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Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Unified Agenda of Federal Regulatory and Deregulatory Actions

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. The purpose of this effort is to encourage public participation in the Department's regulatory process by providing, at an early stage, summarized information about regulatory actions under development. Anyone wishing to communicate to the Department their views on the rulemakings outlined below is invited to do so.

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

SUPPLEMENTARY INFORMATION: The capsulized information provided below 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 notices or final rules within the next 12 months. (Also included, in several Long-Term Action sections, are summaries of actions that we will probably not take any earlier than 12 months after publication of this agenda.)

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

Dated: April 14, 2003.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
744	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991-AB06
745	Claims Collection	0991-AB18
746	Salary Offset	0991-AB19
747	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991-AB23

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
748	Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
749	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991-AB16
750	Tax Refund Offset	0991-AB17
751	Implementation of the Equal Access to Justice Act in Agency Proceedings	0991-AB22

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
752	Revisions to 42 CFR Part 1003	0991-AB03
753	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
754	Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)	0991-AB12

HHS

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
755	Civil Money Penalty Safe Harbor To Protect Payment of Medicare and Medigap Premiums for ESRD Beneficiaries	0991-AB04
756	Administrative Wage Garnishment	0991-AB20
757	U.S. Exchange Visitor Programs; Request for Waiver of the Two-Year Foreign Residence Requirement	0991-AB21
758	Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings	0991-AB24

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
759	SAMHSA Charitable Choice	0930-AA11

Substance Abuse and Mental Health Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
760	Seclusion and Restraint for Non-Medical Residential Facilities	0930-AA10

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
761	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
762	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

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identification Number
763	Control of Communicable Diseases	0920-AA03
764	Possession, Use, and Transfer of Select Agents	0920-AA08

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
765	Over-the-Counter (OTC) Drug Review	0910-AA01
766	Investigational Use New Animal Drug Regulations **(Section 610 Review)**	0910-AB02
767	Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Possible Footnote Statements	0910-AC50

HHS

Food and Drug Administration—Prerule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
768	Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food **(Section 610 Review)**	0910-AC58

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
769	Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics	0910-AA49
770	Blood Initiative	0910-AB26
771	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910-AB34
772	Current Good Manufacturing Practice for Medicated Feeds	0910-AB70
773	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910-AB88
774	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910-AB96
775	Prevention of Salmonella Enteritidis in Shell Eggs	0910-AC14
776	Institutional Review Boards: Registration Requirements	0910-AC17
777	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products	0910-AC19
778	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910-AC21
779	Requirements for Submission of In Vivo Bioequivalence Data	0910-AC23
780	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910-AC25
781	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910-AC30
782	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910-AC32
783	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910-AC35
784	Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910-AC38
785	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910-AC39
786	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910-AC43
787	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910-AC52
788	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910-AC53
789	Food Standards: General Principles and Food Standards Modernization	0910-AC54
790	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910-AC55
791	Revision of the Requirements for Spore-Forming Microorganisms	0910-AC57
792	Reporting Information Regarding Falsification of Data	0910-AC59

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
793	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910-AA04
794	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910-AA61
795	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910-AA89
796	Labeling for Human Prescription Drugs; Revised Format	0910-AA94
797	Supplements and Other Changes to an Approved Application	0910-AB61
798	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims	0910-AB66
799	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)	0910-AB76
800	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format	0910-AB91
801	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910-AC07
802	Aluminum in Large- and Small-Volume Parenterals Used in Total Parenteral Nutrition	0910-AC18
803	Bar Code Label Requirements for Human Drug Products and Blood	0910-AC26
804	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910-AC34

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
805	Registration of Food and Animal Feed Facilities	0910-AC40
806	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910-AC41
807	Presubmission Conferences	0910-AC44
808	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
809	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910-AC56

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
810	Safety Reporting Requirements for Human Drug and Biological Products	0910-AA97
811	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products	0910-AB27
812	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products Establishments; Inspection and Enforcement	0910-AB28
813	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of ''No Residue''	0910-AC45

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
814	Revisions to the General Safety Requirements for Biological Products; Final Rule	0910-AB51
815	Antibiotic Resistance Labeling	0910-AB78
816	Records and Reports Concerning Experience With Approved New Animal Drugs	0910-AC42
817	Bioavailability and Bioequivalence Requirements	0910-AC47

Food and Drug Administration—Discontinued Entries

Regulation Identification Number	Title	Date	Comments
0910-AC15	Premarket Notice Concerning Bioengineered Foods	02/13/2003	Withdrawn--Publication not expected in the next 12 months

Health Resources and Services Administration—Proposed Rule Stage

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

HHS

Health Resources and Services Administration—Long-Term Actions

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

Indian Health Service—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
821	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
822	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925-AA10
823	National Institutes of Health (NIH) Training Grants	0925-AA28
824	Standards for a National Chimpanzee Sanctuary System	0925-AA31
825	National Institutes of Health (NIH) AIDS Research Loan Repayment Program	0925-AA32
826	National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers	0925-AA33
827	National Institutes of Health Pediatric Research Loan Repayment Program	0925-AA34
828	Loan Repayment Program for Health Disparities Research	0925-AA35
829	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925-AA36

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
830	National Institutes of Health Loan Repayment Program for Research Generally	0925-AA18
831	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	0925-AA20
832	National Institutes of Health (NIH) Center Grants	0925-AA24

Office of Public Health and Science—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
833	Public Health Services Policies on Research Misconduct	0940-AA04
834	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940-AA06
835	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
836	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940-AA01

HHS

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
837	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) **(Section 610 Review)**	0938-AG82
838	Hospital Conditions of Participation: Requirements for Certification and Recertification of Transplant Centers To Perform Organ Transplants (CMS-3835-P)	0938-AH17
839	Hospice Care—Conditions of Participation (CMS-3844-P)	0938-AH27
840	Supplier Standards for Home Oxygen, Therapeutic Shoes, Home Nutrition Therapy (CMS-6010-P)	0938-AJ98
841	Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (CMS-3046-P)	0938-AK23
842	Health Insurance Reform: Claims Attachments Standards (CMS-0050-P)	0938-AK62
843	Inpatient Disproportionate Share Hospital (DSH) Adjustment: Calculation of Medicaid Patient and Total Patient Days in the Medicare DSH Adjustment (CMS-1171-P)	0938-AK77
844	Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS-1185-P)	0938-AK79
845	Organ Procurement Organization Conditions for Coverage (CMS-3064-P)	0938-AK81
846	Extending Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity (CMS-4018-P)	0938-AK94
847	Update Interest Assessment on Medicare Overpayment and Underpayment (CMS-6014-P)	0938-AL14
848	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938-AL26
849	Payment for Respiratory Assist Devices With Bi-Level Capability and a Back-Up Rate (CMS-1167-P)	0938-AL27
850	Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS-6016-P)	0938-AL49
851	Prospective Payment System for Inpatient Psychiatric Facilities FY 2004(CMS-1213-P)	0938-AL50
852	Provider Reimbursement Determinations and Appeals (CMS-1727-P)	0938-AL54
853	SCHIP; Purchase of Family Coverage—Benefit Flexibility in Parent Coverage (CMS-2148-P)	0938-AL62
854	Request for Information on Benefit-Specific Waiting Periods (CMS-2150-NC)	0938-AL64
855	DMERC Service Areas and Related Matters (CMS-1219-P)	0938-AL76
856	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938-AL80
857	Medicaid Coverage Rules for Inmates of Public Institutions (CMS-2077-P)	0938-AL85
858	Targeted Case Management (CMS-2061-P)	0938-AL87
859	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-P)	0938-AL88
860	Changes to the Hospital Inpatient Prospective Payment System and FY 2004 Rates (CMS-1470-P)	0938-AL89
861	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2004 (CMS-1469-P)	0938-AL90
862	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS-1471-P)	0938-AL91
863	Home Health Prospective Payment System Rate Update for FY 2004 (CMS-1473-NC)	0938-AL94
864	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004 (CMS-1476-P)	0938-AL96
865	Medicaid Home and Community-Based Services Waivers (CMS-2162-P)	0938-AM05
866	Revisions to Average Wholesale Price Methodology (CMS-1229-P)	0938-AM12
867	Criteria for Determining Whether a Drug is Considered Usually Self-Administered (CMS-1228-P)	0938-AM13
868	Electronic Medicare Claims Submission (CMS-0008-IFC)	0938-AM22
869	Medicaid Estate Recoveries (CMS-2083-P)	0938-AM30
870	Physician Ownership in Specialty Hospitals (CMS-1240-P)	0938-AM35
871	Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services (CMS-3119-P)	0938-AM36
872	Hospital Patients' Rights COP—Standard Safety Compliance Committees (CMS-3120-P)	0938-AM39
873	Ambulance Fee Schedule Condition Codes (CMS-1247-P)	0938-AM45
874	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2005 (CMS-1249-P)	0938-AM46
875	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938-AM50
876	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-P)	0938-AM54
877	Requirements for Nursing Homes To Identify the Number of Licensed and Unlicensed Nursing Staff Per Shift (CMS-3121-P)	0938-AM55

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
878	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-FC)	0938-AG81

HHS

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

Sequence Number	Title	Regulation Identification Number
879	Standard Unique National Health Plan Identifiers (CMS-6017-F)	0938-AH87
880	Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS-0045-F)	0938-AH99
881	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS-6003-F)	0938-AI49
882	Coverage of Religious Non-Medical Health Care Institutions (CMS-1909-F)	0938-AI93
883	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)	0938-AJ10
884	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions, and Establishment of a Quality Assessment and Improvement Program (CMS-1910-F)	0938-AJ17
885	Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)	0938-AJ29
886	Medicare Hospice Care Amendments (CMS-1022-F)	0938-AJ36
887	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938-AJ96
888	All Provider Bad Debt Payment (CMS-1126-F)	0938-AK02
889	Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications (CMS-2226-CN)	0938-AK24
890	Review of National Coverage Determinations and Local Coverage Determinations (CMS-3063-F)	0938-AK60
891	Revised Process for Making Medicare Coverage Determinations (NCDs) (CMS-3062-N)	0938-AK61
892	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS-1810-FC)	0938-AK67
893	Rate of Reimbursement of Photocopy Expenses for Quality Improvement Organizations (CMS-3055-F)	0938-AK68
894	Modifications to Medicare Managed Care Rules (CMS-4041-F)	0938-AK71
895	Modifications to the State Children's Health Insurance Program (CMS-2006-F)	0938-AL00
896	Requirements for Paid Feeding Assistants in Long-Term Care Facilities (CMS-2131-F)	0938-AL18
897	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS-2151-F)	0938-AL43
898	Interim Final Amendment for Mental Health Parity (CMS-2152-IFC)	0938-AL44
899	Electronic Submission of Cost Reports (CMS-1199-F)	0938-AL51
900	Revisions to the Medicare Appeals Process (CMS-4004-F)	0938-AL67
901	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals; Federal Fiscal Year 2002 (CMS-2136-FN)	0938-AL79
902	Prospective Payment System for Long-Term Care Hospitals for FY 2004 (CMS-1472-P)	0938-AL92
903	Prospective Payment System for Inpatient Rehabilitation Hospitals for FY 2004 (CMS-1474-F)	0938-AL95
904	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)	0938-AM01
905	Update of the List of Covered Procedures for Ambulatory Surgical Centers (CMS-1885-FC)	0938-AM02
906	Nondiscrimination in Health Coverage in the Group Market (CMS-2022-F)	0938-AM14
907	Bona Fide Wellness Programs (CMS-2078-F)	0938-AM15
908	Time Limitation on Recalculations and Disputes Under the Drug Rebate Program (CMS-2175-FC)	0938-AM20
909	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2004 (CMS-8016-N)	0938-AM31
910	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2004 (CMS-8017-N)	0938-AM32
911	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
912	Application of the Emergency Medical Treatment and Labor Act (EMTALA) (CMS-1063-F)	0938-AM34
913	Approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Deeming Authority for Hospices (CMS-2177-FN)	0938-AM38
914	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
915	Fee Schedule for Payment of Ambulance Services Update for CY 2004 (CMS-1232-N)	0938-AM44
916	Exclusion of Medicare Benefits for Aliens Not Lawfully Present in the United States (CMS-1222-IFC)	0938-AM47
917	Hospice Wage Index for FY 2004 (CMS-1233-N)	0938-AM56
918	Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas in CY 2003 (CMS-1246-NC)	0938-AM59

