final Rule	09/00/05	
Direct Final Rule	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), HFM–17, 1401 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AF20

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

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

Legal Authority: 21 USC 360c

CFR Citation: 21 CFR 884.5300; 21 CFR 884.5310

Legal Deadline: None

Abstract: The classification regulations for male condoms would be amended to specify a labeling guidance document as a special control for condoms made from natural rubber latex. The new special control guidance document would identify issues presented by these devices, and would provide detailed recommendations for labeling to address these issues. FDA believes that compliance with the recommendations in the guidance, or with some equivalent means of addressing the identified issues together with the general controls, will provide a reasonable assurance of the safety and effectiveness of these devices. These labeling recommendations are also consistent with the labeling requirements of 21 CFR 801. The rule will demonstrate how the agency is moving forward to meet the congressional directive of Public Law 106-554 that FDA review condom labeling to assure that the information regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases is medically accurate.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AF21

858. 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; 21 USC 372; 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 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 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 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, as well as on public comments. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, HFM–17, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448
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Related RIN: Split from 0910–AB26

RIN: 0910–AF25

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	06/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF32

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	06/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF33

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600

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Related RIN: Split from 0910–AA01

RIN: 0910–AF34

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses labeling intended to better inform consumers of potential risks associated with these products. The second action addresses products marketed for children under two years old and weight- and age-based dosing for children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Labeling)	06/00/05	
NPRM (Amendment) (Pediatric)	07/00/05	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	01/00/06	
NPRM (Amendment) (Overindulgence/ Hangover)	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AA01

RIN: 0910–AF36

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF37

864. 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)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AA01

RIN: 0910–AF39

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Phenyl propanolamine)	08/00/05	
NPRM (Benzocaine)	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF45

866. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Priority: Other Significant. Major under 5 USC 801.

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

CFR Citation: 21 CFR 589.2001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
ANPRM	07/14/04	69 FR 42288
ANPRM Comment Period End	08/13/04	
NPRM	08/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF46

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF49

868. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODCUTS

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 hydroquinone.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human

HHS—FDA **Proposed Rule Stage**

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RIN: 0910–AF53

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF56

870. ● DESIGNATION OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

Priority: Other Significant

Legal Authority: 21 USC 360ccc–2

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF60

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

Final Rule Stage

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

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 201

Legal Deadline: None

Abstract: This regulation is one component of the Secretary's initiative to reduce medical errors. The regulation would amend the regulations governing the format and content of professional labeling for human prescription drugs (including biological products that are regulated as drugs), 21 CFR 201.56 and 201.57. The regulation would require that such labeling include highlights of prescribing information and a table of contents for prescribing information. It would reorder currently required information, make minor changes to its content, and establish minimum graphical requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/22/00	65 FR 81082
NPRM Comment Period End	03/22/01	
NPRM Comment Period Reopened	03/30/01	
NPRM Comment Period Reopening End	06/22/01	
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AA94

872. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a to 263–n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Comment Review End	09/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AA97

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

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	07/20/04	69 FR 43357
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AB34

874. 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 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 21 USC 372; 21 USC 372; 21 USC 381; 42 USC 263

CFR Citation: 21 CFR 606; 21 CFR 610

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Related to 0910–AB26

RIN: 0910–AB76

875. 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 of 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	09/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AB88

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

Priority: Routine and Frequent

Legal Authority: 21 USC 331 to 334; 21 USC 341 to 344; 21 USC 348; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 376; 21 USC 381; 21 USC 393; 42 USC 264

CFR Citation: 21 CFR 59

Legal Deadline: None

Abstract: The final rule would establish requirements for importers and other persons who use sampling services and private laboratories in connection with imported food. For example, the rule would pertain to persons who use sample collection services and private laboratories, and would describe some responsibilities for such persons, sample collection services, and private laboratories. These responsibilities would include recordkeeping requirements to ensure that the correct sample is collected and analyzed, and a notification requirement if a person intends to use a sampling service or a private laboratory in connection with imported food. The final rule is intended to help insure the integrity and scientific validity of data and results submitted to FDA.

Timetable:

Action	Date	FR Cite
NPRM	04/29/04	69 FR 23460
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AB96

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

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 50; 21 CFR 56

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Rule	04/24/01	66 FR 20589
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AC07

878. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271; . . .

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

Legal Deadline: None

Abstract: In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of salmonella enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses by 50 percent by 2005 and eliminate egg-related SE illnesses by 2010.

The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

On September 22, 2004, FDA published a proposed rule that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. This proposal would reduce SE prevalence in the egg production environment and consequently in the eggs themselves. Most SE contamination of eggs is a result of SE infection in the laying hen's reproductive tract, called transovarian contamination. The proposed measures are designed to reduce the likelihood of this transovarian contamination and include: (1) provisions for procurement of chicks and pullets; (2) a biosecurity program; (3) a rodent and pest control program; (4) cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm.

Additionally, to verify that the measures have been effective, the rule proposes that producers test the poultry house environment for SE. If the environmental test is positive, eggs from that environment must be tested for SE, and if the egg test is positive, the eggs must be diverted to egg products processing or a treatment process that achieves at least a 5-log destruction of SE.

The proposed rule is one step in a broader farm-to-table egg safety effort that includes FDA's requirements for safe handling statements on egg cartons and refrigerated storage of shell eggs at retail and egg safety education for consumers and retail establishments. The rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings: October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AC14

879. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS

Priority: Info./Admin./Other

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

CFR Citation: 21 CFR 56.106

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	07/06/04	69 FR 40556
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AC17

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

Priority: Other Significant

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

CFR Citation: 21 CFR 50.23

Legal Deadline: None

Abstract: FDA is proposing to 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AC25

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 800.20

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC32

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360e to 360j; 21 USC 360hh to 360ss; 21 USC 371; 21 USC 381

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

Legal Deadline: None

Abstract: This rule amends the performance standard for diagnostic x-ray systems and their components in 21 CFR 1020.30, 1020.31, 1020.32, and 1020.33 to address the changes in technology and practice.

Timetable:

Action	Date	FR Cite
NPRM	12/10/02	67 FR 76056
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC34

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

Priority: Other Significant

Legal Authority: 21 USC 355b

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	04/22/04	69 FR 21778
NPRM Comment Period End	07/21/04	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AC35

HHS—FDA **Final Rule Stage**

884. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority: Other Significant

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

Legal Authority: PL 107–188, sec 305

CFR Citation: 21 CFR 1; 21 CFR 20

Legal Deadline: Final, Statutory, December 12, 2003.
The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 305, directs the Secretary, through FDA, to issue a final regulation establishing registration requirements by December 12, 2003. The statute is self-implementing on this date if FDA does not issue a final regulation that is effective by December 12, 2003.

Abstract: This final rule confirms the interim final rule that FDA issued on October 10, 2003 (68 FR 58894). The interim final rule implements section 415 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The Bioterrorism Act directs the Secretary to require facilities engaged in manufacturing, processing, packing, or holding of food for consumption in the United States to be registered with the Secretary. Section 415 directs the Secretary to promulgate final regulations implementing the requirements by December 12, 2003. The owner, operator, or agent in charge of the facility must submit the registration. Foreign facilities must include the name of the United States agent for the facility. The registration must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. If the Secretary determines it is necessary through guidance, the registration must include the general food category (as identified under 21 CFR 170.3) of foods manufactured, processed, packed, or held at the facility. The registrant is required to notify the Secretary of changes to the information contained in the registration in a timely manner. Under the interim final rule, upon receipt of the completed registration form, FDA will notify the registrant of receipt of the registration and assign a unique registration number to the facility. Section 415 requires the Secretary to compile and maintain an up-to-date list of registered facilities. This list and any registration documents submitted to the Secretary are not subject to disclosure under the Freedom of Information Act. For purposes of section 415, ''facility'' includes any factory, warehouse, or establishment engaged in the manufacturing, processing, packing, or holding of food. Exempt from the registration requirement are farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (except those engaged in processing as defined in 21 CFR 123.3(k)). Foreign facilities required to register include only those from which food is exported to the United States without further processing or packaging outside the United States. The Bioterrorism Act provides that if food from an unregistered foreign facility is offered for import into the United States, the food will be held at the port of entry or at a secure facility, until the foreign facility has registered.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5377
Interim Final Rule	10/10/03	68 FR 58894
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19766
Interim Final Rule Comment Period Reopened End	05/14/04	
Final Rule	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC40

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 107–188, sec 307

CFR Citation: 21 CFR 1.276 et seq

Legal Deadline: Final, Statutory, December 12, 2003.
The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 307, directs the Secretary, through FDA, to issue final regulations establishing prior notice requirements for all imported food by December 12, 2003. If FDA fails to issue final regulations by this date, the statute is self-executing on this date, and requires FDA to receive prior notice of not less than eight hours, nor more than five days until final regulations are issued.

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. Section 801(m) requires notification to FDA prior to the entry of imported food. The required prior notice would provide the identity of the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation identifies the parties responsible for providing the notice and explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5428
Interim Final Rule	10/10/03	68 FR 58974

Action	Date	FR Cite
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19763
Interim Final Rule Comment Period Reopened End	07/13/04	
Final Rule	06/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Mary Ayling, Lead, Inspection and Compliance Team, Food Safety Staff, Department of Health and Human Services, Food and Drug Administration, HFS–32, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AC41

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

Priority: Other Significant. Major status under 5 USC 801 is 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(b)

Legal Deadline: Final, Statutory, July 27, 2005.

