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Monday,
December 13, 2004

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 inventorying all rulemaking actions under development by the Department. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration. Anyone wishing to communicate to the Department their views on the potential rulemakings outlined below is 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.

When the Department publishes a proposed rule, information about it automatically becomes available to the public at www.regulations.gov, the Governmentwide Web site for submission of comments on proposed regulations. Citizens may submit comments on such proposals by clicking the ''Submit a Comment on this Regulation'' link on the Web site, which will open a blank comment form containing instructions on how to submit the comment. Comments submitted via www.regulations.gov are transmitted to the Department daily, and, as legally required, all comments received are reviewed and taken into account if a final regulation is developed.

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.

For this edition of the Department of Health and Human Services' regulatory agenda, the most significant regulatory actions are included in The Regulatory Plan, which appears in part II of this issue of the **Federal Register**. The Regulatory Plan entries are listed in the table of contents below and are denoted by a bracketed bold reference, which directs the reader to the appropriate sequence in part II.

Dated: November 1, 2004.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
910	Health Insurance Portability and Accountability Act—Enforcement	0991–AB29

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
911	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
912	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
913	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
914	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
915	Revisions to Regulations Addressing the OIG's Authority to Impose Civil Money Penalties and Assessments	0991–AB03
916	Claims Collection	0991–AB18
917	Salary Offset	0991–AB19
918	Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions to the Waiver Provisions of the OIG's Exclusion Authorities	0991–AB33

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Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
919	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991–AB06
920	Technical Revisions to HIPDB Data Collection Activities	0991–AB31
921	Participation in Department of Health and Human Services Programs by Religious Organizations; Providing for Equal Treatment of All Department of Health and Human Services Program Participants	0991–AB34

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
922	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
923	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
924	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
925	Possession, Use, and Transfer of Select Agents and Toxins	0920–AA09

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
926	Food Labeling; Prominence of Calories **(Reg Plan Seq No. 41)**	0910–AF22
927	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 **(Reg Plan Seq No. 42)**	0910–AF23
928	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43

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

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
929	Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Certain Biological Drugs, and Animal Drugs **(Reg Plan Seq No. 43)**	0910–AA49

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Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
930	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
931	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52
932	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
933	Food Standards: General Principles and Food Standards Modernization	0910–AC54
934	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
935	Reporting Information Regarding Falsification of Data	0910–AC59
936	Health Claims	0910–AF09
937	Quality Standard Regulation Establishing an Allowable Level for Arsenic in Bottled Water	0910–AF10
938	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation	0910–AF11
939	Cochineal Extract and Carmine Label Declaration	0910–AF12
940	Charging for Investigational Drugs	0910–AF13
941	Treatment Use of Investigational Drugs	0910–AF14
942	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
943	Revocation of the Status of Specific Products; Group A Streptococcus	0910–AF20
944	Obstetrical and Gynecological Devices; Designation of Special Control for Condoms and Condoms with Spermicidal Lubricant	0910–AF21
945	Blood Initiative—Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
946	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
947	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
948	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
949	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
950	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
951	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
952	Substances Prohibited From Use in Animal Food or Feed **(Reg Plan Seq No. 44)**	0910–AF46
953	Over-the-Counter (OTC) Drug Review—Dandruff, Seborrheic Dermatitis, and Psoriasis Products	0910–AF49
954	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
955	Over-the-Counter (OTC) Drug Review—Skin Bleaching Prodcuts	0910–AF53
956	Use of Materials Derived From Cattle In Human and Animal Medical Products **(Reg Plan Seq No. 45)**	0910–AF54
957	Requirements for Human and Animal Medical Products Manufactured From, Processed With, or Otherwise Containing Material From Cattle **(Reg Plan Seq No. 46)**	0910–AF55

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

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
958	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
959	Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products **(Reg Plan Seq No. 47)**	0910–AA94
960	Safety Reporting Requirements for Human Drug and Biological Products **(Reg Plan Seq No. 48)**	0910–AA97
961	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement **(Reg Plan Seq No. 49)**	0910–AB28
962	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
963	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) **(Reg Plan Seq No. 50)**	0910–AB76
964	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements **(Reg Plan Seq No. 51)**	0910–AB88
965	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
966	Prevention of Salmonella Enteritidis in Shell Eggs **(Reg Plan Seq No. 52)**	0910–AC14
967	Institutional Review Boards: Registration Requirements	0910–AC17
968	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32

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Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
969	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
970	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs **(Reg Plan Seq No. 53)**	0910–AC35
971	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 54)**	0910–AC39
972	Registration of Food and Animal Feed Facilities **(Reg Plan Seq No. 55)**	0910–AC40
973	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 56)**	0910–AC41
974	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
975	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol **(Reg Plan Seq No. 57)**	0910–AF18
976	Blood Initiative—Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma	0910–AF26
977	Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
978	Infant Formula Quality Factors	0910–AF28
979	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
980	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
981	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
982	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
983	Use of Materials Derived From Cattle in Human Food and Cosmetics **(Reg Plan Seq No. 58)**	0910–AF47
984	Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle **(Reg Plan Seq No. 59)**	0910–AF48
985	Over-the-Counter (OTC) Drug Review—Antacid Products (Sodium Bicarbonate Labeling)	0910–AF52

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Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
986	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
987	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
988	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
989	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
990	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
991	Food Labeling: Food Allergen Ingredient Labeling	0910–AF07
992	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
993	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
994	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
995	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
996	Presubmission Conferences	0910–AC44
997	Definition of ''Serious Adverse Health Consequences'' Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AF06
998	Over-the-Counter (OTC) Drug Review—Antiperspirant Products	0910–AF30
999	Over-the-Counter (OTC) Drug Review—Sodium Labeling for Over-the Counter Drugs	0910–AF50

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Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1000	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906–AA41
1001	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44
1002	Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA62
1003	National Vaccine Injury Compensation Program; Revisions and Additions to the Vaccine Injury Table	0906–AA66
1004	National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy	0906–AA68
1005	Revision to 42 CFR Subpart D—Public Health Service (PHS) Grant Appeals Procedure	0906–AA69
1006	Healthy Tomorrow's Partnership for Children (HTPC) Program	0906–AA70

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1007	Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
1008	Smallpox Vaccine Injury Compensation Program: Administrative Implementation	0906–AA61
1009	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
1010	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57
1011	Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA63

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1012	Liability Protection for Certain Free Clinic Health Professionals	0906–AA67

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1013	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925–AA10
1014	National Institutes of Health Training Grants	0925–AA28
1015	Standards for a National Chimpanzee Sanctuary System	0925–AA31
1016	National Institutes of Health AIDS Research Loan Repayment Program	0925–AA32
1017	National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers	0925–AA33
1018	National Institutes of Health Pediatric Research Loan Repayment Program	0925–AA34
1019	National Institutes of Health Loan Repayment Program for Health Disparities Research	0925–AA35
1020	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925–AA36
1021	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925–AA41

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National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1022	National Institutes of Health Loan Repayment Program for Research Generally	0925–AA18

National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1023	National Institutes of Health Center Grants	0925–AA24

Office of Public Health and Science—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
1024	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
1025	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940–AA01
1026	Public Health Service Policies on Research Misconduct	0940–AA04
1027	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940–AA06
1028	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
1029	Human Subjects Protection Regs.: Training and Education 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
1030	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)	0938–AG81
1031	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) **(Section 610 Review) (Reg Plan Seq No. 60)**	0938–AG82
1032	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-P) **(Reg Plan Seq No. 61)**	0938–AH17
1033	Hospice Care—Conditions of Participation (CMS-3844-P) **(Reg Plan Seq No. 62)**	0938–AH27
1034	Standard Unique National Health Plan Identifiers (CMS-6017-P)	0938–AH87
1035	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS-6003-P2)	0938–AI49
1036	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)	0938–AJ17
1037	Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS-6010-P)	0938–AJ98
1038	Standards for Electronic Health Care Claim Attachments(CMS-0050-P)	0938–AK62
1039	Organ Procurement Organization Conditions for Coverage (CMS-3064-P) **(Reg Plan Seq No. 63)**	0938–AK81