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
919	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-P)	0938-AH73

HHS

Centers for Medicare & Medicaid Services—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identification Number
920	Fire Safety Requirements for Certain Health Care Facilities (CMS-3047-F)	0938-AK35
921	Hospital Conditions of Participation: Quality Assessment and Performance Improvements (QAPI) (CMS-3050-F)	0938-AK40
922	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

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identification Number
923	Security Standards (CMS-0049-F)	0938-AI57
924	External Quality Review of Medicaid Managed Care Organizations (CMS-2015-F)	0938-AJ06
925	Improvements to the Medicare+Choice Appeals and Grievance Procedures (CMS-4024-FC)	0938-AK48
926	Health Insurance Reform: Modifications to Standards for Electronic Transactions (CMS-0003-FC)	0938-AK64
927	Medicaid Managed Care; New Provisions (CMS-2104-F2)	0938-AK96
928	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 (CMS-1204-F2)	0938-AL21
929	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2003 (CMS-8013-N)	0938-AL56
930	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2003 (CMS-8014-N)	0938-AL63
931	Part A Premiums for Calendar Year 2003 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8015-N)	0938-AL69
932	Fee Schedule for Payment of Ambulance Services—Update for CY 2003 (CMS-1220-N)	0938-AL97
933	Ticket to Work Medicaid Infrastructure Grant (CMS-2165-N)	0938-AM11
934	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Extension of Partial Delay of Effective Date of the ''Set in Advance'' Provision (CMS-1809-F2)	0938-AM21
935	Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas CY 2002 (CMS-1241-NC)	0938-AM37
936	Grants to States for Operation of Qualified High Risk Pools (CMS-2179-FC)	0938-AM42
937	Prospective Payment System for Long-Term Care Hospitals: Implementation and FY 2003 Rates; Correcting Amendment (CMS-1177-F2)	0938-AM49
938	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Second Extension of Delay of Effective Date of the ''Set in Advance'' Provision (CMS-1809-F3)	0938-AM58
939	Ambulance Fee Schedule (CMS-1256-N)	0938-AM60
940	Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings (CMS-0010-IFC)	0938-AM63

Centers for Medicare & Medicaid Services—Discontinued Entries

Regulation Identification Number	Title	Date	Comments
0938-AG79	Revision of Medicare/Medicaid Hospital Conditions of Participation (CMS-3745-F)	03/10/2003	Withdrawn
0938-AH53	Medicare and Medicaid Programs; Terms, Definitions, and Addresses; Technical Amendments (CMS-9877-F)	04/21/2003	Withdrawn
0938-AI21	Medical Child Support and Health Insurance Coverage of Dependent Children (CMS-2081-P)	03/12/2003	Withdrawn
0938-AJ97	Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services) (CMS-1908-IFC)	05/06/2003	Withdrawn
0938-AL12	Medicare Limits on the Valuation of a Depreciable Asset Recognized as an Allowance for Depreciation and Interest on Capital Indebtedness After a Change of Ownership (CMS-1004-F)	02/03/2003	Withdrawn
0938-AL33	Self-Declaration of Citizenship (CMS-2085-P)	03/05/2003	Withdrawn
0938-AL59	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-F)	03/05/2003	Withdrawn
0938-AM10	Comprehensive Employment Demonstration (CMS-2163-N)	11/26/2002	Withdrawn
0938-AM24	Liability of Third Parties To Pay for Care and Services (CMS-2080-P)	01/30/2003	Withdrawn

HHS

Centers for Medicare & Medicaid Services—Discontinued Entries (Continued)

Regulation Identification Number	Title	Date	Comments
0938-AM40	Meeting of the Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics—May 19-20, 2003 and June 2-3, 2003 (CMS-6012-N5)	03/12/2003	Withdrawn

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
941	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970-AC01
942	Developmental Disabilities and Bill of Rights Act	0970-AC07
943	Child Support Enforcement Program; Expenditures for Caseworker Costs	0970-AC11
944	Administrative Costs for Children in Title IV-E Foster Care	0970-AC14

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
945	Construction and Major Renovation of Head Start and Early Head Start Facilities	0970-AB54
946	Child Support Enforcement for Indian Tribes	0970-AB73
947	Child Support Enforcement Program Omnibus Conforming Regulation	0970-AB81
948	Technical Revision of Head Start Regulations To Make Them Conform to Recent Statutory Revisions	0970-AC00
949	Child Support Enforcement Program; Federal Tax Refund Offset	0970-AC09
950	Charitable Choice Provisions Applicable to the Temporary Assistance for Needy Families Program	0970-AC12
951	Community Services Block Grant Charitable Choice	0970-AC13

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
952	Family Child Care Program Option for Head Start Programs	0970-AB90
953	Child Support Enforcement Program; Customer Service Annual State Self-Assessment	0970-AC10

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
954	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

744. 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
NPRM	10/00/03
NPRM Comment Period End	12/00/03

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

Related RIN: Related To 0991-AA91

RIN: 0991–AB06

745. 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
NPRM	07/00/03
NPRM Comment Period End	09/00/03
Final Rule	12/00/03

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

746. SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 5514; 5 CFR 550

CFR Citation: 45 CFR 33

Legal Deadline: None

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

Timetable:

Action	Date
NPRM	07/00/03
NPRM Comment Period End	10/00/03
Final Rule	01/00/04

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

747. • 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
NPRM	08/00/03
NPRM Comment Period End	10/00/03

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) **Final Rule Stage**

Office of the Secretary (OS)

748. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1001

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

Abstract: This final rule establishes a new statutory exception for risk-sharing arrangements under the Federal health care programs' anti-kickback provisions. The rule sets forth an exception from liability for remuneration between an eligible organization and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at ''substantial financial risk'' for the cost or utilization of the items or services that the individual or entity is obligated to provide.

Timetable:

Action	Date	
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	10/00/03	

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

Related RIN: Related To 0991-AB06

RIN: 0991–AA91

749. 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	
NPRM	09/25/02	67 FR 60202
NPRM Comment Period End	10/25/02	
Final Rule	10/00/03	

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

750. TAX REFUND OFFSET

Priority: Substantive, Nonsignificant

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	
NPRM	12/04/02	67 FR 72128
NPRM Comment Period End	02/03/03	
Final Rule	08/00/03	

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 5362, HHS Cohen Building, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 619-0150

RIN: 0991–AB17

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

Priority: Substantive, Nonsignificant

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	
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	11/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

HHS—OS **Final Rule Stage**

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

Related RIN: Previously reported as 0990-AA02

RIN: 0991–AB22

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

Long-Term Actions

752. REVISIONS TO 42 CFR PART 1003

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
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

753. 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
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
Phone: 202 619-0403

RIN: 0991–AB10

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

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

Legal Authority: 5 USC 301; 41 USC 701 et seq, sec 2455; PL 103-355; 31 USC 6101 note; EO 12689; EO 12549

CFR Citation: 45 CFR 76; 45 CFR 82

Legal Deadline: None

Abstract: This proposed common rule is revised to simplify and streamline nonprocurement debarment and suspension requirements, as well as correspond to procurement regulations where possible. The revision will separate the debarment and suspension and Drug-Free Workplace regulations, and will be written in the plain language format.

Timetable:

Action	Date
NPRM	01/23/02 67 FR 3315
NPRM Comment Period End	03/25/02
Next Action Undetermined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Diane Osterhus, Federal Assistance Policy Specialist, Department of Health and Human Services, Office of the Secretary, Room 517D, Office of Grants and Acquisition Management, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 690-5729
Fax: 202 690-6901
Email: diane.osterhus@hhs.gov

RIN: 0991–AB12

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

755. CIVIL MONEY PENALTY SAFE HARBOR TO PROTECT PAYMENT OF MEDICARE AND MEDIGAP PREMIUMS FOR ESRD BENEFICIARIES

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 1003

Completed:

Reason	Date
Notice	12/09/02 67 FR 72896

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0991–AB04

756. ADMINISTRATIVE WAGE GARNISHMENT

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 32

Completed:

Reason	Date
Final Rule	03/28/03 68 FR 15092

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews
Phone: 202 619-0150

Related RIN: Previously reported as 0990-AA05

RIN: 0991–AB20

757. U.S. EXCHANGE VISITOR PROGRAMS; REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Priority: Other Significant

CFR Citation: 45 CFR 50

Completed:

Reason	Date
Interim Final Rule	12/19/02 67 FR 77692

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Joyce Edith Jones
Phone: 202 690-6174
Fax: 202 690-7127

RIN: 0991–AB21

758. ● CIVIL MONEY PENALTIES: PROCEDURES FOR INVESTIGATIONS, IMPOSITION OF PENALTIES, AND HEARINGS

Priority: Other Significant

Legal Authority: 42 USC 1320d-5; 42 USC 1302(a)

CFR Citation: 42 CFR 160

Legal Deadline: None

Abstract: The rule will establish procedures for investigations subpoenas, imposition of penalties, and hearings concerning the imposition of civil money penalties by the Secretary of Health and Human Services pursuant to 42 U.S.C. 1320d-5. The rule will establish procedures that the Secretary will follow and, with respect to hearings, which regulated entities who challenge the proposed imposition of a civil money penalty on the entity will follow.

Timetable:

Action	Date
Interim Final Rule	04/17/03 68 FR 18895

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Karen Shaw, Para Legal, Department of Health and Human Services, Office of the Secretary, Rm: 711E, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 690-7711
Fax: 202 690-5452
Email: karen.shaw@hhs.gov

RIN: 0991–AB24

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

759. ● 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 the Substance Abuse and Mental Health Services Administration (SAMSHA) of the U.S. Department of Health and Human Services.

Timetable:

Action	Date
NPRM	12/17/02 67 FR 77350
Final Rule	06/00/03

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) — Long-Term Actions
Substance Abuse and Mental Health Services Administration (SAMHSA)

760. SECLUSION AND RESTRAINT FOR NON-MEDICAL RESIDENTIAL FACILITIES

Priority: Substantive, Nonsignificant

Legal Authority: PL 106-310

CFR Citation: Not Yet Determined

Legal Deadline: NPRM, Statutory, April 2001.

