Federal Register

Monday,
December 22, 2003

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 the semiannual publication of an inventory of all rulemaking actions under development or review, known as the regulatory agenda. The purpose of this effort is to encourage public participation in the regulatory process by providing, at an early stage, summarized information about regulatory actions that the Department is working on. Citizens interested in communicating to the Department their views on the rulemakings prospectively outlined below are invited to do so.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided below reflects an effort to present for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of a notice of proposed rulemaking, or a final rule within the next 12 months. Also included in the Long-Term Action sections below are summaries of actions that are under development, but which we will probably not complete within the next 12 months.

We welcome hearing the views of all concerned with regard to these planned regulatory or deregulatory actions. Comments may be directed to the agency officials cited in each of the summaries. Or, if early attention at the Secretary#146;s level is seen as warranted, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

The Office of Management and Budget requires that fall editions of the agenda be augmented by a regulatory plan, highlighting the most important regulatory issues across the executive branch. The HHS portion of the Plan appears in part II of this issue of the **Federal Register** with those of other Departments and Agencies. Our Plan entries are included in the table of contents below, denoted by a bracketed bold reference to the appropriate sequence number in part II.

Dated: October 17, 2003.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
961	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991–AB06
962	Claims Collection	0991–AB18
963	Salary Offset	0991–AB19
964	Health Insurance Portability and Accountability Act–Enforcement **(Reg Plan Seq No. 40)**	0991–AB29

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

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
965	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
966	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
967	Tax Refund Offset	0991–AB17
968	Implementation of the Equal Access to Justice Act in Agency Proceedings	0991–AB22
969	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 Identification Number
970	Revisions to Regulations Addressing the OIG's Authority to Impose Civil Money Penalties and Assessments	0991–AB03
971	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

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Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
972	Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)	0991–AB12

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
973	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth **(Reg Plan Seq No. 41)**	0930–AA10
974	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

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Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
975	Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice	0930–AA11

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
976	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 Identification Number
977	Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employee Occupational Illness Compensation Act of 2000	0920–AA07

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
978	Over-the-Counter (OTC) Drug Review	0910–AA01
979	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Part 110) **(Section 610 Review)**	0910–AC58
980	Health Claims	0910–AF09
981	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Derivatives of Blood	0910–AF16

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
982	Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics	0910–AA49

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Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
983	Blood Initiative	0910–AB26
984	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
985	Current Good Manufacturing Practice for Medicated Feeds	0910–AB70
986	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
987	Prevention of Salmonella Enteritidis in Shell Eggs **(Reg Plan Seq No. 42)**	0910–AC14
988	Institutional Review Boards: Registration Requirements	0910–AC17
989	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products	0910–AC19
990	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
991	Exception From General Requirements for Informed Consent; Request for Comments and Information **(Reg Plan Seq No. 43)**	0910–AC25
992	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
993	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs **(Reg Plan Seq No. 44)**	0910–AC35
994	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
995	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52
996	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
997	Food Standards: General Principles and Food Standards Modernization	0910–AC54
998	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
999	Revision of the Requirements for Spore-Forming Microorganisms	0910–AC57
1000	Reporting Information Regarding Falsification of Data	0910–AC59
1001	Definition of ''Serious Adverse Health Consequences'' Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 45)**	0910–AF06
1002	Quality Standard Regulation Establishing Allowable Level for Arsenic in Bottled Water	0910–AF10
1003	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation	0910–AF11
1004	Cochineal Extract and Carmine Label Declaration	0910–AF12
1005	Charging for Investigational Drugs	0910–AF13
1006	Treatment Use of Investigational Drugs	0910–AF14
1007	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
1008	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol **(Reg Plan Seq No. 46)**	0910–AF18

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Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1009	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910–AA04
1010	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
1011	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910–AA89
1012	Labeling for Human Prescription Drugs; Revised Format **(Reg Plan Seq No. 47)**	0910–AA94
1013	Safety Reporting Requirements for Human Drug and Biological Products **(Reg Plan Seq No. 48)**	0910–AA97
1014	Supplements and Other Changes to an Approved Application	0910–AB61
1015	CGMP 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. 49)**	0910–AB76
1016	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements **(Reg Plan Seq No. 50)**	0910–AB88
1017	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format	0910–AB91
1018	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
1019	Bar Code Label Requirements for Human Drug Products and Blood **(Reg Plan Seq No. 51)**	0910–AC26
1020	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
1021	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
1022	Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 52)**	0910–AC38

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Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1023	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 53)**	0910–AC39
1024	Registration of Food and Animal Feed Facilities	0910–AC40
1025	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
1026	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910–AC43
1027	Presubmission Conferences	0910–AC44
1028	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AC56
1029	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08

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Food and Drug Administration—Long-term Actions

Sequence Number	Title	Regulation Identification Number
1030	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue–Based Products	0910–AB27
1031	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products Establishments; Inspection and Enforcement	0910–AB28
1032	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
1033	Food Labeling: Food Allergen Ingredient Labeling	0910–AF07

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1034	Investigational Use New Animal Drug Regulations **(Completion of a Section 610 Review)**	0910–AB02
1035	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims	0910–AB66
1036	Aluminum in Large- and Small-Volume Parenterals Used in Total Parenteral Nutrition	0910–AC18
1037	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of ''No Residue''	0910–AC45
1038	Applications for FDA Approval To Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications	0910–AC48

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1039	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906–AA41
1040	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1041	Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
1042	Smallpox Vaccine Injury Compensation Program: Administrative Implementation **(Reg Plan Seq No. 54)**	0906–AA61

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Health Resources and Services Administration—Long-term Actions

Sequence Number	Title	Regulation Identification Number
1043	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57

Indian Health Service—Completed Actions

Sequence Number	Title	Regulation Identification Number
1044	Indian Child Protection and Family Violence Prevention Act Minimum Standards of Character	0917–AA02

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1045	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925–AA10
1046	National Institutes of Health Training Grants	0925–AA28
1047	Standards for a National Chimpanzee Sanctuary System	0925–AA31
1048	National Institutes of Health AIDS Research Loan Repayment Program	0925–AA32
1049	National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers	0925–AA33
1050	National Institutes of Health Pediatric Research Loan Repayment Program	0925–AA34
1051	National Institutes of Health Loan Repayment Program for Health Disparities Research	0925–AA35
1052	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925–AA36
1053	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925–AA41

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1054	National Institutes of Health Loan Repayment Program for Research Generally	0925–AA18
1055	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	0925–AA20
1056	National Institutes of Health Center Grants	0925–AA24

Office of Public Health and Science—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1057	Public Health Service Policies on Research Misconduct	0940–AA04
1058	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940–AA06
1059	Human Subjects Protection Regulations: Training and Education Requirements for Institutional Officials, Institutional Review Board Members and Staff, Human Protections Administrators, and Investigator	0940–AA08

Office of Public Health and Science—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1060	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940–AA01

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Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1061	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS–3818–P) **(Section 610 Review) (Reg Plan Seq No. 55)**	0938–AG82
1062	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS–3835–P) **(Reg Plan Seq No. 56)**	0938–AH17
1063	Hospice Care—Conditions of Participation (CMS–3844–P)	0938–AH27
1064	Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS–6010–P)	0938–AJ98
1065	Health Insurance Reform: Claims Attachments Standards (CMS–0050–P)	0938–AK62
1066	Organ Procurement Organization Conditions for Coverage (CMS–3064–P) **(Reg Plan Seq No. 57)**	0938–AK81
1067	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS–2130–P) **(Reg Plan Seq No. 58)**	0938–AL26
1068	Prospective Payment System for Inpatient Psychiatric Facilities FY 2004 (CMS–1213–F) **(Reg Plan Seq No. 59)**	0938–AL50
1069	Provider Reimbursement Determinations and Appeals (CMS–1727–P)	0938–AL54
1070	Health Coverage Portability's Request for Information on Benefit–Specific Waiting Periods (CMS–2150–NC)	0938–AL64
1071	DMERC Service Areas and Related Matters (CMS–1219–P)	0938–AL76
1072	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS–3887–P)	0938–AL80
1073	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS–2158–P)	0938–AL88
1074	Criteria for Determining Whether a Drug is Considered Usually Self–Administered (CMS–1228–P)	0938–AM13
1075	Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services (CMS–3119–PN)	0938–AM36
1076	Hospital Patients' Rights CoP—Standard Safety Compliance Committees (CMS–3120–P) **(Reg Plan Seq No. 60)**	0938–AM39
1077	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2005 (CMS–1249–N)	0938–AM46
1078	Modifications to Electronic Transactions and Code Sets (CMS–0009–P)	0938–AM50
1079	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS–6146–P)	0938–AM54
1080	Requirements for Nursing Homes To Identify the Number of Licensed and Unlicensed Nurses (CMS–3121–P)	0938–AM55
1081	Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS–1427–P)	0938–AM75
1082	Changes to the Hospital Inpatient Prospective Payment System and FY 2005 Rates (CMS–1428–P)	0938–AM80
1083	Covered Outpatient Drugs Under the Medicaid Drug Rebate Program (CMS–2174–P)	0938–AM81
1084	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 (CMS–1360–P)	0938–AM82
1085	Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes (Effective 7/1/04) (CMS–1263–P)	0938–AM84
1086	Payment Error Rate Measurement (PERM) Program (CMS–2186–P)	0938–AM86
1087	Requirements for Long-Term Care Facilities: Hospice Services (CMS–3140–P)	0938–AM87
1088	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS–1429–P)	0938–AM90
1089	Home Health Prospective Payment System Rate Update FY 2005 (CMS–1265–P)	0938–AM93
1090	Revisions to Cost Sharing Regulations (CMS–2144–P)	0938–AM94

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Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1091	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS–3819–FC)	0938–AG81
1092	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS–6002–F)	0938–AH73
1093	Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS–0045–F)	0938–AH99
1094	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS–6003–F)	0938–AI49
1095	Coverage of Religious Nonmedical Health Care Institutions (CMS–1909–F)	0938–AI93
1096	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS–3006–F)	0938–AJ10
1097	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS–1910–F)	0938–AJ17
1098	Hospital Conditions of Participation: Laboratory Services (CMS–3014–F)	0938–AJ29
1099	Medicare Hospice Care Amendments (CMS–1022–F)	0938–AJ36
1100	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS–2065–F) **(Reg Plan Seq No. 61)**	0938–AJ96
1101	All Provider Bad Debt Payment (CMS–1126–F)	0938–AK02

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

Sequence Number	Title	Regulation Identification Number
1102	Review of National Coverage Determinations and Local Coverage Determinations (CMS–3063–F)	0938–AK60
1103	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS–1810–FC)	0938–AK67
1104	Rate of Reimbursement of Photocopy Expenses for Quality Improvement Organizations (CMS–3055–F)	0938–AK68
1105	Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS–1185–F)	0938–AK79
1106	Extending Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity (CMS–4018–F)	0938–AK94
1107	Medicare Program; Interest Calculation (CMS–6014–F)	0938–AL14
1108	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS–2151–F)	0938–AL43
1109	Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS–6016–F)	0938–AL49
1110	Revisions to the Medicare Appeals Process (CMS–4004–FC) **(Reg Plan Seq No. 62)**	0938–AL67
1111	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS–1471–F)	0938–AL91
1112	Electronic Medicare Claims Submission (CMS–0008–F)	0938–AM22
1113	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2004 (CMS–8016–N)	0938–AM31
1114	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2004 (CMS–8017–N)	0938–AM32
1115	Part A Premiums for Calendar Year 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS–8018–N)	0938–AM33
1116	Grants to States for Operation of Qualified High Risk Pools (CMS–2179–F)	0938–AM42
1117	Fee Schedule for Payment of Ambulance Services Update for Calendar Year 2004 (CMS–1232–FC)	0938–AM44
1118	Non-Federal Governmental Plans Exempt From HIPAA Title I Requirements (CMS–2033–F)	0938–AM71
1119	Revisions to the Appeals Process for Initial Claim Determinations (CMS–4064–F) **(Reg Plan Seq No. 63)**	0938–AM73
1120	More Flexible Requirements for Powered-Operated Vehicles (CMS–3017–FC)	0938–AM74
1121	Hospice Wage Index FY 2005 (CMS–1264–N)	0938–AM78
1122	Ticket to Work: Defining Individuals with Potentially Severe Disabilities (CMS–2172–N)	0938–AM79
1123	Hospital Conditions of Participation: Requirements For History and Physical Examinations; Authentication of Verbal Orders, Securing Medications and Post-Anesthesia Evaluations (CMS–3122–F)	0938–AM88
1124	Disproportionate Share Hospital (DSH) Payments Institutions for Mental Disease (IMDs) (CMS–2062–N)	0938–AM89

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Centers for Medicare & Medicaid Services—Long-term Actions