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

Sequence Number	Title	Regulation Identifier Number
1040	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P) **(Reg Plan Seq No. 64)**	0938–AL26
1041	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938–AL80
1042	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-P)	0938–AL88
1043	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938–AM50
1044	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938–AM87
1045	Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Post-Anesthesia Evaluations (CMS-3122-P)	0938–AM88
1046	Physician Referral for Nuclear Medicine Services and Supplies (CMS-1261-P)	0938–AN04
1047	Enhanced DSH Treatment for Certain Hospitals (CMS-2198-P)	0938–AN09
1048	Prior Determination Process for Certain Items and Services (CMS-6024-P)	0938–AN10
1049	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-P)	0938–AN14
1050	Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-PN)	0938–AN23
1051	Revisions to HIPAA Code Sets (CMS-0013-P)	0938–AN25
1052	Payment for Clinical Laboratory Tests (CMS-1494-P)	0938–AN26
1053	Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-P)	0938–AN28
1054	Random Prepayment Review (CMS-6022-P)	0938–AN31
1055	Repayment Plans and Limitation on Recoupment of Overpayments (CMS-6025-P)	0938–AN42
1056	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2006 (CMS-1290-P)	0938–AN43
1057	Home Health Prospective Payment System Rate Update for Calendar Year 2006 (CMS-1301-P)	0938–AN44
1058	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-P)	0938–AN46
1059	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6019-P)	0938–AN48
1060	Medicare Modernization Act; Electronic Prescribing (CMS-0011-P)	0938–AN49
1061	Furnishing Hospitals With Information To Compute the Disproportionate Share Hospital Formula (CMS-1283-P)	0938–AN52
1062	End Stage Renal Disease (ESRD) Composite Rate Exception (CMS-1278-P)	0938–AN53
1063	Changes to the Hospital Inpatient Prospective Payment System and FY 2006 Rates (CMS-1500-P)	0938–AN57
1064	Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-P)	0938–AN58
1065	Revisions to the Oversight and Validation Program for Accrediting Organizations Approved for Deeming Authority (CMS-2255-P) **(Reg Plan Seq No. 65)**	0938–AN62
1066	Special Payment Provisions and Standards for Suppliers of Custom Fabricated Orthotics and Prosthetics (CMS-6012-P)	0938–AN63
1067	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2006 (CMS-1282-P)	0938–AN65

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Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1068	Hospital Conditions of Participation: Laboratory Services (CMS-3014-IFC)	0938–AJ29
1069	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS-2151-F)	0938–AL43
1070	Prospective Payment System for Inpatient Psychiatric Facilities for FY 2004 (CMS-1213-F)	0938–AL50
1071	Request for Information on Benefit-Specific Waiting Periods (CMS-2150-NC)	0938–AL64
1072	Revisions to the Medicare Appeals Process (CMS-4004-FC)	0938–AL67
1073	Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-IFC)	0938–AM73
1074	Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles Scooter(CMS-3017-IFC)	0938–AM74
1075	Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS-1427-FC)	0938–AM75
1076	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS-1429-FC)	0938–AM90
1077	Medicare Advantage Program—Title II (CMS-4069-F) **(Reg Plan Seq No. 66)**	0938–AN06
1078	Medicare Drug Benefit Effective Calendar Year 2006—Title I (CMS-4068-F) **(Reg Plan Seq No. 67)**	0938–AN08
1079	Schedule for Publishing Medicare Final Regulations After a Proposed or Interim Final Regulation (CMS-9026-N)	0938–AN12
1080	Evaluation Criteria and Standards for Quality Improvement Program Contracts (CMS-3142-NC)	0938–AN13

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

Sequence Number	Title	Regulation Identifier Number
1081	Medicare Secondary Payer (MSP): Workmen's Compensation (CMS-6272-IFC)	0938–AN27
1082	Fire Safety Requirements for Certain Health Care Facilities; Alcohol-Based Hand Sanitizer Amendment (CMS-3145-IFC)	0938–AN36
1083	Modifications to Managed Care Rules (CMS-4041-IFC)	0938–AN38
1084	Development of New Standards for Medigap Policies (CMS-2197-FN)	0938–AN50
1085	Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program (CMS-2175-F)	0938–AN55
1086	Fiscal Year 2006 SCHIP Allotments (CMS-2219-N)	0938–AN56

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Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1087	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-F)	0938–AH73
1088	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)	0938–AJ10
1089	Medicare Hospice Care Amendments (CMS-1022-F)	0938–AJ36
1090	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938–AJ96
1091	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS-1810-IFC)	0938–AK67
1092	Provider Reimbursement Determinations and Appeals (CMS-1727-F)	0938–AL54
1093	DMERC Service Areas and Related Matters (CMS-1219-F)	0938–AL76
1094	Electronic Medicare Claims Submission (CMS-0008-F)	0938–AM22
1095	Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services (CMS-3119-FN)	0938–AM36
1096	Requirements for Long Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information (CMS-3121-F)	0938–AM55
1097	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-F)	0938–AM98
1098	Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS-1167-F)	0938–AN02
1099	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)	0938–AN19
1100	Medicare Ambulance Fee Schedule Update (CMS-1492-F)	0938–AN24
1101	Nondiscrimination in Health Coverage and Wellness Plans in the Group Market (CMS-2022-F)	0938–AN29
1102	Hospital Conditions of Participation: Patients' Rights (CMS-3018-F)	0938–AN30
1103	Federal Enforcement in Group and Individual Health Insurance Markets (CMS-2019-F)	0938–AN35
1104	Group Market Health Insurance Reform: Guaranteed Availability, Guaranteed Renewability, Disclosures to Small Employers (CMS-2216-F)	0938–AN60
1105	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-2217-F)	0938–AN61

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1106	Continuation of Medicare Entitlement When Disability Benefit Ends Because of Substantial Gainful Activity (CMS-4018-F)	0938–AK94
1107	Interest Calculation (CMS-6014-F)	0938–AL14
1108	Hospital Patients' Rights CoP—Standard Safety Compliance Committees (CMS-3120-P)	0938–AM39
1109	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2006 (CMS-1249-N)	0938–AM46
1110	Title I: Non-Federal Governmental Plans Exempt From HIPAA (CMS-2033-F)	0938–AM71
1111	Hospice Wage Index FY 2005 (CMS-1264-N)	0938–AM78
1112	Ticket to Work: Defining Individuals with Potentially Severe Disabilities and Providing a Work Threshold (CMS-2172-P)	0938–AM79
1113	Changes to the Hospital Inpatient Prospective Payment System and FY 2005 Rates (CMS-1428-F)	0938–AM80
1114	Covered Outpatient Drugs Under the Medicaid Drug Rebate Program (CMS-2174-P)	0938–AM81

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

Sequence Number	Title	Regulation Identifier Number
1115	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 (CMS-1360-N)	0938–AM82
1116	Payment Error Rate Measurement (PERM) Program (CMS-6026-P)	0938–AM86
1117	Home Health Prospective Payment System Rate Update FY 2005 (CMS-1265-F)	0938–AM93
1118	Revisions to Cost Sharing Regulations (CMS-2144-P)	0938–AM94
1119	Medicare Program; Hospital Outpatient Prospective Payment System Payment Reform for Calendar Year 2004 CMS-1371-F	0938–AM96
1120	Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004—Correction Notice CMS-1372-F)	0938–AM97
1121	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date (CMS-1809-F5)	0938–AM99
1122	Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program (CMS-2188-P)	0938–AN01
1123	Extended Availability of Unexpended SCHIP Funds From the Appropriation for FYs 1998 Through 2004; Authority To Use a Portion of SCHIP Funds for Medicaid Expenditures (CMS-2187-N)	0938–AN03
1124	Manufacturers' Submission of Average Sales Price Data for Medicare Part B Drugs and Biologicals (CMS-1380-F)	0938–AN05
1125	Special Rules for Employer-Sponsored Drug Programs: Subsidies To Encourage Retention (Title I) (CMS-2199-P)	0938–AN07
1126	FY 2005 SCHIP Allotments (CMS-2201-N)	0938–AN11
1127	Part A Premiums for Calendar Year 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8022-N)	0938–AN15
1128	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2005 (CMS-8021-N)	0938–AN16
1129	Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2005 (CMS-8020-N)	0938–AN18
1130	Fee Schedule for Payment of Ambulance Services-Update for Calendar Year 2005 (CMS-1267-N)	0938–AN20
1131	Procedure for Producing Guidance Documents Describing Medicare's Coverage Process (CMS-3141-N)	0938–AN21
1132	Amendment to the Interim Final Regulation for Mental Health Parity (CMS-2152-F2)	0938–AN22
1133	Pharmacy Dispensing Fee (CMS-1280-F)	0938–AN34

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1134	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01
1135	Developmental Disabilities and Bill of Rights Act	0970–AC07
1136	Administrative Costs for Children in Title IV-E Foster Care	0970–AC14
1137	Administrative Cost Sharing Under TANF	0970–AC15
1138	Child Care and Development Fund State Match Provisions	0970–AC18

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1139	Head Start Transportation	0970–AC16
1140	Reasonable Quantitative Standard for Review and Adjustment of Child Support Orders	0970–AC19

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1141	Child Support Enforcement Program; Federal Tax Refund Offset	0970–AC09

HHS

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1142	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)

910. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

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

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 USC 1320d-5.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

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

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

911. 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	04/00/05	

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 (OIG), 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

Related RIN: Related to 0991–AB06

RIN: 0991–AA91

912. 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.