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

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

Agency Contact: 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–AA10

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

761. 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
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)

762. 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	
NPRM	06/25/02	67 FR 42962
Final Rule	06/00/03	

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)
Centers for Disease Control and Prevention (CDC)

Completed Actions

763. CONTROL OF COMMUNICABLE DISEASES

Priority: Other Significant

CFR Citation: 42 CFR 70; 42 CFR 71

Completed:

Reason	Date
Interim Final Rule	04/10/03 68 FR 17558

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Jennifer Brooks
Phone: 404 639-2763

RIN: 0920–AA03

764. POSSESSION, USE, AND TRANSFER OF SELECT AGENTS

Priority: Other Significant

CFR Citation: 42 CFR 72; 42 CFR 72.6

Completed:

Reason	Date
Interim Final Rule	12/13/02 67 FR 76886

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Stephen M. Ostroff
Phone: 404 639-3967

RIN: 0920–AA08

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

Prerule Stage

765. 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
- Final Action (Amendment) 12/00/03

Antidiarrheal Products
- Final Action 04/17/03 (68 FR 18869)
- NPRM (Amendment) (Trav.Diar) 04/17/03 (68 FR 18915)

Antiemetic Products
- Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)

Antiperspirant Products
- Final Action 08/00/03

Cough/Cold (Antihistamine) Products
- Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)

Cough/Cold (Antitussive) Products
- Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)

Cough/Cold (Bronchodilator) Products
- Final Action (Amendment) 02/00/04

Cough/Cold (Combination) Products
- Final Action 12/23/02 (67 FR 78158)
- NPRM (Amendment) 02/00/04

Cough/Cold (Nasal Decongestant) Products
- NPRM (Phenylpropanolamine) 10/00/03

External Analgesic Products
- Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
- NPRM (Amendment) (Patches) 12/00/03

Ingrown Toenail Relief Products
- NPRM 10/04/02 (67 FR 62218)
- Final Action 06/00/03

Internal Analgesic Products
- NPRM (Amendment)(Ibuprofen) 08/21/02 (67 FR 54139)
- NPRM (Amendment) (Pediatric) 10/00/03
- NPRM (Amendment) (Labeling) 12/00/03

Labeling of Drug Products for OTC Human Use
- Final Action (Ca/Mg/K/Na) 07/00/03
- Final Action (Sodium Labeling) 07/00/03
- NPRM (Sodium Labeling) 07/00/03
- NPRM (Convenience Sizes) 09/00/03

Laxative Drug Products
- NPRM (Amendment) (Psyllium Granular Dosage Form) 10/00/03

Nighttime Sleep Aid Products
- Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)

Ophthalmic Products
- Final Action (Technical Amendment) 02/19/03 (68 FR 7919)
- NPRM (Emergency First Aid Eyewashes) 02/19/03 (68 FR 7951)
- Final Action (Name Change) 06/00/03

Oral Health Care Products
- ANPRM (Plaque/Gingivitis) 06/00/03

Pediculicide Products
- NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
- Final Action (Labeling Amendment) 02/00/04

Salicylate (Reye's Syndrome)
- Final Action (Warning) 04/17/03 (68 FR 18861)

Skin Protectant Products
- Final Action 07/00/03
- NPRM (Astringent) 09/00/03
- Final Action (Astringent) 09/00/03

Sunscreen Products
- Final Action (Names) 06/20/02 (67 FR 41821)
- ANPRM (and Insect Repellent) 10/00/03
- NPRM (UVA/UVB) 12/00/03

Vaginal Contraceptive Products
- NPRM (Amendment) 01/16/03 (68 FR 2254)

Weight Control Products
- NPRM (Phenylpropanolamine) 10/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD-560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-2241
Fax: 301 827-2315
Email: rachanow@cder.fda.gov

RIN: 0910–AA01

766. INVESTIGATIONAL USE NEW ANIMAL DRUG REGULATIONS (SECTION 610 REVIEW)

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

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 610; 21 USC 351; 21 USC 353; 21 USC 360b; 21 USC 371; 21 USC 321; 21 USC 352

CFR Citation: 21 CFR 511

Legal Deadline: None

Abstract: FDA is initiating a review of 21 CFR 511.1 under section 610 of the Regulatory Flexibility Act. The purpose of the section 610 review is to determine if the rule should be amended to minimize adverse economic impacts on small entities. FDA will solicit and consider 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
ANPRM	11/21/96 61 FR 59209
ANPRM Comment Period End	01/21/97
Begin Review	04/03/00
End Review	12/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0910–AB02

767. • FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING: CONSUMER RESEARCH TO CONSIDER POSSIBLE FOOTNOTE STATEMENTS

Priority: Other Significant

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

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: This advance notice of proposed rulemaking (ANPRM) is intended to publish in the same issue of the Federal Register as the trans fat final rule that would require that the quantitative amount of trans fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for saturated fat. This ANPRM would solicit information and data on whether to consider footnote statements for possible use in the nutrition label about trans fat, either alone or in combination with saturated fat and cholesterol, to enhance consumers' understanding about such fat in foods and how to use the information to make healthy food choices. FDA is soliciting information and data on language in any such statements and the impact on consumers from such statements. Information obtained from this solicitation and that resulting from consumer studies conducted by FDA may be used to help draft a proposed rule that would require the use of a footnote in the Nutrition Facts panel about one or more of the cholesterol-raising lipids to increase consumer understanding of the relative significance of these lipids in foods.

Timetable:

Action	Date
ANPRM	06/00/03

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Susan Thompson, Chemist, Department of Health and Human Services, Food and Drug Administration, (HFS-832), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Related To 0910-AB66

RIN: 0910–AC50

768. • PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD (SECTION 610 REVIEW)

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, 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.

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
Begin Review	05/00/03

Regulatory Flexibility Analysis Required: Undetermined

HHS—FDA **Prerule Stage**

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
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RIN: 0910–AC58

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

769. 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

CFR Citation: 21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 514; 21 CFR 601; 21 CFR 607; 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 NDC number and would require the electronic submission of most registration and listing information.

Timetable:

Action	Date
NPRM	12/00/03

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–AA49

770. 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 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, and donor suitability and testing. 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
- Direct Final Rule 05/14/99 (64 FR 26282)
- NPRM 05/14/99 (64 FR 26344)
- 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
- NPRM 08/19/99 (64 FR 45355)
- Final Action 06/11/01 (66 FR 31165)

Regulations for Human Blood and Blood Components Intended for Transfusion or For Further Manufacturing Use
- NPRM 01/00/04

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents
- 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
- NPRM 12/00/03

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma
- Direct Final Rule 08/19/99 (64 FR 45366)
- NPRM 08/19/99 (64 FR 45375)
- 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

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
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Fax: 301 594-1944

Related RIN: Related To 0910-AB76

RIN: 0910–AB26

771. 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
NPRM	12/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AB34

772. 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
NPRM	09/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: George Graber, Director, Division of Animal Feeds, Department of Health and Human Services, Food and Drug Administration, HFV-220, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
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RIN: 0910–AB70

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

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

CFR Citation: 21 CFR 111

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) announced in an advance notice of proposed rulemaking (ANPRM) on February 6, 1997 (62 FR 5700), its plans to consider developing regulations establishing current good manufacturing practices (CGMP) for dietary supplements and dietary ingredients. The ANPRM was published in order for FDA to solicit comments on whether it should initiate action to establish CGMP regulations, and if so, what constitutes CGMP for these products. FDA announced that this effort was in response to the section of the Federal Food, Drug and Cosmetic Act (the Act) that provides authority to the Secretary of Health and Human Services to promulgate CGMP regulations and to a submission from the dietary supplement industry asking that FDA consider an industry-proposed CGMP framework as a basis for CGMP regulations. The ANPRM also responds to concerns that such regulations are necessary to ensure that consumers are provided with dietary supplement products which have not been adulterated as a result of manufacturing, packing, or holding; which have the identity and provide the quantity of dietary ingredients declared in labeling; and which meet the quality specifications that the supplements are represented to meet.

Timetable:

Action	Date
ANPRM	02/06/97 62 FR 5700
ANPRM Comment Period End	06/06/97
NPRM	05/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Karen Strauss, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, (HFS-820), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AB88

774. 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-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
NPRM	08/00/03

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, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AB96

775. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Priority: Economically Significant. Major under 5 USC 801.

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

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

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

Legal Deadline: None

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

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

In accordance with discussions at the public meetings, FDA intends to publish a proposed rule to require that shell eggs be produced under a plan that is designed to prevent transovarian SE from contaminating eggs at the farm during production.

FDA intends to discuss in its proposal certain provisions of the 1999 Food Code that are relevant to how eggs are handled, prepared, and served at certain retail establishments. In addition, the agency plans to consider whether it should require provisions for certain retail establishments that serve populations most at risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

Timetable:

Action	Date
NPRM	09/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC14

776. 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
NPRM	08/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

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

777. 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
NPRM	03/00/04

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC19

778. 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 (WHO) 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 pre-clinical 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
NPRM	03/00/04

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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

779. 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; 21 USC 356b; 21 USC 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
NPRM	11/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Aileen Ciampa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFD-7, Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20857

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RIN: 0910–AC23

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

Priority: Other Significant

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

CFR Citation: 21 CFR 50.23

Legal Deadline: None

Abstract: FDA is proposing an amendment to the exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear threat agents.

Timetable:

Action	Date
NPRM	12/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 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 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
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

782. 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	
NPRM	03/31/03	68 FR 15404
NPRM Comment Period End	06/30/03	
Final Rule	12/00/04	

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

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

Priority: Other Significant

Legal Authority: 21 USC 355a

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

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

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

Timetable:

Action	Date
NPRM	09/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC35

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

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

Unfunded Mandates: Undetermined

Legal Authority: PL 107-188, sec 303

CFR Citation: 21 CFR 1

Legal Deadline: None

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 303 of the Bioterrorism Act authorizes the Secretary, through FDA, to order the detention of food if an officer or qualified employee of FDA has credible evidence or information indicating an article of food presents a threat of serious adverse health consequences or death to humans or animals. The Act requires the Secretary, through FDA, to issue final regulations to expedite certain enforcement actions (i.e., seizures and injunctions) against perishable foods.

FDA intends to implement section 303 of the Act by proposing a regulation to provide for: 1) a detention procedure; 2) expedited procedures for enforcement actions with respect to perishable foods; and 3) an appeals procedure for detained goods.

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC38

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

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 107-188, sec 306

CFR Citation: 21 CFR 1

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

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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

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

Priority: Substantive, Nonsignificant

Legal Authority: PL 104-250; 21 USC 360b

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
NPRM	06/00/03

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, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
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Related RIN: Previously reported as 0910-AB50

RIN: 0910–AC43

787. ● 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 601.14; 21 CFR 314.94

Legal Deadline: None

Abstract: The Food and Drug Administration 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
NPRM	09/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Nicole K. Mueller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Room 3037, (HFD-7), 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC52

788. ● 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 (FDA) is proposing to amend its current good manufacturing practice (CGMP) 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
NPRM	02/00/04

Regulatory Flexibility Analysis Required: Undetermined

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–AC53

789. ● 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 (60 FR 47453 and 60 FR 67492). These ANPRMs discussed the agencies' regulations and policy governing food standards, the history of food standards, and the possible need to revise the food standards. Several comments in response to the ANPRMs recommended that the agencies establish general principles or a fundamental philosophy for reviewing food standards and revising them. The agencies agreed with these comments and determined that it would be appropriate to develop general principles for reviewing and revising food standards regulations. The agencies also agreed with the comments that stated that the agencies should work in concert to develop consistent food standards regulations. FDA and FSIS are now proposing a set of general principles that define how modern food standards should be structured. If this

proposed rule is adopted, FDA and FSIS will require that a citizen petition for establishing, revising, or eliminating a food standard in 21 CFR parts 130 to 169 and 7 CFR part 410 be submitted in accordance with the general principles. Conversely, the agencies may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles.

Timetable:

Action	Date	
ANPRM	12/29/95	60 FR 67492
ANPRM Comment Period End	04/29/96	
NPRM	12/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC54

790. ● 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.

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
NPRM	12/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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Related RIN: Previously reported as 0910-AB63

RIN: 0910–AC55

791. ● REVISION OF THE REQUIREMENTS FOR SPORE-FORMING MICROORGANISMS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 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
NPRM-Companion to Direct Final Rule	01/00/04
Direct Final Rule	01/00/04

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), 1401 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC57

792. 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; 21 USC 360j; 21 USC 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
NPRM	11/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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Related RIN: Previously reported as 0910-AC02

RIN: 0910–AC59

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

Food and Drug Administration (FDA)

793. 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.

Timetable:

Current Good Mfg. Practices; Qual. Control Proc.; Quality Factors
NPRM 07/09/96 (61 FR 36154)
NPRM Comment Period End 12/06/96
Final Action 12/00/03

Infant Form Cons Comp, Micro Test & Recd Retention Req
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
NPRM Comment Period End 12/06/96
Final Action 12/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AA04

794. 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	
NPRM	06/19/02	67 FR 41642
Final Action	09/00/03	

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, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AA61

795. 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	
Interim Final Rule	10/05/99	64 FR 54180
Final Action	09/00/03	

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, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AA89

796. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

Priority: Other Significant. 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 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: This regulation is one component of the Secretary's initiative to reduce medical errors. The regulation would amend the regulations governing the format and content of professional labeling for human prescription drug and biologic products, 21 CFR 201.56 and 201.57. The regulation would require that professional labeling include a section containing highlights of prescribing information, and a section containing an index to prescribing information; reorder currently required information and make minor changes to its content, and establish minimum graphical requirements for professional labeling.