Sequence Number	Title	Regulation Identification Number
1125	Standard Unique National Health Plan Identifiers (CMS–6017–P)	0938–AH87
1126	Exclusion of Medicare Benefits for Aliens Not Lawfully Present in the United States (CMS–1222–FC)	0938–AM47
1127	Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility (CMS–1262–F)	0938–AM72

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identification Number
1128	Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (CMS–3046–P)	0938–AK23
1129	Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications (CMS–2226–CN)	0938–AK24
1130	Fire Safety Requirements for Certain Health Care Facilities (CMS–3047–F)	0938–AK35
1131	Hospital Conditions of Participation: Quality Assessment and Performance Improvements (QAPI) (CMS–3050–F)	0938–AK40
1132	Revised Process for Making Medicare National Coverage Determinations (CMS–3062–N)	0938–AK61
1133	Modifications to Medicare Managed Care Rules (CMS–4041–F)	0938–AK71
1134	Inpatient Disproportionate Share Hospital (DSH) Adjustment: Calculation of Medicaid Patient and Total Patient Days in the Medicare DSH Adjustment (CMS–1171–P)	0938–AK77
1135	Modifications to the State Children's Health Insurance Program (SCHIP) (CMS–2006–F)	0938–AL00
1136	Requirements for Paid Feeding Assistants in Long-Term Care Facilities (CMS–2131–F)	0938–AL18

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

Sequence Number	Title	Regulation Identification Number
1137	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; Changes to Payment Suspension for Unfiled Cost Reports; Correction to Final Rule (CMS–1206–CN2)	0938–AL19
1138	Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS–1167–F)	0938–AL27
1139	Interim Final Amendment for Mental Health Parity (CMS–2152–IFC)	0938–AL44
1140	Electronic Submission of Cost Reports (CMS–1199–F)	0938–AL51
1141	Exclusions from the Definition of ''Optional Targeted Low-Income Child'' and Purchase of Family Coverage—Benefit Flexibility in Parent Coverage (CMS–2148–P)	0938–AL62
1142	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals; Federal FY 2002 (CMS–2136–FN)	0938–AL79
1143	Medicaid Coverage Rules for Inmates of Public Institutions (CMS–2077–P)	0938–AL85
1144	Targeted Case Management (CMS–2061–P)	0938–AL87
1145	Changes to the Hospital Inpatient Prospective Payment System and FY 2004 Rates (CMS–1470–F)	0938–AL89
1146	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2004 (CMS–1469–F)	0938–AL90
1147	Prospective Payment System for Long-Term Care Hospitals for FY 2004 (CMS–1472–P)	0938–AL92
1148	Home Health Prospective Payment System Rate Update for FY 2004 (CMS–1473–NC)	0938–AL94
1149	Prospective Payment System for Inpatient Rehabilitation Hospitals for FY 2004 (CMS–1474–F)	0938–AL95
1150	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004 (CMS–1476–P)	0938–AL96
1151	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS–1224–F)	0938–AM01
1152	Update of the List of Covered Procedures for Ambulatory Surgical Centers (CMS–1885–FC)	0938–AM02
1153	Medicaid Home and Community Based Services Waivers (CMS–2162–P)	0938–AM05
1154	Payment Reform for Part B Drugs (CMS–1229–F)	0938–AM12
1155	Nondiscrimination in Health Coverage in the Group Market (CMS–2022–F)	0938–AM14
1156	Bona Fide Wellness Programs (CMS–2078–F)	0938–AM15
1157	Time Limitation on Recalculations and Disputes Under the Drug Rebate Program (CMS–2175–FC)	0938–AM20
1158	Medicaid Estate Recoveries (CMS–2083–P)	0938–AM30
1159	Application of the Emergency Medical Treatment and Labor Act (EMTALA) (CMS–1063–F)	0938–AM34
1160	Physician Ownership in Specialty Hospitals (CMS–1240–P)	0938–AM35
1161	Approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Deeming Authority for Hospices (CMS–2177–FN)	0938–AM38
1162	Hospital Cost-to-Charge Ratios Used To Calculate Cost Outlier Payments Under the Medicare Short–Term Inpatient Prospective Payment System (CMS–1243–F)	0938–AM41
1163	Ambulance Fee Schedule Condition Codes (CMS–1247–P)	0938–AM45
1164	Hospice Wage Index for FY 2004 (CMS–1233–N)	0938–AM56
1165	Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas in Calendar Year 2003 (CMS–1246–NC)	0938–AM59
1166	Centers for Medicare and Medicaid Services Action on Liability Insurance Regulations (CMS–1475–FC)	0938–AM64

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1167	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01
1168	Developmental Disabilities and Bill of Rights Act	0970–AC07
1169	Administrative Costs for Children in Title IV–E Foster Care	0970–AC14
1170	Administrative Cost Sharing Under TANF	0970–AC15

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1171	Child Support Enforcement for Indian Tribes	0970–AB73
1172	Child Support Enforcement Program; Federal Tax Refund Offset	0970–AC09
1173	Charitable Choice Provisions Applicable to the Temporary Assistance for Needy Families Program	0970–AC12

HHS

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

Sequence Number	Title	Regulation Identification Number
1174	Community Services Block Grant Charitable Choice	0970–AC13

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
1175	Construction and Major Renovation of Head Start and Early Head Start Facilities	0970–AB54
1176	Child Support Enforcement Program Omnibus Conforming Regulation	0970–AB81
1177	Technical Revision of Head Start Regulations To Make Them Conform to Recent Statutory Revisions	0970–AC00
1178	Child Support Enforcement Program; Expenditures for Caseworker Costs	0970–AC11

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1179	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)
Office of the Secretary (OS)

Proposed Rule Stage

961. SAFE HARBOR FOR ARRANGEMENTS INVOLVING FEDERALLY QUALIFIED HEALTH CENTERS

Priority: Substantive, Nonsignificant

Legal Authority: PL 100–93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule would set forth a new anti-kickback safe harbor addressing remuneration between federally qualified health centers and certain service providers where a significant community benefit exists.

Timetable:

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

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

RIN: 0991–AB06

962. 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	02/00/04	
NPRM Comment Period End	04/00/04	
Final Rule	06/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews, 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

963. SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 5514; 5 CFR 550

HHS—OS **Proposed Rule Stage**

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	03/00/04	
NPRM Comment Period End	05/00/04	
Final Rule	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews, 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

964. ● HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

Regulatory Plan: This entry is Seq. No. 40 in part II of this issue of the **Federal Register**.

RIN: 0991–AB29

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

Final Rule Stage

965. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1320a900–7b; 42 USC 1395hh; PL 104–191, sec 216(b)

CFR Citation: 42 CFR 1001

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

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 Rule	04/00/04	

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

RIN: 0991–AA91

966. 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 Rule	04/00/04	

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

RIN: 0991–AB16

967. TAX REFUND OFFSET

Priority: Other Significant

Legal Authority: 31 USC 3720A; 31 CFR 285.2

CFR Citation: 45 CFR 31

Legal Deadline: None

Abstract: The Department will amend part 31 to title 45 of the Code of Federal Regulations (CFR) to reflect amendments to 31 U.S.C. 3720A made by the tax refund offset provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104–134, 110 Stat. 1321–1358, as implemented by the Department of the Treasury at 31 CFR 285.2. The proposed rule revises the process by which the Department collects its debts. The

proposed rule is required in order to bring the Department's tax refund offset provisions in compliance with the Department of the Treasury regulations.

Timetable:

Action	Date	FR Cite
NPRM	12/04/02	67 FR 72128
NPRM Comment Period End	02/03/03	
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

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

RIN: 0991–AB17

968. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS

Priority: Other Significant

Legal Authority: 5 USC 504(c)(1)

CFR Citation: 45 CFR 13

Legal Deadline: None

Abstract: The Equal Access to Justice Act requires agencies to pay fees to parties prevailing against the Government in certain administrative proceedings. The Act has been amended several times since its 1980 enactment, most recently by the Contract with America Advancement Act of 1996, which increased the amount of the hourly fees payable. The proposed rule revises 45 CFR part 13 (HHS's regulation implementing the Equal Access to Justice Act) to conform with statutory changes.

Timetable:

Action	Date	FR Cite
NPRM	06/19/87	52 FR 23311
NPRM Comment Period End	08/18/87	
Second NPRM	08/13/02	67 FR 52696
Second NPRM Comment Period End	10/12/02	
Final Rule	01/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Transferred from RIN 0990–AA02

Agency Contact: Katherine M. Drews, 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–AB22

969. 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 proposed 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	05/00/04	

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 (OCIG), 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

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

RIN: 0991–AB03

HHS—OS — Long-Term Actions

971. 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

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/06/00	65 FR 76460
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Federal, 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

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

Completed Actions

972. GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT) AND GOVERNMENTWIDE REQUIREMENTS FOR DRUG-FREE WORKPLACE (GRANTS)

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 76; 45 CFR 82

Completed:

Reason	Date	FR Cite
Final Action	11/26/03	68 FR 66533

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Diane Osterhus
Phone: 202 690–5729
Fax: 202 690–6901
Email: diane.osterhus@hhs.gov

RIN: 0991–AB12

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

Proposed Rule Stage

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

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

RIN: 0930–AA10

974. ● 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, NPRM.

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	12/00/03	

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) **Final Rule Stage**
Substance Abuse and Mental Health Services Administration (SAMHSA)

975. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA) CHARITABLE CHOICE

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 54, sec 54.1–13; 42 CFR 54a, sec 54a.1–14

Legal Deadline: None

Abstract: This proposed rule would implement the Charitable Choice statutory provisions of section 581–584 and section 1955 of the Public Health Service Act, applicable to the Substance Abuse Prevention and Treatment (SAPT) Block Grant Program, the Project for Assistance in Transition from Homelessness (PATH) formula grant program, insofar as recipients provide substance abuse services, and to SAMHSA discretionary grants for substance abuse treatment or prevention services, which are all administered by SAMSHA of the U.S. Department of Health and Human Services.

Timetable:

Action	Date	FR Cite
NPRM	12/17/02	67 FR 77350
Final Rule	02/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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

Agency Contact: Winnie Mitchell, Public Health Analyst, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 12C–05, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2324
Fax: 301 443–0247

RIN: 0930–AA11

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

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

Priority: Other Significant

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

CFR Citation: 42 CFR 84

Legal Deadline: None

Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: 1) upgrade of quality assurance requirements; 2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; 3) revised approval label requirements; 4) updated and restructured fee schedule; and 5) fee retention in the respirator program.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	

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) **Final Rule Stage**
Centers for Disease Control and Prevention (CDC)

977. PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEE OCCUPATIONAL ILLNESS COMPENSATION ACT OF 2000

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 7384g; EO 13179

CFR Citation: 42 CFR 83

Legal Deadline: None

Abstract: Pursuant to the Energy Employees Occupational Illness Compensation Program Act, HHS plans to finalize procedures to petition the Secretary to be added to the Special Exposure Cohort.

Timetable:

Action	Date	FR Cite
NPRM	06/25/02	67 FR 42962
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Larry Elliott, Director, Office of Compensation Analysis and Support, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, R44, 5555 Ridge Avenue, Cincinnati, OH 45213
Phone: 513 841–4498

RIN: 0920–AA07

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

Prerule Stage

978. OVER-THE-COUNTER (OTC) DRUG REVIEW

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 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 350

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.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:

