Federal Register

Monday,
December 9, 2002

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 rulemakings that will be under development or review. The purpose of this effort is to encourage public participation in the regulatory process by providing, at an early stage, summarized information about regulatory actions that the Department is working on. All persons interested in communicating to the Department their views on the rulemakings prospectively outlined below are invited to do so.

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

SUPPLEMENTARY INFORMATION: The capsulized information provided below reflects an effort to present for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of an advance notice of proposed rulemaking, a notice of proposed rulemaking, or a final rule within the next 12 months. (Also included in several ''long-term actions'' sections are summaries of actions that we will probably not take any earlier than 12 months after publication of the agenda.) We welcome hearing the views of all concerned with regard to all of 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 believed to be warranted, comments should be directed to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

The Office of Management and Budget requires that fall editions of the agenda be augmented by a regulatory plan, highlighting the most important regulatory actions under development by the Department. Our Plan appears in part II of this issue of the **Federal Register**, along with those of other Departments and agencies. Our Plan entries are listed in the table of contents below, and are denoted by a bracketed bold reference, which directs the reader to the appropriate sequence number in part II.

Dated: September 27, 2002.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
907	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991-AB06
908	Tax Refund Offset	0991-AB17
909	Claims Collection	0991-AB18
910	Salary Offset	0991-AB19

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
911	Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
912	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991-AB16
913	Administrative Wage Garnishment	0991-AB20
914	U.S. Exchange Visitor Programs; Request for Waiver of the Two-Year Foreign Residence Requirement	0991-AB21
915	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
916	Revisions to 42 CFR Part 1003	0991-AB03
917	Civil Money Penalty Safe Harbor To Protect Payment of Medicare and Medigap Premiums for ESRD Beneficiaries	0991-AB04
918	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
919	Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)	0991-AB12

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Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
920	Modifications to Standards for Privacy of Individually Identifiable Health Information	0991-AB14
921	Implementing the Bioterrorism Prevention and Response Act of 2001	0991-AB15

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

Sequence Number	Title	Regulation Identification Number
922	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
923	Control of Communicable Diseases **(Reg Plan Seq No. 29)**	0920-AA03
924	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920-AA04

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

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
925	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
926	Possession, Use, and Transfer of Select Agents **(Reg Plan Seq No. 30)**	0920-AA08

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

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identification Number
927	Methods for Estimating Radiation Dose and Guidelines for Assessing Probability of Cancer for Energy Employees Occupational Illness Compensation Program	0920-AA05

Departmental Management—Completed Actions

Sequence Number	Title	Regulation Identification Number
928	Implementation of the Equal Access to Justice Act in Agency Proceedings	0990-AA02
929	Administrative Wage Garnishment	0990-AA05

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
930	Requirements for Submission of In Vivo Bioequivalence Data	0910-AC23

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Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
931	Establishment Registration and Listing for Drugs and Biologics	0910-AA49
932	Safety Reporting Requirements for Human Drug and Biological Products **(Reg Plan Seq No. 31)**	0910-AA97
933	Blood Initiative	0910-AB26
934	Applications for FDA Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications	0910-AB34
935	Current Good Manufacturing Practice for Medicated Feeds	0910-AB70
936	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements **(Reg Plan Seq No. 32)**	0910-AB88
937	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910-AB96
938	Control of Salmonella Enteritidis in Shell Eggs During Production and Retail **(Reg Plan Seq No. 33)**	0910-AC14
939	Institutional Review Boards: Registration Requirements	0910-AC17
940	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910-AC21
941	Exception From General Requirements for Informed Consent; Request for Comments and Information **(Reg Plan Seq No. 34)**	0910-AC25
942	Bar Code Label Requirements for Human Drug Products **(Reg Plan Seq No. 35)**	0910-AC26
943	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910-AC32
944	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910-AC34
945	Administrative Detention **(Reg Plan Seq No. 36)**	0910-AC38
946	Establishment and Maintenance of Records to Identify Immediate Previous Source and Immediate Subsequent Recipient of Foods **(Reg Plan Seq No. 37)**	0910-AC39
947	Registration of Food and Animal Feed Facilities **(Reg Plan Seq No. 38)**	0910-AC40
948	Establishment of Prior Notification Requirement for All Imported Food Shipments **(Reg Plan Seq No. 39)**	0910-AC41
949	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910-AC43
950	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 **(Reg Plan Seq No. 40)**	0910-AC48

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Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
951	Over-the-Counter (OTC) Drug Review	0910-AA01
952	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910-AA61
953	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910-AA89
954	Labeling for Human Prescription Drugs; Revised Format **(Reg Plan Seq No. 41)**	0910-AA94
955	Revisions to the General Safety Requirements for Biological Products; Final Rule	0910-AB51
956	Supplements and Other Changes to an Approved Application	0910-AB61
957	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims **(Reg Plan Seq No. 42)**	0910-AB66
958	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV (Lookback) **(Reg Plan Seq No. 43)**	0910-AB76
959	Antibiotic Resistance Labeling	0910-AB78
960	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format	0910-AB91
961	Additional Safeguards for Children in Clinical Investigations of FDA Regulated Products	0910-AC07
962	Aluminum in Large- and Small-Volume Parenterals Used in Total Parenteral Nutrition	0910-AC18
963	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs **(Reg Plan Seq No. 44)**	0910-AC35
964	Records and Reports Concerning Experience With Approved New Animal Drugs	0910-AC42
965	Presubmission Conferences	0910-AC44
966	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of ''No Residue''	0910-AC45
967	Bioavailability and Bioequivalence Requirements	0910-AC47

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Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
968	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910-AA04
969	Investigational Use New Animal Drug Regulations **(Section 610 Review)**	0910-AB02
970	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)	0910-AB27
971	Current Good Tissue Practice for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Inspection and Enforcement	0910-AB28
972	Premarket Notice Concerning Bioengineered Foods	0910-AC15
973	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products	0910-AC19
974	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910-AC30

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
975	Use of Ozone-Depleting Substances	0910-AA99
976	Food Additives: Food Contact Substances Notification System	0910-AB94
977	Efficacy Evidence Needed for Products To Be Used Against Toxic Substances When Human Studies Are Unethical	0910-AC05
978	Revocation of Conditions for Marketing Digoxin Products for Oral Use	0910-AC12
979	Postmarket Surveillance	0910-AC31

Food and Drug Administration—Discontinued Entries

Regulation Identification Number	Title	Date	Comments
0910-AB24	FDA Export Reform and Enhancement Act of 1996; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Later Export	08/02/2002	Withdrawn
0910-AB95	Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission Into the United States	08/02/2002	Withdrawn
0910-AC04	Status Reports of Distribution and Use Information for Antimicrobial Animal Drug Products Used in Food-Producing Animals	07/31/2002	Withdrawn
0910-AC20	Postmarketing Reports of Substandard or Ineffective Bulk Ingredients and Bulk Ingredients From Unapproved Sources	08/02/2002	Withdrawn
0910-AC33	Redacting 510(k) Submissions	09/18/2002	Withdrawn

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
980	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906-AA41
981	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
982	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906-AA57

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Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
983	National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table	0906-AA55

Indian Health Service—Final Rule Stage

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

Indian Health Service—Completed Actions

Sequence Number	Title	Regulation Identification Number
985	Tribal Self-Governance Amendments	0917-AA05

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
986	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925-AA10
987	National Institutes of Health (NIH) Center Grants	0925-AA24
988	National Institutes of Health (NIH) Training Grants	0925-AA28
989	National Institutes of Health (NIH) Aids Research Loan Repayment Program	0925-AA32

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
990	National Institutes of Health Loan Repayment Program for Research Generally	0925-AA18
991	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	0925-AA20

National Institutes of Health—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
992	Standards for a National Chimpanzee Sanctuary System	0925-AA31

Office of Public Health and Science—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
993	Public Health Services Policies on Research Misconduct	0940-AA04
994	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940-AA06

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Office of Public Health and Science—Final Rule Stage

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

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
996	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) **(Section 610 Review) (Reg Plan Seq No. 45)**	0938-AG82
997	Criteria for Approval of Facilities to Perform Covered Heart, Liver, Lung, Pancreas, and Intestinal Transplants (CMS-3835-P)	0938-AH17
998	Hospice Care—Conditions of Participation (CMS-3844-P)	0938-AH27
999	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-P)	0938-AH73
1000	National Standard for Identifiers of Health Plans (CMS-6017-P) **(Reg Plan Seq No. 46)**	0938-AH87
1001	Medical Child Support and Health Insurance Coverage of Dependent Children (CMS-2081-P)	0938-AI21
1002	Medicare Hospice Care Amendments (CMS-1022-P)	0938-AJ36
1003	Supplier Standards for Home Oxygen, Therapeutic Shoes, Home Nutrition Therapy (CMS-6010-P)	0938-AJ98
1004	All Provider Bad Debt Payment (CMS-1126-P)	0938-AK02
1005	Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (CMS-3046-P)	0938-AK23
1006	Health Insurance Reform: Claims Attachments Standards (CMS-0050-P) **(Reg Plan Seq No. 47)**	0938-AK62
1007	Rate of Reimbursement of Photocopy Expenses for Prospective Payment System Providers (CMS-3055-P)	0938-AK68
1008	Modifications to Medicare Managed Care Rules (CMS-4041-P)	0938-AK71
1009	Medicare Inpatient Disproportionate Share Hospital (DSH) Adjustment Formula (CMS-1171-P)	0938-AK77
1010	Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS-1185-P)	0938-AK79
1011	Organ Procurement Organization Conditions for Coverage (CMS-3064-P) **(Reg Plan Seq No. 48)**	0938-AK81
1012	Extending Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity (CMS-4018-P)	0938-AK94
1013	Update Interest Assessment on Medicare Overpayment and Underpayment (CMS-6014-P)	0938-AL14
1014	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities that Provide Inpatient or Residential Care (CMS-2130-P) **(Reg Plan Seq No. 49)**	0938-AL26
1015	Payment for Respiratory Assist Devices with Bi-Level Capability and a Back-Up Rate (CMS-1167-P)	0938-AL27
1016	Self-Declaration of Citizenship (CMS-2085-P)	0938-AL33
1017	Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS-6016-P)	0938-AL49
1018	Prospective Payment System for Psychiatric Hospitals (CMS-1213-P) **(Reg Plan Seq No. 50)**	0938-AL50
1019	Provider Reimbursement Determinations and Appeals (CMS-1727-P)	0938-AL54
1020	SCHIP; Purchase of Family Coverage—Benefit Flexibility in Parent Coverage (CMS-2148-P)	0938-AL62
1021	Request for Information on Benefit-Specific Waiting Periods (CMS-2150-N)	0938-AL64
1022	Revisions to the Medicare Appeals Process (CMS-4004-P) **(Reg Plan Seq No. 51)**	0938-AL67
1023	DMERC Service Areas and Related Matters (CMS-1219-P)	0938-AL76
1024	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938-AL80
1025	Medicaid Coverage Rules for Inmates of Public Institutions (CMS-2077-P)	0938-AL85
1026	Targeted Case Management (CMS-2061-P)	0938-AL87
1027	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-P)	0938-AL88
1028	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2004 (CMS-1469-P) **(Reg Plan Seq No. 52)**	0938-AL90
1029	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS-1471-P) **(Reg Plan Seq No. 53)**	0938-AL91
1030	Prospective Payment System for Long-Term Care Hospitals: FY 2004 (CMS-1472-P)	0938-AL92
1031	Home Health Prospective Payment System Rate Update for FY 2004 (CMS-1473-NC)	0938-AL94
1032	Prospective Payment System for Inpatient Rehabilitation Hospitals (CMS-1474-P)	0938-AL95
1033	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004 (CMS-1476-P) **(Reg Plan Seq No. 54)**	0938-AL96
1034	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-P)	0938-AM01
1035	Medicaid Home and Community-Based Services Waivers (CMS-2162-P)	0938-AM05
1036	Ticket to Work Medicaid Infrastructure Grant (CMS-2165-N)	0938-AM11
1037	Revisions to Average Wholesale Price Methodology (CMS-1229-P) **(Reg Plan Seq No. 55)**	0938-AM12
1038	Criteria for Determining Whether a Drug is Considered Usually Self-Administered (CMS-1228-P)	0938-AM13