Timetable:

Action	Date	
NPRM	12/22/00	65 FR 81082
NPRM Comment Period End	03/22/01	
NPRM Comment Period Reopened	03/30/01	
NPRM Comment Period Reopening End	06/22/01	
Final Action	10/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Audrey Thomas, Regulatory Policy Analyst, 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–AA94

797. 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	
NPRM	06/28/99	64 FR 34608
Final Action	10/00/03	

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

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

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; ...

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: Section 403(q) of the Federal Food, Drug, and Cosmetic Act, which was added by the Nutrition Labeling and Education Act of 1990 (NLEA), requires that the label or labeling of food products bear nutrition information. Among other things, section 403(q) of the Act authorizes the Food and Drug Administration (FDA) to add or delete nutrients that are to be declared on the labels or labeling of food products by regulation if it finds such action necessary to assist consumers in maintaining healthy dietary practices. FDA issued final regulations implementing NLEA in 1993. FDA subsequently received a citizen petition requesting that FDA amend its regulations on food labeling to require that the amount of trans fatty acids be listed in the nutrition label and be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disqualifying levels and disclosure levels. In response to this petition and based on new evidence, FDA proposed the actions requested in the petition on November 17, 1999 (64 FR 62746). In addition, FDA proposed to define the claim ''trans fat free.''

Timetable:

Action	Date	
NPRM	11/17/99	64 FR 62746
NPRM Comment Period Reopened	12/05/00	65 FR 75887
NPRM Comment Period End	01/19/01	
NPRM Comment Period Reopened	11/15/02	
NPRM Comment Period End	12/16/02	
Final Rule	06/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State, Tribal, Local

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

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RIN: 0910–AB66

799. 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)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 21 CFR 606; 21 CFR 610

Legal Deadline: None

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

Timetable:

Action	Date
NPRM	11/16/00 65 FR 69377
NPRM Comment Period End	02/14/01
Final Action	12/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0910–AB76

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

Priority: Other Significant

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; ...

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 is required to be submitted. The rule would require that certain labeing content described under section 201.160(d)(3) be submitted to FDA in electronic format.

Timetable:

Action	Date
NPRM	05/03/02 67 FR 22367
Final Action	09/00/03

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

801. 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, The Children's Health Act of 2000 requires that, within six months of the date of its enactment on October 17, 2000, FDA adopt existing HHS regulations providing additional protections for children involved as subjects in research. FDA published an interim rule in April 2001.

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

Timetable:

Action	Date
Interim Rule	04/24/01 66 FR 20589
Final Rule	12/00/03

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

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

Priority: Other Significant

Legal Authority: 21 USC 321(n); 21 USC 352; 21 USC 355; 21 USC 371(a); 21 CFR 201.51; 21 CFR 201.100; 21 CFR 314.125

CFR Citation: 21 CFR 201.323(c)

Legal Deadline: None

Abstract: The final rule will revise 21 CFR 323(c) to permit small-volume parenterals and pharmacy bulk packages that contain 25 mcg/L or less of aluminum to state ''contains no more than 25 mcg/L'' rather than the exact amount of aluminum.

Timetable:

Action	Date	
NPRM	08/12/02	67 FR 52429
Final Action	06/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC18

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

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 21 CFR 201.25; 21 CFR 601.67

Legal Deadline: None

Abstract: This regulation is one component of the Secretary's initiative to reduce medical errors. The final rule would require human drug products and biological products to have a bar code. The bar code would contain certain information about the product, and when used in conjunction with bar code scanners and computer equipment, would help reduce the number of medication errors. The final rule would also require the use of machine-readable information on blood and blood component container labels.

Timetable:

Action	Date	
NPRM	03/14/03	68 FR 12500
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

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, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-0587
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Email: pchao@oc.fda.gov

RIN: 0910–AC26

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 301 et seq; 21 USC 360kk et seq

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, HFZ-215, Center for Devices and Radiological Health, 1350 Piccard Drive, Rockville, MD 20850
Phone: 301 827-2974
Fax: 301 594-4795
Email: jms@cdrh.fda.gov

RIN: 0910–AC34

805. 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.
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. 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 a foreign facility attempts to import food 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
NPRM	02/03/03 68 FR 5377
Final Rule	10/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

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
Phone: 301 436-2378
Fax: 301 436-2637
Email: leslye.fraser@cfsan.fda.gov

RIN: 0910–AC40

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

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 107-188, sec 307

CFR Citation: 21 CFR 1.276 et seq

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

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

Timetable:

Action	Date
NPRM	02/03/03 68 FR 5428
Final Rule	10/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

URL For More Information:
http://www.fda.gov/ohrms/dockets/98fr/03-2444.pdf

URL For Public Comments:
http://www.fda.gov/dockets/ecomments

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

807. 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
NPRM	08/25/00 65 FR 51782
Final Action	03/00/04

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

Related RIN: Previously reported as 0910-AB68

RIN: 0910–AC44

808. 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.

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

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

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)

Legal Deadline: None

Abstract: The final rule would clarify the types of patents for which information must or must not be submitted to FDA. The final rule would also revise the patent declaration to make it more detailed. The rule would also revise the regulations regarding the approval date for certain abbreviated new drug applications or ''505(b)(2) applications'' by stating that there is only one opportunity for a 30-month stay in the approval date of an ANDA or 505(b)(2) application.

Timetable:

Action	Date	
NPRM	10/24/02	67 FR 65448
NPRM Comment Period End	12/23/02	
Final Rule	05/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jarilyn Dupont, Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning and Legislation (HF-11), 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-3360
Fax: 301 594-6777
Email: jdupont@oc.fda.gov

RIN: 0910–AC48

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 360gg-360ss; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264

CFR Citation: 21 CFR 201.59; 21 CFR 610.21

Legal Deadline: None

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

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: 301 594-1944

RIN: 0910–AC56

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

810. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

Unfunded Mandates: Undetermined

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

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

Legal Deadline: None

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

Timetable:

Action	Date	
NPRM	03/14/03	68 FR 12406
Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Audrey Thomas, Regulatory Policy Analyst, 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: 301 594-2041
Fax: 301 827-5562

RIN: 0910–AA97

811. 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 take actions 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	
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: 301 594-1944

RIN: 0910–AB27

812. 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 264; 42 USC 271

CFR Citation: 21 CFR 1270 and 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	
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: 301 594-1944

RIN: 0910–AB28

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

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 351 to 353; 21 USC 360b; 21 USC 371

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

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) amended its regulations relating to the operational definition of the term ''no residue.'' The definition is used in determining whether any residue of carcinogenic compounds used in food-producing animals would ''be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice'' (21 CFR 500.80(a)). Under the previous operational definition of no residue, it was possible for a residue detected by a method approved by FDA to be considered ''no residue.'' FDA revised its regulations to make them consistent with a 1995 Department of Justice opinion regarding this definition. The changes revised the definition of ''no residue'' to mean that no residue is detected with an approved regulatory method. The rule has several conditions that sponsors of carcinogenic compounds must satisfy with respect to the sponsors' proposed regulatory methods.

Timetable:

Action	Date	
NPRM	01/17/02	67 FR 2384
NPRM Comment Period Ends	04/17/02	
Final Action	12/23/02	67 FR 78172
Next Action Undetermined		

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Steven Brynes, Regulatory Scientist, Department of

Health and Human Services, Food and Drug Administration, HFV-151, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855

Phone: 301 827-6975

Email: sbrynes@cvm.fda.gov

Related RIN: Previously reported as 0910-AC13

RIN: 0910–AC45

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

814. REVISIONS TO THE GENERAL SAFETY REQUIREMENTS FOR BIOLOGICAL PRODUCTS; FINAL RULE

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 610.11(g)

Completed:

Reason	Date
Final Action	03/04/03 68 FR 10157

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Stephen M. Ripley
Phone: 301 827-6210

RIN: 0910–AB51

815. ANTIBIOTIC RESISTANCE LABELING

Priority: Other Significant

CFR Citation: 21 CFR 201.24

Completed:

Reason	Date
Final Rule	02/06/03 68 FR 6062

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0910–AB78

816. RECORDS AND REPORTS CONCERNING EXPERIENCE WITH APPROVED NEW ANIMAL DRUGS

Priority: Other Significant

CFR Citation: 21 CFR 514.80

Completed:

Reason	Date
Final Action	03/31/03 68 FR 15255

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Glenn Peterson
Phone: 301 827-0224
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Email: gpeterso@cvm.fda.gov

Related RIN: Previously reported as 0910-AA02

RIN: 0910–AC42

817. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 320

Completed:

Reason	Date
Final Rule	12/19/02 67 FR 77668

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Christine F. Rogers
Phone: 301 594-2041
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Related RIN: Previously reported as 0910-AA51

RIN: 0910–AC47

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

818. 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
NPRM	12/24/98 63 FR 71255
NPRM Comment Period End	02/22/99
Second NPRM	05/00/03

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, Public Health Service, Suite 300, 7519 Standish Place, Rockville, MD 20957

HHS—HRSA **Proposed Rule Stage**

Phone: 301 443-2300
Fax: 301 443-6725

RIN: 0906–AA41

819. 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 (MUPs) and Primary Care Health Professional Shortage Areas (HPSAs). This notice of proposed rulemaking (NPRM) will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

Action	Date	
NPRM	09/01/98	63 FR 46538
NPRM Comment Period End	01/04/99	
Second NPRM	10/00/03	

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)

Long-Term Actions

820. 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 (NPDB).

Timetable:

Action	Date	
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, Public Health Service, 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)

Final Rule Stage

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

Priority: Info./Admin./Other

Legal Authority: 25 USC 3201 et seq

CFR Citation: 42 CFR 36

Legal Deadline: None

Abstract: The Indian Health Service (IHS) is proposing to establish regulations as mandated by the Indian Child Protection and Family Violence Protection Act, Public Law 101-630, 25 U.S.C. 3201 to 3211, that prescribe minimum standards of character for individuals whose duties and responsibilities involve regular contact with, or control over, Indian children.

Timetable:

Action	Date	
NPRM	03/25/99	64 FR 14559
NPRM Comment Period End	07/26/99	
Final Action	10/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Tribal

Agency Contact: Ramona D. Williams, Child Protection Coordinator, Department of Health and Human Services, Indian Health Service, Suite 605, 12300 Twinbrook Parkway, Rockville, MD 20852
Phone: 301 443-1589

RIN: 0917–AA02

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

Proposed Rule Stage

822. 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 the NIH. For each year of scholarship support, the recipient agrees to service (employment) after graduation, at the NIH, for one year. Additionally, the individual agrees to at least 10 consecutive weeks of service (employment) at the 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
NPRM	09/00/03

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

823. NATIONAL INSTITUTES OF HEALTH (NIH) 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 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 that authorizes the Director of National Institute of Child Health and Human Development (NICHHD) in consultation with the Administrator of Health Resources and Services Administration (HRSA), to support activities to provide for an increase in the number and size of institutional training grants supporting pediatric training.

Timetable:

Action	Date
NPRM	09/00/03

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

824. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 287a-3a

CFR Citation: 42 CFR 59

Legal Deadline: NPRM, Statutory, June 18, 2001.

Abstract: The National Institutes of Health proposes to establish standards for operating a national chimpanzee sanctuary system to provide for the permanent retirement of federally-owned or supported chimpanzees no longer needed for research.

Timetable:

Action	Date
NPRM	09/00/03

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

825. NATIONAL INSTITUTES OF HEALTH (NIH) 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
NPRM	09/00/03

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

826. ● 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: The National Institutes of Health 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
NPRM	09/00/03

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

827. ● 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: The National Institutes of Health 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
NPRM	09/00/03

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

828. ● LOAN REPAYMENT PROGRAM FOR HEALTH DISPARITIES RESEARCH

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 68f

Legal Deadline: None

Abstract: The National Institutes of Health 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 research on minority health or other health disparities for a minimum of two years.

Timetable:

Action	Date
NPRM	09/00/03

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

829. ● 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: The National Institutes of Health 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.

Timetable:

Action	Date
NPRM	09/00/03

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

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

830. 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
NPRM	08/05/02 67 FR 50622
Final Rule	09/00/03

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

831. 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 regulations on research misconduct. These regulations, which govern the first level of review, are being amended to reflect current policies and procedures.