Abstract: Under section 410 of the Federal Food, Drug, and Cosmetic Act (the Act), not later than 180 days before the effective date of a National Primary Drinking Water Regulation (NPDWR) issued by the Environmental Protection Agency (EPA) for a contaminant under section 1412 of the Safe Drinking Water Act, the Food and Drug Administration (FDA) is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled water. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. On January 22, 2001, EPA published a final rule revising the existing 0.05 mg/L maximum contaminant level (MCL) for arsenic in public drinking water to 0.01 mg/L (10 ppb). The effective date for this rule was temporarily delayed for 60 days from March 23, 2001, to a new effective date of May 22, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan'' (66 FR 7701; January 24, 2001). On May 22, 2001, EPA announced that it would further delay the effective date for the rule until February 22, 2002, to allow time to complete a reassessment of the information on which the revised arsenic standard is based. On February 22, 2002, the arsenic MCL of 0.01 mg/L in public drinking water rule became effective and water systems must comply with the new standard for arsenic in public drinking water by January 23, 2006. On March 25, 2003 (68 FR 14501 at 14503), EPA revised the rule text in its January 2001 final rule that established the 10 parts per billion arsenic drinking water standard to express the standard as 0.010 mg/L, in order to clarify the implementation of the original rule. In accordance with section 410 of the Act, FDA is required to issue a standard of quality regulation for arsenic in bottled drinking water by July 27, 2005, with an effective date of January 23, 2006, or make a finding that such a regulation is not necessary to protect the public health.

FDA evaluated the MCL for arsenic established by EPA for drinking water and tentatively concluded that, as a standard of quality level for bottled water, it is adequate for the protection of public health. Certain waters used for bottled water may be expected to contain arsenic; thus, FDA believes that adopting EPA's MCL for arsenic will ensure that the quality of bottled water is equivalent to the quality of public drinking water that meets EPA standards. Therefore, on December 2, 2004, FDA proposed an allowable level for arsenic in bottled water of 0.010 mg/L (10 ppb).

Timetable:

Action	Date	FR Cite
NPRM	12/02/04	69 FR 70082
NPRM Comment Period End	01/31/05	
Final Rule	07/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AF10

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

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

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

CFR Citation: 21 CFR 312.120

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/10/04	69 FR 32467
Final Action	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF15

888. BLOOD INITIATIVE—REVISIONS TO LABELING AND STORAGE REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA

Priority: Other Significant

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

CFR Citation: 21 CFR 600; 21 CFR 606; 21 CFR 640

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is amending the labeling requirements for blood, blood components, and 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 and storage temperatures.

Timetable:

Action	Date	FR Cite
NPRM	07/30/03	68 FR 44678
NPRM Comment Period End	10/28/03	
Final Action	12/00/05	

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–AF26

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

Priority: Other Significant

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

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Split from 0910–AA04

RIN: 0910–AF27

890. INFANT FORMULA QUALITY FACTORS

Priority: Other Significant

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

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Split from 0910–AA04

RIN: 0910–AF28

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

Priority: Routine and Frequent

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

21USC 371a; 21 USC 331; 21 USC 360; 21 USC 371

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AA01

RIN: 0910–AF31

892. 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)	08/00/05	
Final Action (Fever Blisters/Cold Sores)	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF42

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e. final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling warning statements for products containing nonoxynol 9.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	11/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF44

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

Priority: Other Significant

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

CFR Citation: 21 CFR 189.5; 21 CFR 700.27

Legal Deadline: None

Abstract: On July 14, 2004, FDA issued an interim final rule, effective immediately, to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) (Beef). Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no

more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. After reviewing comments received to the interim final rule, FDA intends to issue a final rule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/14/04	69 FR 42256
Interim Final Rule Comment Period End	10/12/04	
Final Action	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740
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RIN: 0910–AF47

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

Priority: Other Significant

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

CFR Citation: 21 CFR 189.5; 21 CFR 700.27

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740
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RIN: 0910–AF48

896. 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 (Sodium Bicarbonate Labeling)	01/00/06	
Final Action (Overindulgence Labeling)	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF52

897. ● SUPPLEMENTS AND OTHER CHANGES TO APPROVED NEW ANIMAL DRUG APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 356a

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

Legal Deadline: None

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

of the drug made using the change, changes requiring the submission of a supplement at least 30 days prior to the distribution of the drug, changes requiring the submission of a supplement at the time of distribution

of the drug, and changes to be described in an annual report.

Timetable:

Action	Date	FR Cite
NPRM	10/01/99	64 FR 53281
Final Action	07/00/05	
Final Action Effective	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Dennis Bensley Jr., Chemist, Department of Health and Human Services, Food and Drug Administration, 7500 Standish Place, MPN–2, Room 320, HFV–140, Rockville, MD 20855
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RIN: 0910–AF59

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC360; 21 USC 360b to 360d; 21 USC 360h; 21 USC 360i; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264

CFR Citation: 21 CFR 201.59; 21 CFR 610.21

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/29/04	69 FR 78281
NPRM Comment Period End	03/29/05	
Final Action	07/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Astrid L. Szeto, Senior Regulatory Review Officer, Department of Health and Human Services, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, HFM–17, Rockville, MD 20852
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RIN: 0910–AF62

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

Long-Term Actions

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

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 312.110

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/19/02	67 FR 41642
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy and Planning (HF–23), 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
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RIN: 0910–AA61

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

Priority: Other Significant

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

CFR Citation: Not Yet Determined

Legal Deadline: None

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

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–306, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS–366, College Park, MD 20740
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RIN: 0910–AC21

901. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

Priority: Substantive, Nonsignificant

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Aileen Ciampa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFD–7, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20857
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RIN: 0910–AC23

902. 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: No

Government Levels Affected: Federal

Agency Contact: Julie Moss, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, (HFS–832), HFS–830, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Related to 0910–AB66

RIN: 0910–AC50

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

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 351

CFR Citation: 21 CFR 211.122

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF08

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF35

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products,

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Related RIN: Split from 0910–AA01

RIN: 0910–AF38

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF40

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, HFD–560, Rockville, MD 20857
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RIN: 0910–AF51

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

Priority: Other Significant

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Eric Flamm, Senior Policy Advisor, Office of Policy, Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, 5600 Fishers Lane, Room 15–61, HF–23, Rockville, MD 20857
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Related RIN: Merged with 0910–AF55

RIN: 0910–AF54

HHS—FDA Long-Term Actions

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

Priority: Other Significant

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

CFR Citation: 21 CFR 1.98

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning (HF–23), 5600 Fishers Lane, Room 14C–17, Rockville, MD 20857
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RIN: 0910–AF61

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

910. CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE–BASED PRODUCT ESTABLISHMENTS; INSPECTION AND ENFORCEMENT

Priority: Other Significant

CFR Citation: 21 CFR 16; 21 CFR 1270; 21 CFR 1271

Completed:

Reason	Date	FR Cite
Final Action	11/24/04	69 FR 68612

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Paula S. McKeever
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RIN: 0910–AB28

911. ESTABLISHMENT AND MAINTENANCE OF RECORDS PURSUANT TO THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 (COMPLETION OF A SECTION 610 REVIEW)

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 107–188, sec 306

CFR Citation: 21 CFR 1

Legal Deadline: None

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. The Act authorizes regulations that require the establishment and maintenance of records, for not longer than two years, that would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records are those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food. Farms and restaurants are excluded. The Secretary is directed to take into account the size of a business in promulgating these regulations. Section 306 of the Act also added section 414(a) and amended section 704(a) of FFDCA to permit FDA to inspect these records and other information if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	05/09/03	68 FR 25188
NPRM Comment Period End	07/08/03	
Final Action	12/09/04	69 FR 71562

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

URL For More Information: www.fda.gov/oc/bioterrorism/bioact.html

URL For Public Comments: www.fda.gov/ohrms/dockets/02n0277/02n0277.htm

Agency Contact: Nega Beru, Supervisory Chemist, Office of Plant, Dairy Foods, Department of Health and Human Services, Food and Drug Administration, HFS–305, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AC39

912. FOOD LABELING: FOOD ALLERGEN INGREDIENT LABELING

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

CFR Citation: 21 CFR 101

HHS—FDA **Completed Actions**

Completed:

Reason	Date	FR Cite
Withdrawn	02/16/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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RIN: 0910–AF07

913. USE OF OZONE–DEPLETING SUBSTANCES: REMOVAL OF ESSENTIAL USE DESIGNATION; ALBUTEROL

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 2.125

Completed:

Reason	Date	FR Cite
Final Action	04/04/05	70 FR 17168

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal, State

Agency Contact: Wayne H. Mitchell
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RIN: 0910–AF18

914. REQUIREMENTS FOR HUMAN AND ANIMAL MEDICAL PRODUCTS MANUFACTURED FROM, PROCESSED WITH, OR OTHERWISE CONTAINING MATERIAL FROM CATTLE

Priority: Other Significant

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

Completed:

Reason	Date	FR Cite
Withdrawn	03/11/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Eric Flamm
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Related RIN: Merged with 0910–AF54

RIN: 0910–AF55

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

Proposed Rule Stage

915. 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	07/00/05	

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, Suite 300, 7519 Standish Place, Rockville, MD 20857
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RIN: 0906–AA41

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 5; 42 CFR 51c

Legal Deadline: None

Abstract: This rule would consolidate the process for designating areas of health professional shortage and medical underservice that apply in several department programs, and would improve the criteria for designating medically underserved populations and Primary Care Health Professional Shortage Areas. This notice of proposed rulemaking (NPRM) will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
Second NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Andy Jordan, Acting Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, Room 8C26, National Center for Health Workforce Analysis, Bureau of Health Professions, Parklawn Building, Rockville, MD 20857
Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

917. 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. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 42 CFR 121

Legal Deadline: None

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

As the field of intestinal transplantation evolves, it becomes more critical that intestinal organ allocation policies keep pace with the advances in the field; that policy development include performance indicators to assess how well the policies achieve the goals of an equitable transplant system; that those policies are enforceable; and that patients and physicians have timely access to accurate data that will assist them in making decisions regarding intestinal transplantation.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0906–AA62