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

Sequence Number	Title	Regulation Identification Number
1039	Electronic Medicare Claims Submission (CMS-0008-P) **(Reg Plan Seq No. 56)**	0938-AM22
1040	Liability of Third Parties to Pay for Care and Services (CMS-2080-P)	0938-AM24
1041	Medicaid Definition of Qualified Speech Pathologists and Audiologists (CMS-2132-P)	0938-AM26
1042	Medicaid Estate Recoveries (CMS-2083-P)	0938-AM30

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Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1043	Revision of Medicare/Medicaid Hospital Conditions of Participation (CMS-3745-F) **(Reg Plan Seq No. 57)**	0938-AG79
1044	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-FC)	0938-AG81
1045	Medicare and Medicaid Programs; Terms, Definitions, and Addresses: Technical Amendments (CMS-9877-F)	0938-AH53
1046	Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS-0045-F) **(Reg Plan Seq No. 58)**	0938-AH99
1047	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS-6003-F)	0938-AI49
1048	Security Standards (CMS-0049-F) **(Reg Plan Seq No. 59)**	0938-AI57
1049	Coverage of Religious Non-Medical Health Care Institutions (CMS-1909-F)	0938-AI93
1050	External Quality Review of Medicaid Managed Care Organizations (CMS-2015-F)	0938-AJ06
1051	Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (CMS-3006-IFC)	0938-AJ10
1052	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions, and Establishment of a Quality Assessment and Improvement Program (CMS-1910-F)	0938-AJ17
1053	Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)	0938-AJ29
1054	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938-AJ96
1055	Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services) (CMS-1908-F)	0938-AJ97
1056	Clinical Lab Requirements—Revisions to Regulations Implementing CLIA (CMS-2226-F)	0938-AK24
1057	Fire Safety Requirements for RNHCI, ASC, Hospices, PACE, Hospitals, and Long-Term Care Facilities and ICFs for the Mentally Retarded (CMS-3047-F)	0938-AK35
1058	Hospital Conditions of Participation: Quality Assessment and Performance Improvements (QAPI) (CMS-3050-F) **(Reg Plan Seq No. 60)**	0938-AK40
1059	Improvements to the Medicare+Choice Appeals and Grievance Procedures (CMS-4024-F)	0938-AK48
1060	Review of National Coverage Determinations and Local Coverage Determinations (CMS-3063-F) **(Reg Plan Seq No. 61)**	0938-AK60
1061	Revised Process for Making Medicare Coverage Determinations (NCDs) (CMS-3062-N)	0938-AK61
1062	Health Insurance Reform: Modifications to Standards for Electronic Transactions (CMS-0003-F) **(Reg Plan Seq No. 62)**	0938-AK64
1063	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS-1810-FC)	0938-AK67
1064	Medicaid Managed Care; New Provisions (CMS-2104-F2)	0938-AK96
1065	Modifications to the State Children's Health Insurance Program (CMS-2006-F)	0938-AL00
1066	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)	0938-AL12
1067	Requirements for Paid Feeding Assistants in Long-Term Care Facilities (CMS-2131-F)	0938-AL18
1068	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates (CMS-1206-F)	0938-AL19
1069	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 (CMS-1204-FC)	0938-AL21
1070	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS-2151-F)	0938-AL43
1071	Interim Final Amendment for Mental Health Parity (CMS-2152-IFC)	0938-AL44
1072	Electronic Submission of Cost Reports (CMS-1199-F)	0938-AL51
1073	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2003 (CMS-8013-N)	0938-AL56
1074	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-F)	0938-AL59
1075	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2003 (CMS-8014-N)	0938-AL63

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

Sequence Number	Title	Regulation Identification Number
1076	Part A Premiums for 2003 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8015-N)	0938-AL69
1077	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals; Federal Fiscal Year 2002 (CMS-2136-FN)	0938-AL79
1078	Changes to the Hospital Inpatient Prospective Payment System and FY 2004 Rates (CMS-1470-N) **(Reg Plan Seq No. 63)**	0938-AL89
1079	Fee Schedule for Payment of Ambulance Services—Update for CY 2003 (CMS-1220-N)	0938-AL97
1080	Update of the List of Covered Procedures for Ambulatory Surgical Centers Effective January 1, 2003 (CMS-1885-FC)	0938-AM02
1081	Comprehensive Employment Demonstration (CMS-2163-N)	0938-AM10
1082	Nondiscrimination in Health Coverage in the Group Market (CMS-2022-F)	0938-AM14
1083	Bona Fide Wellness Programs (CMS-2078-F)	0938-AM15
1084	Time Limitation on Recalculations and Disputes Under the Drug Rebate Program (CMS-2175-IFC)	0938-AM20
1085	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-IFC2)	0938-AM21
1086	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2004 (CMS-8016-N)	0938-AM31
1087	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2004 (CMS-8017-N)	0938-AM32
1088	Part A Premiums for 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8018-N)	0938-AM33
1089	Application of Emergency Medical and Treatment Act (EMTALA) (CMS-1063-F) **(Reg Plan Seq No. 64)**	0938-AM34

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Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identification Number
1090	National Standard Employer Identifier (CMS-0047-F)	0938-AI59
1091	Non-Federal Governmental Plans Exempt From Health Insurance Portability Requirements (CMS-2033-F)	0938-AK00
1092	Supplementary Medical Insurance Premium Surcharge Agreements (CMS-1221-F)	0938-AK42
1093	Payment for Upgraded Durable Medical Equipment; Withdrawal of Proposed Rule (CMS-1084-WN)	0938-AK50
1094	Prospective Payment System for Long-Term Care Hospitals for FY 2003 (CMS-1177-F)	0938-AK69
1095	Revisions to Transaction and Code Set Standards for Electronic Transactions (CMS-0005-P)	0938-AK76
1096	Modifications to Managed Care Rules Based on Payment Provisions in BIPA and Technical Corrections (CMS-4040-F)	0938-AK90
1097	Home Health Prospective Payment System Rate Update for FY 2003 (CMS-1198-NC)	0938-AL16
1098	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2003 (CMS-1202-N)	0938-AL20
1099	Inpatient Rehabilitation Facility Prospective Payment System for FY 2003 (CMS-1205-N)	0938-AL22
1100	Hospital Inpatient Prospective Payment System for FY 2003 (CMS-1203-F)	0938-AL23
1101	Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative (CMS-4027-F)	0938-AL28
1102	Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors (CMS-4032-P)	0938-AL30
1103	Peer Review Organizations: Name and Other Changes—Technical Amendments (CMS-3088-FC)	0938-AL38
1104	End-Stage Renal Disease—Rescission of Waiver of Conditions for Coverage Under a State of Emergency in Houston, Texas Area (CMS-3074-F2)	0938-AL39
1105	Prospective Payment System for Inpatient Rehabilitation Hospital; Correcting Amendment (CMS-1069-F2)	0938-AL40
1106	Hospice Wage Index for FY 2003 (CMS-1211-N)	0938-AL41
1107	Physician Fee Schedule for CY 2002: Correction Notice (CMS-1169-CN)	0938-AL48
1108	Notice of Modification of Beneficiary Assessment Requirements for Skilled Nursing Facilities (CMS-1209-N)	0938-AL55
1109	Revision of the Procedures for Requesting Exceptions to Cost Limits for Skilled Nursing Facilities and Elimination of Reclassifications; Correction (CMS-1883-F3)	0938-AL61
1110	Notice of Intent to Conduct Negotiated Rulemaking for Special Payment Provisions and Standards for Suppliers of Custom-Fabricated Orthotics and Prosthetics (CMS-6012-N)	0938-AL68
1111	Medicaid Managed Care: Withdrawal (CMS-2001-F4)	0938-AL83
1112	FY 1999 SCHIP Reallocation Notice (CMS-2137-N)	0938-AL86

HHS

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

Sequence Number	Title	Regulation Identification Number
1113	Criteria for Acceptance of Supplemental Practice Expense Survey Data (CMS-1223-IFC)	0938-AL99