Timetable:

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

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

832. NATIONAL INSTITUTES OF HEALTH (NIH) CENTER GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; PL 106-310; PL 106-505; PL 106-525

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 (PHS 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
NPRM	11/12/02 67 FR 68548
Final Rule	09/00/03

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

833. PUBLIC HEALTH SERVICES 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
NPRM	08/00/03
NPRM Comment Period End	10/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

Related RIN: Related To 0940-AA01

RIN: 0940–AA04

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

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart F to Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, to require registration of institutional review boards (IRBs) with HHS. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS and other Federal agencies, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for 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
NPRM	07/00/03
NPRM Comment Period End	09/00/03

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
Email: istithco@osophs.dhhs.gov

RIN: 0940–AA06

835. • 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 Department of Health and Human Services (DHHS) 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
NPRM	07/00/03
NPRM Comment Period End	09/00/03

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

836. 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	
NPRM	11/28/00	65 FR 70830
NPRM Comment Period End	01/29/01	
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

Related RIN: Related To 0940-AA04

RIN: 0940–AA01

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

Proposed Rule Stage

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

Priority: Other Significant

Legal Authority: 42 USC 1395rr

CFR Citation: 42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410; 42 CFR 412, 42 CFR 413, 414; 42 CFR 488; 42 CFR 489; 42 CFR 494

Legal Deadline: None

Abstract: This proposed rule would revise the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

Timetable:

Action	Date
NPRM	09/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Robert Miller, 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 21244-1850
Phone: 410 786-6797
Email: rmiller@cms.hhs.gov

Teresa Casey, Health Insurance Specalist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-05-04, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7215

RIN: 0938–AG82

838. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR CERTIFICATION AND RECERTIFICATION OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTS (CMS-3835-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would establish conditions of participation for Medicare-covered transplants.

Timetable:

Action	Date
NPRM	09/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Eva Fung, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-06-6, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-7539

Aucha Prachanronarong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9614

RIN: 0938–AH17

839. 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
NPRM	10/00/03

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, 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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6617

RIN: 0938–AH27

840. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, 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 DMEPOS suppliers 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
NPRM	11/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1302

RIN: 0938–AJ98

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

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302; 42 USC 1396d

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

Legal Deadline: None

Abstract: This proposed rule would revise the conditions of participation for ICFs/MR. We would set forth these new requirements that ICFs/MR must meet to adhere to current trends in the field of developmental disabilities. It would address recent developments in some facilities in the District of Columbia to further protect the health and safety of this vulnerable population.

Timetable:

Action	Date
NPRM	12/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-04-26, Office of Clinical Standards & Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5646
Email: apanicker@cms.hhs.gov

RIN: 0938–AK23

842. 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.

Abstract: This rule proposes an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act (HIPAA) of 1966. It would be used to transmit clinical data, beyond those data contained in the claims standard, to help establish medical necessity for coverage.

Timetable:

Action	Date
NPRM	01/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State, Local, Federal, 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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6999

RIN: 0938–AK62

843. 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

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 412106

Legal Deadline: None

Abstract: This proposed rule would revise applicable regulations to clarify certain issues in the calculation of Medicaid patient days and total patient days. It describes the criteria to use in calculating the Medicare DSH adjustment for hospitals for purposes of payment under the hospital inpatient prospective payment system.

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Stephen Phillips, Deputy Division Director, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-

07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4548

RIN: 0938–AK77

844. ELIMINATION OF STATEMENT OF INTENT PROCEDURES FOR FILING MEDICARE CLAIMS (CMS-1185-P)

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 proposed 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
NPRM	07/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: State, Federal

Federalism: Undetermined

Agency Contact: David Walczak, Center for Health Plans and Providers, Plan and Provider Purchasing Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4475

RIN: 0938–AK79

845. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS-3064-P)

Priority: Other Significant

Legal Authority: 42 USC 1320b-8(b)(1)(A)(i); 42 USC 273(b)(2)

CFR Citation: 42 CFR 486.301

Legal Deadline: Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

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

Timetable:

Action	Date
Interim Final Rule	12/28/01 66 FR 67109
Proposed Rule	09/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jacqueline Morgan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4282

RIN: 0938–AK81

846. EXTENDING MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENTITLEMENT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS-4018-P)

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 406.12

Legal Deadline: None

Abstract: This proposed rule would implement the Ticket to Work and Work Incentives Improvement Act of 1999. It would provide 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
NPRM	07/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Denise Cox, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3195

RIN: 0938–AK94

847. UPDATE INTEREST ASSESSMENT ON MEDICARE OVERPAYMENT AND UNDERPAYMENT (CMS-6014-P)

Priority: Other Significant

Legal Authority: Social Security Act, sec 1815(d); Social Security Act, sec 1833(j)

CFR Citation: 42 CFR 405.378

Legal Deadline: None

Abstract: This proposed rule would change the formula for computing interest on provider and supplier overpayments and underpayments to make it consistent with the new CMS accounting system (HIGLAS).

Timetable:

Action	Date
NPRM	08/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Paul Thomas Reed, Financial Management Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3-15-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4001
Email: preed2@cms.hhs.gov

RIN: 0938–AL14

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

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

Unfunded Mandates: Undetermined

Legal Authority: PL 105-554, Children's Health Act of 2000

CFR Citation: Not Yet Determined

Legal Deadline: None

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

Timetable:

Action	Date
NPRM	11/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Frank Sokolik, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-13-23, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-7089

RIN: 0938–AL26

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

Priority: Other Significant

Legal Authority: 42 CFR 1302; 42 CFR 1395hh; 42 CFR 1395rr(b)(1); PL 103-66

CFR Citation: 42 CFR 414

Legal Deadline: None

Abstract: This rule would remove respiratory assist devices with bi-level capability and a back-up rate from the category of items requiring frequent and substantial servicing, as defined in section 1834 (a)(3) of the Act, and place them in the category for other items, or capped rental items, as defined in section 1834(a)(7) of the Act. This rule would correct an error that occurred in 1992, when these devices were inappropriately placed in the category for items requiring frequent and substantial servicing.

Timetable:

Action	Date
NPRM	07/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Joel Kaiser, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4499

RIN: 0938–AL27

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850. PERMITTING PREMIUM REDUCTIONS AS ADDITIONAL BENEFITS UNDER MEDICARE+CHOICE PLANS (CMS-6016-P)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 408.ff

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

Abstract: This proposed rule implements section 606 of BIPA to allow M+C organizations to elect a reduction in capitation payments so that these organizations could offer Medicare part B premium reductions to enrollees.

Timetable:

Action	Date
NPRM	08/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State, Local, Federal

Agency Contact: Michele Sanders, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0808

RIN: 0938–AL49

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851. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FY 2004(CMS-1213-P)

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

Legal Authority: PL 106-113, sec 124

CFR Citation: 42 CFR 412, subpart N

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

Abstract: This proposed rule would set forth a prospective payment system for inpatient psychiatric facilities and psychiatric units.

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State, Local, Federal

Agency Contact: Lana Price, Director, Division of Chronic Care Management, Chronic Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4533

RIN: 0938–AL50

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852. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS-1727-P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1878 of the Social Security Act

CFR Citation: Not Yet Determined

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
NPRM	11/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Morton Marcus, Department of Health and Human

Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4477

RIN: 0938–AL54

853. SCHIP; PURCHASE OF FAMILY COVERAGE—BENEFIT FLEXIBILITY IN PARENT COVERAGE (CMS-2148-P)

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 2110

CFR Citation: 42 CFR 457

Legal Deadline: None

Abstract: This proposed rule would provide flexibility to States in defining their benefit package for adults covered under the State Children's Health Insurance Program (SCHIP) family coverage options.

Timetable:

Action	Date
NPRM	01/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Stacey Bush, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6102

RIN: 0938–AL62

854. REQUEST FOR INFORMATION ON BENEFIT-SPECIFIC WAITING PERIODS (CMS-2150-NC)

Priority: Info./Admin./Other

Legal Authority: None

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
NPRM	09/00/03

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6851

RIN: 0938–AL64

855. DMERC SERVICE AREAS AND RELATED MATTERS (CMS-1219-P)

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 1842; Social Security Act, sec 1834(a)(12); Social Security Act, sec 1834(h)(3); Social Security Act, sec 1834(j)(1)(E)

CFR Citation: 42 CFR 421.210

Legal Deadline: None

Abstract: This proposed rule would allow flexibility in making changes to the DMERC contractor structure.

Timetable:

Action	Date
NPRM	12/00/03

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-2289

RIN: 0938–AL76

856. 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 where possible.

Timetable:

Action	Date
NPRM	04/00/04

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, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5526

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

RIN: 0938–AL80

857. MEDICAID COVERAGE RULES FOR INMATES OF PUBLIC INSTITUTIONS (CMS-2077-P)

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

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act, sec 1905(a)(A)

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

Legal Deadline: None

Abstract: This proposed rule would provide a new interpretation of the statute in order to eliminate confusion among the States and to ensure consistent application of the FFP exclusionary rules for services provided to inmates of a public institution.

Timetable:

Action	Date
NPRM	03/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State, Local

Agency Contact: Tom Shenk, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3295

RIN: 0938–AL85

858. TARGETED CASE MANAGEMENT (CMS-2061-P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1915(g) of the Social Security Act

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

Legal Deadline: None

Abstract: This proposed rule would amend the Medicaid regulations to provide for optional coverage of case management services furnished to specific groups, geographic areas, or political subdivisions within a State. This proposed rule rescinds the proposed rule that was published on October 15, 1993.

Timetable:

Action	Date
NPRM	03/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Kathy Poisal, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5940

RIN: 0938–AL87

859. 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
NPRM	09/00/03

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6851

RIN: 0938–AL88

860. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2004 RATES (CMS-1470-P)

Priority: Economically Significant. Major under 5 USC 801.

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

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

Legal Deadline: NPRM, Statutory, April 1, 2003.
Final, Statutory, August 1, 2003.

Abstract: This proposed rule would revise the Medicare acute hospital inpatient prospective payment systems for operating and capital related costs to implement changes arising from our continuing experience with these systems. These changes apply to discharges occurring on or after October 1, 2003.

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-1304

Steve Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6656

RIN: 0938–AL89

861. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2004 (CMS-1469-P)

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, April 1, 2003.
Final, Statutory, July 31, 2003, final rule to be published before August 1, 2003.

Abstract: This annual proposed rule would update the payment rates used under the skilled nursing facilities prospective payment system beginning October 1, 2003.

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: William Ullman, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 401 786-5667

RIN: 0938–AL90

862. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS-1471-P)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1395L; BBA'97; BBRA'99; BIPA'00

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule proposes to revise the Medicare hospital outpatient payment system beginning January 1, 2004.

Timetable:

Action	Date
NPRM	06/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Cindy Read, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1852

RIN: 0938–AL91

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

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: Other, Statutory, June 28, 2003, notice must be published by the June 28, 2003, deadline in order to meet the statutory effective date of October 1, 2003.

Abstract: This notice with comment period sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies for FY 2004.

Timetable:

Action	Date
Notice	06/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Susan Levy, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-08-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9364

RIN: 0938–AL94

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

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395W-4

CFR Citation: 42 CFR 410; 42 CFR 414

Legal Deadline: None

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

Timetable:

Action	Date
NPRM	06/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Latesha Walker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1101

RIN: 0938–AL96

865. MEDICAID HOME AND COMMUNITY-BASED SERVICES WAIVERS (CMS-2162-P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1915(c) of the Social Security Act

CFR Citation: 42 CFR 441.300

Legal Deadline: None

Abstract: This proposed rule incorporates New Freedom Initiative recommendations/proposals into the HCBS waiver program to allow States greater flexibility in creating community-based long term care alternatives for eligible persons.

Timetable:

Action	Date
NPRM	03/00/04

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Mary Clarkson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5918

RIN: 0938–AM05

866. REVISIONS TO AVERAGE WHOLESALE PRICE METHODOLOGY (CMS-1229-P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1842(o) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would propose revisions to the source and methodology for determining the average wholesale price (AWP) of drugs covered by Medicare incident to a physician's service.