Anorectal Products (0910–AC65)
Final Action (Amendment) 08/26/03 (68 FR 51167)
Antidiarrheal Products (0910–AC82)
NPRM (Amendment) (Trav. Diar) 04/17/03 (68 FR 18915)
Final Action (Amendment) (Trav. Diar) 04/00/04
Antiemetic Products (0910–AC71)
Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)
Antiperspirant Products (0910–AC89)
Final Action 06/09/03 (68 FR 34273)
Cough/Cold (Antihistamine) Products (0910–AD31)
Final Action (Amendment)(Common Cold) 04/00/04
Cough/Cold (Antitussive) Products (0910–AD24)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Cough/Cold (Bronchodilator) Products (0910–AD33)
NPRM (Amendment) 06/00/04
Cough/Cold (Combination) Products (0910–AD25)
Final Action 12/23/02 (67 FR 78158)
NPRM (Amendment) 06/00/04
Cough/Cold (Nasal Decongestant) Products (0910–AD43)
NPRM (Phenylephrine Bitartrate) 04/00/04
NPRM (Phenylpropanolamine) 04/00/04
NPRM (Amendment) (Sinusitis Claim) 06/00/04
External Analgesic Products (0910–AD06)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
NPRM (Amendment) (Patches) 07/17/03 (68 FR 42324)
Ingrown Toenail Relief Products (0910–AD21)
NPRM 10/04/02 (67 FR 62218)
Final Action 05/07/03 (68 FR 24347)
Internal Analgesic Products (0910–AD07)
NPRM (Amendment)(Ibuprofen) 08/21/02 (67 FR 54139)
NPRM (Amendment) (Labeling) 04/00/04
NPRM (Amendment) (Pediatric) 04/00/04
Labeling of Drug Products for OTC Human Use (0910–AD47)
NPRM (Convenience Sizes) 02/00/04
NPRM (Sodium Labeling) 02/00/04
Final Action (Sodium Labeling) 02/00/04
Final Action (Ca/Mg/K/Na) 02/00/04
Laxative Drug Products (0910–AC85)
NPRM (Amendment) (Psyllium Granular Dosage Form) 08/05/03 (68 FR 46133)
Nighttime Sleep Aid Products (0910–AD11)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Ophthalmic Products (0910–AC72)
NPRM (Emergency First Aid Eyewashes) 02/19/03 (68 FR 7951)
Final Action (Technical Amendment) 02/19/03 (68 FR 7919)
Final Action (Name Change) 06/03/03 (68 FR 32981)
Oral Health Care Products (0910–AC98)
ANPRM (Plaque/Gingivitis) 05/29/03 (68 FR 32232)
Pediculicide Products (0910–AC79)
NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
Final Action (Labeling Amendment) 02/00/04
Salicylate (Reye's Syndrome) (0910–AD13)
Final Action (Warning) 04/17/03 (68 FR 18861)
Skin Protectant Products (0910–AC96)
Final Action 06/04/03 (68 FR 33362)
NPRM (Astringent) 06/13/03 (68 FR 35346)
Final Action (Astringent) 06/13/03 (68 FR 35290)
Final Action (Astringent) (Confirm Effective Date) 10/09/03 (68 FR 58273)
Final Action (Technical Amendment) 12/00/03
Sunscreen Products (0910–AC68)
Final Action (Names) 06/20/02 (67 FR 41821)
ANPRM (and Insect Repellent) 04/00/04
NPRM (UVA/UVB) 04/00/04
Vaginal Contraceptive Products (0910–AD19)
NPRM (Amendment) 01/16/03 (68 FR 2254)
Final Action (Warnings) 06/00/04
Weight Control Products (0910–AC93)
NPRM (Phenylpropanolamine) 04/00/04

Regulatory Flexibility Analysis Required: Yes

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, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AA01

979. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD (PART 110)

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 342; 21 USC 371; 21 USC 374; 42 USC 264

CFR Citation: 21 CFR 110

Legal Deadline: None

Abstract: Part 110 (21 CFR part 110) describes regulations for current good manufacturing practice in manufacturing, packing, and holding human food. Part 110 contains regulations describing sanitary practices for personnel, buildings and facilities, and equipment. It also includes regulations on production and process controls for manufacturing practices and on defect action levels for natural or unavoidable defects in food for human use that present no health hazard. FDA is undertaking a review of part 110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) the continued need for the regulations in part 110; (2) the nature of complaints or comments received concerning the regulations in part 110; (3) the complexity of the regulations in part 110; (4) the extent to which the regulations in part 110 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 110.

HHS—FDA **Prerule Stage**

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the princples set forth in the Executive order. The combined effect of the two reviews will be to determine if it is possible to redesign current good manufacturing practices in ways that will maintain or increase the effectiveness of preventive and sanitary controls, and, at the same time, reduce compliance and other costs associated with the regulations.

Timetable:

Action	Date	FR Cite
Begin Review	05/01/03	
End Review	12/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0910–AC58

980. ● 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: This advance notice of proposed rulemaking (ANPRM) was signaled in the July 11, 2003 (68 FR 41387) notice that announced the availability of the Report of Task Force on Consumer Health Information for Better Nutrition (the Task Force) and two guidance documents. The July 11, 2003, notice states that in the near future, the agency intends to publish an ANPRM consistent with the recommendations of the Task Force.

Timetable:

Action	Date	FR Cite
ANPRM	11/25/03	68 FR 66040
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Federalism: Undetermined

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RIN: 0910–AF09

981. ● PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES; DERIVATIVES OF BLOOD

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

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: Other, Statutory, April 1, 2004, Other.
Date final rule takes effect: ?Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures.''.

Abstract: FDA is proposing to amend the implementing regulation of the Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997. The final rule (12/3/99; 64 FR 67720), does not allow a registered blood establishment that provides health care services related to its activities as a blood establishment to concurrently distribute derivatives of blood. The effective date of that rule is April 1, 2004. FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute derivatives of blood.

Timetable:

Action	Date	FR Cite
ANPRM	07/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AF16

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

Proposed Rule Stage

982. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR DRUGS AND BIOLOGICS

Priority: Other Significant

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

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

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations on the registration of producers of drugs and the listing of drugs in commercial distribution. The proposed revisions would reorganize, consolidate, clarify,

and modify current regulations concerning who must register establishments and list drug or biologics regulated as drugs. The proposal describes when, how, and where to register and list, and what information must be submitted for registration and listing. The proposed regulations would also revise the requirements for the National Drug Code number and would require the electronic submission of most registration and listing information.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Mary H. Keyes, Office of Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Reserach, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AA49

983. BLOOD INITIATIVE

Priority: Other Significant. 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 360; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264

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 680

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, Source Plasma, and blood-derivative products 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's, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. The remaining subjects intended to be addressed in the rulemakings include: labeling of blood and blood components and donor eligibility requirements. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Albumin (Human), Plasma Protein Fraction (Human) and Immune Globulin (Human); Revision of Requirements (0910–AE95)
NPRM 05/14/99 (64 FR 26344)
Direct Final Rule 05/14/99 (64 FR 26282)
Direct Final Rule—Confirmation in Part and Technical Amendment 03/14/00 (65 FR 13678)
Final Action 08/28/00 (65 FR 52016)

General Requirements for Blood, Blood Components, and Plasma Derivatives; Notification of Deferred Donors (0910–AE99)
NPRM 08/19/99 (64 FR 45355)
Final Action 06/11/01 (66 FR 31165)

Plasma Derivatives and Similar Recombinant-Based Products; Requirements for Notification of Recalls and Withdrawals (0910–AF02)
ANPRM 08/19/99 (64 FR 45383)

Regulations for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use (0910–AF00)
NPRM 11/00/04

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents (0910–AE98)
NPRM 08/19/99 (64 FR 45340)
Final Action 06/11/01 (66 FR 31146)

Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma (0910–AE96)
NPRM 07/30/03 (68 FR 44678)
Correction Notice 10/27/03 (68 FR 61172)
NPRM Comment Period End 10/30/03
Final Action 10/00/04

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma (0910–AE89)
NPRM 08/19/99 (64 FR 45375)
Direct Final Rule 08/19/99 (64 FR 45366)
Direct Final Rule—Confirmation in Part and Technical Amendment 01/10/01 (66 FR 1834)
Final Action 08/06/01 (66 FR 40886)

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AB26

984. 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	05/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AB34

985. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360b; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 225

Legal Deadline: None

Abstract: This proposal is in response to a citizen petition request to merge the separate requirements of the current good manufacturing practice (CGMP) regulations, 21 CFR part 225 applicable to licensed and unlicensed feed manufacturing facilities, respectively. The merger would produce a single set of updated, streamlined CGMPs that apply to all medicated feed manufacturers. This consolidation of existing CGMPs would preserve and strengthen food safety, be more appropriate given the changing structure of the medicated feed industry, and enhance uniformity and enforcement.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AB70

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 335b; 21 USC 335c; 21 USC 341 to 344; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 376; 21 USC 381; 21 USC 393; 42 USC 262; 42 USC 264

CFR Citation: 21 CFR 59

Legal Deadline: None

Abstract: The proposed rule would establish requirements for importers and other persons who use sampling services and private laboratories in connection with imported food. For example, the proposal 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 private laboratory in connection with imported food. The proposed rule is intended to help insure the integrity and scientific validity of data and results submitted to FDA.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

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. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

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

RIN: 0910–AC14

988. 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 proposed 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 proposed rule would make it easier for FDA to inspect IRBs and to convey information to IRBs.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AC17

989. USE OF MATERIALS DERIVED FROM BOVINE AND OVINE ANIMALS IN FDA-REGULATED PRODUCTS

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

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The U.S. Department of Agriculture's Animal and Plant Health Inspection Service maintains, by regulation in 9 CFR 94.18(a), a list of countries: 1) where bovine spongiform encephalopathy (BSE) exists; and 2) that present an undue risk of

introducing BSE into the United States. This proposed rule would restrict, in FDA-regulated products, the use of most materials derived from bovine and ovine animals born, raised, or slaughtered in a country listed in 9 CFR 94.18(a). In addition, there would be a waiver provision that could be used under appropriate criteria.

Timetable:

Action	Date	FR Cite
NPRM	03/00/04	

Regulatory Flexibility Analysis Required: Undetermined

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, College Park, MD 20740
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RIN: 0910–AC19

990. 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.

In addition to this proposed rule, FDA intends to issue guidance within the next few months on the use in animal feed or material from deer and elk that are positive for CWD or are at high risk of CWD.

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, FDA 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	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC21

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

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

RIN: 0910–AC25

992. 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	12/00/03	

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, 1350 Piccard Drive, Rockville, MD 20850

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RIN: 0910–AC30

993. TOLL-FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

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

RIN: 0910–AC35

994. 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 (ANPRM) 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	
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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RIN: 0910–AC50

995. 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 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	07/00/04	

Regulatory Flexibility Analysis Required: Yes

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), 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC52

996. 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	07/00/04	

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, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC53

997. 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, whether any 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 (61 FR 47453 and 61 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	05/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC54

998. 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 220

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

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	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal, State

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

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RIN: 0910–AC55

999. REVISION OF THE REQUIREMENTS FOR SPORE-FORMING MICROORGANISMS

Priority: Other Significant

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

CFR Citation: 21 CFR 600.10(c); 21 CFR 600.11(e)

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is issuing a direct final rule and a companion proposed rule to amend the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. FDA is taking this action due to advances in facility, system and equipment design, and sterilization technologies, that would allow work with spore-forming microorganisms to be performed in multi-product manufacturing areas.

Timetable:

Action	Date	FR Cite
NPRM—Companion to Direct Final Rule	04/00/04	
Direct Final Rule	04/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910–AC57

1000. 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 70.3; 21 CFR 71.1; 21 CFR 170.3; 21 CFR 171.1; 21 CFR 312.3; 21 CFR 312.56; 21 CFR 510.3; 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 falsified data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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RIN: 0910–AC59

1001. ● DEFINITION OF ''SERIOUS ADVERSE HEALTH CONSEQUENCES'' UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

RIN: 0910–AF06

1002. ● QUALITY STANDARD REGULATION ESTABLISHING 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, Final.

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. 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	09/00/04	
NPRM Comment Period End	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Dr. 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

1003. ● 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	07/00/04	

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), Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AF11

1004. ● 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 701.3; 21 CFR 740.20

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	06/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

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RIN: 0910–AF12

1005. ● CHARGING FOR INVESTIGATIONAL DRUGS

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; 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 application 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	07/00/04	

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), Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AF13

1006. ● TREATMENT USE OF INVESTIGATIONAL DRUGS

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 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 drug applications (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; and (3) larger populations under a treatment protocol or IND.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

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), Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AF14

1007. ● 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

HHS—FDA **Proposed Rule Stage**

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: The proposed rule would 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 are proposing 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. 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	05/00/04	

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, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AF15

1008. ● USE OF OZONE-DEPLETING SUBSTANCES: REMOVAL OF ESSENTIAL USE DESIGNATION; ALBUTEROL

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

RIN: 0910–AF18

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

Final Rule Stage

1009. INFANT FORMULA: REQUIREMENTS PERTAINING TO GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, NOTIFICATION REQUIREMENTS, AND 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:

Current Good Mfg. Practices; Qual. Control Proc.; Quality Factors (0910–AD81)
- NPRM 07/09/96 (61 FR 36154)
- NPRM Comment Period End 12/06/96
- NPRM Comment Period Reopened 04/28/03 (68 FR 22341)
- NPRM Comment Period Extended 06/27/03 (68 FR 38247)
- NPRM Comment Period End 08/26/03
- Final Action 09/00/04

Infant Form Cons Comp, Micro Test & Recd Retention Req (0910–AD80)
- NPRM 01/26/89 (54 FR 3783)
- NPRM Comment Period End 03/27/89
- Final Rule 12/24/91 (56 FR 66566)

Infant Formula Quality Factors (0910–AD77)
- NPRM Comment Period End 12/06/96
- NPRM Comment Period Reopened 04/28/03 (68 FR 22341)
- NPRM Comment Period Extended 06/27/03 (68 FR 38247)
- NPRM Comment Period End 08/26/03
- Final Action 09/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Charlotte Christin, 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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RIN: 0910–AA04

1010. 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	12/00/03	

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

1011. DETERMINATION THAT INFORMED CONSENT IS INFEASIBLE OR IS CONTRARY TO THE BEST INTEREST OF RECIPIENTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n

CFR Citation: 21 CFR 50; 21 CFR 312

Legal Deadline: None

Abstract: The final rule would establish criteria and standards for the President to apply in making a determination that informed consent is not feasible or is contrary to the best interest of military personnel engaged in specific military operations. Under Federal law, the President is authorized to waive the Federal Food, Drug, and Cosmetic Act's informed consent requirements in military operations, if the President finds that obtaining consent is infeasible, contrary to the best interests of recipients, or contrary to national security interests.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/05/99	64 FR 54180
Final Action	01/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

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–AA89

1012. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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

RIN: 0910–AA94

1013. 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

1014. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

Priority: Other Significant

Legal Authority: 21 USC 356a

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: Section 116 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) added section 506A to the Food, Drug, and Cosmetic Act (21 U.S.C. 356a). Pursuant to section 116, the rulemaking will revise current procedures for approving manufacturing changes and generally classify such changes into four categories. Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of a drug, require prior approval of a supplemental application. A second category of changes may be made if FDA has not notified the company within 30 days after the submission of a supplement that prior approval is required. A third category of changes may be made upon submission of a supplement to the agency. The rule will also identify another category of changes that may be made without the submission of a supplement but which must be reported in an annual report.