Centers for Medicare & Medicaid Services—Discontinued Entries

Regulation Identification Number	Title	Date	Comments
0938-AD95	''Without Fault'' and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (CMS-6007-F)	09/12/2002	Withdrawn
0938-AK91	State Allotments for Payment of Medicare Part B Premiums for Qualified Individuals; Federal Fiscal Year 2001 (CMS-2087-FN)	09/12/2002	Withdrawn
0938-AL37	State Children's Health Insurance Program; Eligibility for Unborn Children (CMS-2127-F)	09/12/2002	Withdrawn
0938-AL52	Health Insurance Reform: National Standard for Identifiers of Health Plans (CMS-6017-P)	08/22/2002	Withdrawn
0938-AL53	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-P)	09/12/2002	Withdrawn
0938-AL57	Definition of Severe Medically Determinable Impairment (CMS-2143-P)	09/12/2002	Withdrawn
0938-AL66	Revisions to Medicaid Cost-Sharing Regulations (CMS-2144-P)	09/12/2002	Withdrawn
0938-AL72	Effect of Change of Ownership on Provider and Supplier Penalties (CMS-2215-P)	10/10/2002	Withdrawn
0938-AL81	Flexibility in Payment Methods for Services of Hospitals, Nursing Facilities, and Intermediate Care Facilities for the Mentally Retarded (CMS-2004-F)	09/12/2002	Withdrawn
0938-AL84	Continue To Allow States an Option Under the Medicaid Spousal Impoverishment Provisions To Increase the Community Spouse's Income When Adjusting the Protected Resource Allowance (CMS-2128-F)	09/12/2002	Withdrawn
0938-AL93	Prospective Payment System for Psychiatric Hospitals (CMS-1477-P)	08/08/2002	Withdrawn

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1114	Safeguarding Child Support and Expanded FPLS Information	0970-AC01
1115	Developmental Disabilities and Bill of Rights Act	0970-AC07
1116	Child Support Enforcement Program; Customer Service Annual State Self-Assessment	0970-AC10
1117	Child Support Enforcement Program; Expenditures for Caseworker Costs	0970-AC11

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1118	Construction and Major Renovation of Head Start and Early Head Start Facilities	0970-AB54
1119	Child Support Enforcement for Indian Tribes	0970-AB73
1120	Child Support Enforcement Program Omnibus Conforming Regulation	0970-AB81
1121	Family Child Care Program Option for Head Start Programs	0970-AB90
1122	Technical Revision of Head Start Regulations To Make Them Conform to Recent Statutory Revisions	0970-AC00
1123	Child Support Enforcement Program; Federal Tax Refund Offset	0970-AC09

HHS

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
1124	Program Performance Standards for the Operation of Head Start Programs	0970-AB99

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1125	Grants for State and Community Programs on Aging, Training, Research, and Discretionary Programs; Vulnerable Elder Rights; and Grants to Indians and Native Hawaiians	0985-AA00

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

Proposed Rule Stage

907. SAFE HARBOR FOR ARRANGEMENTS INVOLVING FEDERALLY QUALIFIED HEALTH CENTERS

Priority: Substantive, Nonsignificant

Legal Authority: PL 100-93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
NPRM Comment Period End	02/00/03	

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

908. ● 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. 1321-358, as implemented by the Department of 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 Department of Treasury regulations.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
NPRM Comment Period End	02/00/03	

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

909. ● 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 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 Department of Treasury regulations.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	
NPRM Comment Period End	03/00/03	
Final Rule	06/00/03	

Regulatory Flexibility Analysis Required: No

HHS—OS **Proposed Rule Stage**

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

910. ● SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

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 USC 5514, as implemented by the Office of Personnel Management at 5 CFR part 550, subpart K. The proposed rule is required in order to bring the Department's salary offset provisions in compliance with Governmentwide regulations published by the Office of Personnel Management.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	
NPRM Comment Period End	03/00/03	
Final Rule	06/00/03	

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–AB19

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

Final Rule Stage

911. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1001

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

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

Timetable:

Action	Date	FR Cite
ANPRM	05/23/97	62 FR 28410
ANPRM Comment Period End	06/09/97	
Interim Final Rule	11/19/99	64 FR 63504
Final Rule	02/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Additional Information: Interim final regulations were published on November 19, 1999 (64 FR 63504) and are currently in effect. See 42 CFR 1001.952(t) and (u).

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

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

Priority: Substantive, Nonsignificant

Legal Authority: PL 100-93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/25/02	67 FR 60202
NPRM Comment Period End	10/25/02	
Final Rule	04/00/03	

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

913. ADMINISTRATIVE WAGE GARNISHMENT

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 3720D; 31 CFR 285.11

CFR Citation: 42 CFR 32

Legal Deadline: None

Abstract: The Department will add a new part 32 to title 42 of the Code of Federal Regulations (CFR) to implement the Administrative Wage Garnishment provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, codified at 31 U.S.C. 3720D, and implemented by the Department of Treasury at 31 C.F.R. 285.11. The proposed rule will be another tool for the Department to collect its debts by allowing the Department to garnish the wages of non-Federal employees administratively (i.e., without the need for a court order). The wage withholding order will be required to withold amounts from an employee's wages and pay those amounts to the Department in satisfaction of the indebtedness.

Timetable:

Action	Date	FR Cite
NPRM	03/13/02	67 FR 11264
NPRM Comment Period End	05/13/02	
Final Rule	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Transferred from RIN 0990-AA05

Agency Contact: Timothy M. White, Associate General Counsel, Business and Administrative Law Division, Department of Health and Human Services, Room 5362, HHS Cohen Building, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0150

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-AA05

RIN: 0991–AB20

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

Priority: Other Significant

Legal Authority: 22 USC 2451 et seq; 8 USC 1182(e)

CFR Citation: 45 CFR 50

Legal Deadline: None

Abstract: This regulation will expand the Department's role in requesting waivers of the two year foreign residence requirement. HHS previously only requested waivers for J-1 visa holders for research. This will permit the review of applications based on 40 hours per week primary care in an HHS-designated health manpower shortage area or a medically underserved area.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Joyce Edith Jones, International Affairs Specialist, Department of Health and Human Services, Office of the Secretary, Room 639H, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 690-6174
Fax: 202 690-7127

RIN: 0991–AB21

915. 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	FR Cite
NPRM	06/19/87	52 FR 23311
NPRM Comment Period End	08/18/87	
Second NPRM	08/13/02	67 FR 52696
Second NPRM Comment Period End	10/12/02	
Final Rule	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Additional Information: Transferred from RIN 0990-AA02

Agency Contact: Katherine M. Drews, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0150

Related RIN: Previously reported as 0990-AA02

RIN: 0991–AB22

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

916. 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	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991–AB03

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

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 1128A(a)(5)

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: The proposed final rule would set forth in the OIG's civil money penalty provisions in 42 CFR part 1003 a new safe harbor for unlawful inducements to beneficiaries to provide protection for independent dialysis facilities that pay, in whole or in part, premiums for Supplementary Medical Insurance (Medicare part B) or Medicare Supplemental Health Insurance policies (Medigap) for financially needy Medicare beneficiaries with end-stage renal disease (ESRD). The safe harbor would specifically establish various standards that, if met, would result in the particular arrangement being protected from civil penalties under section 1128A(a)(5) of the Social Security Act.

Timetable:

Action	Date	FR Cite
Final Rule	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–AB04

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

Priority: Other Significant

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

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

Legal Deadline: None

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

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Federal, Tribal

Agency Contact: Robinsue Frohboese, Principal Deputy Director, Office for Civil Rights, Department of Health and Human Services, Office of the Secretary Phone: 202 619-0403

RIN: 0991–AB10

919. 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	FR Cite
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,

HHS—OS — Long-Term Actions

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)

920. MODIFICATIONS TO STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 160; 45 CFR 164

Completed:

Reason	Date	FR Cite
Final Rule	08/14/02	67 FR 53182

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal, State, Local, Tribal

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

Agency Contact: Susan McAndrew
Phone: 202 205-8725

RIN: 0991–AB14

921. IMPLEMENTING THE BIOTERRORISM PREVENTION AND RESPONSE ACT OF 2001

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	09/06/02	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Tribal, Federal

Agency Contact: Alex Azar
Phone: 202 690-7741

RIN: 0991–AB15

Department of Health and Human Services (HHS) — Long-Term Actions
Substance Abuse and Mental Health Services Administration (SAMHSA)

922. 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)

923. CONTROL OF COMMUNICABLE DISEASES

Regulatory Plan: This entry is Seq. No. 29 in part II of this issue of the **Federal Register**.

RIN: 0920–AA03

924. 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

HHS—CDC **Proposed Rule Stage**

restructured fee schedule; and 5) fee retention in the respirator program.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

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)

925. 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 Par 83

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/25/02	67 FR 42962
Final Rule	01/00/03	

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

926. ● POSSESSION, USE, AND TRANSFER OF SELECT AGENTS

Regulatory Plan: This entry is Seq. No. 30 in part II of this issue of the **Federal Register**.

RIN: 0920–AA08

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

927. METHODS FOR ESTIMATING RADIATION DOSE AND GUIDELINES FOR ASSESSING PROBABILITY OF CANCER FOR ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM

Priority: Other Significant

CFR Citation: 42 CFR 81; 42 CFR 82

Completed:

Reason	Date	FR Cite
Final Rule	05/02/02	67 FR 22296

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Larry Elliott
Phone: 513 841-4498

RIN: 0920–AA05

Department of Health and Human Services (HHS) — Completed Actions
Departmental Management (HHSDM)

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

Timetable:

Action	Date	FR Cite
Transferred to RIN 0991-AB22	10/01/02	

RIN: 0990–AA02

929. ADMINISTRATIVE WAGE GARNISHMENT

Timetable:

Action	Date	FR Cite
Transferred to RIN 0991-AB20	08/23/02	

RIN: 0990–AA05

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

Prerule Stage

930. 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	FR Cite
ANPRM	11/00/02	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Aida L. Sanchez, Special Assistant to the Director, Department of Health and Human Services, Food and Drug Administration, HFD-650, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-5847

RIN: 0910–AC23

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

Proposed Rule Stage

931. ESTABLISHMENT REGISTRATION AND LISTING 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 biological products. 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 require the electronic submission of most registration and listing information.