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

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 100, sec 100.2

Legal Deadline: None

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

Subtitle 2 of title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act of 1986, as amended, (the Act) 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 (the Court). 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.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Thom E. Balbier Jr., Director, Division of Vaccine Injury Compensation, Department of Health and Human Services, Health Resources and Services Administration, Room 8A–46, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–6593
Fax: 301 443–8196
Email: tbalbier@hrsa.gov

RIN: 0906–AA68

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

Priority: Other Significant

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 50.402

Legal Deadline: None

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

HHS—HRSA **Proposed Rule Stage**

and Mental Health Services Administration and the Indian Health Service) which no longer require the use of an informal appeal procedure.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

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

RIN: 0906–AA69

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

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

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

CFR Citation: 42 CFR 51(a)

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0906–AA70

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

Final Rule Stage

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

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

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/27/03	68 FR 51492
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Vito Caserta, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 10th Floor, 4350 East West Highway, Bethesda, MD 20814
Phone: 301 443–4956
Email: smallpox@hrsa.gov

RIN: 0906–AA60

922. SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

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

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/16/03	68 FR 70080
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Department of Health and Human Services, Health Resources and Services Administration, 10th Floor HRSA/OSP, 4350 East West Highway, Bethesda, MD 20814
Phone: 888 496–0338
Email: small@hrsa.gov

Related RIN: Related to 0906–AA60

RIN: 0906–AA61

HHS—HRSA **Final Rule Stage**

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

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

Legal Authority: 42 USC 300ff–71

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/12/03	68 FR 47923
NPRM Comment Period End	09/11/03	
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0906–AA65

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

Long-Term Actions

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396r–2

CFR Citation: 45 CFR 60

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

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, Suite 300, 7519 Standish Place, Rockville, MD 20857
Phone: 301 443–2300

RIN: 0906–AA57

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

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

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

CFR Citation: 42 CFR 121

Legal Deadline: None

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

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0906–AA63

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

Completed Actions

926. NATIONAL VACCINE INJURY COMPENSATION PROGRAM; REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE

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

CFR Citation: 42 CFR 100

Completed:

Reason	Date	FR Cite
Withdrawn	03/16/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Geoffrey Evans
Phone: 301 443–4198
Fax: 301 443 8196
Email: gevansr@hrsa.gov

RIN: 0906–AA66

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

Proposed Rule Stage

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

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

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	
NPRM Comment Period End	10/00/05	
Final Action	12/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0917–AA07

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

Proposed Rule Stage

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

Priority: Substantive, Nonsignificant

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 the National Institutes of Health Revitalization Act of 1993, creates a program offering scholarships, in an amount not to exceed $20,000 per year of academic study, 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 cover this program.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0925–AA10

929. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 216; 42 USC 288–1

CFR Citation: 42 CFR 68

Legal Deadline: None

Abstract: Section 487A of the Public Health Service Act creates a program through which appropriately qualified health professionals may obtain federally funded repayment of educational loans by conducting AIDS research as NIH employees. NIH is issuing regulations that will govern the program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA32

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–5a

CFR Citation: 42 CFR 68g

Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for the Extramural Loan Repayment Program for Clinical Researchers, authorized under section 487F of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct clinical research.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA33

931. NATIONAL INSTITUTES OF HEALTH PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–6

CFR Citation: 42 CFR 68e

Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for Pediatric Research Loan Repayment Program, authorized under section 487F of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct pediatric research.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA34

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 287c–33

CFR Citation: 42 CFR 68f

Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for the Loan Repayment Program for Health Disparities Research, authorized under section 485G of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct minority-health or other health-disparities research for a minimum of two years.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA35

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–5

CFR Citation: 42 CFR 68a

Legal Deadline: None

Abstract: NIH proposes to amend the regulations governing the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds to reflect the new maximum annual loan amount of $35,000 and a change in program eligibility to include qualified health professionals who are not NIH employees, as well as to amend the definition of ''disadvantaged.''

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA36

HHS—NIH **Proposed Rule Stage**

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

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

Legal Authority: 42 USC 216; 42 USC 288–2

CFR Citation: 42 CFR 68c

Legal Deadline: None

Abstract: NIH proposes to amend its current regulations governing the National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program to make the eligibility requirements of the Program consistent with the eligibility requirements of the other extramural loan repayment programs administered by NIH.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA41

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

Final Rule Stage

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–3

CFR Citation: 42 CFR 68d

Legal Deadline: None

Abstract: Regulations will be issued to govern the awarding of educational loan repayments to qualified health professionals who agree to conduct research as employees of the National Institutes of Health.

Timetable:

Action	Date	FR Cite
NPRM	08/05/02	67 FR 50622
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0925–AA18

936. NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 63a

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA28

937. 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA31

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

Prerule Stage

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

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

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
ANPRM	08/00/05	
ANPRM Comment Period End	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Julie A. Kaneshiro, Policy Team Leader, Office for Human Research Protections, Department of Health and Human Services, Office of Public Health and Science, Suite 200, 1101 Wootton Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–2071
Email: jakaneshiro@ophs.dhhs.gov

RIN: 0940–AA11

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

Final Rule Stage

939. PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Priority: Other Significant

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

CFR Citation: 42 CFR 93

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes substantial revisions to the existing regulations at 42 CFR part 50, subpart A, ''Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science,'' 54 FR 32449, August 8, 1989. The National Institutes of Health Revitalization Act of 1993 (NIH Act), Public Law 103-43, contains provisions that affect the current rule. For example, section 161 of the NIH Act established the Office of Research Integrity (ORI) as an independent entity reporting to the Secretary, and recent organizational changes have also affected the ORI's operations. In addition, the Office of Science and Technology Policy (OSTP) published a Governmentwide policy that applies to federally-funded research and proposals submitted to the Federal agencies for research funding, 65 FR 76260, December 6, 2000. The proposed revised regulation will implement this OSTP policy, which contains a definition of research misconduct and basic guidelines for the response of Federal agencies and research institutions to allegations of research misconduct. The current regulation, which implemented section 493(e) of the Public Health Service Act, would be deleted, and a new part 93, subparts A, B, C, D, and E would be added.

Timetable:

Action	Date	FR Cite
NPRM	04/16/04	69 FR 20778
NPRM Comment Period End	06/15/04	
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Suite 750, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 443–3400
Fax: 301 443–5351

Related RIN: Related to 0940–AA01

RIN: 0940–AA04

940. 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

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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	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Irene Stith–Coleman Ph.D, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA06

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 45 CFR 46

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, Suite 200, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA10

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

Long-Term Actions

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 94

Legal Deadline: None

Abstract: To implement section 493(e) of the Public Health Service Act (added by section 163 of the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: 1) persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to an allegation of research misconduct; and 2) persons who cooperate in good faith with an investigation of research misconduct.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Suite 750, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 443–3400
Fax: 301 443–5351

Related RIN: Related to 0940–AA04

RIN: 0940–AA01

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

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

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart E to the Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, and would require that institutions engaged in human subjects research covered by an assurance of compliance filed with the Office for Human Research Protections ensure that institutional officials, institutional review board (IRB) chairpersons, and human protection administrators receive appropriate training and education about the institution's

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assurance and that IRB chairpersons and members, IRB staff, investigators, and other personnel involved in the conduct or oversight of human subjects research receive appropriate training and education about relevant human subjects protection requirements. The proposed training and education requirements will help to ensure that responsible individuals at assured institutions understand and meet their regulatory responsibilities for human subjects protection.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, Suite 200, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA08

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

944. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P)

Priority: Other Significant

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

CFR Citation: 42 CFR 484

Legal Deadline: None

Abstract: This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of the Administration's efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Mercedes Benitez–McCray, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–05–14, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5716

Scott Cooper, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–05–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9465

RIN: 0938–AG81

945. HOSPICE CARE—CONDITIONS OF PARTICIPATION (CMS–3844–P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 418

Legal Deadline: None

Abstract: This proposed rule is a regulatory reform initiative that would revise existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The proposed requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6617
Email: dshearer@cms.hhs.gov

RIN: 0938–AH27

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

Priority: Other Significant. Major under 5 USC 801.

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

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

CFR Citation: 45 CFR 160; 45 CFR 162

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

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

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

Agency Contact: Helen Dietrick, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1–07–17, Office of Financial Management, Program Integrity Group, Divison of Provider/Supplier Enrollment, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7448

RIN: 0938–AH87

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 405.874

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Second NPRM	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ralph Goldberg, Division of Provider and Supplier Enrollment, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4870

RIN: 0938–AI49

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 405; 42 CFR 491

Legal Deadline: None

Abstract: This rule amends the Medicare certification and payment requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997. It changes the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establishes criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated as medically underserved; and limits nonphysician practitioner staffing requirements. This rule imposes payment limits on provider-based RHCs and prohibits the use of RHC space, professional staff, equipment, and other RHC resources by another Medicare entity. The rule also requires RHCs to establish a quality assessment and performance improvement program.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74792
Second NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

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

RIN: 0938–AJ17

949. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)

Priority: Substantive, Nonsignificant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 424.57

Legal Deadline: None

Abstract: This proposed rule would implement certain provisions in the statute relating to suppliers of durable medical equipment, prosthetics, orthotics, and supplies and establish service standards for suppliers of home oxygen equipment and therapeutic shoes home nutrition therapy. Establishing these standards would ensure that suppliers are qualified to provide the appropriate health care services and help safeguard the Medicare program and its beneficiaries from any instances of fraudulent or abusive billing practices.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ralph Goldberg, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–02–16, Center for Medicaid and State Operations, C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4870

RIN: 0938–AJ98

950. STANDARDS FOR ELECTRONIC HEALTH CARE CLAIM ATTACHMENTS (CMS–0050–P)

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: 42 USC 1320d–2(a)(2)(B)

CFR Citation: 45 CFR 162

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

Abstract: This rule proposes an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It would be used to transmit clinical data, in addition to the data contained in the claims standard, to help establish medical necessity for coverage and payment.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal, Local, State, Tribal

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

Agency Contact: Lorraine Doo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Health Insurance Portability and Accountability Act Standards, S2–25–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6597

RIN: 0938–AK62

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

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

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jan Tarantino, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Survey and Certification Group, Division of Contining Care Providers, S2–11–27, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786–0905

RIN: 0938–AL26

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

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

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

Jacqueline Morgan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–02–01, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4282

RIN: 0938–AL80

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

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

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 162.1002; 42 CFR 162.1802

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

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

Agency Contact: Gladys C. Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of HIPAA Standards, S2–24–18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0273

RIN: 0938–AM50

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

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

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This proposed rule would establish requirements for hospice services that long term care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. We are proposing this new requirement to ensure that quality hospice care is provided to eligible residents. This rule is intended to assist in meeting the Administration's goals for broad-based improvements in the quality of health care furnished through the Medicare and Medicaid programs.