Timetable:

Action	Date
NPRM	07/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Robert Niemann, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4569

RIN: 0938–AM12

867. 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: Social Security Act, sec 1861(s)(2)(B)

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
NPRM	11/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Robert Niemann, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4569

RIN: 0938–AM13

868. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS-0008-IFC)

Priority: Other Significant

Legal Authority: PL 107-105

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed 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
NPRM	07/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Elizabeth Holland, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1309

RIN: 0938–AM22

869. MEDICAID ESTATE RECOVERIES (CMS-2083-P)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would require States to seek adjustment or recovery from the estates of Medicaid beneficiaries for amounts correctly spent by Medicaid on permanently institutionalized individuals (any age) and aged 55 or older for certain services.

Timetable:

Action	Date
NPRM	01/00/04

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Ingrid Osborne, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-16-25, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4461

RIN: 0938–AM30

870. ● PHYSICIAN OWNERSHIP IN SPECIALTY HOSPITALS (CMS-1240-P)

Priority: Substantive, Nonsignificant

Legal Authority: PL 101-239, OBRA 1989; PL 101-508, OBRA 1990; PL 103-66, OBRA 1993; PL 103-432, Social Security Act Amendments of 1994

CFR Citation: 42 CFR 411

Legal Deadline: None

Abstract: This proposed rule would revise the regulations to specify that, for purposes of the physician self-referral prohibition, certain physician ownership or investment interests in specialty hospitals would not qualify for the ''whole hospital'' exception. In addition, this proposed rule would amend the definitions of ''radiology and certain other imaging services'' and ''radiation therapy services and supplies'' to include diagnostic and therapeutic nuclear medicine services and supplies, respectively.

Timetable:

Action	Date
NPRM	07/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jackie Proctor, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-8852

RIN: 0938–AM35

871. ● PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS-3119-P)

Priority: Routine and Frequent

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 rule would establish the procedures to be used for maintaining the lists of codes that were included in the national coverage determinations (NCDs) announced in the Federal Register on November 25, 2001 (66 FR 58788).

Timetable:

Action	Date
NPRM	09/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jacqueline Sheridan, Office of Clinical Standards and Quality, Department of Health and

Human Services, Centers for Medicare . Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4635

RIN: 0938–AM36

872. ● HOSPITAL PATIENTS' RIGHTS COP—STANDARD SAFETY COMPLIANCE COMMITTEES (CMS-3120-P)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would allow hospitals to waive the current requirement that a physician or licensed independent practitioner perform a one-hour face-to-face evaluation of a patient in restraint or seclusion for the purpose of behavior management. Under this proposed rule, a hospital could choose to have the one-hour assessment performed by another practitioner, such as a registered nurse, if that hospital established a Protections Compliance Committee to oversee the use of restraint or seclusion

Timetable:

Action	Date
NPRM	07/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Undetermined

Federalism: Undetermined

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: 401 786-0596

RIN: 0938–AM39

873. ● AMBULANCE FEE SCHEDULE CONDITION CODES (CMS-1247-P)

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

Unfunded Mandates: Undetermined

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

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule would propose the creation of condition codes to be used in billing for ambulance services.

Timetable:

Action	Date
NPRM	03/00/04

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Don Thompson, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-10-26, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4586

RIN: 0938–AM45

874. ● PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2005 (CMS-1249-P)

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, Requires the final rule to be published by August 1, 2004.

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
NPRM	03/00/04

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: William Ullman, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 401 786-5667

RIN: 0938–AM46

875. ● 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 HIPPA.

Timetable:

Action	Date
NPRM	02/00/04

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal, Federal

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

876. ● 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

HHS—CMS **Proposed Rule Stage**

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
NPRM	10/00/03

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

877. ● REQUIREMENTS FOR NURSING HOMES TO IDENTIFY THE NUMBER OF LICENSED AND UNLICENSED NURSING STAFF PER SHIFT (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 BIPA, 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
NPRM	12/00/03

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: 401 786-0596

RIN: 0938–AM55

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

Final Rule Stage

878. 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	
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Final Rule	12/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Mercedes Benitex-McCray, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5716

Steve Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6656

RIN: 0938–AG81

879. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIERS (CMS-6017-F)

Priority: Other Significant. Major under 5 USC 801.

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

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

CFR Citation: 45 CFR 160; 45 CFR 162

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

Abstract: This final rule implements a standard identifier to identify health plans that process and pay certain electronic health care transactions. It implements one of the requirements for administrative simplification in section 262 of the Health Insurance Portability & Accountability Act of 1996.

Timetable:

Action	Date
Final Action	08/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

Agency Contact: Helen Dietrick, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1-07-17, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-7448

RIN: 0938–AH87

880. 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.

Abstract: This final rule establishes a standard unique ID 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	
NPRM	05/07/98	63 FR 25320
NPRM Comment Period End	07/06/98	
Final Action	07/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal, State, Local, 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

881. 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. We 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	
NPRM	10/25/99	64 FR 57431
Final Rule	01/00/04	

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
Email: rgoldberg@cms.hhs.gov

RIN: 0938–AI49

882. COVERAGE OF RELIGIOUS NON-MEDICAL 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; 42 CFR 440.170; 42 CFR 488.2; 42 CFR 488.6; 42 CFR 489.102; 42 CFR 412.90; 42 CFR 412.98; 42 CFR 431.610; 42 CFR 440.155; 42 CFR 442.12; 42 CFR 456.351; 42 CFR 456.601; 42 CFR 476.1

Legal Deadline: Final, Statutory, July 1, 1998, BBA, section 4454(d).

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

Timetable:

Action	Date	
Interim Final Rule	11/30/99	64 FR 67028
Final Action	09/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0938–AI93

883. 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	
Interim Final Rule	01/25/99	64 FR 3748
Final Rule	12/00/03	

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: Mercedes Benitex-McCray, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5716

RIN: 0938–AJ10

HHS—CMS **Final Rule Stage**

884. 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. 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	
NPRM	02/28/00	65 FR 10450
Final Rule	06/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: David Worgo, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-15-18, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5919

RIN: 0938–AJ17

885. 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	
NPRM	11/16/00	65 FR 69416
Final Rule	11/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Mary Collins, OCSQ, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3189

RIN: 0938–AJ29

886. MEDICARE HOSPICE CARE AMENDMENTS (CMS-1022-F)

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

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	
NPRM	11/22/02	67 FR 70363
Final Action	01/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Thomas Saltz, Bureau of Policy Development, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4480

Related RIN: Previously reported as 0938-AH73

RIN: 0938–AJ36

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

Priority: Economically Significant

Legal Authority: 42 USC 1302; 42 USC 1396d

CFR Citation: 42 CFR 441; 42 CFR 483

Legal Deadline: None

Abstract: This final rule addresses standards of practices that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints and seclusion.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Larry Cutler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5903

RIN: 0938–AJ96

888. 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 1395.l(a); 42 USC 1395.l(i); 42 USC 1395.l(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	
NPRM	02/10/03	68 FR 6682
NPRM Comment Period End	04/11/03	
Final Action	11/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Katie Walker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-7278

RIN: 0938–AK02

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

Priority: Other Significant

Legal Authority: PL 100-578

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This rule finalizes certain laboratory requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Timetable:

Action	Date	
Final Rule	01/24/03	68 FR 3640
Notice	06/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Cecelia Hinkel, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services
Phone: 410 786-3347

RIN: 0938–AK24

890. 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, The effective date for regulation changes is October 1, 2001.

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	
NPRM	08/22/02	67 FR 54534
NPRM Comment Period End	10/21/02	
Final Action	09/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

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

891. REVISED PROCESS FOR MAKING MEDICARE COVERAGE DETERMINATIONS (NCDS) (CMS-3062-N)

Priority: Other Significant

Legal Authority: Sec 522 of the BIPA

CFR Citation: None

Legal Deadline: Other, Statutory, October 1, 2001, Revision notice.

Abstract: This notice will announce a revised process for making Medicare NCDs. It implements section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). (The statute requires this notice be effective by October 1, 2001.)

Timetable:

Action	Date
Notice	07/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal

Agency Contact: Vadim Lubarsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0840

RIN: 0938–AK61

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

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

Legal Authority: 42 USC 1877

CFR Citation: 42 CFR 411

HHS—CMS **Final Rule Stage**

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
Final Action	06/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer, Technical Advisor, CMM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4620

RIN: 0938–AK67

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893. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS-3055-F)

Priority: Economically Significant

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 (QIOs). Our current regulations identify the photocopying reimbursement methodology for prospective payment system hospitals.

Timetable:

Action	Date	
NPRM	11/22/02	67 FR 70358
Final Rule	10/00/03	

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7223

RIN: 0938–AK68

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894. MODIFICATIONS TO MEDICARE MANAGED CARE RULES (CMS-4041-F)

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

Legal Authority: BIPA, sec 605; BIPA, sec 606; BIPA, sec 612; BIPA, sec 615 to 617; BIPA, sec 620; BIPA, sec 621; BIPA, sec 623

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

Legal Deadline: None

Abstract: This final rule implements certain Medicare payment provisions of the Benefits and Improvement Act of 2000. Policy changes include premium reductions for M+C enrollees, uniform coverage for M+C plans in multiple locations, eliminating health disparities, ESRD enrollees, and increased civil money penalties for M+C organizations that terminate contracts mid-year. It also describes CMS's authority to waive or modify requirements that hinder the design of, or enrollment, in the M+C plans offered to employees or labor unions.

Timetable:

Action	Date	
NPRM	10/25/02	67 FR 65672
Final Rule	07/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Additional Information: CMS-4041-P was previously identified as CMS-1180-P.

Agency Contact: Patricia Kurtz, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4670

RIN: 0938–AK71

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895. MODIFICATIONS TO THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM (CMS-2006-F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 105-33

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

Legal Deadline: None

Abstract: This final rule finalizes the June 25, 2001, interim final rule that revised certain provisions of the January 11, 2001, final rule on the State Children's Health Insurance Program (SCHIP). This final rule responds to public comments and makes further refinements to the SCHIP.

Timetable:

Action	Date	
Interim Final Rule	06/25/01	66 FR 33810
Interim Final Rule Comment Period End	07/26/01	
Interim Final Rule Effective	08/24/01	
Final Rule	08/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

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

Agency Contact: Cheryl Austein-Casnoff, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4196

RIN: 0938–AL00

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896. REQUIREMENTS FOR PAID FEEDING ASSISTANTS IN LONG-TERM CARE FACILITIES (CMS-2131-F)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1819(a) to (f) of the Social Security Act; sec 1919(a) to (g) of the Social Security Act; PL 100-203

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

Legal Deadline: None

Abstract: This rule will allow long-term care facilities to use paid feeding assistants to supplement the services of

certified nurse aides. If facilities choose this option, feeding assistants must complete a specified training program.

Timetable:

Action	Date
NPRM	03/29/02 67 FR 15149
NPRM Comment Period End	05/28/02
Final Rule	08/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: Nola Petrovich, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4671

RIN: 0938–AL18

897. 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 notice requests information on the use of benefit-specific waiting periods by group health plans and group health insurance issuers.

Timetable:

Action	Date
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	09/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6851

RIN: 0938–AL43

898. INTERIM FINAL AMENDMENT FOR MENTAL HEALTH PARITY (CMS-2152-IFC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 2705; PL 107-116; PL 104-191

CFR Citation: 45 CFR 146.136

Legal Deadline: None

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

Timetable:

Action	Date
Interim Final Rule	11/22/97 62 FR 66932
Interim Final Rule Effective	01/01/98
Interim Final Rule Comment Period End	03/23/98
Interim Final Rule	07/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State, Local

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6851

RIN: 0938–AL44

899. ELECTRONIC SUBMISSION OF COST REPORTS (CMS-1199-F)

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 1815(a); Social Security Act, sec 1833(e)

CFR Citation: 42 CFR 413.24

Legal Deadline: None

Abstract: This final rule establishes the requirement for ESRD facilities, hospices, rural health clinics, federally qualified health centers, and community mental health centers to file cost reports in a standardized electronic format. It provides a delay or waiver of this requirement if implementation would result in financial hardship. The provisions of this rule allow for more accurate preparation and more efficient processing of each cost report.