Timetable:

Action	Date	FR Cite
NPRM	05/00/03	

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
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910–AA49

932. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Regulatory Plan: This entry is Seq. No. 31 in part II of this issue of the **Federal Register**.

RIN: 0910–AA97

933. 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 a comprehensive review of the regulations that has been performed by FDA. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on House Resources and Intergovernmental Relations; the General Accounting Office; the Institute of Medicine, as well as public comments. Some of the subjects intended to be addressed in the rulemakings include: 1) labeling; 2) notification of end users of plasma-derivative products of product safety information; and 3) requirements for 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 09/00/03
Requlations 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 05/00/03
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
Phone: 301 827-6210
Fax: 301 594-1944

Related RIN: Related To 0910-AB76

RIN: 0910–AB26

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

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	

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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Fax: 301 827-5562
Email: pendletonb@cder.fda.gov

RIN: 0910–AB34

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935. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 225

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

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
Phone: 301 827-6651
Email: ggraber@cvm.fda.gov

RIN: 0910–AB70

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

Regulatory Plan: This entry is Seq. No. 32 in part II of this issue of the **Federal Register**.

RIN: 0910–AB88

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937. 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	FR Cite
NPRM	03/00/03	

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
Phone: 301 827-0587
Fax: 301 827-4774
Email: pchao@oc.fda.gov

RIN: 0910–AB96

938. CONTROL OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION AND RETAIL

Regulatory Plan: This entry is Seq. No. 33 in part II of this issue of the **Federal Register**.

RIN: 0910–AC14

939. INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS

Priority: Info./Admin./Other

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

CFR Citation: 21 CFR 56.106

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/03	

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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Email: pchao@oc.fda.gov

RIN: 0910–AC17

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

Priority: Other Significant

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

CFR Citation: Not Yet Determined

Legal Deadline: None

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

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

CWD is endemic in cervid populations in certain areas of Wisconsin, Colorado, Nebraska, Wyoming, Kansas, Montana, Oklahoma, South Dakota, New Mexico, Minnesota, and Canada. The disease has been identified in wild and farmed elk and wild deer populations. 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. Scientific studies in the literature suggest 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 likely to be infectious. Therefore, FDA is proposing to require that food or cosmetic products derived from animals exposed to CWD not enter into commerce.

Timetable:

Action	Date	FR Cite
NPRM	09/00/03	

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

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

Regulatory Plan: This entry is Seq. No. 34 in part II of this issue of the **Federal Register**.

RIN: 0910–AC25

942. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS

Regulatory Plan: This entry is Seq. No. 35 in part II of this issue of the **Federal Register**.

RIN: 0910–AC26

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 800.20

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

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
Phone: 301 827-2974
Fax: 301 594-4795
Email: jms@cdrh.fda.gov

RIN: 0910–AC32

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944. 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	FR Cite
NPRM	07/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

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

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945. • ADMINISTRATIVE DETENTION

Regulatory Plan: This entry is Seq. No. 36 in part II of this issue of the **Federal Register**.

RIN: 0910–AC38

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946. • ESTABLISHMENT AND MAINTENANCE OF RECORDS TO IDENTIFY IMMEDIATE PREVIOUS SOURCE AND IMMEDIATE SUBSEQUENT RECIPIENT OF FOODS

Regulatory Plan: This entry is Seq. No. 37 in part II of this issue of the **Federal Register**.

RIN: 0910–AC39

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947. • REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Regulatory Plan: This entry is Seq. No. 38 in part II of this issue of the **Federal Register**.

RIN: 0910–AC40

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948. • ESTABLISHMENT OF PRIOR NOTIFICATION REQUIREMENT FOR ALL IMPORTED FOOD SHIPMENTS

Regulatory Plan: This entry is Seq. No. 39 in part II of this issue of the **Federal Register**.

RIN: 0910–AC41

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949. 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	FR Cite
NPRM	03/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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
Phone: 301 827-6652

HHS—FDA **Proposed Rule Stage**

Fax: 301 594-4512

Related RIN: Previously reported as 0910-AB50

RIN: 0910–AC43

950. ● 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

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

RIN: 0910–AC48

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

951. 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 310; 21 CFR 340 to 345; 21 CFR 330; 21 CFR 333 to 339

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:

Antidiarrheal Products
NPRM (Amendment)(Trav. Diar.) 04/00/03
Final Action 04/00/03
Antiemetic Products
Final Action (Amendment) (Warning) 12/00/02
Antiperspirant Products
Final Action 04/00/03
Cough/Cold (Antihistamine) Products
Final Action (Amendment)(Warning) 12/00/02
Cough/Cold (Antitussive) Products
Final Action (Amendment)(Warning) 12/00/02
Cough/Cold (Combination) Products
Final Action 04/00/03
Cough/Cold (Nasal Decongestant) Products
NPRM (Phenylpropanolamine) 04/00/03
External Analgesic Products
Final Action (Amendment)(Warning) 12/00/02
Ingrown Toenail Relief Products
NPRM 10/04/02 (67 FR 62218)
Internal Analgesic Products
NPRM (Amendment)(Ibuprofen) 08/12/02 (67 FR 54139)
NPRM (Amendment) (Pediatric) 04/00/03
Labeling of Drug Products for OTC Human Use
NPRM (Convenience Sizes) 03/00/03
Final Action (Ca/Mg/K/Na) 06/00/03
Final Action (Sodium Labeling) 06/00/03
NPRM (Sodium Labeling) 06/00/03
Laxative Drug Products
NPRM (Amendment) (Psyllium Granular Dosage Form) 10/00/03
Nighttime Sleep Aid Products
Final Action (Amendment)(Warning) 12/00/02
Ophthalmic Products
NPRM (Emergency First Aid Eyewashes) 01/00/03
Final Action (Technical Amendment) 01/00/03
Oral Health Care Products
ANPRM (Plaque/Gingivitis) 04/00/03
Pediculicide Products
NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
Salicylate (Reye Syndrome)
Final Action (Warning) 04/00/03
Skin Protectant Products
Final Action 04/00/03
Final Action (Astringent) 06/00/03
NPRM (Astringent) 06/00/03
Status of Certain Category II and III Ingredients
Final Action 05/09/02 (67 FR 31123)
Final Action 05/09/02 (67 FR 31125)
Sunscreen Products
Final Action (Names) 06/20/02 (67 FR 41821)
ANPRM (and Insect Repellent) 02/00/03
NPRM (UVA/UVB) 08/00/03
Vaginal Contraceptive Products
NPRM (Amendment) 03/00/03
Weight Control Products
NPRM (Phenylpropanolamine) 04/00/03

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
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RIN: 0910–AA01

952. 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 proposed rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the proposed rule would provide four different routes for exporting an unapproved new drug product for investigational use. One route would permit exportation, if the drug is the subject of an investigational new drug application (IND) and is being exported for use in the investigation. A second route would permit exportation,

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

Timetable:

Action	Date	FR Cite
NPRM	06/19/02	67 FR 41642
Final Action	05/00/03	

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
Phone: 301 827-0587
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RIN: 0910–AA61

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

Priority: Other Significant

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

CFR Citation: 21 CFR 50; 21 CFR 312

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/05/99	64 FR 54180
Final Action	03/00/03	

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

954. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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

RIN: 0910–AA94

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

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 351

CFR Citation: 21 CFR 610.11(g)

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) issued a direct final rule and companion proposed rule to amend the biologics regulations by adding ''cellular therapy products'' to the list of products excepted from the general safety test (GST) and by adding an administrative procedure for obtaining an exemption from the GST requirements for other biological products. Because the agency received significant adverse comment on the administrative procedure portion of the direct final rule, FDA withdrew that portion of the rule and confirmed the remaining portion. FDA intends to finalize the companion proposed rule to respond to the significant adverse comment on the administrative procedure portion of the rule. FDA is taking this action because the GST may not be relevant or necessary for all biological products, including cellular therapy products, currently in various stages of development. This action is part of FDA's continuing effort to achieve the objectives of the ''Reinventing Government'' initiative, and is intended to reduce the burden of unnecessary regulations on biological products without diminishing the protection of the public health.

Timetable:

Action	Date	FR Cite
Direct Final Rule	04/20/98	63 FR 19399
Proposed Rule - Companion Document to Direct Final Rule	04/20/98	63 FR 19431
Direct Final Rule Confirmation in Part	08/05/98	63 FR 41718
Direct Final Rule Withdrawn in Part	08/05/98	63 FR 41718
Final Action	03/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Stephen M. Ripley, Team Leader, 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

RIN: 0910–AB51

956. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

Priority: Other Significant

Legal Authority: 21 USC 356a

CFR Citation: 21 CFR 314

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	06/28/99	64 FR 34608
Final Action	09/00/03	

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
Phone: 301 594-2041
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RIN: 0910–AB61

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

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

RIN: 0910–AB66

958. CGMPS FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV (LOOKBACK)

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

RIN: 0910–AB76

959. ANTIBIOTIC RESISTANCE LABELING

Priority: Other Significant

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

CFR Citation: 21 CFR 201.24

Legal Deadline: None

Abstract: The final rule would require the inclusion of certain statements about the use of antibiotics in the prescription drug labeling of these products. These statements will emphasize the proper use of these products in an effort to reduce the development of drug-resistant bacterial strains.

Timetable:

Action	Date	FR Cite
NPRM	09/19/00	65 FR 56511
Final Rule	03/00/03	

Regulatory Flexibility Analysis Required: No

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–AB78

960. REQUIREMENTS FOR SUBMISSION OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS IN ELECTRONIC 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; 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	FR Cite
NPRM	05/03/02	67 FR 22367
Final Action	09/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Virginia G. Beakes, 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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Email: beakesv@cder.fda.gov

RIN: 0910–AB91

961. 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 10/17/2000, 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 and provide additional protections for children involved as subjects in clinical investigations of FDA-regulated products, as required by the Children's Health Act of 2000.

Timetable:

Action	Date	FR Cite
Interim Rule	04/24/01	66 FR 20589
Final Rule	06/00/03	

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

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962. 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 no more than 25 ug/L of aluminum to state ''contains no more than 25ug/L'' rather than the exact amount of aluminum.