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Anita Panicker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Quality Standards Group, Division of Institutional Quality Standards, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5646
Fax: 410–786–8532
Email: apanicker@cms.hhs.gov

RIN: 0938–AM87

955. ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

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

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

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, S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3263
Email: jfrizzera@cms.hhs.gov

RIN: 0938–AN09

956. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES (CMS–6024–P)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Sec 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

CFR Citation: Not Yet Determined

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

Abstract: Section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act requires that physicians and beneficiaries be able to receive a prior determination regarding coverage of certain items and physicians' services (effective June 8, 2005).

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Misty D. Whitaker, Health Insurance Specialist, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Program Integrity Group, Division of Medical Review & Education, C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3087
Email: mwhitaker@cms.hhs.gov

RIN: 0938–AN10

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 108–173, MMA

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

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

Abstract: Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will also create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. (The statute requires competitive bidding be implemented by January 1, 2007. Proposed and final rules must be published six months prior to implementation.)

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, State

Agency Contact: Michael Keane, Health Policy Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4495
Email: mkeane@cms.hhs.gov

RIN: 0938–AN14

958. 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 the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003. The Secretary intends to propose any replacements for specific code sets.

Timetable:

Action	Date	FR Cite
NPRM	04/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, 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: Patricia Peyton, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of HIPAA Standards, S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1812
Email: ppeyton@cms.hhs.gov

RIN: 0938–AN25

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

Priority: Substantive, Nonsignificant

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

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The Medicare Modernization Act of 2003 (MMA), Public Law 108-173, requires codification of the payment basis for determining Medicare payments for new clinical laboratory tests under the clinical laboratory fee schedule. Also, section 416 of the MMA eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the two-year period beginning on July 1, 2004. Section 1833(h) of the Social Security Act mandates payment for outpatient clinical laboratory tests under a clinical laboratory fee schedule.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anita Greenberg, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, SL–11–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4601
Email: agreenberg@cms.hhs.gov

RIN: 0938–AN26

960. TERMINATION OF NON–RANDOM PREPAYMENT MEDICAL REVIEW (CMS–6022–P)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Sec 934 of the MMA

CFR Citation: Not Yet Determined

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

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

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Marie Casey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7861
Email: mcasey2@cms.hhs.gov

RIN: 0938–AN31

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

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

Legal Authority: Section 935 of the MMA

CFR Citation: None

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

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

Timetable:

Action	Date	FR Cite
NPRM	01/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0938–AN42

HHS—CMS **Proposed Rule Stage**

962. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2006 (CMS–1290–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1886(l) of the Social Security Act; PL 105–33; PL 106–554; PL 106–113

CFR Citation: Not Yet Determined

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

Abstract: The proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2006.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Robert Kuhl, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–11–06, Center for Medicare Management, C5–06–24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4597
Email: bkuhl@cms.hhs.gov

RIN: 0938–AN43

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

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

Legal Authority: Sec 1895 of the Social Security Act

CFR Citation: Not Yet Determined

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

Abstract: This poposed rule would set forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Randy Throndset, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C5–09–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0131

RIN: 0938–AN44

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

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

Legal Authority: BBA; BBRA; BIPA; MMA

CFR Citation: Not Yet Determined

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

Abstract: The proposed rule would adjust payments under the Medicare hospital outpatient payment system beginning January 1, 2006.

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

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

Agency Contact: Rebecca Kane, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1589
Email: rkane@cms.hhs.gov

RIN: 0938–AN46

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

Priority: Info./Admin./Other

Legal Authority: PL 108–173, sec 949 of MMA

CFR Citation: 42 CFR 402.400

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

Abstract: Section 949 of the Medicare Modernization Act changed the designation of authority to request waiver of a program exclusion under the Social Security Act from the State to the Administrator of a Federal health care program. This rule proposes to outline a process for health care providers to follow if they wish CMS to request a waiver of exclusion on their behalf (effective December 8, 2003).

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Cohen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3349
Email: jcohen@cms.hhs.gov

RIN: 0938–AN48

966. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2006 RATES (CMS–1500–P)

Priority: Economically Significant. Major under 5 USC 801.

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

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

Legal Deadline: NPRM, Statutory, April 1, 2005.
Final, Statutory, August 1, 2005.

Abstract: This rule proposes to revise the Medicare hospital inpatient prospective payment system (IPPS) for

operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this proposed rule, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These proposed changes would be applicable to discharges occurring on or after October 1, 2005. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Marc Hartstein, Acting Deputy Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Acute Care, Hospital and Ambulatory Policy Group, Center for Medicare Management, C4–25–11, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786–6192

RIN: 0938–AN57

967. SPECIAL PAYMENT PROVISIONS AND STANDARDS FOR SUPPLIERS OF CUSTOM FABRICATED ORTHOTICS AND PROSTHETICS (CMS–6012–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Benefits Improvement Protection Act of 2000 (BIPA 2000)

CFR Citation: 42 CFR 410; 42 CFR 414; 42 CFR 424

Legal Deadline: None

Abstract: This proposed rule would cover prosthetics and certain custom-fabricated orthotics only if furnished by a ''qualified practitioner'' and fabricated by a ''qualified practitioner'' or ''qualified supplier. In consultation with experts this rule would set forth a process to establish and periodically update a list of custom-fabricated orthotics and prosthetics subject to this rule.

Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Theresa Linkowich, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–02–16, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786–9249
Email: tlinkowich@cms.hhs.gov

Ralph Goldberg, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–21–28, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786–8864

RIN: 0938–AN63

968. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2006 (CMS–1282–P)

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

Unfunded Mandates: Undetermined

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

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, July 30, 2005.

Abstract: This rule proposes updates to payment rates used under the Skilled Nursing Facility Prospective Payment System (SNF PPS) beginning October 1, 2005.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: William Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–13–15, Center for Medicare Management, Chronic Care Policy Group, Division of Institutional Post Acute Care, C5–07–08, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 401 786–5667

RIN: 0938–AN65

969. ● PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; COMMUNITYWIDE HEALTH INFORMATION SYSTEMS AND ELECTRONIC PRESCRIBLING EXCEPTION (CMS–1303–P)

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

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 411.357

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

Abstract: This rule proposes an exception to the physician self-referral prohibition for certain nonmonetary remuneration related to electronic prescribing (section 1860D-4 of the Medicare Modernization Act). (This rule and subsequent final rule must be published by November 1, 2005, to be effective January 1, 2006.)

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0938–AN69

970. ● NATIONAL PLAN AND PROVIDER ENUMERATION SYSTEM (NPPES) DATA DISSEMINATION (CMS–6060–N)

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

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

CFR Citation: 45 CFR 163

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Notice	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Helen Dietrick, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Program Integrity Group, Division of Provider/Supplier Enrollment, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21244
Phone: 410 786–7448
Email: hdietrick@cms.hhs.gov

RIN: 0938–AN71

971. ● MEDICARE INTEGRITY PROGRAM, FISCAL INTERMEDIARY AND CARRIER FUNCTIONS, AND CONFLICT OF INTEREST REQUIREMENTS (CMS–6030–P2)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 902 of the MMA

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: On March 20, 1998, we issued a proposed rule to implement provisions of section 1893 of the Act to which we received comments (HCFA-7020-P, 63 FR 13590). Due to time constraints, a final rule was never published within the three-year time frame required by section 902 of the MMA. Without a proposed MIP regulation in effect, we lack the authority to contract with entities to perform section 1893 program integrity activities upon the implementation of the part D Pharmaceutical benefit. Accordingly, we must issue a proposed rule prior to the effective date of the part D Pharmaceutical benefit regulations.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Lauren Haley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services
Phone: 410 786–1730

Related RIN: Related to 0938–AI09

RIN: 0938–AN72

972. ● 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: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0938–AN73

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1895

CFR Citation: 42 CFR 484

Legal Deadline: Final, Statutory, July 31, 2006, To allow five months for systems change before the January 1, 2007, effective date.

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

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payment system since its implementation in October of 2000.

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0938–AN76

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

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

Unfunded Mandates: Undetermined

Legal Authority: PL 106–113, sec 124 BBRA

CFR Citation: 42 CFR 412.400, subpart N

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

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local

Federalism: Undetermined

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

RIN: 0938–AN82

975. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2006 (CMS–1502–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 410; 42 CFR 414

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

Abstract: This rule would make several changes affecting the Medicare part B payment.