Timetable:

Action	Date	FR Cite
NPRM	06/28/99	64 FR 34608
Final Action	01/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AB61

1015. CGMP 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. 49 in part II of this issue of the **Federal Register**.

RIN: 0910–AB76

1016. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

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

RIN: 0910–AB88

1017. REQUIREMENTS FOR SUBMISSION OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS IN ELECTRONIC FORMAT

Priority: Other Significant

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 262; . . .

CFR Citation: 21 CFR 314; 21 CFR 601

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the format in which certain labeling in new drug applications, abbreviated new drug applications, certain biological license applications, supplements, and annual reports are required to be submitted. The rule would require that certain labeling content described under section 201.100(d)(3) be submitted to FDA in electronic format.

Timetable:

Action	Date	FR Cite
NPRM	05/03/02	67 FR 22367
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Nicole K. Mueller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Room 3037, (HFD–7), 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AB91

1018. 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: Other, Statutory, April 17, 2001, Other.

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 Rule	03/00/04	

Regulatory Flexibility Analysis Required: Undetermined

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, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC07

1019. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS AND BLOOD

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

RIN: 0910–AC26

1020. 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 Rule	09/00/04	

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, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC32

1021. AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

Priority: Substantive, Nonsignificant

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

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, and 1020.32 to address the changes in technology and practice and to fully utilize the currently accepted metric system.

Timetable:

Action	Date	FR Cite
NPRM	12/10/02	67 FR 76056
Final Action	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

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RIN: 0910–AC34

1022. ADMINISTRATIVE DETENTION OF FOOD FOR HUMAN OR ANIMAL CONSUMPTION UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

RIN: 0910–AC38

1023. 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. 53 in part II of this issue of the **Federal Register**.

RIN: 0910–AC39

1024. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 107–188, sec 305

CFR Citation: 21 CFR 1

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

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

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5377
Interim Final Rule	10/10/03	68 FR 58894
Interim Final Rule Comment Period Reopened	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Leslye M. Fraser, Associate Director for Regulations, Office of Regulations and Policy, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AC40

HHS—FDA **Final Rule Stage**

1025. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 107–188, sec 307

CFR Citation: 21 CFR 1.276 et seq

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

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

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5428
Interim Final Rule	10/10/03	68 FR 58974
Interim Final Rule Comment Period Reopened	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

Agency Contact: Mary Ayling, Lead, Inspection and Compliance Team, Food Safety Staff, Department of Health and Human Services, Food and Drug Administration, HFS–32, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–2131
Fax: 301 436–2605
Email: mary.ayling@cfsan.fda.gov

RIN: 0910–AC41

1026. REQUIREMENTS FOR LIQUID MEDICATED FEED AND FREE-CHOICE MEDICATED FEED

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b; 21 USC 371

CFR Citation: 21 CFR 558.5; 21 CFR 510.455

Legal Deadline: None

Abstract: In response to a citizen petition filed by the American Feed Industry Association, the Food and Drug Administration (FDA) is proposing to amend the requirements for liquid medicated animal feed to clarify what information and data are required to demonstrate chemical and positional stability. The amended regulations would also clarify the provisions for the submission of such data through a master file and the reference to master files by subsequent applicants. Additionally, FDA is proposing to amend the regulations for free-choice medicated feed to ensure consistency with the requirements for liquid medicated feed. Finally, FDA is proposing to amend the regulations for free-choice medicated feed and liquid medicated feed so that these provisions comply with the terms of the Animal Drug Availability Act of 1996.

Timetable:

Action	Date	FR Cite
NPRM	05/28/03	68 FR 31645
Final Action	09/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: William D. Price, Special Assistant, Department of Health and Human Services, Food and Drug Administration, HFV–200, HFV–220, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827–6652
Fax: 301 594–4512

RIN: 0910–AC43

1027. PRESUBMISSION CONFERENCES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b

CFR Citation: 21 CFR 514

Legal Deadline: None

Abstract: This rule will implement section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the Act). This section of the Act states that any person intending to file a new animal drug application or supplemental new animal drug application, or to investigate a new animal drug is entitled to one or more conferences with the agency prior to submission to reach an agreement establishing a submission or investigational requirement. This rule would describe how to request a presubmission conference and describe the procedures for the conduct of presubmission conferences.

Timetable:

Action	Date	FR Cite
NPRM	08/25/00	65 FR 51782
Final Action	06/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Gail Schmerfeld, Special Assistant, Department of Health and Human Services, Food and Drug Administration, HFV–100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827–0205

RIN: 0910–AC44

HHS—FDA

Final Rule Stage

1028. BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 201.59; 21 CFR 610.21

Legal Deadline: None

Abstract: The final rule amends the FDA biologics regulations in response to the report and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids with Standards of Potency (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. On the basis of the Panel's findings and recommendations, FDA is classifying these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category IIIB (off the market pending completion of studies permitting a determination of effectiveness).

Timetable:

Action	Date	FR Cite
NPRM	12/13/85	50 FR 51002
NPRM Comment Period End	03/13/86	
Final Action	04/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Astrid L. Szeto, Senior Reguatory Review Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AC56

1029. ● 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: Not Yet Determined

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 cartonscontaining 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	09/00/04	

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, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594–5601
Fax: 301 827–5562
Email: mullerh@cder.fda.gov

RIN: 0910–AF08

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

Long-Term Actions

1030. ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Priority: Other Significant

Legal Authority: 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 210.1(c); 21 CFR 210.2(a); 21 CFR 210.2(b); 21 CFR 211.1(b); 21 CFR 820.1(a)(1); 21 CFR 820.1(c); 21 CFR 1271

Legal Deadline: None

Abstract: The Food and Drug Administration is requiring certain manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps) to screen and test the donors of cells and tissues used in those products for evidence of, or risk factors for, relevant communicable disease. As part of this action, the agency is amending the current good manufacturing practice regulations that apply to HCT/Ps regulated as drugs, medical devices, and/or biological products to incorporate the new donor eligibility requirements into existing good manufacturing practice regulations for those products.

Timetable:

Action	Date	FR Cite
NPRM	09/30/99	64 FR 52696
NPRM Comment Period End	12/29/99	
NPRM Comment Period Reopened	04/18/00	65 FR 20774
NPRM Comment Period Reopened End	07/17/00	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food

and Drug Administration, Suite 200N (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
Phone: 301 827–6210
Fax: 301 827–9434

RIN: 0910–AB27

1031. CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE-BASED PRODUCTS ESTABLISHMENTS; INSPECTION AND ENFORCEMENT

Priority: Other Significant

Legal Authority: 42 USC 216; 42 USC 243; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 1270; 21 CFR 1271

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is requiring human cell, tissue, and cellular and tissue-based products (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, recordkeeping, and the establishment of a quality program. FDA is also issuing regulations pertaining to labeling, reporting, inspections, and enforcement.

Timetable:

Action	Date	FR Cite
NPRM	01/08/01	66 FR 1508
NPRM Comment Period End	05/08/01	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

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

RIN: 0910–AB28

1032. 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
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

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, 1451 Rockville Pike, Rockville, MD 20857
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC23

1033. ● 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 342; 21 USC 343; 21 USC 371

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: The purpose of this rulemaking is to reduce mortality and morbidity by providing sensitive individuals with additional food allergen information to help them protect themselves from serious allergic reactions, including life-threatening anaphylactic shock. The eight most common food allergens are: 1) peanuts; 2) soybeans; 3) milk; 4) eggs; 5) fish; 6) crustacea (e.g., lobster, crab, shrimp); 7) tree nuts (e.g., almonds, chestnuts, macadamia nuts, pecans, walnuts, hazelnuts or filberts, cashews, brazil nuts, pistachios, pine nuts); and 8) wheat. The rule would propose to require that foods that contain certain protein ingredients include information on the label in plain English terms that clearly identifies the presence of these ingredients.

The agency is also proposing to require food allergen labeling on spices, flavors, noncertified colors and incidental additives found in foods as ingredients that contain certain allergic proteins. Currently, section 403(i) of the Federal Food, Drug, and Cosmetic Act allows spices, flavors and noncertified colors used as ingredients of foods to be declared collectively on the label without naming each one. Federal regulations at 21 C.F.R. 101.100(a)(3) exempt incidental additives from ingredient declaration on the label if they are present in the food at an insignificant amount and do not have any technical or functional effect in the finished food.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

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
Phone: 301 436–2371
Fax: 301 436–2636
Email: rkane2@cfsan.fda.gov

RIN: 0910–AF07

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

Completed Actions

1034. INVESTIGATIONAL USE NEW ANIMAL DRUG REGULATIONS

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

Legal Authority: 21 USC 321; 21 USC 351 to 353; 21 USC 360b; 21 USC 371

CFR Citation: 21 CFR 511

Legal Deadline: None

Abstract: FDA initiated a review of 21 C.F.R. 511.1 under section 610 of the Regulatory Flexibility Act. The purpose of the section 610 review was to determine if the rule should be amended to minimize adverse economic impacts on small entities. FDA solicited and considered comments on the following: 1) the continued need for the rule; 2) the nature of complaints or comments received concerning the rule; 3) the complexity of the rule; 4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Timetable:

Action	Date	FR Cite
ANPRM	11/21/96	61 FR 59209
ANPRM Comment Period End	01/21/97	
Begin Review	04/03/00	
End Review	06/02/03	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Marty Schoenemann, Department of Health and Human Services, Food and Drug Administration, HFV–126, HFV–100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827–0220

RIN: 0910–AB02

1035. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 101

Completed:

Reason	Date	FR Cite
Final Rule	07/11/03	68 FR 41434

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Local, State, Tribal

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

Agency Contact: Julie Schrimpf
Phone: 301 436–2373
Fax: 301 436–2639
Email: julie.schrimpf@cfsan.fda.gov

RIN: 0910–AB66

1036. ALUMINUM IN LARGE- AND SMALL-VOLUME PARENTERALS USED IN TOTAL PARENTERAL NUTRITION

Priority: Other Significant

CFR Citation: 21 CFR 201.323(c)

Completed:

Reason	Date	FR Cite
Final Action	06/03/03	68 FR 32979

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Christine F. Rogers
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AC18

1037. REGULATION OF CARCINOGENIC COMPOUNDS USED IN FOOD-PRODUCING ANIMALS; DEFINITION OF ''NO RESIDUE''

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 500.80; 21 CFR 500.82; 21 CFR 500.84; 21 CFR 500.88

Completed:

Reason	Date	FR Cite
Final Action	12/23/02	67 FR 78172

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Steven Brynes
Phone: 301 827–6975
Email: sbrynes@cvm.fda.gov

RIN: 0910–AC45

1038. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG: PATENT LISTING REQUIREMENTS AND APPLICATION OF 30-MONTH STAYS ON APPROVAL OF ABBREVIATED NEW DRUG APPLICATIONS

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 314.52(a)(3); 21 CFR 314.53(b); 21 CFR 314.53(c)(1); 21 CFR 314.53(c)(2); 21 CFR 314.95(a)(3)

Completed:

Reason	Date	FR Cite
Final Rule	06/18/03	68 FR 36676

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jarilyn Dupont
Phone: 301 827–3360
Fax: 301 594–6777
Email: jdupont@oc.fda.gov

RIN: 0910–AC48

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

Proposed Rule Stage

1039. 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	04/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, Suite 300, 7519 Standish Place, Rockville, MD 20957
Phone: 301 443–2300
Fax: 301 443–6725

RIN: 0906–AA41

1040. 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	04/00/04	

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
Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

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

Final Rule Stage

1041. ● 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	03/00/04	

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

1042. ● SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

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

RIN: 0906–AA61

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

Long-Term Actions

1043. 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: John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, Suite 300, 7519 Standish Place, Rockville, MD 20957
Phone: 301 443–2300
Fax: 301 443–6725

RIN: 0906–AA57

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

Completed Actions

1044. INDIAN CHILD PROTECTION AND FAMILY VIOLENCE PREVENTION ACT MINIMUM STANDARDS OF CHARACTER

Priority: Info./Admin./Other

CFR Citation: 42 CFR 36

Completed:

Reason	Date	FR Cite
Withdrawn	11/18/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Tribal

Agency Contact: Ramona D. Williams
Phone: 301 443–1589

RIN: 0917–AA02

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

Proposed Rule Stage

1045. 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	03/00/04	

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

1046. 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	03/00/04	

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

1047. 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, NPRM.