Timetable:

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

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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Fax: 301 827-5562

RIN: 0910–AC18

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

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

RIN: 0910–AC35

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964. ● RECORDS AND REPORTS CONCERNING EXPERIENCE WITH APPROVED NEW ANIMAL DRUGS

Priority: Other Significant

Legal Authority: 21 USC 360b(l)

CFR Citation: 21 CFR 514.80

Legal Deadline: None

Abstract: In the Federal Register of December 17, 1991 (56 FR 65581), FDA published a proposed rule to revise Section 510.300 (21 CFR 510.300) and to redesignate it a Section 514.80 (21 CFR 514.80). This regulation implements section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)), which provides that, following approval of a new animal drug application or an abbreviated new animal drug application, applicants must establish and maintain records and make reports to the agency as prescribed by regulation or order. FDA proposed the revision to define more clearly the kinds of information to be maintained and submitted by the applicant and to revise the timing and content of certain reports to enhance the usefulness of the information.

After considering comments submitted in response to the proposed rule for records and reports, FDA adopted the rule in modified form. Therefore, FDA issued an interim final rule on February 4, 2002 (67 FR 5046), which differed in some respects from the proposed rule. For instance, the interim final rule did not address medicated feed applications because they were eliminated by the Animal Drug Availability Act of 1996. Also, while the proposed rule for records and reports proposed to remove 21 CFR 510.310, which addressed records and reports for new animal drugs approved before June 20, 1963, FDA issued a final rule that revoked this provision in response to the Administration's ''Reinventing Government Initiative'' (61 FR 37680, July 19, 1996). The proposed rule for records and reports followed a style and format similar to the human drug records and reports regulations in part 314 (21 CFR part 314). The interim final rule maintained a similar style and format, but removed many of the proposed records and reports requirements that are not necessary to monitor animal drugs.

FDA received 33 comments to the interim final rule. In response to those comments, the agency further streamlined and clarified the regulation. FDA is affirming the interim final rule on its requirements for records and reports concerning experiences with approved new animal drugs (67 FR 5046) with modifications. The modifications include: revising the definitions of ''applicant'' and ''serious adverse drug experience;'' modifying the reporting requirement for summary reports of increased frequency of adverse drug experiences; clarifying what safety and efficacy records a nonapplicant versus an applicant must maintain; changing one word in the title of the section of the regulation pertaining to nonclinical laboratory studies and clinical data; eliminating the requirement of submission of prepublication manuscripts relating to completed clinical trials; changing

distributor's labeling so that the qualifying phrase that must precede the name and address of the distributor is as permitted by 21 CFR 201.1; and revising the section of the rule pertaining to distributor's signed statements to state that the distributor will promote the product only for use under the conditions stated in the approved labeling.

Timetable:

Action	Date	FR Cite
NPRM	12/17/91	56 FR 65581
NPRM Comment Period End	02/18/92	
Interim Final Rule	02/04/02	67 FR 5046
Interim Final Rule Comment Period End	04/05/02	
Interim Final Rule Effective Date Delayed	07/31/02	67 FR 49568
Final Action	01/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Glenn Peterson, Mathematician/Statistician (Biomedical), Department of Health and Human Services, Food and Drug Administration, HFV-212, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
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Email: gpeterso@cvm.fda.gov

Related RIN: Previously reported as 0910-AA02

RIN: 0910–AC42

965. PRESUBMISSION CONFERENCES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b

CFR Citation: 21 CFR 514

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/25/00	65 FR 51782
Final Action	06/00/03	

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

966. 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 500.82; 21 CFR 500.84; 21 CFR 500.88

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is amending 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 current operational definition of no residue, it is possible for a residue detected by a method approved by FDA to be considered ''no residue.'' FDA is revising its regulations to make them consistent with a 1995 Department of Justice opinion regarding this definition. The changes revise 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	FR Cite
NPRM	01/17/02	67 FR 2384
NPRM Comment Period Ends	04/17/02	
Final Action	01/00/03	

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
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Email: sbrynes@cvm.fda.gov

Related RIN: Previously reported as 0910-AC13

RIN: 0910–AC45

967. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 320

Legal Deadline: None

Abstract: The final rule revises and clarifies certain sections of parts 314 and 320 and eliminates duplication and inconsistencies.

Timetable:

Action	Date	FR Cite
NPRM	11/19/98	63 FR 64222
NPRM Comment Period End	02/02/99	
Final Rule	05/00/03	

Regulatory Flexibility Analysis Required: 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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Related RIN: Previously reported as 0910-AA51

RIN: 0910–AC47

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

Long-Term Actions

968. 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.
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 07/09/96 (61 FR 36154)
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

Agency Contact: Shellee Anderson, Food Technologist, Department of Health and Human Services, Food and Drug Administration, HFS-800, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AA04

969. 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; 21 CFR 512

Legal Deadline: None

Abstract: FDA is proposing to revise its regulations governing investigational use of new animal drugs by proposing to delete 21 CFR 511 and establish in 21 CFR part 512 revised investigational use of new animal drug regulations. The investigational use new animal drug regulations are expected to include regulations to implement provisions of the Animal Drug Availability Act of 1996, specifically presubmission conferences, and implement parts of the President's National Performance Report, ''Reinventing the Regulation of Animal Drugs,'' May 1996. In the reinventing regulations report, FDA proposed to revise its regulations to reflect numerous new process changes and programs that will enable a more streamlined animal drug application review and approval process, and that would result in less regulatory burden upon industry and FDA while maintaining the safety and effectiveness of new animal drugs. In addition, FDA is initiating a review of this rule 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	FR Cite
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

970. ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)

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 to take actions to screen 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 human cells, tissues, and cellular and tissue-based products regulated as drugs, medical devices, and/or biological products to incorporate the new donor suitability requirements into existing good manufacturing practice regulations for those products.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

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

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

971. CURRENT GOOD TISSUE PRACTICE FOR MANUFACTURERS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS); INSPECTION AND ENFORCEMENT

Priority: Other Significant

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

CFR Citation: 21 CFR 1271

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to require certain manufacturers of human cells and tissue to follow current good tissue practice (GTP), which includes proper handling, processing, and storage of human cells and tissue, recordkeeping, the maintenance of a quality program labeling and reporting. FDA is also proposing inspection and enforcement provisions.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

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

972. PREMARKET NOTICE CONCERNING BIOENGINEERED FOODS

Priority: Other Significant

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

CFR Citation: 21 CFR 192; 21 CFR 592

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is requiring the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is requiring that this submission be made at least 120 days prior to the commercial distribution of such foods. FDA took this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The action will permit the agency to assess on an ongoing basis whether plant-derived bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act.

Timetable:

Action	Date	FR Cite
NPRM	01/18/01	66 FR 4706
Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Linda Kahl, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-206, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Fax: 202 418-3131
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RIN: 0910–AC15

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

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

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The U.S. Department of Agriculture's Animal and Plant Health Inspection Service maintains, by regulation in 9 CFR 94.18(a), a list of countries: 1) where bovine spongiform encephalopathy (BSE) exists; and 2) that present an undue risk of introducing BSE into the United States. This proposed rule would restrict, in FDA-regulated products, the use of most materials derived from bovine and ovine animals born, raised, or slaughtered in a country listed in 9 CFR 94.18(a). In addition, there would be a waiver provision that could be used under appropriate criteria.

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-306, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AC19

974. 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 rule will enable all manufacturers to most easily comply by implementing a phase-in compliance approach that will minimize the cost. FDA seeks to reclassify these devices under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1)).

Timetable:

Action	Date	FR Cite
NPRM	12/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0910–AC30

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

Completed Actions

975. USE OF OZONE-DEPLETING SUBSTANCES

Priority: Other Significant

CFR Citation: 21 CFR 2

Completed:

Reason	Date	FR Cite
Final Action	07/24/02	67 FR 48370

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Wayne H. Mitchell
Phone: 301 594-2041
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RIN: 0910–AA99

976. FOOD ADDITIVES: FOOD CONTACT SUBSTANCES NOTIFICATION SYSTEM

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 20.100; 21 CFR 58.3; 21 CFR 170.3; 21 CFR 170.100 to 170.105; 21 CFR 171.1; 21 CFR 171.4; 21 CFR 174.5; 21 CFR 179.25; 21 CFR 170.106; ...

Completed:

Reason	Date	FR Cite
Final Rule	05/21/02	67 FR 35724

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Mitchell Alan Cheeseman
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RIN: 0910–AB94

977. EFFICACY EVIDENCE NEEDED FOR PRODUCTS TO BE USED AGAINST TOXIC SUBSTANCES WHEN HUMAN STUDIES ARE UNETHICAL

Priority: Other Significant

CFR Citation: 21 CFR 314; 21 CFR 601

Completed:

Reason	Date	FR Cite
Final Action	05/31/02	67 FR 37988

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Wayne H. Mitchell
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RIN: 0910–AC05

978. REVOCATION OF CONDITIONS FOR MARKETING DIGOXIN PRODUCTS FOR ORAL USE

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 310.500

Completed:

Reason	Date	FR Cite
Final Rule	06/26/02	67 FR 42992

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Mary E. Catchings
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RIN: 0910–AC12

979. POSTMARKET SURVEILLANCE

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 822

Completed:

Reason	Date	FR Cite
Final Action	06/06/02	67 FR 38878

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Joseph M. Sheehan
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RIN: 0910–AC31

Department of Health and Human Services (HHS)

Health Resources and Services Administration (HRSA)

Proposed Rule Stage

980. 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 NPRM proposes to require that, in addition to reporting to the National Practitioner Data Bank medical malpractice payments made where physicians or other health care practitioners are named in medical malpractice actions or claims, judgments or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgments or settlements but who furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health care entity to ''shield'' practitioners. It would also require malpractice payers, in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified and to provide the name of the corporate health care entity.