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Diane Milstead, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3355

Related RIN: Related to 0938–AN04

RIN: 0938–AN84

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

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 424

Legal Deadline: None

Abstract: This final rule is needed as part of the Administration's anti-fraud and abuse efforts. It would give HHS the authority to enroll and reenroll providers with time frames for reenrollment.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0938–AH73

977. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–IFC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This interim final rule with comment period requires hospitals that transfuse blood and blood products to prepare and follow written procedures for appropriate action when it is determined that blood and blood

products the hospital received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Interim Final Rule With Comment	10/00/05	

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, Clincial Standards Group, Division of Institutional Quality Standards, S3–05–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3189

RIN: 0938–AJ29

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 418

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

Related RIN: Previously reported as 0938–AH73

RIN: 0938–AJ36

979. CONDITIONS FOR COVERAGE OF POWER MOBILITY DEVICES, INCLUDING POWERED WHEELCHAIRS AND POWER–OPERATED VEHICLES SCOOTER (CMS–3017–IFC)

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

Legal Authority: Sec 1102 of the Social Security Act; Sec 1871 of the Social Security Act; 42 USC 1302 ; 42 USC 1359 hh

CFR Citation: 42 CFR 410.38

Legal Deadline: None

Abstract: This rule will make the requirements to purchase power operated vehicles, functioning as wheelchairs, less stringent.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Karen Daily, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0189
Email: kdaily@cms.hhs.gov

RIN: 0938–AM74

980. NONDISCRIMINATION IN POST–HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 105–33, sec 4321 of the BBA

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule establishes a process for collecting and maintaining information about hospitals referring Medicare patients to home health agencies (HHAs) with which the hospitals have a financial interest. Collected information will be available to the public to enhance its understanding and awareness of the availability of Medicare-certified HHAs to serve the Medicare population. (This final rule must be published by November 22, 2005, to meet the three-year publication deadline.)

Timetable:

Action	Date	FR Cite
NPRM	11/22/02	67 FR 70373
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Sarah Shipey, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–11–05, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0187

RIN: 0938–AN19

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

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

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

Abstract: This final rule updates the list of Medicare-covered ASC procedures.

Timetable:

Action	Date	FR Cite
NPRM	11/26/04	69 FR 69178
Interim Final Rule	05/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Dana Burley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C4–05–17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4547
Email: dburley@cms.hhs.gov

RIN: 0938–AN23

982. MEDICARE SECONDARY PAYER AMENDMENTS (CMS–6272–IFC)

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

Legal Authority: Sec 301 of the Medicare Prescripition Drug, Improvement, and Modernization Act of 2003

CFR Citation: 42 CFR 411

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

Abstract: Section 301 of the Medicare Modernization Act clarifies when CMS may make a conditional Medicare payment when other insurance cannot reasonably be expected to make a prompt payment (effective December 8, 2003).

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment	08/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Agency Contact: Suzanne Ripley, Health Insurance Specialist , Office of Finanical Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Financial Services Group, Division of MSP Policy & Operations, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–0970
Email: sripley@cms.hhs.gov

RIN: 0938–AN27

983. PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–F)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: Not Yet Determined

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

Abstract: This final rule proposes the payment rate update for the 2006 prospective payment system for Medicare long-term care hospitals. The new rates will be based on cost reports from the first LTC PPS rate year.

Timetable:

Action	Date	FR Cite
NPRM	02/03/05	70 FR 5723
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judy Richter, Health Insurance Specialist, CMS/CMM/HAPG/DAC, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AN28

984. DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES (CMS–4087–FN)

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

Legal Authority: Section 104 of the MMA

CFR Citation: None

Legal Deadline: None

Abstract: According to section 104 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medigap issuers must send written notice to beneficiaries with Medigap drug coverage during the 60-day period immediately preceding the initial Medicare Part D enrollment period which begins November 15, 2005. Therefore, Medigap issuers will have to send the notices from mid-September 2005 to mid-November 2005. This final notice will set forth the standards for the written notice that Medigap issuers must provide to policyholders with drug coverage.

Timetable:

Action	Date	FR Cite
Final Notice	08/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Julie Walton, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Division of Private Health Insurance, S3–16–16, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786–4622
Email: jwalton@cms.hhs.gov

Related RIN: Related to 0938–AN08

RIN: 0938–AN50

985. FISCAL YEAR 2006 SCHIP ALLOTMENTS (CMS–2219–N)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 457

Legal Deadline: Final, Statutory, September 30, 2005.

Abstract: This notice sets forth the final allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year 2006.

Timetable:

Action	Date	FR Cite
Notice	08/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss, Director, Division of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2019
Email: rstrauss@cms.hhs.gov

RIN: 0938–AN56

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

Priority: Other Significant

Legal Authority: SSA, sec 1834

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

Legal Deadline: None

Abstract: This final rule will achieve a consistent bad debt reimbursement policy for all providers currently

eligible to receive payments from Medicare for bad debt. It implements a court settlement agreement and removes the cap on End Stage Renal Disease (ESRD) bad debt reimbursement, which limits payment of allowable bad debts to the facility's unrecovered costs

Timetable:

Action	Date	FR Cite
Final Action	02/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Katie Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center of Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7278
Email: kwalker@cms.hhs.gov

Related RIN: Related to 0938–AK02

RIN: 0938–AN75

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987. • STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP); REDISTRIBUTION OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FISCAL YEAR (FY) 2002 (CMS–2230–FN)

Priority: Other Significant

Legal Authority: 42 USC 1397dd; 42 USC 1397ee; Social Security Act, sec 2104(e); Social Security Act, sec 2104(f)

CFR Citation: 42 CFR 457.600 to 457.630

Legal Deadline: None

Abstract: This notice responds to comments from the notice with comment published January 19, 2005, announcing the procedure for redistribution of States' unexpended FY 2002 allotments that remained at the end of FY 2004 to those States that fully expended the FY 2002 SCHIP allotment. These redistributed allotments will be available through the end of FY 2005 (September 30, 2005).

Timetable:

Action	Date	FR Cite
Notice	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Richard Strauss, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Offfice of Financial Management, S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2019
Email: rstrauss@cms.hhs.gov

RIN: 0938–AN78

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988. • EXTENDING SUNSET DATE FOR THE INTERIM FINAL REGULATION ON MENTAL HEALTH PARITY (CMS–4094–F3)

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

Legal Authority: Mental Health Parity Act

CFR Citation: 42 CFR 146

Legal Deadline: None

Abstract: On October 4, 2004, legislation was enacted that extended the Public Health Service (PHS) Act provisions of the Mental Health Parity Act (MHPA) to services furnished through December 31, 2005. As a result of the most recently enacted legislation, it is now necessary to again publish conforming changes to the interim final regulation published June 27, 2003. These changes conform the regulatory sunset date to the new statutory sunset date (December 31, 2005), and extend the duration of the increased cost exemption to be consistent with the new sunset date. The conforming changes make absolutely no substantive changes to the existing regulation. (It is important to publish this amendment expeditiously, because it will have no meaning if published after December 31, 2005 (or, if published immediately before that date)).

Timetable:

Action	Date	FR Cite
Final Action	07/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: dmlawsky@cms.hhs.gov

Related RIN: Related to 0938–AN22

RIN: 0938–AN80

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

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: BBA; BBRA

CFR Citation: 42 CFR 405

Legal Deadline: None

Abstract: This rule finalizes the December 13, 2002, interim final rule and sets forth the process for establishing realistic and equitable payment amounts for all Medicare part B items and services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. The rule describes the factors CMS (or its carriers) will consider, and the procedures that will be followed in establishing realistic and equitable payment amounts. This rule implements section 4316 of the BBA, and section 223 of the BBRA that required CMS to publish this subsequent final rule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/13/02	67 FR 76684
Interim Final Rule Comment Period End	02/11/03	
Final Rule	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bill Long, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C5–08–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5655
Email: blong@cms.hhs.gov

RIN: 0938–AN81

HHS—CMS — Final Rule Stage

990. ● ELECTRONIC SUBMISSION OF COST REPORTS: REVISION TO COST REPORTING PERIOD (CMS–1199–IFC)

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

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This interim final rule follows a August 26, 2003, final rule that requires ESRD facilities, hospices, rural health clinics, federally qualified health centers, and community mental health centers to file cost reports in a standardized electronic format. It provided a delay or waiver of this requirement if implementation would result in financial hardship. Because the software packages for accepting the cost reports are not available yet, this final rule changes the cost report ending date from December 31, 2004, to March 31, 2005.

Timetable:

Action	Date	FR Cite
Interim Final Rule Comment Period End	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Darryl E. Simms, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–03–30, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4524
Email: dsimms@cms.hhs.gov

Related RIN: Related to 0938–AL51

RIN: 0938–AN87

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) — Long-Term Actions

991. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–F) (SECTION 610 REVIEW)

Priority: Other Significant

Legal Authority: 42 USC 1395rr et al

CFR Citation: 42 CFR 400; 42 CFR 405; 42 CFR 410; 42 CFR 412 to 414; 42 CFR 488; 42 CRR 494

Legal Deadline: None

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 Specalist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–05–04, Clinical Standards Group, Division of Non–Institutional Quality Standards, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7215

Robert Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–02–01, Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–04–25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6797

RIN: 0938–AG82

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

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

Legal Deadline: None

Abstract: This rule establishes conditions of participation for Medicare-covered transplant centers.

Timetable:

Action	Date	FR Cite
NPRM	02/04/05	70 FR 6140
Final Action	02/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Eva Fung, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–06–6, Office of Clinical Standards and Quality, S3–06–06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7539

RIN: 0938–AH17

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

Priority: Other Significant. Major under 5 USC 801.