HHS—OS **Final Rule Stage**

Timetable:

Action	Date	FR Cite
NPRM	12/06/00	65 FR 76460
Final Action	03/00/05	

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

913. 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	04/00/05	

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 (OIG), 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

RIN: 0991–AB16

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

Priority: Substantive, Nonsignificant

Legal Authority: Sec 112B (6) (6)(A) of the Social Security Act

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/15/03	68 FR 53939
NPRM Comment Period End	11/14/03	
Final Action	04/00/05	

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 (OIG), 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

RIN: 0991–AB23

Department of Health and Human Services (HHS)
Office of the Secretary (OS) **Long-Term Actions**

915. 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 (OIG), 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0089

RIN: 0991–AB03

916. 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: Jefferey 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, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0150

RIN: 0991–AB18

917. 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: Jefferey 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, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619–0150

RIN: 0991–AB19

918. MEDICARE AND FEDERAL HEALTH CARE PROGRAMS: FRAUD AND ABUSE; REVISIONS TO THE WAIVER PROVISIONS OF THE OIG'S EXCLUSION AUTHORITIES

Priority: Substantive, Nonsignificant

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

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 healthcare 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 (OIG), 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)

919. SAFE HARBOR FOR ARRANGEMENTS INVOLVING FEDERALLY QUALIFIED HEALTH CENTERS

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 1001

Completed:

Reason	Date	FR Cite
Withdrawn – Superceded by 0991–AB37	09/07/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer Phone: 202 619–0089

Related RIN: Related to 0991–AA91

RIN: 0991–AB06

920. TECHNICAL REVISIONS TO HIPDB DATA COLLECTION ACTIVITIES

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 61

Completed:

Reason	Date	FR Cite
Interim Final Rule	06/17/04	69 FR 33866

HHS—OS **Completed Actions**

Reason	Date	FR Cite
Interim Final Rule Comment Period End	07/19/04	
Final Action	11/02/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Jay Schaer
Phone: 202 619–0089

RIN: 0991–AB31

921. ● PARTICIPATION IN DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS BY RELIGIOUS ORGANIZATIONS; PROVIDING FOR EQUAL TREATMENT OF ALL DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAM PARTICIPANTS

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301

CFR Citation: 45 CFR 74

Legal Deadline: None

Abstract: This rulemaking completes the Department's effort to implement executive branch policy that, within the framework of constitutional church-state guidelines, religiously affiliated (or ''faith-based'') organizations should be able to compete on an equal footing with other organizations for the Department's funding without impairing the religious character of such organizations. It revises Department regulations to remove barriers to the participation of faith-based organizations in Department programs, and to ensure that these programs are implemented in a manner consistent with applicable statutes and the requirements of the Constitution.

Timetable:

Action	Date	FR Cite
NPRM	03/09/04	69 FR 10991
Final Action	07/16/04	69 FR 42586

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Bobby Polito, Director, Center for Faith–Based and Community Initiatives, Department of Health and Human Services, Room 120F, 200 Independence Avenue NW., Washington, DC 20201
Phone: 202 358–3595

Related RIN: Previously reported as 0991–AB32

RIN: 0991–AB34

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

922. 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	04/00/05	

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)

923. 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	04/00/05	

HHS—SAMHSA **Final Rule Stage**

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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

RIN: 0930–AA12

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

924. 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	02/00/05	

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–AA04

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

925. • POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Priority: Other Significant

Legal Authority: PL 107–188

CFR Citation: 42 CFR 72; 42 CFR 72.6

Legal Deadline: None

Abstract: Title II of subtitle B of Public Law 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), repeals, expands, and incorporates the Secretary's current authority to regulate the transfer of certain biological agents and toxins (select agents). The Bioterrorism Act specifies that the Secretary develop and biennially review a specified list of select agents. Safety procedures must be established and enforced for the possession, use, and transfer of the listed agents and toxins; access to select agents is limited to individuals and entities that pass background checks administered by the Attorney General. The Bioterrorism Act exempts certain information from disclosure under the Freedom of Information Act, including information that would identify the location of regulated entities or their security measures. Subtitle C of the Bioterrorism Act outlines the required interagency coordination between the Department of Health and Human Services and the Department of Agriculture regarding agents that are regulated by both departments (overlap agents). This action will bring to completion the Department's rulemaking in this area.

Timetable:

Action	Date	FR Cite
Final Action	01/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Additional Information: Under RIN 0920-AA08, this regulation published as an interim final rule on December 13, 2002, at 67 FR 76886. An amended interim final rule with a request for comments was also published on November 3, 2003, at 68 FR 62245. Subsequently, RIN 0920-AA08 was inadvertently completed in the april 2003 Unified Agenda.

Agency Contact: Mark Hemphill, Chief of Policy, Select Agent Program, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Rd, MS E–79, Atlanta, GA 30333
Phone: 404 498–2255

Related RIN: Previously reported as 0920–AA08

RIN: 0920–AA09

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

Prerule Stage

926. FOOD LABELING; PROMINENCE OF CALORIES

Regulatory Plan: This entry is Seq. No. 41 in part II of this issue of the **Federal Register**.

RIN: 0910–AF22

927. 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

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

RIN: 0910–AF23

928. 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)	01/00/05	
NPRM (UVA/UVB)	03/00/05	

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
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

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

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

RIN: 0910–AA49

930. 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; 21 CFR 868.5905

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	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, HFZ–215, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
Phone: 301 827–2974
Fax: 301 594–4765
Email: joseph.sheehan@fda.hhs.gov

RIN: 0910–AC30

931. 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	06/00/05	

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
Phone: 301 594–2041
Fax: 301 594–6197
Email: muellern@cder.fda.gov

RIN: 0910–AC52

932. 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

933. 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 7 CFR part 410 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	12/00/04	

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

934. 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	01/00/05	

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

935. 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	05/00/05	

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

936. 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	07/00/05	

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

937. 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.

Timetable:

Action	Date	FR Cite
NPRM	12/02/04	69 FR 70082
NPRM Comment Period End	01/31/05	
Final Rule	06/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Henry Kim, Supervisory Interdisciplinary Scientist, Department of Health and Human Services, Food and Drug Administration, HFS–306, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AF10

938. 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	06/00/05	

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
Phone: 301 594–2041
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RIN: 0910–AF11

939. 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

940. 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	05/00/05	

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

941. 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	03/00/05	

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

942. 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	06/00/05	

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, Rockville, MD 20852
Phone: 301 827–6210
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RIN: 0910–AF16

943. 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 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	05/00/05	
Direct Final Rule	05/00/05	

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

944. 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 NR latex. The new special control guidance document would identify issues requiring special controls and provide detailed recommendations for labeling to address these issues that together with the general controls, provides a reasonable assurance of the safety and effectiveness of these devices. These labeling recommendations are also consistent with the labeling requirements of 21 CFR 801. The rule will demonstrate how the agency is moving forward to meet the congressional directive of Public Law 106-554 that FDA review condom labeling to assure that the information regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases is medically accurate.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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

945. 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0910–AF25

946. 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)	12/00/04	

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

947. 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)	12/00/04	

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

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482
NPRM (Phenyl propanolamine)	12/00/04	

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–AF34

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949. 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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Labeling)	12/00/04	
NPRM (Amendment) (Pediatric)	02/00/05	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	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–AF36

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950. 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)	02/00/05	

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

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

Priority: Routine and Frequent

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Phenyl propanolamine)	12/00/04	
NPRM (Benzocaine)	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–AF45

952. ● SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

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

RIN: 0910–AF46

953. ● 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)	02/00/05	

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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RIN: 0910–AF49

954. ● 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)	02/00/05	

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,

HHS—FDA **Proposed Rule Stage**

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RIN: 0910–AF51

955. • 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	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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RIN: 0910–AF53

956. • USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN AND ANIMAL MEDICAL PRODUCTS

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

RIN: 0910–AF54

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

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

RIN: 0910–AF55

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

Final Rule Stage

958. 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	02/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AA61

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

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

RIN: 0910–AA94

960. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

RIN: 0910–AA97

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

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

RIN: 0910–AB28

962. 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.

Unfunded Mandates: 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: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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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RIN: 0910–AB34

963. 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)

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

RIN: 0910–AB76

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

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

RIN: 0910–AB88

965. 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: Final, Statutory, April 17, 2001.

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	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 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–AC07

966. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

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

RIN: 0910–AC14

967. ● 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	04/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AC17

968. 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	03/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

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

969. 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	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, HFZ–215, Center for Devices and Radiological Health, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC34

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

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

RIN: 0910–AC35

971. ESTABLISHMENT AND MAINTENANCE OF RECORDS PURSUANT TO THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Regulatory Plan: This entry is Seq. No. 54 in part II of this issue of the **Federal Register**.

RIN: 0910–AC39

972. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Regulatory Plan: This entry is Seq. No. 55 in part II of this issue of the **Federal Register**.