Timetable:

Action	Date
NPRM	07/26/02 67 FR 48840
Final Action	05/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Thomas Talbott, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-01-01, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4592

RIN: 0938–AL51

900. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS-4004-F)

Priority: Other Significant

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 405

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

Abstract: This final regulation incorporates recommendations from an SSA/HHS workgroup to improve the Administrative Law Judge (ALJ) hearing process. ALJ-conducted hearings for Medicare fee-for-service and managed care cases are governed by SSA disability regulations which apply to SSA disability cases, not to Medicare. Regulations improve the integrity of the appeals process, because they are specific to the adjudication of Medicare cases. They also incorporate the revisions to appeals policy required by section 521 of BIPA.

Timetable:

Action	Date
NPRM	11/15/02 67 FR 69312
Final Rule	09/00/03

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Michale Edmondson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6478

RIN: 0938–AL67

901. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS; FEDERAL FISCAL YEAR 2002 (CMS-2136-FN)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Social Security Act, sec 1902(a)(10); Social Security Act, sec 1933; 42 USC 139; PL 105-33

CFR Citation: None

Legal Deadline: None

Abstract: This final notice announces the Federal FY 2002 allotments that are available for State agencies to pay Medicare part B premiums for two distinct categories of low-income Medicare beneficiaries. The eligible groups are called qualified individuals.

Timetable:

Action	Date
Notice	08/30/02 67 FR 55851
Final Action	08/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Robert Nakielny, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4466

RIN: 0938–AL79

902. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS FOR FY 2004 (CMS-1472-P)

Priority: Substantive, Nonsignificant

Legal Authority: BBRA 1999, sec 123; BIPA 2000, sec 307(b)

CFR Citation: 42 CFR 412; 42 CFR 413

Legal Deadline: None

Abstract: This rule updates the Prospective Payment System for Medicare payment of long-term care hospitals. It implements section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

Timetable:

Action	Date
NPRM	03/07/03 68 FR 11234
Final Rule	05/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-1304

RIN: 0938–AL92

903. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS FOR FY 2004 (CMS-1474-F)

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 1886(j); PL 105-33; PL 106-554; PL 106-113

CFR Citation: 42 CFR 412 to 413

Legal Deadline: None

Abstract: This proposed rule will update rates for the prospective payment system for inpatient rehabilitation facilities for FY 2004.

Timetable:

Action	Date
Final Rule	08/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Robert Kuhl, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4597

Related RIN: Related To 0938-AM57

RIN: 0938–AL95

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

Priority: Substantive, Nonsignificant

Legal Authority: PL 105-33, Sec 4321 of the BBA

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule establishes a process for collecting and maintaining information about hospitals referring Medicare patients to home health agencies (HHAs) with which the hospitals have a financial interest. Moreover, collected information will be available to the public to enhance its understanding and awareness of the availability of Medicare-certified HHAs to serve the Medicare population.

Timetable:

Action	Date
NPRM	11/22/02 67 FR 70373
Final Action	10/00/03

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Elizabeth Carmody, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-10-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7533

RIN: 0938–AM01

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

Priority: Other Significant

Legal Authority: 1883(i)(l) and (2) of the Social Security Act

CFR Citation: 42 CFR 416

Legal Deadline: None

Abstract: This final rule makes final the proposed additions to, and deletions from, the current list of Medicare covered Ambulatory Surgical Centers procedures.

Timetable:

Action	Date
Final Action	05/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Bob Cereghino, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-03-06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4645

Related RIN: Related To 0938-AH81

RIN: 0938–AM02

906. NONDISCRIMINATION IN HEALTH COVERAGE IN THE GROUP MARKET (CMS-2022-F)

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

Legal Authority: 42 USC 300gg

CFR Citation: 45 CFR 146.121

Legal Deadline: None

Abstract: This document contains final rules governing the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan.

Timetable:

Action	Date	
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/17/97	
Interim Final Rule Effective	07/17/97	
Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Effective	03/09/01	
Interim Final Rule Comment Period End	04/09/01	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Local

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6851

RIN: 0938–AM14

907. BONA FIDE WELLNESS PROGRAMS (CMS-2078-F)

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

Legal Authority: 42 USC 300gg

CFR Citation: 45 CFR 146.121(f)

Legal Deadline: None

Abstract: This final rule implements and clarifies the term ''bona fide wellness program'' as it relates to regulations implementing the nondiscrimination provisions of the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act, as added by the Health Insurance Portability and Accountability Act of 1996.

Timetable:

Action	Date	
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	
NPRM	01/08/01	66 FR 1421
NPRM Comment Period End	04/09/01	
Final Action	03/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Local

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6851

Related RIN: Related To 0938-AK91

RIN: 0938–AM15

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

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

Legal Authority: 42 USC 1396r-8

CFR Citation: 42 CFR 447.534

Legal Deadline: None

Abstract: This rule will establish a three year time limitation on drug manufacturer's requests to recalculate their drug prices for the purposes of reporting data to CMS, as well as manufacturer's ability to dispute claims for rebates.

Timetable:

Action	Date
Final Rule	08/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Federalism: Undetermined

Agency Contact: Marge Lee Watchorn, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1-01-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4361

RIN: 0938–AM20

909. 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.

Abstract: This final rule implements a standard identifier to identify health plans that process and pay certain electronic health care transactions. It implements one of the requirements for administrative simplification in section 262 of the Health Insurance Portability & Accountability Act of 1996.

HHS—CMS **Final Rule Stage**

Timetable:

Action	Date
Notice	10/00/03

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6390

RIN: 0938–AM31

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

Priority: Other Significant

Legal Authority: 42 CFR 1395r; Social Security Act, Sec 1839

CFR Citation: 42 CFR 407; 42 CFR 408

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

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 also announces the monthly SMI premium to be paid by all enrollees during 2004.

Timetable:

Action	Date
Notice	10/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carter S. Warfield, Office of Medicare and Medicaid Cost Estimates, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3-26-00, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6396

RIN: 0938–AM32

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911. 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.

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
Notice	10/00/03

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6390

RIN: 0938–AM33

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

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This regulation will clarify special responsibilities of Medicare hospitals that offer services for treatment of emergency medical conditions, to promote consistent application of the Emergency Medical Treatment and Labor Act to situations not discussed in current regulations.

Timetable:

Action	Date
Final Rule	05/00/03

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rebecca Hirshorn, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-06-06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3411

Related RIN: Related To 0938-AL23

RIN: 0938–AM34

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

Priority: Routine and Frequent

Legal Authority: 42 USC 139bb

CFR Citation: None

Legal Deadline: None

Abstract: This final notice announces our decision to approve JCAHO for continued recognition as a national accreditation program for hospices that wish to participate in Medicare.

Timetable:

Action	Date	
NPRM	01/24/03	68 FR 3532
NPRM Comment Period End	03/24/03	
Final Action	05/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Cindy Melanson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-12-25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0310

RIN: 0938–AM38

914. ● 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.

Legal Authority: 42 USC 1102 of the Social Security Act; 42 USC 1871 of the Social Security Act

CFR Citation: 42 CFR 412.84; 42 CFR 412.116

Legal Deadline: None

Abstract: This proposed rule would change the methodology for determining payments for extraordinarily high-cost cases (cost outliers) made to Medicare-participating hospitals under the acute care hospital inpatient prospective payment system. We have become aware that, in some cases, hospitals' recent rates of charge increases greatly exceed their rates of cost increases. This disparity results in their cost-to-charge ratios being set too high, which in turn results in overestimation of their current costs per case. Therefore, we need to make revisions to our outlier payment methodology to correct those situations in which hospitals would otherwise receive overpayments for outlier cases due to excessive charge increases.

Timetable:

Action	Date	
NPRM	03/05/03	68 FR 10420
NPRM Comment Period End	04/04/03	
Final Action	05/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Stephen Phillips, Deputy Division Director, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4548

RIN: 0938–AM41

915. ● FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES UPDATE FOR CY 2004 (CMS-1232-N)

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
Notice	11/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anne Tayloe, Health Insurance Speacialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0000

RIN: 0938–AM44

916. ● EXCLUSION OF MEDICARE BENEFITS FOR ALIENS NOT LAWFULLY PRESENT IN THE UNITED STATES (CMS-1222-IFC)

Priority: Substantive, Nonsignificant

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 interim final rule amends regulations to prohibit Medicare benefits to an alien who is not lawfully present in the United States. Section 5561 of the BBA 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
Interim Final Rule	09/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Frederick William Grabau, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD
Phone: 410 786-0206

RIN: 0938–AM47

917. ● HOSPICE WAGE INDEX FOR FY 2004 (CMS-1233-N)

Priority: Routine and Frequent

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 418.306(C)

Legal Deadline: None

Abstract: This notice will announce the annual update to the hospice wage index. The update is effective October 1, 2003, through September 30, 2004. 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 was originally published on August 8, 1997.

Timetable:

Action	Date
Notice	08/00/03

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Carol Blackford, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5909
Email: cblackford@hcfa.gov

RIN: 0938–AM56

918. ● ANNOUNCEMENT OF APPLICATIONS FROM HOSPITALS REQUESTING WAIVERS FOR ORGAN PROCUREMENT SERVICE AREAS IN CY 2003 (CMS-1246-NC)

Priority: Routine and Frequent

Legal Authority: 42 USC 1138(2)(A)

CFR Citation: 42 CFR 486.306

Legal Deadline: None

Abstract: This notice announces three applications that we have received from

HHS—CMS **Final Rule Stage**

hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs), in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant these waivers.

Timetable:

Action	Date
Notice	11/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Mark Horney, CHPP, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4554

RIN: 0938–AM59

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

Long-Term Actions

919. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (CMS-6002-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 424

Legal Deadline: None

Abstract: This proposed regulation is needed as part of the Administration's anti-fraud and abuse efforts. It would give us the authority to enroll and reenroll providers, with time frames for re-enrollment.

Timetable:

Action	Date	
NPRM	04/25/03	68 FR 22064
Next Action Undetermined		

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: Formerly known as HCFA-1023-P

Agency Contact: Michael Collett, OFM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6121

RIN: 0938–AH73

920. FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES (CMS-3047-F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

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

Legal Deadline: None

Abstract: This rule adopts the 2000 edition of the National Fire Protection Association's Life Safety Code as the fire standards for Religious Non-Medical Health Care Institutions, Ambulatory Surgery Centers, Hospices that provide in-patient services, Programs of All-Inclusive Care for the Elderly (PACE), Hospitals, Long-Term Care Facilities, Critical Access Hospitals, and Intermediate Care Facilities for the Mentally Retarded.

Timetable:

Action	Date	
NPRM	10/26/01	66 FR 54179
Final Action	01/10/03	68 FR 1374
Next Action Undetermined		

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6617

RIN: 0938–AK35

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 482.21

Legal Deadline: None

Abstract: This final rule addresses provisions relating to the development and implementation of a QAPI program and its components. It imposes several requirements that are designed to increase patient safety and track the methodologies, and/or programs or both, used to increase patient safety. The final rule requires a hospital in collaboration with CMS and other Federal agencies, the Peer Review Organizations (PROs), State survey agencies, and accrediting bodies to ensure that it is involved in a QAPI program that will track and exhibit activities that address all issues related to patient safety and medical errors. In addition, hospitals must work with these groups to identify errors and potential errors that may affect patient outcomes.

Timetable:

Action	Date	
NPRM	12/19/97	62 FR 66725
NPRM Comment Period End	02/17/98	
Final Rule	01/24/03	68 FR 3435
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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: 401 786-0596

RIN: 0938–AK40

HHS—CMS

Long-Term Actions

922. 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.

Legal Authority: 42 USC 1395(L); BBA '97; BBRA '99; BIPA '00

CFR Citation: 42 CFR 405; 42 CFR 419

Legal Deadline: None

Abstract: This notice corrects an error that appeared in the Outpatient PPS final rule with comment period published on November 1, 2002 (67 FR 66719). This notice is a supplement to that rule and sets forth our rationale for waiving the notice and comment period for certain provisions.