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	03/00/04	

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

1048. 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	03/00/04	

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

1049. 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	03/00/04	

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

1050. 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	03/00/04	

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

1051. 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

HHS—NIH — Proposed Rule Stage

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	03/00/04	

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

1052. 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	03/00/04	

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

1053. ● 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	03/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA41

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

1054. 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 Rule	03/00/04	

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

HHS—NIH **Final Rule Stage**

1055. SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 282(b)(6); 42 USC 284(c)(3); 42 USC 289a; 42 USC 290aa–3

CFR Citation: 42 CFR 52h

Legal Deadline: None

Abstract: NIH staff have found ambiguities, misstatements, and voids in the existing peer review regulations. These regulations, which govern the first level of review, are being amended to reflect current policies and procedures.

Timetable:

Action	Date	FR Cite
NPRM	09/21/00	65 FR 57132
Final Rule	03/00/04	

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–AA20

1056. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 284g; 42 USC 285a–6(c)(1)(E); 42 USC 285a–7(c)(1)(G); 42 USC 285b–4; 42 USC 285c–5; 42 USC 285c–8; 42 USC 285d–6; 42 USC 285e–2; 42 USC 285e–3; 42 USC 285e–10a; . . .

CFR Citation: 42 CFR 52a

Legal Deadline: None

Abstract: NIH proposes to amend the current center grants regulations to reflect new authorities set forth in sections 409C, 445I, 452E, and 485F of the Public Health Service Act. Section 409C concerns centers of excellence regarding research on autism; section 445I concerns centers of excellence in Alzheimer's disease research and treatment; section 452E concerns centers regarding research on ''fragile X;'' and section 485F concerns centers of excellence for research education and training for individuals who are members of minority health disparity populations.

Timetable:

Action	Date	FR Cite
NPRM	11/12/02	67 FR 68548
Final Rule	03/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

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–AA24

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

Proposed Rule Stage

1057. 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	12/00/03	
NPRM Comment Period End	02/00/04	

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

RIN: 0940–AA04

1058. 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

HHS—OPHS **Proposed Rule Stage**

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 will simultaneously publish a proposed rule regarding FDA IRB registration requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	
NPRM Comment Period End	03/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0940–AA06

1059. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND EDUCATION REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATOR

Priority: Other Significant

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	03/00/04	
NPRM Comment Period End	06/00/04	

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, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA08

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

Final Rule Stage

1060. 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	06/00/04	

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

HHS—OPHS **Final Rule Stage**

Fax: 301 443–5351
RIN: 0940–AA01

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

1061. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–P)

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

RIN: 0938–AG82

1062. 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. 56 in part II of this issue of the **Federal Register**.

RIN: 0938–AH17

1063. HOSPICE CARE-CONDITIONS OF PARTICIPATION (CMS–3844–P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395x(dd); 42 USC 1395hh

CFR Citation: 42 CFR 418

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Mary Rossi Coajou, 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: 410 786–6051

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–AH27

1064. 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	08/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Frank Whelan, 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: 410 786–1302

RIN: 0938–AJ98

1065. HEALTH INSURANCE REFORM: CLAIMS ATTACHMENTS STANDARDS (CMS–0050–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–2(a)(2)(B)

CFR Citation: 45 CFR 162

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

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 those data contained in the claims standard, to help establish medical necessity for coverage.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

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: James Krall, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Health Insurance Portability and Account Act Standards, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6999

RIN: 0938–AK62

1066. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–P)

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

RIN: 0938–AK81

1067. 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. 58 in part II of this issue of the **Federal Register**.

RIN: 0938–AL26

1068. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FY 2004 (CMS–1213–F)

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

RIN: 0938–AL50

1069. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1878 of the Social Security Act

CFR Citation: 42 CFR 405

Legal Deadline: None

Abstract: This proposed 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	09/00/04	

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

1070. HEALTH COVERAGE PORTABILITY'S REQUEST FOR INFORMATION ON BENEFIT—SPECIFIC WAITING PERIODS (CMS–2150–NC)

Priority: Info./Admin./Other

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
NPRM	05/00/04	

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

1071. DMERC SERVICE AREAS AND RELATED MATTERS (CMS–1219–P)

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)(E) of the Social Security Act

CFR Citation: 42 CFR 421.210

Legal Deadline: None

Abstract: This proposed rule would allow flexibility in making changes to the Durable Medical Equipment Regional Carrier contractor structure.

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Kim Nyland, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1–14–27, Center for Medicare Management, 7500 Security Boulevard, S1–14–27, Baltimore, MD 21244
Phone: 410 786–2289

RIN: 0938–AL76

1072. 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: Social Security Act, sec 1102; Social Security Act, sec 1832; Social Security Act, sec 1871

CFR Citation: 42 CFR 410; 42 CFR 424; 42 CFR 416; 42 CFR 488; 42 CFR 489

Legal Deadline: None

Abstract: This 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	09/00/04	

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

1073. 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 300 gg; 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. This proposed rule would 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	05/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Local, Federal

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

1074. CRITERIA FOR DETERMINING WHETHER A DRUG IS CONSIDERED USUALLY SELF-ADMINISTERED (CMS–1228–P)

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

Legal Authority: Sec 1861(s)(2)(B) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would solicit comments on the criteria to determine whether a drug is considered usually self-administered and therefore, not covered under part B of Medicare.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Angela Mason, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244
Phone: 410 786–7452

RIN: 0938–AM13

1075. PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS–3119–PN)

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: Not Yet Determined

Legal Deadline: None

Abstract: This proposed notice would establish the procedures to be used for maintaining the lists of codes that were included in the national coverage determinations announced in the Federal Register on November 25, 2001 (66 FR 58788). It would also clarify the date of service provisions related to archived speciments from that same final rule.

Timetable:

Action	Date	FR Cite
NPRM	01/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

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

1076. HOSPITAL PATIENTS' RIGHTS COP–STANDARD SAFETY COMPLIANCE COMMITTEES (CMS–3120–P)

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

RIN: 0938–AM39

1077. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2005 (CMS–1249–N)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Sec 1888(e) of the Social Security Act

CFR Citation: 42 CFR 413.330 to 413.350

Legal Deadline: NPRM, Statutory, July 30, 2004, NPRM.

Abstract: This annual proposed rule updates the payment rates used under the skilled nursing facilities prospective payment system beginning October 1, 2004.

Timetable:

Action	Date	FR Cite
Notice	06/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

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–AM46

1078. 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: Social Security Act, sec 1171 to 1179

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	09/00/04	

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: Stanley B. Nachimson, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–16–03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6153

RIN: 0938–AM50

1079. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: PL 97–35, sec 2105; PL 104–191, sec 231(C); PL 105–33, sec 4311(b); PL 105–33, sec 4317; PL 105–33, sec 4031(a)(2); PL 105–33, sec 4531(b)(2)

CFR Citation: 42 CFR 402, subpart C

Legal Deadline: None

Abstract: This 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	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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–AM54

1080. REQUIREMENTS FOR NURSING HOMES TO IDENTIFY THE NUMBER OF LICENSED AND UNLICENSED NURSES (CMS–3121–P)

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 proposed rule will implement section 941 of the Benefits Improvement and Protection Act of 2000, which requires nursing homes to post daily, for each shift, the number of licensed and unlicensed nursing staff directly responsible for resident care.

Timetable:

Action	Date	FR Cite
NPRM	02/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Nancy Archer, Office of Clinical Standards and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–05–27, 7500 Security Boulevard, Baltimore, MD 21244–1850
Phone: 410 786–0596

RIN: 0938–AM55

1081. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE SYSTEM AND CALENDAR YEAR 2005 PAYMENT RATES (CMS–1427–P)

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

Legal Authority: 42 USC 1935L; 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: NPRM, Statutory, January 1, 2004, NPRM.

Abstract: The proposed rule would revise the Medicare hospital outpatient prospective payment system beginning January 1, 2005. (The statute requires that this proposed rule and subsequent final rule be published by November 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: Yes

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

RIN: 0938–AM75

1082. ● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2005 RATES (CMS–1428–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, 2004, NPRM.
Final, Statutory, August 1, 2004, Final.

Abstract: We would revise 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. In addition, in the Addendum, we describe 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, 2004. We also set 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 that this proposed and subsequent final rule be published by August 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

Agency Contact: Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, Center for Medicare Management, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–4487

RIN: 0938–AM80

1083. ● COVERED OUTPATIENT DRUGS UNDER THE MEDICAID DRUG REBATE PROGRAM (CMS–2174–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act, sec 1905 (a) (12); Social Security Act, sec 1903 (a); Social Security Act, sec 1902 (a) (54); Social Security Act, sec 1903 (i) (10); Social Security Act, sec 1927; . . .

CFR Citation: 42 CFR 441 ; 42 CFR 447

Legal Deadline: None

Abstract: This proposed rule will repropose and request public comments on numerous provisions related to the Medicaid drug rebate program. The agency published a proposed rule on September 19, 1995. However, in light of new issues, the agency seeks an opportunity to propose new provisions and seeks comments.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Marge Watchorn, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, S2–05–16, Baltimore, MD 21244
Phone: 410 786–4361

RIN: 0938–AM81

1084. ● PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2005 (CMS–1360–P)

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

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

CFR Citation: 42 CFR 412; 42 CFR 413

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

Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2005. (The statute requires that the subsequent final rule be published by August 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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–AM82

1085. ● PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES (EFFECTIVE 7/1/04) (CMS–1263–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 123 of BBRA 1999; Sec 307(b) of BIPA 2000

CFR Citation: 42 CFR 412 ; 42 CFR 413

Legal Deadline: Final, Statutory, April 30, 2004, Final.

Abstract: This rule proposes the payment rate update for the 2005 prospective payment system for Medicare long-term care hospitals. The new rates will be based on cost reports from the first long-term care prospective payment system rate year. (The final rule must be published by April 30, 2004, to be effective July 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	04/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, Center for Medicare Management, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–4487

RIN: 0938–AM84

1086. ● PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–2186–P)

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

Legal Authority: Sections 1902 (a)(6) of the Social Security Act; Sec 2107 (b)(1) of the Social Security Act; Improper Payments Information Act of 2002 (IPIA) (Public Law 107–300)

CFR Citation: None

Legal Deadline: None

Abstract: Sections 1902(a)(6)and 2107(b)(1) of the Act, governing

Medicaid and SCHIP, respectively, require States to provide to the Secretary information to monitor program performance. This rule would require States under the current statutory provisions and the IPIA and through this regulation to estimate improper payments using the CMS PERM methodolgy for the reporting year in the Medicaid and SCHIP programs. The States are further required to submit payment error rates to CMS for the purpose of calculating a natinal level payment error rate as required by the IPIA.

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Wayne Alden Slaughter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, S3–13–15, Baltimore, MD 21244
Phone: 410 786–0038

RIN: 0938–AM86

1087. ● 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 will clarify the hospice care of residents in long-term care facilities. This rule will reflect the changes in the hospice proposed rule (CMS–3844–P, 42 CFR 418) that is to reflect the interdisciplinary view of resident care and improve the quality of healthcare furnished through the Medicare and Medicaid programs reflect the interdisciplinary view of resident care and improve the quality of health care furnished through the Medicare and Medicaid programs.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Anita Panicker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Bloulevard, S3–04–26, Baltimore, MD 21244
Phone: 410 786–5646

RIN: 0938–AM87

1088. ● REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2005 (CMS–1429–P)

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

Legal Authority: 42 USC 1395W–4

CFR Citation: 42 CFR 410; 42 CFR 414

Legal Deadline: NPRM, Statutory, June 1, 2004, NPRM.

Abstract: This rule would make several changes affecting Medicare part B payment. (The statute requires that the final rule be published by November 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: Yes

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

RIN: 0938–AM90

1089. ● HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FY 2005 (CMS–1265–P)

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

Legal Authority: 42 USC 1395ff

CFR Citation: None

Legal Deadline: None

Abstract: This proposed rule would set forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies. As part of this proposed rule, we are proposing to rebase and revise the home health market basket to reflect total cost and modifying certain variables for some of the cost categories. (The proposed and final rules must be published by July 1, 2004, to allow three months for systems changes.)