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

Legal Authority: 42 USC 1302; 42 USC 1395(hh)

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

Legal Deadline: None

Abstract: This final rule requires home health agencies to electronically report OASIS data as a condition of participation in the Medicare program.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/25/99	64 FR 3748
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: State, Local, Tribal

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

Agency Contact: Rebecca Donnay, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Division of Non–Institutional Quality Standards, SL–17–04, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1428

RIN: 0938–AJ10

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1396d

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/22/01	66 FR 7148
60–Day Delay of Effective Date To 05/22/2001	03/21/01	66 FR 15800
Interim Final Rule Comment Period End	03/23/01	
Interim Final Rule Effective	03/23/01	
Interim Final Rule Amendment with Clarification	05/22/01	66 FR 28110
Interim Final Rule Comment Period End	07/23/01	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Larry Cutler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2–14–26, Disabled & Elderly Health Programs Group, Division of Benefits & Coverage Policy, S2–12–11, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5903

RIN: 0938–AJ96

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

Priority: Other Significant

Legal Authority: 42 USC 1877

CFR Citation: 42 CFR 411; 42 CFR 424

Legal Deadline: None

Abstract: This final rule incorporates into regulation certain statutory provisions that preclude payment for services under Medicare if a physician makes a referral to a facility in which he or she has a financial interest. It addresses comments from the January 9, 1998, proposed rule concerning the ownership, investment, and compensation exceptions. It also addresses comments from the January 4, 2001, final rule with comment period.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/26/04	69 FR 16054
Interim Final Rule Comment Period End	06/24/04	
Correction Notice	04/06/04	69 FR 17933
Second Correction Notice	09/24/04	69 FR 57226
Final Action	06/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Chronic Care Policy Group, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4620

RIN: 0938–AK67

996. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1302 et al

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

Legal Deadline: Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

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

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Diane Corning, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Division of Institutional Quality Standards, S3–05–06, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786–8486
Email: dcorning@cms.hhs.gov

RIN: 0938–AK81

997. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–F)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1878 of the Social Security Act

CFR Citation: 42 CFR 405

Legal Deadline: None

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

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Morton Marcus, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4477

RIN: 0938–AL54

998. HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS–2158–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg; PL 104–191

CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145

Legal Deadline: None

Abstract: This final rule will clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. It also implements changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

Timetable:

Action	Date	FR Cite
NPRM	12/30/04	69 FR 78800
Final	12/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal, Local, State

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

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–26, Center for Beneficiary Choices, Medicare Plan Policy Group, Division of Private Health Insurance, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AL88

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

Priority: Other Significant

Legal Authority: PL 107–105

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This final rule implements the requirements for electronic submission of Medicare claims, submitted on or after October 16, 2003. In addition, this rule also implements the conditions upon which a waiver could be granted for these requirements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/15/03	68 FR 48805
Interim Final Rule Comment Period End	10/16/03	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Stewart Streimer, Director, Provider Billing Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–10–07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9318
Email: sstrimer@cms.hhs.gov

RIN: 0938–AM22

1000. REQUIREMENTS FOR LONG–TERM CARE FACILITIES; NURSING SERVICES; POSTING OF NURSE STAFFING INFORMATION (CMS–3121–F)

Priority: Other Significant

Legal Authority: Sec 1819(b) of the Social Security Act; 42 USC 1395i–3(b)

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This final rule implements section 941 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and requires nursing homes to post daily, for each shift, the number of full-time equivalents (FTEs) of registered nurses, licensed practical nurses, licensed vocational nurses, and certified nurse aides who are directly responsible for resident care.

Timetable:

Action	Date	FR Cite
NPRM	02/27/04	69 FR 9282
NPRM Comment Period End	04/27/04	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–04–26, Clinical Standards Goup, Division of Institutional Quality Standards, S3–04–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5646
Fax: 410 786–8532
Email: apanicker@cms.hhs.gov

RIN: 0938–AM55

1001. REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–IFC)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 40S

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/08/05	70 FR 11419
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Michele Edmondson–Parrott, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1–05–06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6478

Related RIN: Related to 0938–AK69

RIN: 0938–AM73

1002. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS; SECURING MEDICATIONS; AND POST–ANESTHESIA EVALUATIONS (CMS–3122–P2)

Priority: Other Significant

Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would revise four of the conditions of participation that hospitals must meet to participate in the Medicare and Medicaid programs to decrease the burden on hospitals and allow hospitals to conform to current standards of practice. They must establish and maintain policies and procedures that ensure that the hospital meets these requirements by using standard practices related to history and physical examinations, verbal orders securing of medications, and completion of the post-anesthesia evaluation.

Timetable:

Action	Date	FR Cite
NPRM	03/25/05	70 FR 15266
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: Decreases burden for hospitals and clinicaians.

Agency Contact: Patricia Chmielewski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Clinical Standards Group, Division of Institutional Quality Standards, S3–04–05, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6899
Email: pchmielewski@cms.hhs.gov

RIN: 0938–AM88

1003. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–F)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This final rule proposes revisions to the CMS civil money penalty authorities. These proposed revisions are intended to add the specific exclusion sanction authorities as established in the procedures for imposing civil money penalties, assessments, and exclusions for certain violations of the Medicare and Medicaid programs.

Timetable:

Action	Date	FR Cite
NPRM	07/23/04	69 FR 43956
Final Action	07/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joel Cohen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–04–06, Office of Financial Management, C3–04–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3349

RIN: 0938–AM98

1004. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

Priority: Other Significant

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

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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

Related RIN: Related to 0938–AL27

RIN: 0938–AN02

1005. EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–FN)

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: Sec 1153(h)(2) of the Social Security Act

CFR Citation: None

Legal Deadline: Final, Statutory, August 31, 2004.
There is a 60 day comment period required for the evaluation criteria used in evaluating the Quality Improvement Organizations.

Abstract: Section 1153(h)(2) of the Act Social Security requires the Secretary to publish in the Federal Register the general criteria and standards that will be used to evaluate the Quality Improvement Organizations (QIOs), and provide opportunity for public comment. This notice will describe the evaluation criteria CMS will use to evaluate the QIOs. There should be no additional costs associated with this requirement. The evaluation portion of

the contract has already been factored into the award.

Timetable:

Action	Date	FR Cite
Notice With Comment Period	07/23/04	69 FR 44031
Comment Period End	08/23/04	
Final Action	07/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Maria L. Hammel, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, S2–01–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1775
Email: mhammel@cms.hhs.gov

RIN: 0938–AN13

1006. MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–F)

Priority: Other Significant

Legal Authority: Sec 1834(i) of the Social Security Act; Sec 414 of the MMA

CFR Citation: 42 CFR 414, subpart H

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

Abstract: This interim final rule codifies the four payment provisions for Medicare covered ambulance servies contained in section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/01/04	69 FR 40288
Interim Final Rule Comment Period End	08/30/04	
Final Action	07/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local

Agency Contact: Robert Niemann, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–05–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4596
Email: rnieman@cms.hhs.gov

RIN: 0938–AN24

1007. NONDISCRIMINATION IN HEALTH COVERAGE AND WELLNESS PLANS IN THE GROUP MARKET (CMS–4081–F)

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

Legal Authority: 42 USC 300gg

CFR Citation: 45 CFR 146.121

Legal Deadline: None

Abstract: This final rule governs the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996. It also addresses comments we received on the Bonafide Wellness Plan proposed rule (CMS-2078-P).

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/17/97	
Interim Final Rule Effective	07/17/97	
Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Effective	03/09/01	
Interim Final Rule Comment Period End	04/09/01	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: dmlawsky@cms.hhs.gov

RIN: 0938–AN29

1008. HOSPITAL CONDITIONS OF PARTICIPATION: PATIENTS' RIGHTS (CMS–3018–F)

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

Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule sets forth standards for the use of restraints and seclusion in Medicare- and Medicaid-participating hospitals as part of the Patients' Rights Condition of Participation (CoP) and finalizes other patients' rights at afforded by that CoP. It finalizes six standards that ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to: notification of his or her rights; the exercise of his or her rights in regard to his or her care; privacy and safety; confidentiality of patient records; freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and freedom from seclusion and restraint for behavior management unless clinically necessary.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/02/99	64 FR 36069
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Janice Graham, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Division of Institutional Quality Standards, S3–05–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–8020
Email: jgraham@cms.hhs.gov

RIN: 0938–AN30

1009. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–4091–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg–22; 42 USC 300gg–31

CFR Citation: 45 CFR 150.101 to 150.465

Legal Deadline: None

Abstract: This rule finalizes, without any substantive changes, an interim final regulation (HCFA-2019-IFC) that sets forth the process by which CMS enforces the HIPAA title I requirements with regard to State and local governmental group health plans. It also finalizes the process by which CMS assumes direct enforcement responsibility in a State with regard to group and individual market health insurance issues.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/20/99	64 FR 1999
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–26, Center for Beneficiary Choices, Medicare Plan Policy Group, Division of Private Health Insurance, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AN35

1010. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES; ALCOHOL–BASED HAND SANITIZER AMENDMENT (CMS–3145–IFC)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 403; 42 CFR 416; 42 CFR 418; 42 CFR 460; 42 CFR 482; 42 CFR 483; 42 CFR 485

Legal Deadline: None

Abstract: This interim final rule with comments amends the fire safety standard for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long-term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals that participate in Medicare and Medicaid. The rule adopts a change made to the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). We adopted the 2000 edition of the LSC in January 2003. The LSC change will allow facilities to place alcohol-based hand sanitizer dispensers in exit corridors under certain conditions. These sanitizers have proven to be effective in increasing hand hygiene and have the potential to improve infection control practice. Adopting the LSC change will increase a provider's flexibility in meeting infection control goals while minimizing potential fire safety concerns. Additionally, this rule would include a requirement for placement of battery operated smoke detectors in resident rooms in non-sprinkled SNFs.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comments	03/25/05	70 FR 15229
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Providers requesting publication of this regulation.