Timetable:

Action	Date	FR Cite
NPRM	12/24/98	63 FR 71255
NPRM Comment Period End	02/22/99	
Second NPRM	11/00/02	

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

RIN: 0906–AA41

981. 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 NPRM will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
NPRM Comment Period End	01/04/99	
Second NPRM	11/00/02	

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, National Center for Health Workforce Analysis, Bureau of Health Professions, 4350 East-West Highway, Bethesda, MD 20814
Phone: 301 594-0816
Email: dsd@hrsa.gov

RIN: 0906–AA44

982. 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 which 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	FR Cite
NPRM	11/00/02	

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)
Health Resources and Services Administration (HRSA)

Completed Actions

983. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 100

Completed:

Reason	Date	FR Cite
Final Rule	07/25/02	67 FR 48558

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Marian Jordan
Phone: 301 443-4998
Fax: 301 443-8196
Email: gevans@hrsa.gov

Related RIN: Duplicate of 0906-AA58

RIN: 0906–AA55

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

Final Rule Stage

984. 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	FR Cite
NPRM	03/25/99	64 FR 14559
NPRM Comment Period End	07/26/99	
Final Action	11/00/02	

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)
Indian Health Service (IHS)

Completed Actions

985. TRIBAL SELF-GOVERNANCE AMENDMENTS

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Rule	05/17/02	67 FR 35333

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal, Tribal

Agency Contact: Paula K. Williams
Phone: 301 443-7821

RIN: 0917–AA05

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

Proposed Rule Stage

986. 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	FR Cite
NPRM	11/00/02	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of

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

987. 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	FR Cite
NPRM	12/00/02	

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

988. 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	FR Cite
NPRM	03/00/03	

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

989. ● 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	FR Cite
NPRM	03/00/03	

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

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

Final Rule Stage

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 68d

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/05/02	67 FR 50622
Final Rule	12/00/02	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0925–AA18

HHS—NIH **Final Rule Stage**

991. 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 been reexamining the peer review process as part of its reinvention of Government initiatives and have found ambiguities, misstatements, and voids in the existing regulations. These regulations, which govern the first level of review, are being amended to reflect current policies and procedures.

Timetable:

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

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

Department of Health and Human Services (HHS)
National Institutes of Health (NIH) **Long-Term Actions**

992. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 287a-3a

CFR Citation: 42 CFR 52b

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: Next Action Undetermined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0925–AA31

Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS) **Proposed Rule Stage**

993. 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	FR Cite
NPRM	11/00/02	
NPRM Comment Period End	02/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Barbara Bullman, Policy Analyst, Department of Health and Human Services, Office of Public Health and Science, Suite 700, 5515 Security Lane, Rockville, MD 20852
Phone: 301 443-5300
Fax: 301 443-5351

Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Public Health and Science, Suite 700, 5515 Security Lane, Rockville, MD 20852
Phone: 301 443-3400

Related RIN: Related To 0940-AA01

RIN: 0940–AA04

HHS—OPHS — Proposed Rule Stage

994. ● 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 reqire registration of institutional review boards (IRBs) with the Department of Health and Human Services (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 te Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single, HHS IRB Registration system. FDA will simultaneously publish a proposed rule regarding FDA IRB registration requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	
NPRM Comment Period End	03/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: George Gasparis, Department of Health and Human Services, Office of Public Health and Science, Office for Human Research Protections, The Tower Building, Suite 200, 1101 Wootton Parkway, Rockville, MD 20852
Phone: 301 496-7005

RIN: 0940–AA06

Department of Health and Human Services (HHS) — Final Rule Stage
Office of Public Health and Science (OPHS)

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 94

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	11/28/00	65 FR 70830
NPRM Comment Period End	01/29/01	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Barbara Bullman, Policy Analyst, Department of Health and Human Services, Office of Public Health and Science, Suite 700, 5515 Security Lane, Rockville, MD 20852
Phone: 301 443-5300
Fax: 301 443-5351

Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Public Health and Science, Suite 700, 5515 Security Lane, Rockville, MD 20852
Phone: 301 443-3400

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

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

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

RIN: 0938–AG82

997. CRITERIA FOR APPROVAL OF FACILITIES TO PERFORM COVERED HEART, LIVER, LUNG, PANCREAS, AND INTESTINAL 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	FR Cite
Proposed Rule	07/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Marty Abeln, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-1032

Kathy Linstromberg, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-8279

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

RIN: 0938–AH17

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

Timetable:

Action	Date	FR Cite
Proposed Rule	07/00/03	

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

Rachael Weinstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6775

RIN: 0938–AH27

999. 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 rule is needed as part of the Administration's anti-fraud and abuse efforts. It would give us the authority to enroll and re-enroll providers with time frames for re-enrollment.

Timetable:

Action	Date	FR Cite
Proposed Rule	01/00/03	

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

1000. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (CMS-6017-P)

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

RIN: 0938–AH87

1001. MEDICAL CHILD SUPPORT AND HEALTH INSURANCE COVERAGE OF DEPENDENT CHILDREN (CMS-2081-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1396(a)(25); 42 USC 1396(a)(45); 42 USC 1396(a)(60); 42 USC 1396(o); 42 USC 1396g-1; 42 USC 1396(k)

CFR Citation: 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.170

Legal Deadline: None

Abstract: This proposed rule would require States to provide assurances that laws relating to medical child support have satisfactorily been implemented in accordance with the Social Security Act. These laws would impose requirements on insurers, employers, and State Medicaid agencies that would result in greater enrollment opportunities for children, facilitate the filing of claims by custodial parents, and establish new payment disbursement criteria. This requirement would implement section 13623, OBRA of 1993.

Timetable:

Action	Date	FR Cite
Proposed Rule	02/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Sue Knefley, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0488

RIN: 0938–AI21

1002. MEDICARE HOSPICE CARE AMENDMENTS (CMS-1022-P)

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 proposed rule revises certain regulations governing coverage and payments for hospice care under the Medicare program as required by the Balanced Budged Act of 1997, the Medicare, Medicaid, and State Child Health Insurance Program Balanced Budget Refinement Act of 1999, and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

Timetable:

Action	Date	FR Cite
Proposed Rule	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

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

Related RIN: Previously reported as 0938-AH73

RIN: 0938–AJ36

1003. 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 establish service standards for suppliers of home oxygen equipment, therapeutic shoes, and home infusion therapy.

Timetable:

Action	Date	FR Cite
Proposed Rule	08/00/03	

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

1004. ALL PROVIDER BAD DEBT PAYMENT (CMS-1126-P)

Priority: Other Significant

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 proposed rule would implement a court settlement agreement and remove the cap on End Stage Renal Disease (ESRD) bad debt reimbursement, which limits payment of allowable bad debts to the facility's unrecovered costs. This rule would also reduce the amount of reimbursement for bad debt for all providers and suppliers that receives reimbursement by 30 percent.

Timetable:

Action	Date	FR Cite
Proposed Rule	11/00/02	

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

1005. 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	FR Cite
NPRM	03/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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–AK23

HHS—CMS **Proposed Rule Stage**

1006. HEALTH INSURANCE REFORM: CLAIMS ATTACHMENTS STANDARDS (CMS-0050-P)

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

RIN: 0938–AK62

1007. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR PROSPECTIVE PAYMENT SYSTEM PROVIDERS (CMS-3055-P)

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 proposed rule would increase the rate of reimbursement of photocopy expenses as required by the regulations governing Utilization and Quality Control Peer Review Organizations. Our current regulations identify the photocopying reimbursement methodology for prospective payment system hospitals.

Timetable:

Action	Date	FR Cite
Proposed Rule	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Valerie Mattison-Brown, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5958

RIN: 0938–AK68

1008. MODIFICATIONS TO MEDICARE MANAGED CARE RULES (CMS-4041-P)

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 proposed rule would implement certain Medicare payment provisions of the Medicare, Medicaid, and SCHIP Benefits and Improvement Act of 2000. The 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. Moreover, this proposed rule describes authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in the M+C plans offered to employers or labor unions.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	

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: Frank Szeflinski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services
Phone: 303 844-7119

RIN: 0938–AK71

1009. MEDICARE INPATIENT DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FORMULA (CMS-1171-P)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 412106

Legal Deadline: None

Abstract: This proposed rule clarifies the Medicare DSH adjustment calculation in reference to the inclusion of Medicaid 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	FR Cite
Proposed Rule	01/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Stephen Phillips, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4548

RIN: 0938–AK77

1010. 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: This proposed rule would revise the requirements concerning the written statement of intent procedures for filing Medicare claims from the current Medicare regulation.

Timetable:

Action	Date	FR Cite
Proposed Rule	04/00/03	

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, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4475

RIN: 0938–AK79

1011. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS-3064-P)

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

RIN: 0938–AK81

1012. EXTENDING MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENTITLEMENT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS-4018-P)

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

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 rule would provide working disabled individuals with continued Medicare entitlement for an additional 54 months beyond the current limit. It would implement the Ticket to Work and Work Incentives Improvement Act of 1999.

Timetable:

Action	Date	FR Cite
Proposed Rule	03/00/03	

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

1013. 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 used to compute interest on provider, supplier overpayments and underpayments.

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

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

1014. USE OF RESTRAINT AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS-2130-P)

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

RIN: 0938–AL26

1015. 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 removes respiratory assist devices with bi-level capability and a back-up rate from the category for items requiring frequent and substantial servicing, and places them in the category for other items, or capped rental items. This rule corrects an error that occurred in 1992, where these devices were inappropriately placed in the category for items requiring frequent and substantial servicing.

Timetable:

Action	Date	FR Cite
Proposed Rule	03/00/03	

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

1016. SELF-DECLARATION OF CITIZENSHIP (CMS-2085-P)

Priority: Info./Admin./Other

Legal Authority: Public Law 104-193, Sec 431

CFR Citation: 42 CFR 435.410; 42 CFR 436.410

Legal Deadline: None

Abstract: This proposed rule would require States, on a post-determination basis, to carry out a process for verifying citizenship in a sample of cases to ensure that program integrity is being maintained. This proposed rule would also clearly state that acceptance of the individual's self-declaration is an option.

Timetable:

Action	Date	FR Cite
Proposed Rule	01/00/03	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Sarah DeLone, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7010

RIN: 0938–AL33

1017. 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 would implement 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	FR Cite
Proposed Rule	03/00/03	

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

1018. PROSPECTIVE PAYMENT SYSTEM FOR PSYCHIATRIC HOSPITALS (CMS-1213-P)

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

RIN: 0938–AL50

1019. 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.