RIN: 0910–AC40

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

Regulatory Plan: This entry is Seq. No. 56 in part II of this issue of the **Federal Register**.

RIN: 0910–AC41

974. 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.

Unfunded Mandates: 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	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

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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RIN: 0910–AF15

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

Regulatory Plan: This entry is Seq. No. 57 in part II of this issue of the **Federal Register**.

RIN: 0910–AF18

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

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

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	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0910–AF26

977. 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	09/00/05	

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

978. 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	09/00/05	

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

979. 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)	04/00/05	

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–AF31

980. 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
Final Action (Emergency First Aid Eyewashes)	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–AF39

981. 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. This action addresses labeling for products formulated and marketed as lip protectants.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	01/00/05	

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–AF42

982. 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)	04/00/05	

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

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

Regulatory Plan: This entry is Seq. No. 58 in part II of this issue of the **Federal Register**.

RIN: 0910–AF47

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

Regulatory Plan: This entry is Seq. No. 59 in part II of this issue of the **Federal Register**.

RIN: 0910–AF48

985. • OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS (SODIUM BICARBONATE LABELING)

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 the labeling of products containing sodium bicarbonate as an active ingredient.

Timetable:

Action	Date	FR Cite
Final Action	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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RIN: 0910–AF52

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

986. 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	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15–61 (HF–23), Office of Policy and Planning, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AB96

987. 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	01/00/06	

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

988. 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

989. 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
NPRM	12/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Catherine Lorraine, Director, Policy Development and Coordination Group, Department of Health and Human Services, Food and Drug Administration, 14–101–11, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AC25

990. 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 noitce 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 Schrimpf, Department of Health and Human Services, Food and Drug Administration, (HFS–832), HFS–800, 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

991. FOOD LABELING: FOOD ALLERGEN INGREDIENT LABELING

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

Legal Authority: 21 USC 321 ; 21 USC 331; 21 USC 343; 21 USC 371

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: FDA initially intended to issue a proposed rule to establish requirements for labeling foods that contain common food allergens. The purpose of this rulemaking was to reduce mortality and morbidity by making it easier for persons who have a food allergy to identify when packaged foods contain certain allergenic ingredients. Subsequently, on August 2, 2004, the President signed into law the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCP Act) (Pub. L. 108-282), which amended sections 201 and 403 of the Federal, Food, Drug and Cosmetic Act (FFD&C Act). FDA is now in the process of determining the approach it intends to take in light of the new statutory requirements.

The FALCP Act amended section 201 of the FFD&C Act to define a major food allergen as: 1) milk, egg, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, pecans, walnuts), wheat, peanuts, and soybeans and 2) any ingredient that contains a protein derived from these foods. Excluded from this definition are: 1) highly refined oils derived from the food source of a major food allergen and ingredients derived from such oils and 2) a food ingredient that is exempt under the petition or notification process specified in the law. The FALCP Act also amended section 403 of the FFD&C Act to require that the labels of packaged foods use plain English terms to identify the food source of each of the major food allergens it contains as an ingredient. This requirement is applicable to all ingredients, including flavors, non-certified colors, and incidental additives. The law provides a choice between two methods for declaring the food sources of any major food allergens contained in the ingredients of packaged foods: either within the ingredient list or in a separate summary statement immediately following or adjacent to the ingredient list.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Rhonda Rhoda Kane M.S., R.D., Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–820, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AF07

992. 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

993. 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

994. 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, 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–AF38

995. 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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF40

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

Completed Actions

996. PRESUBMISSION CONFERENCES

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 514

Completed:

Reason	Date	FR Cite
Final Action	08/18/04	69 FR 51162

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Gail Schmerfeld
Phone: 301 827–0205

Related RIN: Previously reported as 0910–AB68

RIN: 0910–AC44

997. DEFINITION OF ''SERIOUS ADVERSE HEALTH CONSEQUENCES'' UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

CFR Citation: 21 CFR 1.3(c)

Completed:

Reason	Date	FR Cite
Withdrawn	10/07/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF06

998. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTIPERSPIRANT PRODUCTS

Priority: Routine and Frequent

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

Completed:

Reason	Date	FR Cite
Final Action (Partial Stay)	10/15/04	69 FR 61148

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–AF30

999. • OVER–THE–COUNTER (OTC) DRUG REVIEW—SODIUM LABELING FOR OVER–THE COUNTER DRUGS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360a; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 371a; 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 sodium content labeling for rectal drug products containing sodium phosphates.

Timetable:

Action	Date	FR Cite
Final Action	11/29/04	69 FR 69278

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–AF50

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

Proposed Rule Stage

1000. 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
Phone: 301 443–2300

RIN: 0906–AA41

1001. 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	11/00/04	

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
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RIN: 0906–AA44

1002. 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	11/00/04	

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
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RIN: 0906–AA62

1003. NATIONAL VACCINE INJURY COMPENSATION PROGRAM; REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE

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

Legal Authority: 42 USC 300aa–14, sec 2114; PL 103–66, sec 13632(a)

CFR Citation: 42 CFR 100

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) is proposing to revise and make additions to the Vaccine Injury Table (Table). Section 2114(e) (2) of the Public Health Service Act provides for the inclusion of additional vaccines in the National Vaccine Injury Compensation Program when they are recommended by the Centers for Disease Control and Prevention for routine administration to children. In compliance with the Omnibus Budget Reconciliation Act of 1993, which added a new section 2114(e) (3) to the Act, a vaccine added to the Table through Section 2114(e) will be included in the Table, effective when an excise tax to provide funds for the payment of compensation with respect to such vaccines takes effect. HHS has determined that there are no resources required to implement these changes. Section 2114 (c) permits the Secretary of HHS to modify the Table.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857
Phone: 301 443–4198
Fax: 301 443 8196
Email: gevansr@hrsa.gov

RIN: 0906–AA66

1004. 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, ''If, over time, the average cost of health insurance, as calculated by the method described above, significantly differs from subsequent HIAA survey results or other authoritative sources then available, the Secretary of HHS will consider appropriate revisions of this rule.'' 57 FR 28098 (June 24, 1992). When the latest average monthly 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	11/00/04	

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

1005. ● REVISION TO 42 CFR SUBPART D—PUBLIC HEALTH SERVICE (PHS) GRANT APPEALS PROCEDURE

Priority: Other Significant

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 50.402

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	
Interim Final Rule	02/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: 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

1006. ● HEALTHY TOMORROW'S PARTNERSHIP FOR CHILDREN (HTPC) PROGRAM

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

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

CFR Citation: 42 CFR 51(a)

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

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

HHS—HRSA **Proposed Rule Stage**

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**

1007. 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	11/00/04	

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

1008. 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	11/00/04	

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

1009. 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	11/00/04	

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

1010. 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

1011. 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

1012. LIABILITY PROTECTION FOR CERTAIN FREE CLINIC HEALTH PROFESSIONALS

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

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Withdrawn	09/29/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Felicia Collins
Phone: 301 594–0818
Fax: 301 594 5224

RIN: 0906–AA67

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

Proposed Rule Stage

1013. 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	04/00/05	

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

1014. 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	04/00/05	

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

1015. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Substantive, Nonsignificant

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	01/00/05	

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

1016. 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	02/00/05	

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

1017. 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	03/00/05	

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

1018. 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	04/00/05	

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

1019. 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	04/00/05	

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

1020. 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	04/00/05	

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

1021. 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	01/00/05	

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
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RIN: 0925–AA41

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

Final Rule Stage

1022. 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	04/00/05	

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

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

Completed Actions

1023. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 52a

Completed:

Reason	Date	FR Cite
Final Action	12/15/03	68 FR 6961

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: None

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

RIN: 0925–AA24

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

Prerule Stage

1024. 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 Nation 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	03/00/05	
ANPRM Comment Period End	09/00/05	

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, 1101 Wootton Parkway, Suite 200, 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

1025. 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	02/00/05	

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–AA04

RIN: 0940–AA01

1026. PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Priority: Substantive, Nonsignificant

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

1027. HUMAN SUBJECTS PROTECTION REGULATIONS: INSTITUTIONAL REVIEW BOARDS REGISTRATION REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	07/04/04	69 FR 40584
NPRM Comment Period End	10/04/04	
Final Action	04/00/05	

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

HHS—OPHS **Final Rule Stage**

Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA06

1028. 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	12/00/04	

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

1029. HUMAN SUBJECTS PROTECTION REGS.: TRAINING AND EDUCATION REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATORS

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

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, 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

1030. 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 CoPs that 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	05/00/05	

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, Office of Clinical Standards and Quality, 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, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9465

RIN: 0938–AG81

1031. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–P) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 60 in part II of this issue of the **Federal Register**.