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards Group, Division of Non–Institutional Quality Standards, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6617
Email: dshearer@cms.hhs.gov

RIN: 0938–AN36

1011. MEDICARE MODERNIZATION ACT; ELECTRONIC PRESCRIBING (CMS–0011–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, September 1, 2005, Required e–prescribing before outset of January 1, 2006, Medicare part D drug benefit.

Abstract: This rule requires Medicare part D plans and Medicare Advantage Plans to enable transmission of basic prescription data to and from doctors and pharmacies, and to adopt a number of the initial standards required for electronic prescribing by section 1860(d) of the Medicare Modernization Act.

Timetable:

Action	Date	FR Cite
NPRM	02/04/05	70 FR 6255
Final Action	02/00/08	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal, Local, State, Tribal

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

Agency Contact: Gladys Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0273
Email: gwheeler@cms.hhs.gov

RIN: 0938–AN49

1012. MEDICARE PART B COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–F)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 414

Legal Deadline: Final, Statutory, January 1, 2006, MMA of 2003, section 303(d) or section 1847(B)(a)(1) of the Social Security Act.

Abstract: Section 303(d) of the Medicare Modernization Act requires the implementation of a competitive bidding program for Medicare part B drugs not paid on a cost or prospective payment system basis. Beginning January 1, 2006, physicians will be given a choice between purchasing these drugs and being paid by Medicare under the average sales price (ASP) system, or obtaining these drugs from

vendors selected in a competitive bidding process. If the physician elects to obtain drugs from a competitive vendor, the vendor will bill Medicare for the drug.

Timetable:

Action	Date	FR Cite
NPRM	03/04/05	70 FR 10745
Final Action	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Edmund E. Kasaitis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0477
Email: ekasaitis@cms.hhs.gov

RIN: 0938–AN58

1013. GROUP MARKET HEALTH INSURANCE REFORM: GUARANTEED AVAILABILITY, GUARANTEED RENEWABILITY, DISCLOSURES TO SMALL EMPLOYERS (CMS–4102–F)

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

Legal Authority: 42 USC 300gg–92

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

Legal Deadline: None

Abstract: This regulation finalizes the interim final regulation (BPD-890-IFC) guaranteeing the availability of health insurance coverage to small employers, and guaranteeing the renewability of health insurance coverage to small and large employers.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Mediare Plan Policy Group, Division of Private Health Insurance, S3–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 877 267–2323
Email: dmlawsky@cms.hhs.gov

Related RIN: Related to 0938–AI08

RIN: 0938–AN60

1014. INDIVIDUAL MARKET HEALTH INSURANCE REFORM: PORTABILITY FROM GROUP TO INDIVIDUAL COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIVIDUAL MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (CMS–4103–F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 300gg–92

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

Legal Deadline: None

Abstract: This regulation finalizes the interim final rule (BPD-890-IFC) that guarantees availability of health coverage to certain individuals, guarantees renewability of coverage in the individual market, and sets standards for State alternative mechanisms for guaranteeing coverage to certain individuals.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David R. Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Medicare Plan Policy Group, Division of Private Health Insurance, S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 877 267–2323
Email: dmlawsky@cms.hhs.gov

Related RIN: Related to 0938–AI08

RIN: 0938–AN61

1015. REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)

Priority: Other Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 488.1 to 488.9

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

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

RIN: 0938–AN62

1016. ● PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–F)

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

Legal Authority: Improper Payment Information Act of 2002

CFR Citation: 42 CFR 431; 42 CFR 457

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

Abstract: This rule requires States to estimate improper payments in the

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Medicaid program and the State Children's Health Insurance Program. The State level estimates will be used to produce estimates of improper payments for both Medicaid and SCHIP at the national level. These national level estimates will enable us to comply with the Improper Payments Information Act of 2002. The intended effect of this regulation is for States to produce estimates of improper payments for their Medicaid and SCHIP programs and identify existing and emerging vulnerabilities that can be effectively targeted for corrective actions by the States.

Timetable:

Action	Date	FR Cite
Final Action	08/00/07	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Chrstine Jones, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3722
Email: cjones@cms.hhs.gov

Related RIN: Related to 0938–AM86

RIN: 0938–AN77

1017. ● FIRE SAFETY REQUIREMENTS FOR LONG–TERM CARE FACILITIES: SPRINKLER SYSTEMS (CMS–3191–P)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 483

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/06	

Regulatory Flexibility Analysis Required: Undetermined

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, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6617
Fax: 410 786–8532
Email: dshearer@cms.hhs.gov

RIN: 0938–AN79

1018. ● PROGRAM FOR ALL–INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS–1201–F)

Priority: Other Significant

Legal Authority: PL 108–173, sec 902 of MMA; BIPA, sec 903

CFR Citation: 42 CFR 460

Legal Deadline: None

Abstract: This rule finalizes two interim final rules with comment periods. The November 24, 1999, rule established requirements for Programs of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs and the October 1, 2002, rule that implemented section 903 of BIPA. These are pre-paid, capitated programs for beneficiaries who meet special eligibility requirements and who elect to enroll.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Federalism: Undetermined

Agency Contact: Paul Olenick, Director, Division of Beneficiary and Insurance Issues, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–4472

Related RIN: Previously reported as 0938–AL59

RIN: 0938–AN83

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

Completed Actions

1019. HEALTH COVERAGE PORTABILITY FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE ISSUERS (CMS–2151–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 144.103; 45 CFR 146.111; 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.119; 45 CFR 146.120; 45 CFR 146.125; 45 CFR 146.143; . . .

Completed:

Reason	Date	FR Cite
Final Action	12/30/04	69 FR 78720

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

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

Agency Contact: David Mlawsky
Phone: 410 786–6851

RIN: 0938–AL43

1020. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FOR FY 2004 (CMS–1213–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 412, subpart N; 42 CFR 413; 42 CFR 424

Completed:

Reason	Date	FR Cite
Final Action	11/15/04	69 FR 66922

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

Agency Contact: Lana Price
Phone: 410 786–4533
Email: lprice@cms.hhs.gov

RIN: 0938–AL50

1021. REQUEST FOR INFORMATION ON BENEFIT–SPECIFIC WAITING PERIODS (CMS–2150–NC)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	12/30/04	69 FR 78825

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David Mlawsky
Phone: 410 786–6851

RIN: 0938–AL64

1022. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS–4004–FC)

Priority: Other Significant

CFR Citation: 42 CFR 405

Completed:

Reason	Date	FR Cite
Final Action	11/26/04	69 FR 69251

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Janet Miller
Phone: 410 786–1588

RIN: 0938–AL67

1023. DMERC SERVICE AREAS AND RELATED MATTERS (CMS–1219–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 421.210

Completed:

Reason	Date	FR Cite
Final Action	02/25/05	70 FR 9232
Notice	02/25/05	70 FR 9358

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Colette Shatto
Phone: 410 786–6932

RIN: 0938–AL76

1024. PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS–3119–FN)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	02/25/05	70 FR 9355

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jacqueline Sheridan–Moore
Phone: 410 786–4635

RIN: 0938–AM36

1025. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE SYSTEM AND CALENDAR YEAR 2005 PAYMENT RATES (CMS–1427–FC)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Final Action	11/15/04	69 FR 65682

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Joan Sanow
Phone: 410 786–9739
Email: jsanow@cms.hhs.gov

Related RIN: Related to 0938–AM96

RIN: 0938–AM75

1026. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2005 (CMS–1429–FC)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 410; 42 CFR 414

Completed:

Reason	Date	FR Cite
Final Action	11/15/04	69 FR 66235

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Diane Milstead
Phone: 410 786–3355

Related RIN: Related to 0938–AM97

RIN: 0938–AM90

1027. PHYSICIAN REFERRAL FOR NUCLEAR MEDICINE SERVICES AND SUPPLIES (CMS–1261–P)

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

CFR Citation: 42 CFR 411.351

Completed:

Reason	Date	FR Cite
Merged With 0938–AN84	05/03/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer
Phone: 410 786–4620
Email: jsinsheimer@cms.hhs.gov

RIN: 0938–AN04

1028. MEDICARE ADVANTAGE PROGRAM—TITLE II (CMS–4069–F)

Priority: Other Significant

CFR Citation: 42 CFR 417; 42 CFR 422

Completed:

Reason	Date	FR Cite
Final Action	01/28/05	70 FR 4588

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jane Andrews
Phone: 410 786–3133
Email: jandrews@cms.hhs.gov

RIN: 0938–AN06

1029. MEDICARE DRUG BENEFIT EFFECTIVE CALENDAR YEAR 2006—TITLE I (CMS–4068–F)

Priority: Other Significant

CFR Citation: 42 CFR 417; 42 CFR 423

Completed:

Reason	Date	FR Cite
Final Action	01/28/05	70 FR 4193

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal, State, Tribal

Agency Contact: Tracey McCutcheon
Phone: 410 786–6715
Email: tmccutcheon@cms.hhs.gov

Related RIN: Related to 0938–AN07

RIN: 0938–AN08

1030. SCHEDULE FOR PUBLISHING MEDICARE FINAL REGULATIONS AFTER A PROPOSED OR INTERIM FINAL REGULATION (CMS–9026–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	12/30/04	69 FR 78442

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Renee Swann
Phone: 410 786–4492
Email: rswann@cms.hhs.gov

RIN: 0938–AN12

1031. MODIFICATIONS TO MANAGED CARE RULES (CMS–4041–IFC)

Priority: Other Significant

CFR Citation: 42 CFR 422

Completed:

Reason	Date	FR Cite
Interim Final Rule	12/30/04	69 FR 78336

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Tony Hausner
Phone: 410 786–1093