Timetable:

Action	Date	FR Cite
Proposed Rule	05/00/03	

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, C4-26-22, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4477

RIN: 0938–AL54

1020. 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	FR Cite
Proposed Rule	04/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Terese Klitenic, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5942

RIN: 0938–AL62

1021. REQUEST FOR INFORMATION ON BENEFIT-SPECIFIC WAITING PERIODS (CMS-2150-N)

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	FR Cite
Notice	05/00/03	

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

1022. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS-4004-P)

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

RIN: 0938–AL67

1023. 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(c); 42 CFR 421.210(d); 42 CFR 421.210(e)

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Proposed Rule	07/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: James Holt, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1-14-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1953
Email: jholt@cms.hhs.gov

RIN: 0938–AL76

1024. 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 proposed rule would revise the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement.

Timetable:

Action	Date	FR Cite
Proposed Rule	06/00/03	

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

RIN: 0938–AL80

1025. 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	FR Cite
Proposed Rule	07/00/03	

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

1026. 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 10/15/93.

Timetable:

Action	Date	FR Cite
Proposed Rule	06/00/03	

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

1027. 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 rule would implement changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

Timetable:

Action	Date	FR Cite
Proposed Rule	05/00/03	

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

1028. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2004 (CMS-1469-P)

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

RIN: 0938–AL90

1029. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS-1471-P)

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

RIN: 0938–AL91

1030. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS: 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 inpatient hospital.

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	FR Cite
NPRM	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

1031. 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 06/28/2003 deadline in order to meet statutory effective date of 10/01/2003.

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. (We must publish this notice by 06/28/04 to meet the statutory effective date of 10/01/04.)

Timetable:

Action	Date	FR Cite
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

1032. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS (CMS-1474-P)

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 systems for inpatient rehabilitation facilities for FY 2004.

Timetable:

Action	Date	FR Cite
Proposed Rule	04/00/03	

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

RIN: 0938–AL95

1033. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2004 (CMS-1476-P)

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

RIN: 0938–AL96

1034. ● NONDISCRIMINATION IN POST-HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS-1224-P)

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would establish 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 would be made available to the public in order to enhance its understanding and awareness regarding the availability of Medicare-certified HHAs to serve the Medicare population.

Timetable:

Action	Date	FR Cite
NPRM	11/00/02	

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

1035. ● 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	FR Cite
Proposed Rule	06/00/03	

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

1036. ● TICKET TO WORK MEDICAID INFRASTRUCTURE GRANT (CMS-2165-N)

Priority: Routine and Frequent

Legal Authority: Social Security Act, sec 203; PL 106-170

CFR Citation: None

Legal Deadline: None

Abstract: This notice is an annual event that gives State agencies official notification of the Medicaid Grant Infrastructure Grant solicitation process.

Timetable:

Action	Date	FR Cite
Notice	02/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Joe A Razes, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-12-28, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6126
Email: jrazes@cms.hhs.gov

RIN: 0938–AM11

1037. ● REVISIONS TO AVERAGE WHOLESALE PRICE METHODOLOGY (CMS-1229-P)

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

RIN: 0938–AM12

1038. ● 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: 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	FR Cite
Proposed Rule	09/00/03	

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

1039. ● ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS-0008-P)

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

RIN: 0938–AM22

1040. ● LIABILITY OF THIRD PARTIES TO PAY FOR CARE AND SERVICES (CMS-2080-P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 13622 of OBRA '93; Sec 4741(a)(2) of BBA '97; Sec 4701(b) of BBA '97

CFR Citation: 42 CFR Part 433

Legal Deadline: None

Abstract: This rule would amend regulations governing third party liability. It adds Employee Retirement Income Security Act of 1974 (ERISA) plans, service benefit plans, and health maintenance organizations to the definition of liable third parties.

Timetable:

Action	Date	FR Cite
Proposed Rule	03/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

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–AM24

1041. ● MEDICAID DEFINITION OF QUALIFIED SPEECH PATHOLOGISTS AND AUDIOLOGISTS (CMS-2132-P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1905(a)(11) of the Social Security Act; 42 USC 1396d

CFR Citation: 42 CFR 440.110(a)

Legal Deadline: None

Abstract: This proposed rule would set forth changes in existing Medicaid regulations to establish provider standards consistent with those in the Medicare program. The Medicare definition of speech pathologist/audiologist defers to the States for the definition, and if States do not license these providers, defines specific training and education standards.

Timetable:

Action	Date	FR Cite
Proposed Rule	12/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Linda Peltz, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-3399

RIN: 0938–AM26

1042. ● 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.

HHS—CMS **Proposed Rule Stage**

Timetable:

Action	Date	FR Cite
Proposed Rule	09/00/03	

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

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

1043. REVISION OF MEDICARE/MEDICAID HOSPITAL CONDITIONS OF PARTICIPATION (CMS-3745-F)

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

RIN: 0938–AG79

1044. 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 with comment period revises the existing CoPs that HHAs must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of the Administration's efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs, while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Final Rule	07/00/03	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Janice Stevenson, Office of Clinical Standards and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4882

Rachael Weinstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6775

RIN: 0938–AG81

1045. MEDICARE AND MEDICAID PROGRAMS; TERMS, DEFINITIONS, AND ADDRESSES: TECHNICAL AMENDMENTS (CMS-9877-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395x(v)(1)(A); 42 USC 1395hh

CFR Citation: 42 CFR 400 to 440; 42 CFR 442 to 447; 42 CFR 455; 42 CFR 456; 42 CFR 462 to 466; 42 CFR 473 to 476; 42 CFR 482 to 489; 42 CFR 491 to 498

Legal Deadline: None

Abstract: This final rule would initiate the rationalization of our system of definitions, correct outdated addresses and formulas, clarify which steps of the appeals process are binding and which are final, remove content that is duplicative or unnecessary, and make other clarifying editorial changes.

Timetable:

Action	Date	FR Cite
NPRM	01/25/02	67 FR 3641
NPRM Comment Period End	03/26/02	
Final Rule	06/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Margaret Teeters, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-14-03, Division of Regulation and Issuances, 7500 Security Boulevard, Balitmore, MD 21244
Phone: 410 786-4678

RIN: 0938–AH53

1046. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS-0045-F)

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

RIN: 0938–AH99

1047. 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 would extend appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations.

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Final Rule	04/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Charles Waldhauser, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850 Phone: 410 786-6140

Yvonne West, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786-6479

RIN: 0938–AI49

1048. SECURITY STANDARDS (CMS-0049-F)

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

RIN: 0938–AI57

1049. 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 466.1

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

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/30/99	64 FR 67028
Final Action	08/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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

RIN: 0938–AI93

1050. EXTERNAL QUALITY REVIEW OF MEDICAID MANAGED CARE ORGANIZATIONS (CMS-2015-F)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302

CFR Citation: 42 CFR 438

Legal Deadline: None

Abstract: This final rule will require State agencies to contract with managed care organizations and to monitor and evaluate their performances through annual external, independent reviews conducted by accrediting organizations that are approved by CMS.

Timetable:

Action	Date	FR Cite
NPRM	12/01/99	64 FR 67223
Final Rule	12/00/02	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: State

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

Agency Contact: Sharon Gilles, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786-1177

RIN: 0938–AJ06

1051. REPORTING OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA AS PART OF THE CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES (CMS-3006-IFC)

Priority: Other Significant. Major under 5 USC 801.

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

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

CFR Citation: 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68

Legal Deadline: None

Abstract: This final rule requires home health agencies to electronically report OASIS data as a condition of participation in the Medicare program.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/25/99	64 FR 3748
Interim Final Rule	04/00/03	

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: Janice Stevenson, Office of Clinical Standards and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786-4882

RIN: 0938–AJ10

1052. 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.

Timetable:

Action	Date	FR Cite
NPRM	02/28/00	65 FR 10450
Final Rule	01/00/03	

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

1053. 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 final rule revises requirements for hospitals that transfuse blood and blood products regarding written procedures, quarantine, testing, and counseling for hepatitis C virus (HCV) and records maintenance.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Final Rule	06/00/03	

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

1054. 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	FR Cite
Interim Final Rule	01/22/01	66 FR 7148
60-Day Delay of Effective Date To 05/22/2001	03/21/01	66 FR 15800
Interim Final Rule Comment Period End	03/23/01	
Interim Final Rule Effective	03/23/01	
Interim Final Rule Amendment with Clarification	05/22/01	66 FR 28110
Interim Final Rule Comment Period End	07/23/01	
Final Action	06/00/03	

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

1055. APPLICATION OF INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES (OTHER THAN PHYSICIAN SERVICES) (CMS-1908-F)

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

Legal Authority: PL 105-33, sec 4316

CFR Citation: 42 CFR 405

Legal Deadline: None

Abstract: This final rule sets forth the process for establishing realistic and equitable payment amounts for all Medicare part B items and services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/07/98	63 FR 687
Final Action	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: William J. Long, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-08-27, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21228
Phone: 410 786-5655
Email: wlong@hcfa.gov

RIN: 0938–AJ97

1056. CLINICAL LAB REQUIREMENTS—REVISIONS TO REGULATIONS IMPLEMENTING CLIA (CMS-2226-F)

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	FR Cite
Final Action	11/00/02	

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

HHS—CMS

Final Rule Stage

1057. FIRE SAFETY REQUIREMENTS FOR RNHCI, ASC, HOSPICES, PACE, HOSPITALS, AND LONG-TERM CARE FACILITIES AND ICFS FOR THE MENTALLY RETARDED (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 final 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, Hospitals, Long-Term Care Facilities, and Intermediate Care Facilities for the Mentally Retarded.

Timetable:

Action	Date	FR Cite
Proposed Rule	10/26/01	66 FR 54179
Final Action	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tamara Syrek, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services
Phone: 410 786-3529

RIN: 0938–AK35

1058. HOSPITAL CONDITIONS OF PARTICIPATION: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENTS (QAPI) (CMS-3050-F)

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

RIN: 0938–AK40

1059. IMPROVEMENTS TO THE MEDICARE+CHOICE APPEALS AND GRIEVANCE PROCEDURES (CMS-4024-F)

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

Unfunded Mandates: Undetermined

Legal Authority: BBA, sec 4001; PL 105-33; Social Security Act, sec 1851 to 1859

CFR Citation: 42 CFR 422; 42 CFR 489

Legal Deadline: NPRM, Judicial, January 19, 2001.