RIN: 0938–AG82

1032. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS–3835–P)

Regulatory Plan: This entry is Seq. No. 61 in part II of this issue of the **Federal Register**.

RIN: 0938–AH17

1033. HOSPICE CARE—CONDITIONS OF PARTICIPATION (CMS–3844–P)

Regulatory Plan: This entry is Seq. No. 62 in part II of this issue of the **Federal Register**.

RIN: 0938–AH27

1034. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIERS (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	04/00/05	

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 Information Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7448

RIN: 0938–AH87

1035. APPEALS OF CARRIER DETERMINATION 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 rule extends appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations. In addition, certain appeal provisions are revised to correspond with the existing appeal provisions in those other sections of our regulations. The rule also extends appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. This rule will incorporate provisions from section 936 of the Medicare Modernization Act (MMA).

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Second NPRM	02/00/05	

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

1036. 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	02/00/05	

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, 7500 Security Boulevard, C4–15–18, Baltimore, MD 21244
Phone: 410 786–5919

RIN: 0938–AJ17

1037. 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	01/00/05	

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, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21244
Phone: 410 786–4870

RIN: 0938–AJ98

1038. 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, August 21, 1998.

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	01/00/05	

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

1039. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–P)

Regulatory Plan: This entry is Seq. No. 63 in part II of this issue of the **Federal Register**.

RIN: 0938–AK81

1040. USE OF RESTRAINT AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS–2130–P)

Regulatory Plan: This entry is Seq. No. 64 in part II of this issue of the **Federal Register**.

RIN: 0938–AL26

1041. 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	09/00/05	

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

1042. HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS–2158–P)

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 proposed rule would clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. It would also implement 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	11/00/04	

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 Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AL88

1043. 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	06/00/05	

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0273

RIN: 0938–AM50

1044. 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 proposed 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	06/00/05	

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, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–04–26, Baltimore, MD 21244
Phone: 410 786–5646

RIN: 0938–AM87

1045. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS; SECURING MEDICATIONS; AND POST–ANESTHESIA EVALUATIONS (CMS–3122–P)

Priority: Economically 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 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	02/00/05	

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6899
Email: pchmielewski@cms.hhs.gov

RIN: 0938–AM88

1046. PHYSICIAN REFERRAL FOR NUCLEAR MEDICINE SERVICES AND SUPPLIES (CMS–1261–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1877 of the Social Security Act

CFR Citation: 42 CFR 411.351

Legal Deadline: None

Abstract: This proposed rule would amend the definitions of ''radiology and certain other imaging services'' and ''radiation therapy services and supplies'' to include diagnostic and therapeutic nuclear medicine services and supplies, respectively.

Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4620
Email: jsinsheimer@cms.hhs.gov

RIN: 0938–AN04

1047. 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 beginning December 8, 2003.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

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

RIN: 0938–AN09

1048. 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 beginning June 8, 2005. (The final rule must be published by March 25, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

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, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21244
Phone: 410 786–3087
Email: mwhitaker@cms.hhs.gov

RIN: 0938–AN10

1049. 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: NPRM, Statutory, April 1, 2005.
Final, Statutory, May 1, 2006.

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	06/00/05	

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, 7500 Security Boulevard, C5–08–27, Baltimore, MD 21244
Phone: 410 786–4495

Email: mkeane@cms.hhs.gov

RIN: 0938–AN14

1050. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–PN)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

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

Abstract: This proposed notice updates the list of Medicare-covered ASC procedures. (The subsequent final notice must be published by March 25, 2005, to be effective July 1, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Bob Cereghino, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244
Phone: 410 786–4645
Email: bcereghino@cms.hhs.gov

RIN: 0938–AN23

1051. 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 rule proposes revisions to 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	06/00/05	

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

1052. 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 2-year period beginning on July 1, 2004. Section 1833(h) of the Act mandates payment for outpatient clinical laboratory tests under a clinical laboratory fee schedule.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anita Greenberg, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–4601
Email: agreenberg@cms.hhs.gov

RIN: 0938–AN26

1053. PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–P)

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: None

Abstract: This 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. The proposed and final rules must be published by April 29, 2005, to be effective July 1, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

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, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AN28

1054. RANDOM PREPAYMENT 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 proposed rule would provide guidelines for terminating a provider of services or supplier from non-random payment review.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

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

RIN: 0938–AN31

1055. ● REPAYMENT PLANS AND 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 two provisions of Section 935 of the Medicare Modernization Act which added a new subsection to Section 1893 of the Social Security Act. It would establish criteria and procedures for a repayment plan where repaying a Medicare overpayment would be a hardship for a provider or supplier absent specific exceptions. It also 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	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Lisa A. Vriezen, Director, Division of Medicare Overpayment, Financial Services Group, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1492
Email: lvriezen@cms.hhs.gov

RIN: 0938–AN42

1056. ● 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, 2004, Rates for PPS.

Abstract: The proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2006. (The statute requires that this notice be published by August 1, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

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, 7500 Security Boulevard, C5–06–24, Baltimore, MD 21244
Phone: 410 786–4597

RIN: 0938–AN43

1057. ● 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: None

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	05/00/05	

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, 7500 Security Boulevard, C5–09–15, Baltimore, MD 21244
Phone: 410 786–0131

RIN: 0938–AN44

1058. ● 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: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/00/05	

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: Dana Buley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4547
Email: dbuley@cms.hhs.gov

RIN: 0938–AN46

1059. ● 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, 2005.

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 will 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	04/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Cohen, Health Insurance Specialist, CMS/OFM/PIG, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3349
Email: jcohen@cms.hhs.gov

RIN: 0938–AN48

1060. ● MEDICARE MODERNIZATION ACT; ELECTRONIC PRESCRIBING (CMS–0011–P)

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: 42 USC 1395

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, September 2005, Required e–prescribing before outset of January 2006 Medicare part D drug benefit.

Abstract: This rule proposes 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. (The proposed and subsequent final rule must be published by September 1, 2005, in order for the e-prescribing provisions to be in effect in advance of the beginning of the part D benefit and e-prescribing pilot projects in January 2006.)

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal, Local, State, Tribal

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

1061. ● FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE THE DISPROPORTIONATE SHARE HOSPITAL FORMULA (CMS–1283–P)

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

Legal Authority: Section 1886 (d)(5)(F) of the Social Security Act; MMA, sec 951

CFR Citation: Not Yet Determined

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

This provision is a requirement of the MMA and is effective one year after the date of the enactment of the Act (December 8, 2004).

Abstract: Section 1886(d)(5)(F) of the Social Security Act provides additional payments to subsection (d) hospitals that serve a disproportionate share of low-income patients. Section 951 of the Medicare Modernization Act requires the Secretary to furnish hospitals with the data necessary to compute the number of patient days used in calculating the disproportionate patient percentage. This provision is effective December 8, 2004. We request this new regulation to solicit public comments and subsequently implement this required MMA provision.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Sherry Amstead, Health Insurance Specialist, CMS/CMM/HAPG/DAC, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4342
Email: samstead@cms.hhs.gov

RIN: 0938–AN52

1062. ● END STAGE RENAL DISEASE (ESRD) COMPOSITE RATE EXCEPTION (CMS–1278–P)

Priority: Substantive, Nonsignificant

Legal Authority: MMA, sec 623; BIPA, sec 422

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule will revise and update existing regulations to comply with the statutory changes in BIPA and MMA. Most changes will result in significant deletions to existing Regulation text. This notice is in response to MMA section 623 and BIPA section 422. The BIPA 2000 statute eliminates all future opportunities for renal dialysis facilities to file exception requests to obtain higher composite payment rates The MMA statute of 2003 (via changes to

BIPA 2000) restored composite rate exceptions only for pediatric renal dialysis facilities.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael E Powell, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4557
Email: mpowell@cms.hhs.gov

RIN: 0938–AN53

1063. ● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2006 RATES (CMS–1500–P)

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

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 revises the Medicare acute hospital inpatient prospective payment system for operating and capital-related costs to implement changes arising from our continuing experience with these systems. It describes changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes apply to discharges on or after October 1, 2005. The rule also sets forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the prospective payments systems. (The statute requires the final rule to be published by August 1, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4487
Email: thefter@cms.hhs.gov

RIN: 0938–AN57

1064. ● MEDICARE PART B COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

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	02/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Edmund Erdvilas Kasaitis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C4–01–26, Baltimore, MD 21224
Phone: 410 786–0477
Email: ekasaitis@cms.hhs.gov

RIN: 0938–AN58

1065. ● REVISIONS TO THE OVERSIGHT AND VALIDATION PROGRAM FOR ACCREDITING ORGANIZATIONS APPROVED FOR DEEMING AUTHORITY (CMS–2255–P)

Regulatory Plan: This entry is Seq. No. 65 in part II of this issue of the **Federal Register**.