Timetable:

Action	Date	FR Cite
NPRM	01/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

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

RIN: 0938–AM93

1090. ● REVISIONS TO COST SHARING REGULATIONS (CMS–2144–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act, sec 1916; Social Security Act, sec 1902(a)(4)

CFR Citation: 42 CFR 447.51 to 447.56

Legal Deadline: None

Abstract: This proposed rule would revise the cost sharing requirements in our current regulation to allow for the imposition of higher levels of cost sharing and more flexibility in the way in which cost sharing is imposed and administered under current statutory requirements. (The cost sharing requirements have remained unchanged since 1974. States have requested that we update the cost sharing requirements.)

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

HHS—CMS **Proposed Rule Stage**

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal, State

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

Agency Contact: Alissa Deboy, Special Assistant, Department of Health and Human Services, Centers for Medicare & Medicaid Services, CMSO, S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6041

RIN: 0938–AM94

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

1091. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–FC)

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 final rule revises 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	
Final Rule	06/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Mercedes Benitex-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

1092. 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 us the authority to enroll and re-enroll providers with time frames for re-enrollment.

Timetable:

Action	Date	FR Cite
NPRM	04/25/03	68 FR 22064
Final Action	09/00/04	

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

1093. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS–0045–F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1320D–2(b)(1)

CFR Citation: 42 CFR 160; 42 CFR 162

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

Abstract: This final rule establishes a standard unique identifier for all health care providers under the Health Insurance Portability and Accountability Act (HIPAA) of 1966 (Pub. L. 104–191). The rule implements administrative simplification initiatives that have a national scope beyond Medicare and Medicaid.

Timetable:

Action	Date	FR Cite
NPRM	05/07/98	63 FR 25320
NPRM Comment Period End	07/06/98	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal, Local, State, Tribal

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

Additional Information: None

Agency Contact: Patricia Peyton, Office of Information Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–20–05, 7500 Security Boulevard, Baltimore, MD 21224–1850
Phone: 410 786–1812

RIN: 0938–AH99

1094. APPEALS OF CARRIER DETERMINATION THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS–6003–F)

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 final rule will extend appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations. In addition, we will revise certain appeal provisions to correspond with the existing appeal provisions in those other sections of our regulations. CMS will also extend appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard.

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Final Rule	04/00/04	

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

1095. COVERAGE OF RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTIONS (CMS–1909–F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395i–5; 42 USC 1395x(e); 42 USC 1395x(y); 42 USC 1395x(ss); 42 USC 1302

CFR Citation: 42 CFR 403.736; 42 CFR 403. 738; 42 CFR 489.102

Legal Deadline: Final, Statutory, July 1, 1998, Final.

Abstract: This final rule follows an interm final rule with comment that removed all references in the Medicare regulations to specific religious institutions to broaden Medicare coverage to include all religious nonmedical institutions.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/30/99	64 FR 67028
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jean Marie Moore, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C5–05–05, Baltimore, MD 21244
Phone: 410 786–3508

RIN: 0938–AI93

1096. 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 Rule	06/00/04	

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: Aucha Prachanronarong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–9614

RIN: 0938–AJ10

1097. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS–1910–F)

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(BBA 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. (The statute required that this rule be published by January 1, 1999.)

Timetable:

Action	Date	FR Cite
NPRM	02/28/00	65 FR 10450
Final Rule	12/00/03	

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

HHS—CMS **Final Rule Stage**

1098. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 482.27

Legal Deadline: None

Abstract: This rule 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 HCF 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
Final Rule	08/00/04	

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

1099. 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 to 4449; PL 106–113, sec 131; PL 106–554, sec 321 to 322

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	09/00/04	

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, Centers for Medicare Management, 7500 Security Boulevard, C4–05–27, Baltimore, MD 21244
Phone: 410 786–4480

RIN: 0938–AJ36

1100. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS–2065–F)

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

RIN: 0938–AJ96

1101. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g; 42 USC 1395l(a); 42 USC 1395l(i); 42 USC 1395l(n); 42 USC 1395x(v); 42 USC 1395cc; 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395tt

CFR Citation: 42 CFR 413.80; 42 CFR 413.178

Legal Deadline: None

Abstract: This final rule will achieve a consistent bad debt reimbursement policy for all providers currently eligible to receive payments from Medicare for bad debt. It implements a court settlement agreement and removes the cap on End Stage Renal Disease (ESRD) bad debt reimbursement, which limits payment of allowable bad debts to the facility's unrecovered costs.

Timetable:

Action	Date	FR Cite
NPRM	02/10/03	68 FR 6682
NPRM Comment Period End	04/11/03	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Katie Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C5–03–03, Baltimore, MD 21244
Phone: 410 786–7278

RIN: 0938–AK02

1102. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS–3063–F)

Priority: Other Significant

Legal Authority: Sec 522 of the BIPA 2000

CFR Citation: 42 CFR 405

Legal Deadline: NPRM, Statutory, October 1, 2001, NPRM.

Abstract: This final rule would announce a new process for beneficiaries to appeal national and local coverage determinations (LCDs), including the role that the Department Appeals Board and, in the case of LCDs, Administrative Law Judges, will have in reviewing the decisions. It implements section 522 of the Benefits Improvement and Protection Act of 2000 (BIPA).

Timetable:

Action	Date	FR Cite
NPRM	08/22/02	67 FR 54534
NPRM Comment Period End	10/21/02	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: James Bossenmeyer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–16–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9317

Email: jbossenmeyer@hcfa.gov

RIN: 0938–AK60

1103. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—PHASE II (CMS–1810–FC)

Priority: Other Significant

Legal Authority: 42 USC 1877

CFR Citation: 42 CFR 411

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. It addresses comments from the January 9, 1998, proposed rule concerning the ownership, investment, and compensation exceptions. It also addresses comments from the January 4, 2001, final rule with comment period.

Timetable:

Action	Date	FR Cite
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: Yes

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

1104. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS–3055–F)

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1154; Social Security Act, sec 1159; Social Security Act, sec 1866; Social Security Act, sec 1871

CFR Citation: 42 CFR 476.78

Legal Deadline: None

Abstract: This rule increases the rate of reimbursement of photocopy expenses as required by the regulations governing utilization and quality control quality improvement organizations. CMS' current regulations identify the photocopying reimbursement methodology for prospective payment system hospitals.

Timetable:

Action	Date	FR Cite
NPRM	11/22/02	67 FR 70358
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Les Caplan, 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: 410 786–7223

RIN: 0938–AK68

1105. ELIMINATION OF STATEMENT OF INTENT PROCEDURES FOR FILING MEDICARE CLAIMS (CMS–1185–F)

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

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 424

Legal Deadline: None

Abstract: The final rule would eliminate the written statement of intent procedures for filing Medicare claims from the current Medicare regulation. Providers, suppliers, and other qualified claimants would still have 15 to 27 months to submit valid claims to Medicare.

Timetable:

Action	Date	FR Cite
NPRM	07/25/03	68 FR 44000
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, State

Agency Contact: David Walczak, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Health Plans and Providers, Plan and Provider Purchasing Policy Group, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4475

RIN: 0938–AK79

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

Priority: Substantive, Nonsignificant

Legal Authority: Sec 202 of the TWWIIA of 1999; PL 106–170

CFR Citation: 42 CFR 406.12

Legal Deadline: None

Abstract: This final rule implements the Ticket to Work and Work Incentives Improvement Act of 1999. It provides working disabled individuals with continued Medicare entitlement for an additional 54 months beyond the current limit, for a total of 78 months of Medicare coverage following the 15th month of the extended period of eligibility.

Timetable:

Action	Date	FR Cite
NPRM	07/25/03	68 FR 43998
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Denise Cox, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Health Insurance Specialist, 7500 Security Boulevard, S1–05–06, Baltimore, MD 21244
Phone: 410 786–3195

RIN: 0938–AK94

1107. MEDICARE PROGRAM; INTEREST CALCULATION (CMS–6014–F)

Priority: Other Significant

Legal Authority: Sec 1815(d) of the Social Security Act; Sec 1833 (j) of the Social Security Act

CFR Citation: 42 CFR 405.378

Legal Deadline: None

Abstract: This final rule will change the formula for computing interest on provider and supplier overpayments

and underpayments to make it consistent with the new CMS accounting system, Healthcare Integrated General Ledger Accounting System.

Timetable:

Action	Date	FR Cite
NPRM	07/25/03	68 FR 43995
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Nancy Braymer, Financial Management Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4323

RIN: 0938–AL14

1108. HEALTH COVERAGE PORTABILITY FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE ISSUERS (CMS–2151–F)

Priority: Other 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	05/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, 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–AL43

1109. PERMITTING PREMIUM REDUCTIONS AS ADDITIONAL BENEFITS UNDER MEDICARE+CHOICE PLANS (CMS–6016–F)

Priority: Substantive, Nonsignificant

Legal Authority: 606 of BIPA

CFR Citation: 42 CFR 408

Legal Deadline: Final, Statutory, January 1, 2003, Final.

Abstract: This final rule implements section 606 of the Benefits Improvement and Protection Act of 2000 to allow Medicare+Choice organizations to elect a reduction in capitation payments so that these organizations could offer Medicare part B premium reductions to enrollees.

Timetable:

Action	Date	FR Cite
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

Agency Contact: Michele Sanders, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financing Management, 7500 Security Boulevard, S1–06–27, Baltimore, MD 21244
Phone: 410 786–0808

RIN: 0938–AL49

1110. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS–4004–FC)

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

RIN: 0938–AL67

1111. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS–1471–F)

Priority: Other 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: None

Abstract: This final rule adjusts payments under the Medicare hospital outpatient payment system beginning January 1, 2004.

Timetable:

Action	Date	FR Cite
NPRM	08/12/03	68 FR 47966
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

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

RIN: 0938–AL91

1112. 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

Action	Date	FR Cite
Interim Final Rule Comment Period End	10/16/03	
Final Rule	09/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Stewart Streimer, Director, Division of Operations Standards, Office of Program Administration, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 1–C–6 Meadows East Building, 6325 Security Boulevard, Baltimore, MD 21207
Phone: 410 786–9318

RIN: 0938–AM22

1113. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2004 (CMS–8016–N)

Priority: Other Significant

Legal Authority: 42 USC 1395e–2(b)(2); Sec 1813(b)(2) of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 15, 2003, NPRM.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2004 under medicare's hospital Insurance Program (Medicare part A). The Medicare statute specifies the formulae used to determine these amounts.

Timetable:

Action	Date	FR Cite
Notice	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–26–00, Office of the Actuary, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6390

RIN: 0938–AM31

1114. MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2004 (CMS–8017–N)

Priority: Other Significant

Legal Authority: 42 USC 1395r; Sec 1839 of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 30, 2003, NPRM.

Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in the Medicare Supplementary Medical Insurance (SMI) program for 2004. It announces the monthly SMI premium to be paid by all enrollees during 2004.

Timetable:

Action	Date	FR Cite
Notice	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carter S. Warfield, Deputy Director, Medicare and Medicaid Cost Estimates Group, OACT, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center of Medicaid and State Operations, 7500 Security Boulevard, N3–26–00, Baltimore, MD 21244
Phone: 410 786–6396

RIN: 0938–AM32

1115. PART A PREMIUMS FOR CALENDAR YEAR 2004 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8018–N)

Priority: Other Significant

Legal Authority: 42 USC 1395i–2(d)(2); 42 USC 1395i–2a(d)(2); Sec 1818(d)(2) of the Social Security Act; Sec 1818A(d)(2) of the Social Security Act

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 30, 2003, NPRM.

Abstract: This notice announces the hospital insurance premium for calendar year 2004 under Medicare's Hospital Insurance Program (Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

Action	Date	FR Cite
Notice	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3–26–00, Office of the Actuary, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6390

RIN: 0938–AM33

1116. GRANTS TO STATES FOR OPERATION OF QUALIFIED HIGH RISK POOLS (CMS–2179–F)

Priority: Other Significant

Legal Authority: PL 107–210

CFR Citation: 45 CFR 148

Legal Deadline: None

Abstract: This final rule announces a grant program to provide $40 million for FY 2003 and $40 million for FY 2004 to Sates that have qualified high risk pools under the Trade Adjustment Assistance Reform Act of 2002.