Related RIN: Related to 0938–AK71

RIN: 0938–AN38

1032. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE THE DISPROPORTIONATE SHARE HOSPITAL FORMULA (CMS–1283–P)

Priority: Economically Significant

CFR Citation: 42 CFR 412

Completed:

Reason	Date	FR Cite
Merged With 0938–AN57	02/16/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Sherry Amstead
Phone: 410 786–4342
Email: samstead@cms.hhs.gov

RIN: 0938–AN52

1033. END STAGE RENAL DISEASE (ESRD) COMPOSITE RATE EXCEPTION (CMS–1278–P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 405

Completed:

Reason	Date	FR Cite
Merged With 0938–AN84	03/04/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael E Powell
Phone: 410 786–4557
Email: mpowell@cms.hhs.gov

RIN: 0938–AN53

1034. TIME LIMITATION ON RECORDKEEPING REQUIREMENTS UNDER THE DRUG REBATE PROGRAM (CMS–2175–F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 447.534

Completed:

Reason	Date	FR Cite
Final Action	11/26/04	69 FR 68815

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Kimberly M. Howell
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Larry Reed
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Email: lr@cms.hhs.gov

Related RIN: Related to 0938–AM20

RIN: 0938–AN55

1035. ● RECOGNITION OF NAIC STANDARDS FOR REGULATION OF MEDICARE SUPPLEMENTAL INSURANCE (CMS–4080–N)

Priority: Other Significant

Legal Authority: MMA, sec 104

CFR Citation: None

Legal Deadline: None

Abstract: The notice recognizes the revised NAIC Model standards (per Medicare Modernization Act section 104) for regulation of Medicare supplemental insurance. State departments of insurance need CMS' official recognition of the NAIC Model standards as soon as possible after the NAIC adopts the revised Model at their September 2004 meeting. (The States need sufficient lead time to prepare their legislative proposals, which generally take place in the Spring. States must implement the revised NAIC Model standards by September 2005.)

Timetable:

Action	Date	FR Cite
Notice	03/25/05	70 FR 15394

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Julie Walton, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4622
Email: jwalton@cms.hhs.gov

RIN: 0938–AN66

HHS—CMS

Completed Actions

1036. ● QUALITY IMPROVEMENT ORGANIZATIONS CONTRACTS: SOLICITATION OF STATEMENTS OF INTEREST FROM IN–STATE ORGANIZATIONS—ALASKA, HAWAII, IDAHO, MAINE, SOUTH CAROLINA, VERMONT, AND WYOMING (CMS–3155–N)

Priority: Other Significant

Legal Authority: Social Security Act, sec 1153(i); Social Security Act, sec 1152; Social Security Act, sec 1153; Omnibus Budget Reconcilation Action of 1987, PL 100–203

CFR Citation: 42 CFR 475.102; 42 CFR 475.103

Legal Deadline: None

Abstract: Under Section 1153(i) of the Social Security Act, this notice provides at least six months advanced notice of the expiration dates of contracts with out-of-State Utilization and Quality Control Peer Review Organizations.

Timetable:

Action	Date	FR Cite
Notice	02/04/05	70 FR 6012

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Udo Nwachukwu, Office of Clinical Standards and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7234

RIN: 0938–AN67

1037. ● PROCEDURES FOR THE SUBMISSION OF NON–PRIVACY ADMINISTRATIVE SIMPLIFICATION COMPLAINTS UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (CMS–0014–N)

Priority: Other Significant

Legal Authority: 42 USC 1302a; 42 USC 1320d to 1320d–8

CFR Citation: None

Legal Deadline: None

Abstract: This notice sets forth the procedures for filing with the Secretary of the Department of Health and Human Services, a complaint of noncompliance by a covered entity with certain provisions of the administrative simplification rules under 45 CFR parts 160, 162, and 164. It also describes the procedures the Department employs to review the complaints. These procedures are intended to facilitate the investigation and resolution of these complaints.

Timetable:

Action	Date	FR Cite
Notice	03/25/05	70 FR 15329

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Lori E. Davis, Deputy Director, Office of HIPPAA Standards, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4160
Email: ldavis1@cms.hhs.gov

RIN: 0938–AN68

1038. ● CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; CONTINUANCE OF EXEMPTION OF LABORATORIES LICENSED BY THE STATE OF WASHINGTON (CMS–2207–N)

Priority: Other Significant

Legal Authority: None

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This notice announces that clinical laboratories located in the State of Washington that possess a valid license under the Medical Test Site Licensure Law continue to be exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) until March 31, 2007. (This notice should be published by March 31, 2005, as the date for continued approval of this authority has passed. Delay in publishing this notice could cause confusion for labs licensed by the State of Washington as to which requirements Federal or State they must conform.)

Timetable:

Action	Date	FR Cite
Notice	04/29/05	70 FR 22317

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Sandra Farragut, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2–12–25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3503
Email: sfarragut@cms.hhs.gov

RIN: 0938–AN70

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

Proposed Rule Stage

1039. SAFEGUARDING CHILD SUPPORT AND EXPANDED FEDERAL PARENT LOCATOR SERVICES (FPLS) INFORMATION

Priority: Substantive, Nonsignificant

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	09/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State, Tribal

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

RIN: 0970–AC01

1040. 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, State, Tribal

Agency Contact: Elsbeth Wyatt, Program Specialist, Department of Health and Human Services, Administration for Children and Families, ADD HHH–300F, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 690–5841

RIN: 0970–AC07

1041. ADMINISTRATIVE COST SHARING UNDER TANF

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 263; 45 CFR 263.14

Legal Deadline: None

Abstract: This proposed rule will enable States (including the District of Columbia) and territories to use either the ''primary program'' cost allocation methodology previously allowed under the Aid to Families with Dependent Children (AFDC) program to allocate the common administrative costs of determining eligibility in the Temporary Assistance for Needy Families (TANF) program, the Medicaid program, and the Food Stamp programs, or to continue to use a ''benefiting'' cost allocation methodology. Pursuant to a determination by Secretary Leavitt, States and territories would be able to elect to use their Federal TANF funds to pay for costs that are common to the administration of the TANF, Medicaid, and Food Stamps Programs, in accordance with the primary program cost allocation methodology previously allowed under the former AFDC program.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Grant Collins, Deputy Director, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–6953
Email: gcollins@acf.hhs.gov

RIN: 0970–AC15

1042. ● 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Maureen Dunn, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
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RIN: 0970–AC20

1043. ● 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
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RIN: 0970–AC21

HHS—ACF — Proposed Rule Stage

1044. ● MEDICAL SUPPORT

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 302; 45 CFR 303; 45 CFR 304; 45 CFR 305

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Local, State

Agency Contact: Elizabeth C. Matheson, Director, Policy and Planning Division, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447
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RIN: 0970–AC22

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

Final Rule Stage

1045. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

Priority: Other Significant

Legal Authority: 42 USC 672; 42 USC 674; 42 USC 1302

CFR Citation: 45 CFR 1356.60(c)

Legal Deadline: None

Abstract: This notice of proposed rulemaking implements the title IV-E foster care eligibility and administrative cost provisions in sections 472 and 474 of the Social Security Act. We propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unlicensed foster family homes, with the exception of children in relative foster family homes while the State is in the process of licensing the home. We also propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unallowable facilities, with the exception of the month prior to a child's transition into an allowable facility.

Timetable:

Action	Date	FR Cite
NPRM	01/31/05	70 FR 4803
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
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Email: kmchugh@acf.hhs.gov

RIN: 0970–AC14

1046. HEAD START TRANSPORTATION

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

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1310

Legal Deadline: None

Abstract: This final rule will extend for 150 days those parts of the Head Start transportation regulation that deal with the requirement that each vehicle used to transport children is equipped for use of child safety restraint systems and the requirement that each bus have a bus monitor. Additionally, these rules will provide Head Start grantees the opportunity to request further extension of the effective date when such an extension is in the best interest of the children they serve.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/16/04	69 FR 2513
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Windy Hill, Associate Commissioner, Head Start Bureau, Department of Health and Human Services, 330 C Street SW., Washington, DC 20447
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RIN: 0970–AC16

1047. CHILD CARE AND DEVELOPMENT FUND STATE MATCH PROVISIONS

Priority: Other Significant

Legal Authority: 42 USC 9858C

CFR Citation: 45 CFR 98.16

Legal Deadline: None

Abstract: This proposed rule revises the Child Care and Development Fund (CCDF) regulations to permit States to designate multiple public and/or private entities as eligible to receive private donations that may be certified as child care expenditures for purposes of receiving Federal CCDF matching funds.

Timetable:

Action	Date	FR Cite
NPRM	11/09/04	69 FR 64881
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Karen Tvedt, Policy Director, Child Care Bureau, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Room 2046, Washington, DC 20447
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RIN: 0970–AC18

HHS—ACF **Final Rule Stage**

1048. REASONABLE QUANTITATIVE STANDARD FOR REVIEW AND ADJUSTMENT OF CHILD SUPPORT ORDERS

Priority: Other Significant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 303

Legal Deadline: None

Abstract: This interim final rule permits States to use reasonable quantitative standards in adjusting an existing child support award amount after conducting review of the order, regardless of the method review.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/04	69 FR 77659
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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RIN: 0970–AC19

Department of Health and Human Services (HHS)
Administration on Aging (AOA) **Completed Actions**

1049. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, TRAINING, RESEARCH, AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; GRANTS TO INDIANS AND NATIVE HAWAIIANS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1321; 45 CFR 1326; 45 CFR 1328

Completed:

Reason	Date	FR Cite
Withdrawn	03/02/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Federalism: Undetermined

Agency Contact: Edwin Walker
Phone: 202 401–4634

RIN: 0985–AA00

[FR Doc. 05–7660 Filed 05–13–05; 8:45 am]
BILLING CODE 4150–24–S