RIN: 0938–AN62

1066. ● 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: Under this provision, Medicare will cover prosthetics and certain custom-fabricated orthotics only if furnished by a ''qualified practitioner'' and fabricated by a ''qualified practitioner'' or ''qualified supplier.'' The Secretary, in consultation with experts, is required to establish and periodically update a list of custom-fabricated orthotics and prosthetics subject to this rule. (Congress required that a final rule be published not later than one year after the date that section 427 of the BIPA was enacted.)

Timetable:

Action	Date	FR Cite
NPRM	07/00/05	

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, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21224
Phone: 410 786–9249

HHS—CMS **Proposed Rule Stage**

Email: tlinkowich@cms.hhs.gov

RIN: 0938–AN63

1067. ● 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: NPRM, Statutory, August 1, 2005, Updates payment rates.

Abstract: This proposed rule updates payment rates used under the SNF PPS beginning October 1, 2005.

Timetable:

Action	Date	FR Cite
NPRM	04/00/05	

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 Medicaid and State Operations, 7500 Security Boulevard, C5–07–08, Baltimore, MD 21244
Phone: 401 786–5667

RIN: 0938–AN65

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

Final Rule Stage

1068. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–IFC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 482.27

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 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	06/00/05	

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, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244
Phone: 410 786–3189

RIN: 0938–AJ29

1069. HEALTH COVERAGE PORTABILITY FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE ISSUERS (CMS–2151–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 300gg; PL 104–191

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; . . .

Legal Deadline: None

Abstract: This final rule provides portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan under the Health Insurance Portability and Accountability Act of 1996. This regulation addresses limitations or preexisting exclusion periods on requests for special enrollments.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/07/97	
Interim Final Rule Effective	07/07/97	
Final Action	11/00/04	

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, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–16–26, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AL43

1070. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FOR FY 2004 (CMS–1213–F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 106–113; Sec 124 of the BBRA ; Sec 1886 of the Social Security Act

CFR Citation: 42 CFR 412, subpart N; 42 CFR 413; 42 CFR 424

Legal Deadline: NPRM, Statutory, October 1, 2002, Public Law 106–113, sec 124.

Abstract: This final rule would set forth a prospective payment system for Inpatient hospital services furnished by psychiatric hospitals and psychiatric units that will be effective January 1, 2005 (to establish the new system).

Timetable:

Action	Date	FR Cite
NPRM	11/28/03	68 FR 66919

Action	Date	FR Cite
NPRM Comment Period End	02/26/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

Agency Contact: Lana Price, Director, Division of Chronic Care Management, Chronic Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–05–27, Center for Medicare Management, 7500 Security Boulevard, C5–05–27, Baltimore, MD 21244
Phone: 410 786–4533
Email: lprice@cms.hhs.gov

RIN: 0938–AL50

1071. REQUEST FOR INFORMATION ON BENEFIT–SPECIFIC WAITING PERIODS (CMS–2150–NC)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: This notice requests information on the use of benefit-specific waiting periods by group health plan and group health insurance issuers.

Timetable:

Action	Date	FR Cite
Notice	11/00/04	

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, S3–16–26, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AL64

1072. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS–4004–FC)

Priority: Other Significant

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 405

Legal Deadline: NPRM, Statutory, October 1, 2002, Statutory effective date October 1, 2002.

Abstract: This final rule with comment period addresses one discrete aspect of the November 15, 2002 proposed rule, ''Changes to the Medicare Claims Appeal Procedures'' (67 FR 69312). As required by section 1869(b)(1)(F) of the Social Security Act, this rule establishes expedited determination and reconsideration procedures for beneficiaries who are informed by a provider that Medicare coverage of their services is about to end. This rule implements section 937 of the Medicare Modernization Act which requires a process for correction of minor errors and omissions without pursing the appeals process.

Timetable:

Action	Date	FR Cite
NPRM	11/15/02	67 FR 69312
NPRM Comment Period End	01/14/03	
Final Action	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Janet Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–14–26, S1–06–04, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1588

RIN: 0938–AL67

1073. REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–IFC)

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

Unfunded Mandates: Undetermined

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-tiered (five levels) of review. It will remove the distinction between the processing of initial determination 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	12/00/04	

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, 7500 Security Boulevard, S1–05–06, Baltimore, MD 21244
Phone: 410 786–6478

Related RIN: Related to 0938–AK69

RIN: 0938–AM73

1074. 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	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Lorrie Ballantine, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7543

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

1075. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE SYSTEM AND CALENDAR YEAR 2005 PAYMENT RATES (CMS–1427–FC)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395L; Balanced Budget Act of 1997; Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999; Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

CFR Citation: Not Yet Determined

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

Abstract: The rule revises the Medicare hospital outpatient prospective payment system beginning January 1, 2005. It also responds to comments received from the 2004 Outpatient PPS update (CMS-1371-IFC).

Timetable:

Action	Date	FR Cite
NPRM	08/16/04	69 FR 50497
Final Action	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Cindy Read, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Mangement, 7500 Security Boulevard, C4–05–07, Baltimore, MD 21244
Phone: 410 786–1852

Related RIN: Related to 0938–AM96

RIN: 0938–AM75

1076. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2005 (CMS–1429–FC)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395W–4

CFR Citation: 42 CFR 410; 42 CFR 414

Legal Deadline: NPRM, Statutory, June 1, 2004, Revisions to Payment Policies. Final, Statutory, January 1, 2005.

Abstract: This final rule with comment period makes several changes affecting Medicare part B payment. It also includes several provisions on preventive care from the Medicare Modernization Act including, initial preventive physical examination, cardiovascular screening blood tests, and diabetes screening tests.

Timetable:

Action	Date	FR Cite
NPRM	08/05/04	69 FR 47488
NPRM Comment Period End	09/24/04	
Final Action	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Latesha Walker, 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: 410 786–1101

Related RIN: Related to 0938–AM97

RIN: 0938–AM90

1077. MEDICARE ADVANTAGE PROGRAM—TITLE II (CMS–4069–F)

Regulatory Plan: This entry is Seq. No. 66 in part II of this issue of the **Federal Register**.

RIN: 0938–AN06

1078. MEDICARE DRUG BENEFIT EFFECTIVE CALENDAR YEAR 2006—TITLE I (CMS–4068–F)

Regulatory Plan: This entry is Seq. No. 67 in part II of this issue of the **Federal Register**.

RIN: 0938–AN08

1079. SCHEDULE FOR PUBLISHING MEDICARE FINAL REGULATIONS AFTER A PROPOSED OR INTERIM FINAL REGULATION (CMS–9026–N)

Priority: Other Significant

Legal Authority: Sec 902 of the Medicare Modernization Act of 2003

CFR Citation: None

Legal Deadline: None

Abstract: In accordance with Section 902 of the Medicare Modernization Act of 2003, this rule establishes a regular timeline for the publication of final regulations based on the previous publication of a proposed or interim final regulation.

Timetable:

Action	Date	FR Cite
Notice	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Renee Swann, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4492
Email: rswann@cms.hhs.gov

RIN: 0938–AN12

1080. EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–NC)

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. (This notice with comment period must be published by May 28, 2004, to allow sufficient time

for receipt and response to comments prior to the first round of QIO evaluations beginning November 2004. Delaying the first round of evaluations will delay the statutory requirement to notify QIOs of nonrenewal of their current contracts 90 days prior to their expiration, as well as extend the QIOs' work beyond the current contract period.)

Timetable:

Action	Date	FR Cite
Notice With Comment Period	07/23/04	69 FR 44031
Comment Period End	08/23/04	
Final Action	04/00/05	

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, 7500 Security Boulevard, S2–01–01, Baltimore, MD 21244
Phone: 410 786–1775
Email: mhammel@cms.hhs.gov

RIN: 0938–AN13

1081. MEDICARE SECONDARY PAYER (MSP): WORKMEN'S COMPENSATION (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 Period	06/00/05	

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, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–0970
Email: sripley@cms.hhs.gov

RIN: 0938–AN27

1082. 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: None

Legal Deadline: None

Abstract: This interim final rule with comments would amend 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 would adopt 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 would 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 would 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	12/00/04	

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 and Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6617

RIN: 0938–AN36

1083. ● MODIFICATIONS TO MANAGED CARE RULES (CMS–4041–IFC)

Priority: Other Significant

Legal Authority: 1857(g)(3)(a)

CFR Citation: 42 CFR 422

Legal Deadline: None

Abstract: In the August 22, 2003, issue of the Federal Register, we published a final rule titled '' Modifications to Medicare Rules'' (68 FR 50840). The effective date for that final rule was September 22, 2003. This interim final rule with comment period corrects a limited number of technical and typographical errors identified in the August 22, 2003, final rule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Tony Hausner, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–24–02, Baltimore, MD 21244
Phone: 410 786–1093

Related RIN: Related to 0938–AK71

RIN: 0938–AN38

1084. ● DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES (CMS–2197–FN)

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

Legal Authority: Section 104 of the MMA

HHS—CMS

Final Rule Stage

CFR Citation: None

Legal Deadline: None

Abstract: According to section 104 of the 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. (The final notice must be published by May 27, 2005, to give Medigap issuers sufficient time to send notices).