Timetable:

Action	Date	FR Cite
Final Rule with Comment	05/02/03	68 FR 23410
Final Rule Comment Period End	07/01/03	
Final Rule Effective	06/02/03	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: James Mayhew, 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: 410 786–9244

RIN: 0938–AM42

HHS—CMS **Final Rule Stage**

1117. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES UPDATE FOR CALENDAR YEAR 2004 (CMS–1232–FC)

Priority: Other Significant

Legal Authority: 42 USC 1395m(1)(1)

CFR Citation: None

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Anne Tayloe, Health Insurance Speacialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–4546

RIN: 0938–AM44

1118. ● NON—FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA TITLE I REQUIREMENTS (CMS–2033–F)

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

Legal Authority: Sec 2721(b)(2) of the Public Health Service Act

CFR Citation: 45 CFR 146.180

Legal Deadline: None

Abstract: This final rule adopts as final the exemption election requirements that apply to self-funded non-Federal governmental plans. Since we received no public comments on the July 26, 2002, interim final with comment period, this rule finalizes the circumstances under which plan sponsors may exempt these plans from most of the requirements of title XXVII of the Public Health Service Act and provides guidance on the procedures, limitations, and documentation associated with exemption elections.

Timetable:

Action	Date	FR Cite
Final Action	05/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Dave Holstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Insurance Standards Team, S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1564

RIN: 0938–AM71

1119. ● REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–F)

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

RIN: 0938–AM73

1120. ● MORE FLEXIBLE REQUIREMENTS FOR POWERED-OPERATED VEHICLES (CMS–3017–FC)

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

CFR Citation: 42 CFR ch IV, sec 410, subpart B; 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
Final Action with Comment	02/00/04	

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

RIN: 0938–AM74

1121. ● HOSPICE WAGE INDEX FY 2005 (CMS–1264–N)

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

Legal Authority: 1814(i)(A)

CFR Citation: 42 CFR 418.306(d)

Legal Deadline: Final, Statutory, October 1, 2004, Final.
Wage Index update is effective October 1, of each year.

Abstract: This notice will announce the annual update to the hospice wage index for FY 2005. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

Timetable:

Action	Date	FR Cite
Notice	08/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Terri Deutseh, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–08–28, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–9462

RIN: 0938–AM78

1122. ● TICKET TO WORK: DEFINING INDIVIDUALS WITH POTENTIALLY SEVERE DISABILITIES (CMS–2172–N)

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

Legal Authority: Ticket to Work and Work Incentives Improvement Act of 1999

CFR Citation: None

Legal Deadline: None

Abstract: This proposed rule would provide a definition of ''medically determinable severe impairment'' under the Ticket to Work and Work Incentives Improvement Act of 1999.

Timetable:

Action	Date	FR Cite
Notice	08/00/04	

Regulatory Flexibility Analysis Required: No

HHS—CMS **Final Rule Stage**

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carey O'Connor, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, S2–14–26, Baltimore, MD 21224
Phone: 410 786–2117

RIN: 0938–AM79

1123. ● HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS, SECURING MEDICATIONS AND POST-ANESTHESIA EVALUATIONS (CMS–3122–F)

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

Legal Authority: 42 USC 1395 x; 42 USC 1396 d; 42 USC 1395 bb

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule will change the existing requirements to decrease the burden on hospitals to conform to current standards of practice. Hospitals must meet these final requirements to participate in the Medicare and Medicaid programs. They must establish and maintain policies and procedures that will ensure their hospital will meet these requirements by using standard practices with regards to history and physical examinations, and completion of the post-anesthesia evaluation.

Timetable:

Action	Date	FR Cite
Final Action	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

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

RIN: 0938–AM88

1124. ● DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2062–N)

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

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the preliminary Federal share disproportionate share hospital (DSH) allotments for Federal fiscal year (FFY) 2002 in accordance with the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. It also announces the FFY 1999, 2000, and 2001 limitations on aggregate DSH payments that States may make to institutions for mental disease and other mental health facilities. In addition, it specifies a format to be used by States when submitting the annual DSH report mandated by the statute

Timetable:

Action	Date	FR Cite
Notice	03/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jim Frizzera, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, CMSO, S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9535

RIN: 0938–AM89

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

Long-Term Actions

1125. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIERS (CMS–6017–P)

Priority: Substantive, Nonsignificant. 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, Final.

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 in section 262 of the Health Insurance Portability & Accountability Act of 1996.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

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

1126. EXCLUSION OF MEDICARE BENEFITS FOR ALIENS NOT LAWFULLY PRESENT IN THE UNITED STATES (CMS–1222–FC)

Priority: Other Significant

Legal Authority: Sec 5561 of BBA 1997; Sec 401(b) of the Personal Responsibility and Work Opportunity Act of 1996; 42 USC 1611(b)

CFR Citation: 42 CFR 411.11

Legal Deadline: None

Abstract: This final rule with comment period amends our regulations to prohibit Medicare benefits to an alien who is not lawfully present in the United States. Section 5561 of the Balanced Budget Act amended section 401(b) of the Personal Responsibility and Work Opportunity Act of 1996 to prohibit Medicare payments for services furnished to an alien who is

not ''lawfully present in the United States'' and meets certain other conditions.

Timetable:

Action	Date	FR Cite
Interim Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Frederick William Grabau, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center of Medicaid and State Operations, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–0206

RIN: 0938–AM47

1127. ● CHANGES TO THE CRITERIA FOR BEING CLASSIFIED AS AN INPATIENT REHABILITATION FACILITY (CMS–1262–F)

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

Legal Authority: Sec 1886 of the Social Security Act; 42 USC 1395cc

CFR Citation: 42 CFR 412

Legal Deadline: None

Abstract: This final rule would revise classification criteria, commonly known as the ''75 percent rule,'' for a hospital to be classified as an inpatient rehabilitation facility (IRF). It would also modify and expand the medical conditions listed in the 75 percent rule regulatory requirements. We are proposing these changes to ensure that patients in IRF settings receive appropriate intensive inpatient rehabilitation services.

Timetable:

Action	Date	FR Cite
NPRM	09/09/03	68 FR 53266
Final Rule	10/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Robert Kuhl, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4597

RIN: 0938–AM72

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

Completed Actions

1128. CONDITIONS OF PARTICIPATION OF INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION (CMS–3046–P)

Priority: Other Significant

CFR Citation: 42 CFR 400; 42 CFR 435; 42 CFR 440; 42 CFR 441; 42 CFR 483

Completed:

Reason	Date	FR Cite
Withdrawn	08/19/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Anita Panicker
Phone: 410 786–5646

RIN: 0938–AK23

1129. LABORATORY REQUIREMENTS RELATING TO QUALITY SYSTEMS AND CERTAIN PERSONNEL QUALIFICATIONS (CMS–2226–CN)

Priority: Other Significant

CFR Citation: 42 CFR 493

Completed:

Reason	Date	FR Cite
Correction Notice	08/22/03	68 FR 50722

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Cecelia Hinkel
Phone: 410 786–3347

RIN: 0938–AK24

1130. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES (CMS–3047–F)

Priority: Other Significant

CFR Citation: 42 CFR 403; 42 CFR 416; 42 CFR 418; 42 CFR 460; 42 CFR 482; 42 CFR 483

Completed:

Reason	Date	FR Cite
Final Action	01/10/03	68 FR 1374

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Danielle Shearer
Phone: 410 786–6617

RIN: 0938–AK35

1131. HOSPITAL CONDITIONS OF PARTICIPATION: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENTS (QAPI) (CMS–3050–F)

Priority: Other Significant

CFR Citation: 42 CFR 482.21

Completed:

Reason	Date	FR Cite
Final Rule	01/24/03	68 FR 3435

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State

Agency Contact: Nancy Archer
Phone: 410 786–0596

RIN: 0938–AK40

1132. REVISED PROCESS FOR MAKING MEDICARE NATIONAL COVERAGE DETERMINATIONS (CMS–3062–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	09/26/03	68 FR 187

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Vadim Lubarsky
Phone: 410 786–0840

RIN: 0938–AK61

1133. MODIFICATIONS TO MEDICARE MANAGED CARE RULES (CMS–4041–F)

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

CFR Citation: 42 CFR 409; 42 CFR 417; 42 CFR 422

Completed:

Reason	Date	FR Cite
Final Rule	08/22/03	68 FR 50839

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

Agency Contact: Tony Hausner
Phone: 410 786–1093

RIN: 0938–AK71

1134. INPATIENT DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT: CALCULATION OF MEDICAID PATIENT AND TOTAL PATIENT DAYS IN THE MEDICARE DSH ADJUSTMENT (CMS–1171–P)

Priority: Other Significant

CFR Citation: 42 CFR 412106

Completed:

Reason	Date	FR Cite
Merged With 0938–AL89	08/08/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Stephen Phillips
Phone: 410 786–4548

RIN: 0938–AK77

1135. MODIFICATIONS TO THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM (SCHIP) (CMS–2006–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 435; 42 CFR 436; 42 CFR 457

Completed:

Reason	Date	FR Cite
Withdrawn	11/18/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

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

Agency Contact: Cheryl Austein-Casnoff
Phone: 410 786–4196

RIN: 0938–AL00

1136. REQUIREMENTS FOR PAID FEEDING ASSISTANTS IN long-term CARE FACILITIES (CMS–2131–F)

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

CFR Citation: 42 CFR 483.73; 42 CFR 483.75(c)

Completed:

Reason	Date	FR Cite
Final Rule	09/26/03	68 FR 55528

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal, State

Agency Contact: Nola Petrovich
Phone: 410 786–4671

RIN: 0938–AL18

1137. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2003 PAYMENT RATES; CHANGES TO PAYMENT SUSPENSION FOR UNFILED COST REPORTS; CORRECTION TO FINAL RULE (CMS–1206–CN2)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 405; 42 CFR 419

Completed:

Reason	Date	FR Cite
Correction Notice	10/01/03	67 FR 69146
Correction Notice	02/10/03	68 FR 6636

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

Agency Contact: Cindy Read
Phone: 410 786–1852

RIN: 0938–AL19

1138. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI-LEVEL CAPABILITY AND A BACK-UP RATE (CMS–1167–F)

Priority: Other Significant

CFR Citation: 42 CFR 414

Completed:

Reason	Date	FR Cite
NPRM	08/22/03	68 FR 50 735
Withdrawn	10/10/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Joel Kaiser
Phone: 410 786–4499

RIN: 0938–AL27

1139. INTERIM FINAL AMENDMENT FOR MENTAL HEALTH PARITY (CMS–2152–IFC)

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 146.136

Completed:

Reason	Date	FR Cite
Second Interim Final Rule	06/27/03	68 FR 38206
Second Interim Final Rule Effective	07/28/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

Agency Contact: David Mlawsky
Phone: 410 786–6851

RIN: 0938–AL44

1140. ELECTRONIC SUBMISSION OF COST REPORTS (CMS–1199–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 413.24

Completed:

Reason	Date	FR Cite
Final Action	08/22/03	68 FR 50717

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Carol Blackford
Phone: 410 786–5909

RIN: 0938–AL51

1141. EXCLUSIONS FROM THE DEFINITION OF ''OPTIONAL TARGETED LOW-INCOME CHILD'' AND PURCHASE OF FAMILY COVERAGE—BENEFIT FLEXIBILITY IN PARENT COVERAGE (CMS–2148–P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 457

Completed:

Reason	Date	FR Cite
Withdrawn	11/18/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Stacey Bush
Phone: 410 786–6102

RIN: 0938–AL62

1142. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS; FEDERAL FY 2002 (CMS–2136–FN)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	08/22/03	68 FR 50790

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Robert Nakielny
Phone: 410 786–4466

RIN: 0938–AL79

1143. MEDICAID COVERAGE RULES FOR INMATES OF PUBLIC INSTITUTIONS (CMS–2077–P)

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

CFR Citation: 42 CFR 435.1008; 42 CFR 435.1009; 42 CFR 435.1012; 42 CFR 436.1004

Completed:

Reason	Date	FR Cite
Withdrawn	08/08/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

Agency Contact: Tom Shenk
Phone: 410 786–3295

RIN: 0938–AL85

1144. TARGETED CASE MANAGEMENT (CMS–2061–P)

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Withdrawn	08/08/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Kathy Poisal
Phone: 410 786–5940

RIN: 0938–AL87

1145. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2004 RATES (CMS–1470–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	05/19/03	68 FR 27154
Final Action	08/01/03	68 FR 45346

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Tzvi Hefter
Phone: 410 786–4487

Scott Cooper
Phone: 410 786–9465

RIN: 0938–AL89

1146. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2004 (CMS–1469–F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 413.330 to 413.350

Completed:

Reason	Date	FR Cite
NPRM	05/16/03	68 FR 26758
Final Rule	08/04/03	68 FR 46036

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: William Ullman
Phone: 401 786–5667

RIN: 0938–AL90

1147. PROSPECTIVE PAYMENT SYSTEM FOR long-term CARE HOSPITALS FOR FY 2004 (CMS–1472–P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 412; 42 CFR 413

Completed:

Reason	Date	FR Cite
Final Action	06/06/03	68 FR 34122

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Tzvi Hefter
Phone: 410 786–4487