Timetable:

Action	Date	
Notice	03/18/02	67 FR 11969
Proposed Rule	08/09/02	67 FR 52092
Comment Period End	10/07/02	
Final Action	11/01/02	67 FR 66718
Correction Notice	11/15/02	67 FR 69146
Correction Notice	02/10/03	68 FR 6636

Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Cindy Read, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786-1852

Related RIN: Related To 0938-AK59

RIN: 0938–AL19

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

Completed Actions

923. SECURITY STANDARDS (CMS-0049-F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 162

Completed:

Reason	Date	
Final Rule	02/20/03	68 FR 8334

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State, Local, Tribal, Federal

Agency Contact: Barbara Clark Phone: 410 786-3017

RIN: 0938–AI57

924. EXTERNAL QUALITY REVIEW OF MEDICAID MANAGED CARE ORGANIZATIONS (CMS-2015-F)

Priority: Other Significant

CFR Citation: 42 CFR 438

Completed:

Reason	Date	
Final Rule	01/24/03	68 FR 3586

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

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

Agency Contact: Sharon Gilles Phone: 410 786-1177

RIN: 0938–AJ06

925. IMPROVEMENTS TO THE MEDICARE+CHOICE APPEALS AND GRIEVANCE PROCEDURES (CMS-4024-FC)

Priority: Other Significant

CFR Citation: 42 CFR 422; 42 CFR 489

Completed:

Reason	Date	
Final Rule	04/16/03	68 FR 16652

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Chrislyn Gayhead Phone: 410 786-6429

RIN: 0938–AK48

926. HEALTH INSURANCE REFORM: MODIFICATIONS TO STANDARDS FOR ELECTRONIC TRANSACTIONS (CMS-0003-FC)

Priority: Other Significant

CFR Citation: 45 CFR 162

Completed:

Reason	Date	
Final Action	02/20/03	68 FR 8381

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Gladys Wheeler Phone: 410 786-0273

RIN: 0938–AK64

927. MEDICAID MANAGED CARE; NEW PROVISIONS (CMS-2104-F2)

Priority: Info./Admin./Other

CFR Citation: 42 CFR 400

Completed:

Reason	Date	
Correction Notice	10/25/02	67 FR 65504

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Bruce Johnson Phone: 410 786-0615

Deirdre Duzor Phone: 410 786-4626

RIN: 0938–AK96

928. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2003 (CMS-1204-F2)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 410; 42 CFR 414

Completed:

Reason	Date	
Notice	11/05/02	67 FR 67318
Final Rule with Comment Period	12/31/02	67 FR 79966
Final Action	02/28/03	68 FR 9567

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal

Agency Contact: Marc Hartstein

Phone: 410 786-4539

RIN: 0938–AL21

929. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2003 (CMS-8013-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date
Notice	10/21/02 67 FR 64641

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786-6390

RIN: 0938–AL56

930. MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2003 (CMS-8014-N)

Priority: Economically Significant

CFR Citation: None

Completed:

Reason	Date
Notice	10/21/02 67 FR 64643

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Carter S. Warfield
Phone: 410 786-6396

RIN: 0938–AL63

931. PART A PREMIUMS FOR CALENDAR YEAR 2003 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS-8015-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date
Notice	10/21/02 67 FR 64649

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786-6390

RIN: 0938–AL69

932. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2003 (CMS-1220-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date
Notice	11/22/02 67 FR 70442

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Robert Niemann
Phone: 410 786-4569

RIN: 0938–AL97

933. TICKET TO WORK MEDICAID INFRASTRUCTURE GRANT (CMS-2165-N)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date
Notice	02/28/03 68 FR 9672

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Joe A Razes
Phone: 410 786-6126
Email: jrazes@cms.hhs.gov

RIN: 0938–AM11

934. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; EXTENSION OF PARTIAL DELAY OF EFFECTIVE DATE OF THE ''SET IN ADVANCE'' PROVISION (CMS-1809-F2)

Priority: Other Significant

CFR Citation: 42 CFR 411.354

Completed:

Reason	Date
Final Action	11/22/02 67 FR 70322
Final Action Effective	11/22/02

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer
Phone: 410 786-4620

Related RIN: Related To 0938-AL29

RIN: 0938–AM21

935. ● ANNOUNCEMENT OF APPLICATIONS FROM HOSPITALS REQUESTING WAIVERS FOR ORGAN PROCUREMENT SERVICE AREAS CY 2002 (CMS-1241-NC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1138(2)(A)

CFR Citation: 42 CFR 486.306

Legal Deadline: None

Abstract: This notice announces three applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs), in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant these waivers.

Timetable:

Action	Date
Notice	11/22/02 67 FR 70435

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Mark Horney, CHPP, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4554

RIN: 0938–AM37

936. ● GRANTS TO STATES FOR OPERATION OF QUALIFIED HIGH RISK POOLS (CMS-2179-FC)

Priority: Other Significant

Legal Authority: PL 107-210

CFR Citation: 45 CFR 148

Legal Deadline: None

Abstract: This final rule with comment period 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
Final Action	05/02/03 68 FR 23410

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

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

Agency Contact: James Mayhew, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD Phone: 410 786-9244

RIN: 0938–AM42

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937. ● PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS: IMPLEMENTATION AND FY 2003 RATES; CORRECTING AMENDMENT (CMS-1177-F2)

Priority: Substantive, Nonsignificant

Legal Authority: None

CFR Citation: 42 CFR 442.22

Legal Deadline: None

Abstract: This correcting amendment corrects citation in the regulation text of the August 2002 final rule concerning satellite facilities. It will revise section 412.22(h)(3)(ii) so that the section will cite 412.23(e)(2)(ii) instead of 412.23(e)(2).

Timetable:

Action	Date
Final Rule	03/07/03 68 FR 10987

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Judith H. Richter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-2590

Tzvi Hefter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-1304

Related RIN: Related To 0938-AK69

RIN: 0938–AM49

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938. ● PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS; SECOND EXTENSION OF DELAY OF EFFECTIVE DATE OF THE ''SET IN ADVANCE'' PROVISION (CMS-1809-F3)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395nn

CFR Citation: 42 CFR 411.354

Legal Deadline: None

Abstract: This final rule temporarily delays for an additional six months or until publication of phase II the effective date of the ''set in advance'' provision in section 411.354(d)(1) contained in the rule entitled ''Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships,'' published in the Federal Register on January 4, 2001 (66 FR 856).

Timetable:

Action	Date
Final Action	04/25/03 68 FR 20347

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Karen Raschke, Health Insurance Specalist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0016

Related RIN: Related To 0938-AM21

RIN: 0938–AM58

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939. ● AMBULANCE FEE SCHEDULE (CMS-1256-N)

Priority: Other Significant

Legal Authority: None

CFR Citation: None

Legal Deadline: None

Abstract: The purpose of this notice is to implement a Federal court order requiring the retroactive implementation of the Ambulance Fee Schedule to be established by the statutory effective date of January 1, 2000.

Timetable:

Action	Date
Notice	04/16/03 68 FR 18654

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Robert Niemann, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4569

RIN: 0938–AM60

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940. ● CIVIL MONEY PENALTIES: PROCEDURES FOR INVESTIGATIONS, IMPOSITION OF PENALTIES, AND HEARINGS (CMS-0010-IFC)

Priority: Other Significant

Legal Authority: 42 USC 1302(a); 42 USC 1320(d)(5)

CFR Citation: 45 CFR 160

Legal Deadline: None

Abstract: This interim final rule establishes rules of procedures for the imposition, by the Secretary of Health and Human Services, of civil money penalties on entities that violate standards adopted by the Secretary under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We intend that this be the first installment of a rule that we term the ''Enforcement Rule.'' The Enforcement Rule, when issued in complete form, will set forth procedural and substantive requirements for imposition of civil money penalties. In the interim, we are issuing these rules of procedure to inform regulated entities of our approach to enforcement and to advise regulated entities of certain procedures that will be followed as we enforce the HIPAA Administrative Simplification standards (HIPAA standards).

Timetable:

Action	Date
Interim Final Rule	04/17/03 68 FR 18895

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Marilou King, Attorney, Department of Health and Human Services, Centers for Medicare

HHS—CMS **Completed Actions**

& Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AM63

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

941. 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
NPRM	12/00/03

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
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RIN: 0970–AC01

942. 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.

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
NPRM	12/00/03

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

943. CHILD SUPPORT ENFORCEMENT PROGRAM; EXPENDITURES FOR CASEWORKER COSTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 655

CFR Citation: 45 CFR 304.23

Legal Deadline: None

Abstract: This proposed rule will revise existing regulations on expenditures for which Federal Financial Participation is available under the Child Support Enforcement program. Under the current regulations, Federal Financial Participation is not available in any costs of caseworkers who are also performing the assistance payments or social services functions under title IV-A (TANF) or title XX (Social Services Block Grants) of the Social Security Act. This proposed regulation will remove the prohibition to reflect current business practices of the Department of Health and Human Services under which costs are allocated to the benefiting program.

Timetable:

Action	Date
NPRM	12/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Sheck Chin, Special Assistant to the Division Director, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
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RIN: 0970–AC11

944. ● 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
NPRM	12/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
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RIN: 0970–AC14

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

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

Priority: Other Significant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1309

Legal Deadline: None

Abstract: This rule establishes procedures to be used by Head Start and Early Head Start agencies in requesting to use Head Start grant funds to construct or perform major renovation on a Head Start or Early Head Start Facility.

Timetable:

Action	Date	
NPRM	02/08/99	64 FR 6013
NPRM Comment Period End	04/09/99	
Final Action	05/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447
Phone: 202 205-8569
Email: dklafehn@acf.dhhs.gov

RIN: 0970–AB54

946. 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	
NPRM	08/21/00	65 FR 50800
Final Action	09/00/03	

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

947. CHILD SUPPORT ENFORCEMENT PROGRAM OMNIBUS CONFORMING REGULATION

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 301 to 305

Legal Deadline: None

Abstract: This rule eliminates child support enforcement program regulations rendered obsolete or inconsistent with the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, and its technical amendments, the Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997, and the Child Support Performance and Incentive Act of 1998.

Timetable:

Action	Date	
Interim Final Rule	02/09/99	64 FR 6237
Final Action	05/00/03	

Regulatory Flexibility Analysis Required: 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
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RIN: 0970–AB81

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

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

Legal Deadline: None

Abstract: This rule will make technical changes and conforming amendments to make the wording of the regulations consistent with amended provisions of the Head Start Act, eliminate obsolete references, and make other necessary technical changes to the regulations.

HHS—ACF **Final Rule Stage**

Timetable:

Action	Date
Interim Final Rule	09/00/03

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: None

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447
Phone: 202 205-8569
Email: dklafehn@acf.dhhs.gov

RIN: 0970–AC00

949. 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
Interim Final Rule	09/00/03

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
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RIN: 0970–AC09

950. ● 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 (PRWORA) 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	
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
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RIN: 0970–AC12

951. ● COMMUNITY SERVICES BLOCK GRANT CHARITABLE CHOICE

Priority: Substantive, Nonsignificant

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

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 (CSBG Act). These provisions apply to 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	
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

URL For More Information:
http://www.acf.hhs.gov/hypenews

URL For Public Comments:
http://www.acf.hhs.gov/hypernews.topic822

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
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RIN: 0970–AC13

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

Completed Actions

952. FAMILY CHILD CARE PROGRAM OPTION FOR HEAD START PROGRAMS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1304; 45 CFR 1306

Completed:

Reason	Date
Withdrawn	03/07/03

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local, Tribal

Agency Contact: Douglas Klafehn
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RIN: 0970–AB90

953. CHILD SUPPORT ENFORCEMENT PROGRAM; CUSTOMER SERVICE ANNUAL STATE SELF-ASSESSMENT

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 308.2; 45 CFR 308.3

Completed:

Reason	Date
Withdrawn	03/07/03

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Annie Miller
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RIN: 0970–AC10

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

Proposed Rule Stage

954. 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 2003.

Timetable:

Action	Date
NPRM	05/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Federalism: Undetermined

Agency Contact: Edwin Walker, Deputy Assistant Secretary for Policy and Programs, Department of Health and Human Services, Administration on Aging, Washington, DC 20201
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RIN: 0985–AA00

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