Timetable:

Action	Date	FR Cite
Final Notice	05/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Kathryn D. McCann, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–16, Baltimore, MD 21224
Phone: 410 786–7623
Email: kmccann@cms.hhs.gov

RIN: 0938–AN50

1085. ● TIME LIMITATION ON RECORDKEEPING REQUIREMENTS UNDER THE DRUG REBATE PROGRAM (CMS–2175–F)

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

Legal Authority: 42 USC 1396

CFR Citation: 42 CFR 447.534

Legal Deadline: None

Abstract: This final rule finalizes the 10-year recordkeeping requirements. Manufacturers must retain records for 10 years from the date the manufacturer reports data to us for a rebate period. This final rule also finalizes the requirement that manufacturers must retain records beyond the 10-year period if the records are known by the manufacturer to be the subject of an audit or a government investigation. Furthermore, it responds to public comments on the January 6, 2004, interim final rule with comment period and the proposed rule pertaining to the 10-year recordkeeping comments, respectively.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comments	01/06/04	69 FR 508
Final Action	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Kimberly M. Howell, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6762
Email: khowell@cms.hhs.gov

Larry Reed, Chief, Medicaid Noninstitutional Payment Policy Branch, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3325

Related RIN: Related to 0938–AM20

RIN: 0938–AN55

1086. ● FISCAL YEAR 2006 SCHIP ALLOTMENTS (CMS–2219–N)

Priority: Economically Significant

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

CFR Citation: 42 CFR 457

Legal Deadline: None

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. (The notice must be published on August 27, 2004, so that the funds can be distributed to the States before September 30, 2005, as required by the statute.)

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

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

Long-Term Actions

1087. 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, C3–02–06, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6121

RIN: 0938–AH73

1088. 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, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–1428

RIN: 0938–AJ10

1089. 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: Thomas Saltz, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–05–27, Centers for Medicare Management, 7500 Security Boulevard, C4–05–27, Baltimore, MD 21244 Phone: 410 786–4480

Related RIN: Previously reported as 0938–AH73

RIN: 0938–AJ36

1090. 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 to 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, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–5903

RIN: 0938–AJ96

1091. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—PHASE II (CMS–1810–IFC)

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/she has a financial interest.

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, CMM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4620

RIN: 0938–AK67

1092. 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 would redefine, clarify, and update the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Morton Marcus, Heal Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4477

RIN: 0938–AL54

1093. DMERC SERVICE AREAS AND RELATED MATTERS (CMS–1219–F)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1842 of the Social Security Act; Sec 1834(a)(12) of the Social Security Act; Sec 1834(h)(3) of the Social Security Act; Sec 1834(j)(1) of the Social Security Act

CFR Citation: 42 CFR 421.210

Legal Deadline: None

Abstract: This rule allows flexibility in making changes to the DMERC contractor structure.

Timetable:

Action	Date	FR Cite
NPRM	03/26/04	69 FR 15755
NPRM Comment Period End	05/25/04	
Final Action	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Colette Shatto, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1–01–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6932

RIN: 0938–AL76

1094. 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	08/00/06	

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, 7500 Security Boulevard, C4–10–07, Baltimore, MD 21244
Phone: 410 786–9318
Email: sstrimer@cms.hhs.gov

RIN: 0938–AM22

1095. PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS–3119–FN)

Priority: Other Significant

Legal Authority: 42 USC 1395h(a); 42 USC 1395e; 42 USC 1395u(a); 42 USC 1395x; 42 USC 1395y(a)(1)(A); 42 USC 1395y(a)(7)

CFR Citation: None

Legal Deadline: None

Abstract: This final rule establishes the procedures to be used for maintaining the lists of codes that were included in the national coverage determinations (NCDs) announced on November 25, 2001.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74607
NPRM Comment Period End	02/23/04	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jacqueline Sheridan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, C1–09–06, Baltimore, MD 21244
Phone: 410 786–4635

RIN: 0938–AM36

1096. 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, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–04–26, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244
Phone: 410 786–5646

RIN: 0938–AM55

1097. 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, Office of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–04–06, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–3349

RIN: 0938–AM98

1098. 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 respirator 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
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, 7500 Security Boulevard, C5–07–26, Baltimore, MD 21244
Phone: 410 786–4499
Email: jkaiser@cms.hhs.gov

Related RIN: Related to 0938–AL27

RIN: 0938–AN02

1099. 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: Elizabeth Carmody, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C4–10–07, Baltimore, MD 21244
Phone: 410 786–7533
Email: ecarmody@cms.hhs.gov

RIN: 0938–AN19

1100. MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–F)

Priority: Economically 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, Interim final.

Abstract: Section 414 of the Medicare Modernization Act provides for temporary increases to the Medicare ambulance fee schedule beginning July 1, 2004. It also increases mileage payments for certain long trips.

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, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244
Phone: 410 786–4596
Email: rnieman@cms.hhs.gov

RIN: 0938–AN24

1101. NONDISCRIMINATION IN HEALTH COVERAGE AND WELLNESS PLANS IN THE GROUP MARKET (CMS–2022–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 document contains final rules governing 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 1966. 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 Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851
Email: dmlawsky@cms.hhs.gov

RIN: 0938–AN29

1102. 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 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: Patricia Chmielewski, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244
Phone: 410 786–6899
Email: pchmielewski@cms.hhs.gov

RIN: 0938–AN30

1103. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–2019–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 Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AN35

1104. ● GROUP MARKET HEALTH INSURANCE REFORM: GUARANTEED AVAILABILITY, GUARANTEED RENEWABILITY, DISCLOSURES TO SMALL EMPLOYERS (CMS–2216–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 Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 877 267–2323
Email: dmlawsky@cms.hhs.gov

RIN: 0938–AN60

1105. • 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–2217–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 Medicaid and State Operations, 7500 Security Boulevard, S3–16–16, Baltimore, MD 21244
Phone: 877 267–2323
Email: dmlawsky@cms.hhs.gov

RIN: 0938–AN61

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

Completed Actions

1106. CONTINUATION OF MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS–4018–F)

Priority: Economically Significant

CFR Citation: 42 CFR 406.12

Completed:

Reason	Date	FR Cite
Final Action	09/24/04	69 FR 57224

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Denise Cox
Phone: 410 786–3195

RIN: 0938–AK94

1107. INTEREST CALCULATION (CMS–6014–F)

Priority: Other Significant

CFR Citation: 42 CFR 405.378; 42 CFR 411.24

Completed:

Reason	Date	FR Cite
Final Action	07/30/04	69 FR 45604

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Nancy Braymer
Phone: 410 786–4323

RIN: 0938–AL14

1108. HOSPITAL PATIENTS' RIGHTS COP—STANDARD SAFETY COMPLIANCE COMMITTEES (CMS–3120–P)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 482

Completed:

Reason	Date	FR Cite
Withdrawn	06/30/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rachael Weinstein
Phone: 410 786–6775

RIN: 0938–AM39

1109. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2006 (CMS–1249–N)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 413.330 to 413.350

Completed:

Reason	Date	FR Cite
Notice	07/30/04	69 FR 45775

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: William Ullman
Phone: 401 786–5667

RIN: 0938–AM46

1110. TITLE I: NON–FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA (CMS–2033–F)

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 146.180

Completed:

Reason	Date	FR Cite
Final Action	07/23/04	69 FR 43926

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Dave Holstein
Phone: 410 786–1564

Related RIN: Related to 0938–AK00

RIN: 0938–AM71

1111. HOSPICE WAGE INDEX FY 2005 (CMS–1264–N)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	08/27/04	69 FR 52710

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Terri Deutseh
Phone: 410 786–9462
Email: tdeutseh@cms.hhs.gov

RIN: 0938–AM78

1112. TICKET TO WORK: DEFINING INDIVIDUALS WITH POTENTIALLY SEVERE DISABILITIES AND PROVIDING A WORK THRESHOLD (CMS–2172–P)

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

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	06/30/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carey Appold
Phone: 410 786–2117

RIN: 0938–AM79

1113. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2005 RATES (CMS–1428–F)

Priority: Economically Significant. Major under 5 USC 801.