RIN: 0938–AL92

1148. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR FY 2004 (CMS–1473–NC)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	07/02/03	68 FR 39763

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Randy Throndset
Phone: 410 786–0131

RIN: 0938–AL94

1149. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS FOR FY 2004 (CMS–1474–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 412; 42 CFR 413

Completed:

Reason	Date	FR Cite
NPRM	05/16/03	68 FR 26786
Final Action	08/01/03	68 FR 45674

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Robert Kuhl
Phone: 410 786–4597

RIN: 0938–AL95

1150. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2004 (CMS–1476–P)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR Part 410; 42 CFR Part 414

Completed:

Reason	Date	FR Cite
NPRM	08/15/03	68 FR 49029
Final Action	11/07/03	68 FR 63196

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

Agency Contact: Diane Milstead Phone: 410 786–3355

RIN: 0938–AL96

1151. NONDISCRIMINATION IN POST-HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 482

Completed:

Reason	Date	FR Cite
Withdrawn	11/18/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Elizabeth Carmody Phone: 410 786–7533

RIN: 0938–AM01

1152. UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS (CMS–1885–FC)

Priority: Other Significant

CFR Citation: 42 CFR 416

Completed:

Reason	Date	FR Cite
Final Rule	03/28/03	68 FR 32406
Final Rule Comment Period End	05/28/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Bob Cereghino Phone: 410 786–4645

RIN: 0938–AM02

1153. MEDICAID HOME AND COMMUNITY BASED SERVICES WAIVERS (CMS–2162–P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 441.300

Completed:

Reason	Date	FR Cite
Withdrawn	10/30/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Mary Clarkson Phone: 410 786–5918

RIN: 0938–AM05

1154. PAYMENT REFORM FOR PART B DRUGS (CMS–1229–F)

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

CFR Citation: 42 CFR 405

Completed:

Reason	Date	FR Cite
Merged With 0938–AL96	08/20/03	68 FR 50428

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Marjorie Baldo Phone: 410 786–4617

RIN: 0938–AM12

1155. NONDISCRIMINATION IN HEALTH COVERAGE IN THE GROUP MARKET (CMS–2022–F)

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

CFR Citation: 45 CFR 146.121

Completed:

Reason	Date	FR Cite
Withdrawn	11/18/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

Agency Contact: David Mlawsky Phone: 410 786–6851

RIN: 0938–AM14

1156. BONA FIDE WELLNESS PROGRAMS (CMS–2078–F)

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

CFR Citation: 45 CFR 146.121(f)

Completed:

Reason	Date	FR Cite
Withdrawn	08/27/03	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State, Local

Agency Contact: David Mlawsky Phone: 410 786–6851

RIN: 0938–AM15

1157. TIME LIMITATION ON RECALCULATIONS AND DISPUTES UNDER THE DRUG REBATE PROGRAM (CMS–2175–FC)

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

CFR Citation: 42 CFR 447.534

Completed:

Reason	Date	FR Cite
Final Rule with Comment	08/29/03	68 FR 51912
Comment Period End	10/28/03	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal, Local, State

Agency Contact: Marge Lee Watchorn Phone: 410 786–4361

RIN: 0938–AM20

1158. MEDICAID ESTATE RECOVERIES (CMS–2083–P)

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

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	08/27/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Ingrid Osborne Phone: 410 786–4461

RIN: 0938–AM30

1159. APPLICATION OF THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) (CMS–1063–F)

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

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Final Rule	09/09/03	68 FR 53222

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Rebecca Hirshorn
Phone: 410 786–3411

RIN: 0938–AM34

1160. PHYSICIAN OWNERSHIP IN SPECIALTY HOSPITALS (CMS–1240–P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 411

Completed:

Reason	Date	FR Cite
Withdrawn	08/19/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jackie Proctor
Phone: 410 786–8852

RIN: 0938–AM35

1161. APPROVAL OF THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO) FOR DEEMING AUTHORITY FOR HOSPICES (CMS–2177–FN)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	05/30/03	68 FR 32528

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Cindy Melanson
Phone: 410 786–0310

Cathaleen Ahern
Phone: 410 786–4515

RIN: 0938–AM38

1162. HOSPITAL COST-TO-CHARGE RATIOS USED TO CALCULATE COST OUTLIER PAYMENTS UNDER THE MEDICARE SHORT-TERM INPATIENT PROSPECTIVE PAYMENT SYSTEM (CMS–1243–F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 412.84; 42 CFR 412.116

Completed:

Reason	Date	FR Cite
Final Action	06/09/03	68 FR 34494

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Stephen Phillips
Phone: 410 786–4548

RIN: 0938–AM41

1163. AMBULANCE FEE SCHEDULE CONDITION CODES (CMS–1247–P)

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

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Withdrawn	11/18/03	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Anne Tayloe
Phone: 410 786–4546

RIN: 0938–AM45

1164. HOSPICE WAGE INDEX FOR FY 2004 (CMS–1233–N)

Priority: Routine and Frequent

CFR Citation: 42 CFR 418.306(C)

Completed:

Reason	Date	FR Cite
Notice	09/30/03	68 FR 56478

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Carol Blackford
Phone: 410 786–5909

RIN: 0938–AM56

1165. ANNOUNCEMENT OF APPLICATIONS FROM HOSPITALS REQUESTING WAIVERS FOR ORGAN PROCUREMENT SERVICE AREAS IN CALENDAR YEAR 2003 (CMS–1246–NC)

Priority: Routine and Frequent

CFR Citation: 42 CFR 486.306

Completed:

Reason	Date	FR Cite
Withdrawn	09/04/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Mark Horney
Phone: 410 786–4554

RIN: 0938–AM59

1166. ● CENTERS FOR MEDICARE AND MEDICAID SERVICES ACTION ON LIABILITY INSURANCE REGULATIONS (CMS–1475–FC)

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

Legal Authority: Sec 1862(b)(2)(A) of the Social Security Act; 42 USC 1395y

CFR Citation: 42 CFR 411.54(C)(2)(i)

Legal Deadline: None

Abstract: The court ruled that our 1991 regulation is inconsistent with the statutory provision, which prohibits Medicare from making payment when other insurance is available and permits a provider or supplier (including a physician) to seek payment from a liability or a beneficiary's liability settlement. CMS has not removed the unenforceable regulation.

Timetable:

Action	Date	FR Cite
Final Rule with Comment	07/25/03	68 FR 43940
Final Rule Effective	08/25/03	
Final Rule Comment Period End	09/23/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Suzanne Ripley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–25–02, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–0970

RIN: 0938–AM64

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

Proposed Rule Stage

1167. 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, offset of Federal payments for purposes of collecting child support, and 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	03/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local, Tribal

Agency Contact: Eileen C. Brooks, Deputy Director, Policy Division, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, OCSE, DPP, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–5369
TDD Phone: 800 877–8339
Fax: 202 401–4054
Email: ebrooks@acf.hhs.gov

RIN: 0970–AC01

1168. DEVELOPMENTAL DISABILITIES AND BILL OF RIGHTS ACT

Priority: Substantive, Nonsignificant

Legal Authority: PL 106–402; USC 15001 et seq

CFR Citation: 45 CFR 1385 to 1388

Legal Deadline: Final, Statutory, October 30, 2001, Final.

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	03/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, 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

1169. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

Priority: Substantive, Nonsignificant

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	02/00/04	

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

1170. ● ADMINISTRATIVE COST SHARING UNDER TANF

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

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	03/00/04	

HHS—ACF **Proposed Rule Stage**

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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

Agency Contact: 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

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

Final Rule Stage

1171. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES

Priority: Other Significant

Legal Authority: 42 USC 655(f)

CFR Citation: 45 CFR 309

Legal Deadline: None

Abstract: This rule specifies how tribes can obtain direct payments from the Department of Health and Human Services for provision of child support enforcement services if they submit a plan meeting the objectives of title IV–D, including establishment of paternity, modification and enforcement of support orders, and location of absent parents.

Timetable:

Action	Date	FR Cite
NPRM	08/21/00	65 FR 50800
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Tribal

Agency Contact: Paige Biava, Division of Policy and Planning, 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

RIN: 0970–AB73

1172. CHILD SUPPORT ENFORCEMENT PROGRAM; FEDERAL TAX REFUND OFFSET

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 664; 42 USC 1302

CFR Citation: 45 CFR 303.72

Legal Deadline: None

Abstract: This interim final rule will revise existing regulations on collecting child support arrears through the Federal Tax Refund Offset process. The revisions are needed to reflect changes in data processing protocols with the Department of the Treasury. We are also updating the regulation to reflect current business practices and requests from the state child support agencies.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/26/03	68 FR 37978
Final Action	06/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Eileen C. Brooks, Deputy Director, Policy Division, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, OCSE, DPP, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–5369
TDD Phone: 800 877–8339
Fax: 202 401–4054
Email: ebrooks@acf.hhs.gov

RIN: 0970–AC09

1173. CHARITABLE CHOICE PROVISIONS APPLICABLE TO THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES PROGRAM

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 604(a)

CFR Citation: 45 CFR 260.30; 45 CFR 260.34

Legal Deadline: None

Abstract: The proposed rule would implement the Charitable Choice statutory provisions at section 104 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 as amended. It is the policy of the Administration for Children and Families that, within constitutional church-state guidelines, faith-based organizations should be able to compete on an equal footing for funding under the Temporary Assistance for Needy Families (TANF) program. In addition to giving families a greater choice of TANF-funded providers, these rules ensure that the character of religious providers is not impaired and that the religious freedom of TANF beneficiaries is not impaired.

Timetable:

Action	Date	FR Cite
NPRM	12/17/02	67 FR 77362
NPRM Comment Period End	02/18/03	
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: 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–AC12

1174. COMMUNITY SERVICES BLOCK GRANT CHARITABLE CHOICE

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9901; PL 105–285, sec 672; 42 USC 9902; PL 105–285, sec 673

CFR Citation: 45 CFR 1050

Legal Deadline: None

Abstract: This proposed rule would implement the Charitable Choice statutory provisions at section 679 of the Community Services Block Grant Act. These provisions apply to

HHS—ACF **Final Rule Stage**

programs authorized under the Act, including the Community Services Block grant program, Training, Technical Assistance and Capacity Building program, Community Food and Nutrition Program, National Youth Sports program, and discretionary grants for economic development, rural community development, and neighborhood innovation, which are all administered by the Administration for Children and Families (ACF). It is ACF's policy that, within the framework of constitutional church-State guidelines, faith-based organizations should be able to compete on an equal footing for funding, and ACF supports the participation of faith-based organizations in these programs.

Timetable:

Action	Date	FR Cite
NPRM	12/17/02	67 FR 77364
NPRM Comment Period End	02/18/03	
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Clarence Carter, Director, Office of Community Services, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–9333
Email: ccarter@acf.hhs.gov

RIN: 0970–AC13

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

1175. CONSTRUCTION AND MAJOR RENOVATION OF HEAD START AND EARLY HEAD START FACILITIES

Priority: Other Significant

CFR Citation: 45 CFR 1309

Completed:

Reason	Date	FR Cite
Final Action	05/01/03	68 FR 23212

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, Tribal

Agency Contact: Douglas Klafehn
Phone: 202 205–8569
Email: dklafehn@acf.dhhs.gov

RIN: 0970–AB54

1176. CHILD SUPPORT ENFORCEMENT PROGRAM OMNIBUS CONFORMING REGULATION

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 301 to 305

Completed:

Reason	Date	FR Cite
Final Action	05/12/03	68 FR 25293

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Eileen C. Brooks
Phone: 202 401–5369
TDD Phone: 800 877–8339
Fax: 202 401–4054
Email: ebrooks@acf.hhs.gov

RIN: 0970–AB81

1177. TECHNICAL REVISION OF HEAD START REGULATIONS TO MAKE THEM CONFORM TO RECENT STATUTORY REVISIONS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1301 to 1303; 45 CFR 1305; 45 CFR 1308

Completed:

Reason	Date	FR Cite
Withdrawn	08/29/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Douglas Klafehn
Phone: 202 205–8569
Email: dklafehn@acf.dhhs.gov

RIN: 0970–AC00

1178. CHILD SUPPORT ENFORCEMENT PROGRAM; EXPENDITURES FOR CASEWORKER COSTS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 304.23

Completed:

Reason	Date	FR Cite
Withdrawn	08/29/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Sheck Chin
Phone: 202 260–5830
TDD Phone: 800 877–8339
Fax: 202 401–4054
Email: schin@acf.hhs.gov

RIN: 0970–AC11

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

Administration on Aging (AOA)

1179. 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 spring of 2004.

Timetable:

Action	Date	FR Cite
NPRM	05/00/04	

Regulatory Flexibility Analysis Required: Yes

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

[FR Doc. 03–27071 Filed 12–19–03; 8:45 am]

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