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

Completed:

Reason	Date	FR Cite
NPRM	05/18/04	69 FR 28195
Correction Notice	06/25/04	69 FR 35920
Final Action	08/11/04	69 FR 48916

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Tzvi Hefter
Phone: 410 786–4487

RIN: 0938–AM80

1114. COVERED OUTPATIENT DRUGS UNDER THE MEDICAID DRUG REBATE PROGRAM (CMS–2174–P)

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

CFR Citation: 42 CFR 441 ; 42 CFR 447

Completed:

Reason	Date	FR Cite
Withdrawn	08/10/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Marge Watchorn
Phone: 410 786–4361

RIN: 0938–AM81

1115. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2005 (CMS–1360–N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	07/30/04	69 FR 45721

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Robert Kuhl
Phone: 410 786–4597

RIN: 0938–AM82

1116. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–6026–P)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	05/28/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Christine Saxonis
Phone: 410 786–3722
Email: csaxonis@cms.hhs.gov

RIN: 0938–AM86

1117. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FY 2005 (CMS–1265–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 484

Completed:

Reason	Date	FR Cite
NPRM	06/02/04	69 FR 31248
Correction Notice	07/03/04	69 FR 45775
Final Action	10/22/04	69 FR 62124

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Randy Throndset
Phone: 410 786–0131

RIN: 0938–AM93

1118. REVISIONS TO COST SHARING REGULATIONS (CMS–2144–P)

Priority: Other Significant

CFR Citation: 42 CFR 447.51 to 447.56

Completed:

Reason	Date	FR Cite
Withdrawn	08/16/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, State

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

Agency Contact: Alissa Deboy
Phone: 410 786–6041

RIN: 0938–AM94

1119. MEDICARE PROGRAM; HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PAYMENT REFORM FOR CALENDAR YEAR 2004 CMS–1371–F

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Merged With 0938–AM75	11/15/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Dana Buley
Phone: 410 786–4547
Email: dbuley@cms.hhs.gov

RIN: 0938–AM96

1120. CHANGES TO MEDICARE PAYMENT FOR DRUGS AND PHYSICIAN FEE SCHEDULE PAYMENTS FOR CALENDAR YEAR 2004—CORRECTION NOTICE CMS–1372–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 405; 42 CFR 414

Completed:

Reason	Date	FR Cite
Correction	06/25/04	69 FR 35527
Merged With 0938–AM90	11/15/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Marc Hartstein
Phone: 410 786–4539
Email: mhartstein@cms.hhs.gov

RIN: 0938–AM97

1121. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS: EXTENSION OF PARTIAL DELAY OF EFFECTIVE DATE (CMS–1809–F5)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	07/07/04	69 FR 35529

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Karen Raschke
Phone: 410 786–0016
Email: kraschke@cms.hhs.gov

Related RIN: Related to 0938–AL29, Related to 0938–AM21, Related to 0938–AM58, Related to 0938–AM95

RIN: 0938–AM99

1122. TIME LIMITATION ON RECORDKEEPING REQUIREMENTS UNDER THE DRUG REBATE PROGRAM (CMS–2188–P)

Priority: Other Significant

CFR Citation: 42 USC 447.534

Completed:

Reason	Date	FR Cite
Merged With 0938–AN55	08/10/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Marge Watchorn
Phone: 410 786–4361
Email: mwatchorn@cms.hhs.gov

RIN: 0938–AN01

1123. EXTENDED AVAILABILITY OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FYS 1998 THROUGH 2004; AUTHORITY TO USE A PORTION OF SCHIP FUNDS FOR MEDICAID EXPENDITURES (CMS–2187–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	07/23/04	69 FR 44013

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Richard Strauss
Phone: 410 786–2019
Email: rstrauss@cms.hhs.gov

RIN: 0938–AN03

1124. MANUFACTURERS' SUBMISSION OF AVERAGE SALES PRICE DATA FOR MEDICARE PART B DRUGS AND BIOLOGICALS (CMS–1380–F)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Rule	09/16/04	69 FR 55763

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal

Agency Contact: Angela Mason
Phone: 410 786–7452
Email: amason@cms.hhs.gov

RIN: 0938–AN05

1125. SPECIAL RULES FOR EMPLOYER–SPONSORED DRUG PROGRAMS: SUBSIDIES TO ENCOURAGE RETENTION (TITLE I) (CMS–2199–P)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 423

Completed:

Reason	Date	FR Cite
Merged With 0938–AN08	07/23/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: None

Agency Contact: James Mayhew
Phone: 410 786–9344

Email: jmayhew@cms.hhs.gov

RIN: 0938–AN07

1126. FY 2005 SCHIP ALLOTMENTS (CMS–2201–N)

Priority: Economically Significant

CFR Citation: 42 CFR 457

Completed:

Reason	Date	FR Cite
Notice	08/27/04	69 FR 52700

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss
Phone: 410 786–2019
Email: rstrauss@cms.hhs.gov

RIN: 0938–AN11

1127. PART A PREMIUMS FOR CALENDAR YEAR 2005 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8022–N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	09/09/04	69 FR 54673

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov

RIN: 0938–AN15

1128. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2005 (CMS–8021–N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	09/09/04	69 FR 54671

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov

RIN: 0938–AN16

1129. MEDICARE PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2005 (CMS–8020–N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	09/09/04	69 FR 54674

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov

RIN: 0938–AN18

1130. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES–UPDATE FOR CALENDAR YEAR 2005 (CMS–1267–N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 414.620(f); 42 CFR 414.610(c)(5); 42 CFR 414.615; 42 CFR 414.605

Completed:

Reason	Date	FR Cite
Notice	11/15/04	69 FR 66918

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ann Tayloe
Phone: 410 786–4546
Email: atayloe@cms.hhs.gov

RIN: 0938–AN20

1131. PROCEDURE FOR PRODUCING GUIDANCE DOCUMENTS DESCRIBING MEDICARE'S COVERAGE PROCESS (CMS–3141–N)

Priority: Info./Admin./Other

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	09/24/04	69 FR 57325

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Vadim Lubarsky
Phone: 410 786–0840
Email: vlubarsky@cms.hhs.gov

RIN: 0938–AN21

1132. AMENDMENT TO THE INTERIM FINAL REGULATION FOR MENTAL HEALTH PARITY (CMS–2152–F2)

Priority: Other Significant

CFR Citation: 45 CFR 146.136

Completed:

Reason	Date	FR Cite
Final Action	07/23/04	69 FR 43924

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: David Mlawsky
Phone: 410 786–6851

RIN: 0938–AN22

1133. PHARMACY DISPENSING FEE (CMS–1280–F)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	11/09/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Angela Mason
Phone: 410 786–7452
Email: amason@cms.hhs.gov

RIN: 0938–AN34

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

Proposed Rule Stage

1134. 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	03/00/05	

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

1135. 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 will be published in the Federal Register 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	03/00/05	

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

1136. 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	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
Phone: 202 401–5789
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov

RIN: 0970–AC14

1137. 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 Thompson, 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	03/00/05	

Regulatory Flexibility Analysis Required: No

HHS—ACF — Proposed Rule Stage

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: April Kaplan, Deputy Director, Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–5138
Email: akaplan@acf.hhs.gov

RIN: 0970–AC15

1138. ● 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	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Karen Tvedt, Policy Director, Child Care Bureau, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Room 2046, Washington, DC 20447
Phone: 202 401–5130
Email: ktvedt@acf.hhs.gov

RIN: 0970–AC18

Department of Health and Human Services (HHS) Administration for Children and Families (ACF) — Final Rule Stage

1139. 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	03/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Windy Hill, Associate Commisioner, Head Start Bureau, Department of Health and Human Services, 330 C Street SW., Washington, DC 20447
Phone: 202 205–8573
Email: whill@acf.hhs.gov

RIN: 0970–AC16

1140. ● REASONABLE QUANTITATIVE STANDARD FOR REVIEW AND ADJUSTMENT OF CHILD SUPPORT ORDERS

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

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	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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

RIN: 0970–AC19

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

Completed Actions

1141. CHILD SUPPORT ENFORCEMENT PROGRAM; FEDERAL TAX REFUND OFFSET

Priority: Other Significant

CFR Citation: 45 CFR 303.72

Completed:

Reason	Date	FR Cite
Final Action	10/26/04	69 FR 62413

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Elizabeth C. Matheson
Phone: 202 401–9386
Email: bmatheson@acf.dhhs.gov

RIN: 0970–AC09

Department of Health and Human Services (HHS)
Administration on Aging (AOA)

Proposed Rule Stage

1142. 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

Legal Authority: 42 USC 3001 et seq

CFR Citation: 45 CFR 1321; 45 CFR 1326; 45 CFR 1328

Legal Deadline: None

Abstract: In response to the reauthorization of the Older Americans Act, Public Law 106-501, the Administration on Aging (AoA) proposes to issue a notice of proposed rulemaking by February 2005.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Federalism: Undetermined

Agency Contact: Edwin Walker, Deputy Assistant Secretary for Policy and Programs, Department of Health and Human Services, Administration on Aging, Washington, DC 20201
Phone: 202 401–4634

RIN: 0985–AA00

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