Abstract: This final rule sets forth several improvements to the Medicare+Choice (M+C) appeal and grievance procedures. This rule addresses the termination date of provider services, independent review process, and discharge notices.

Timetable:

Action	Date	FR Cite
NPRM	01/24/01	66 FR 7593
Final Rule	02/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: The Settlement Agreement in Grijalva v. Shalala contemplates that a final rule will be published by the end of 2002.

Agency Contact: Tony Culotta, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4661

RIN: 0938–AK48

1060. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS-3063-F)

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

RIN: 0938–AK60

1061. 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 National Coverage Ddecisions.

Timetable:

Action	Date	FR Cite
Notice	12/00/02	

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

1062. HEALTH INSURANCE REFORM: MODIFICATIONS TO STANDARDS FOR ELECTRONIC TRANSACTIONS (CMS-0003-F)

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

RIN: 0938–AK64

1063. 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

Legal Deadline: None

Abstract: This final rule with comment period incorporates into regulations the provisions concerning ownership and investment exceptions in paragraphs (c) and (d) and the compensation exceptions in paragraph (e) of Section 1877 of the Social Security Act.

Timetable:

Action	Date	FR Cite
Final Action	05/00/03	

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

HHS—CMS **Final Rule Stage**

1064. MEDICAID MANAGED CARE; NEW PROVISIONS (CMS-2104-F2)

Priority: Info./Admin./Other

Legal Authority: BIPA '00

CFR Citation: 42 CFR 400

Legal Deadline: None

Abstract: This notice will correct typographical errors, cross references, and other discrepancies, in the rule published on June 14, 2002.

Timetable:

Action	Date	FR Cite
NPRM	08/20/01	66 FR 43613
NPRM Comment Period End	10/19/01	
Final Rule	06/14/02	67 FR 40989
Correction Notice	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Bruce Johnson, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD
Phone: 410 786-0615

Deirdre Duzor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4626

RIN: 0938–AK96

1065. 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 responds to public comments received and will revise certain provisions to the State Children's Health Insurance Program (SCHIP) final rule, published on January 11, 2002.

Timetable:

Action	Date	FR Cite
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	05/00/03	

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: Regina Fletcher, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3293

RIN: 0938–AL00

1066. 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)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Sec 1861(v)(1)(O) of the Social Security Act, as amended

CFR Citation: 42 CFR 413.134

Legal Deadline: None

Abstract: This final rule responds to public comments received and makes technical corrections to the Medicare provider reimbursement regulations that set forth requirements related to allowable costs.

Timetable:

Action	Date	FR Cite
Final Action	04/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Ann Pash, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4516
Email: apash@hcfa.gov

RIN: 0938–AL12

1067. 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 final rule would 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	FR Cite
Proposed Rule	03/29/02	67 FR 15149
Comment Period End	05/28/02	
Final Rule	03/00/03	

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

1068. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2003 PAYMENT RATES (CMS-1206-F)

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

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

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This final rule revises the Medicare hospital outpatient payment system beginning 01/01/03.

Timetable:

Action	Date	FR Cite
Notice	03/18/02	67 FR 11969

Action	Date	FR Cite
Proposed Rule	08/09/02	67 FR 52092
Comment Period End	10/07/02	
Final Action	11/00/02	

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: 410 786-0378

RIN: 0938–AL19

1069. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2003 (CMS-1204-FC)

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	FR Cite
Proposed Rule	06/28/02	67 FR 43846
Final Action	11/00/02	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

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

RIN: 0938–AL21

1070. 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 146.101; 45 CFR 146.111; 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.119; 45 CFR 146.145; ...

Legal Deadline: None

Abstract: This final rule addresses limitations on preexisting exclusions periods and requests for special enrollments.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/07/97	
Interim Final Rule Effective	07/07/97	
Final Action	05/00/03	

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

1071. 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 interim final rule changes the sunset date of regulations under the Mental Health Parity Act of 1996.

Timetable:

Action	Date	FR Cite
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	04/00/03	

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

1072. 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 would establish the requirement for community mental health cneters, ESRD facilities, hospices, rural health clinics, and federally qualified health centers to file cost reports in a standardized electronic format. This rule would also provide a delay or waiver of this requirement where implementation would result in financial hardship. The provisions of this rule would allow for more accurate preparation and more efficient processing of each cost report.

Timetable:

Action	Date	FR Cite
Proposed Rule	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

1073. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2003 (CMS-8013-N)

Priority: Other Significant

Legal Authority: 42 USC 1395e-2(g)(2)

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2003 under the Medicare hospital insurance program (part A). The Medicare statute specifies the formula used to determine these amounts.

Timetable:

Action	Date	FR Cite
Notice	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Directory, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6390

RIN: 0938–AL56

1074. PROGRAM FOR ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS-1201-F)

Priority: Other Significant

Legal Authority: 42 USC 1395, as revised by sec 903 of BIPA; 42 USC 1396, as revised by sec 903 of BIPA

CFR Citation: 42 CFR 460ff

Legal Deadline: None

Abstract: This rule revises the interim final rule with comment period that established requirements for Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. These are pre-paid, capitated programs for beneficiaries who meet special eligibility requirements and who elect to enroll. The revisions in this rule will implement section 903 of BIPA.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/01/02	67 FR 61496
Final Action	09/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Organizations

Government Levels Affected: State, Tribal

Federalism: Undetermined

Agency Contact: Janet Samen, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-08-15, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-9161

RIN: 0938–AL59

1075. MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2003 (CMS-8014-N)

Priority: Economically Significant

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

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 27, 2002.

Abstract: This notice announces the monthly actuarial rates for aged and disabled enrollees in the Medicare Supplementary Medical Insurance (SMI) program for 2003. It also announces the monthly SMI premium to be paid by all enrollees during 2003.

Timetable:

Action	Date	FR Cite
Notice	11/00/02	

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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6396

RIN: 0938–AL63

1076. PART A PREMIUMS FOR 2003 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS-8015-N)

Priority: Other Significant

Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2)

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the hospital insurance premium for calendar year 2003 under Medicare's hospital insurance program (part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Timetable:

Action	Date	FR Cite
Notice	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Directory, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6390

RIN: 0938–AL69

1077. 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	FR Cite
Proposed Notice	08/30/02	67 FR 55851
Final Notice	05/00/03	

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

1078. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2004 RATES (CMS-1470-N)

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

RIN: 0938–AL89

1079. ● FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2003 (CMS-1220-N)

Priority: Other Significant

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

CFR Citation: None

Legal Deadline: None

Abstract: This notice updates the fee schedule published 2/27/02 for ambulance services under the Medicare program, implementing section 1834(l) of the Social Security Act.

Timetable:

Action	Date	FR Cite
Notice	11/00/02	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

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–AL97

1080. ● UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS EFFECTIVE JANUARY 1, 2003 (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 with comment period will make additions to and deletions from the current list of Medicare covered Ambulatory Surgical Centers procedures.

Timetable:

Action	Date	FR Cite
Final Action	12/00/02	

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

1081. ● COMPREHENSIVE EMPLOYMENT DEMONSTRATION (CMS-2163-N)

Priority: Other Significant

Legal Authority: PL 106-170, sec 203

CFR Citation: None

Legal Deadline: None

Abstract: This notification of funding availability announces the establishment of the comprehensive employment opportunities demonstration whereby up to $9.0 million in funding will be awarded via a competitive process to remove barriers to employment for individuals with a disability.

Timetable:

Action	Date	FR Cite
Notice	02/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Karen L. Tritz, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0789
Fax: 410 786-9004
Email: ktritz@cms.hhs.gov

RIN: 0938–AM10

1082. ● 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	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/17/97	
Interim Final Rule Effective	07/17/97	
Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Effective	03/09/01	
Interim Final Rule Comment Period End	04/09/01	
Final Action	06/00/03	

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

HHS—CMS **Final Rule Stage**

1083. ● 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	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/07/97	
Interim Final Rule Effective	07/07/97	
NPRM	01/08/01	66 FR 1421
NPRM Comment Period End	04/09/01	
Final Action	07/00/03	

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

RIN: 0938–AM15

1084. ● TIME LIMITATION ON RECALCULATIONS AND DISPUTES UNDER THE DRUG REBATE PROGRAM (CMS-2175-IFC)

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	FR Cite
Interim Final Rule	12/00/02	

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

1085. ● 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-IFC2)

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 six months or until publication of phase II the effective date of the last sentence 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	FR Cite
Extension of Partial Delay of Final Rule Effective Date	11/00/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

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

Related RIN: Related To 0938-AL29

RIN: 0938–AM21

1086. ● INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR 2004 (CMS-8016-N)

Priority: Other Significant

Legal Authority: 42 USC 1395e-2(g)(2)

CFR Citation: None

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Notice	10/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Directory, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6390

RIN: 0938–AM31

1087. ● 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 27, 2002.

HHS—CMS — Final Rule Stage

Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (underage 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	FR Cite
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, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6396

RIN: 0938–AM32

1088. ● PART A PREMIUMS FOR 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)

CFR Citation: None

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Notice	10/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Directory, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6390

RIN: 0938–AM33

1089. ● APPLICATION OF EMERGENCY MEDICAL AND TREATMENT ACT (EMTALA) (CMS-1063-F)

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

RIN: 0938–AM34

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

1090. NATIONAL STANDARD EMPLOYER IDENTIFIER (CMS-0047-F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 162

Completed:

Reason	Date	FR Cite
Final Rule	05/03/02	67 FR 38009

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State

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

Agency Contact: Patricia Peyton
Phone: 410 786-1812

RIN: 0938–AI59

1091. NON-FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HEALTH INSURANCE PORTABILITY REQUIREMENTS (CMS-2033-F)

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 146

Completed:

Reason	Date	FR Cite
Interim Final Rule	07/26/02	67 FR 48802

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Dave Holstein
Phone: 410 786-1564

RIN: 0938–AK00

1092. SUPPLEMENTARY MEDICAL INSURANCE PREMIUM SURCHARGE AGREEMENTS (CMS-1221-F)

Priority: Other Significant

CFR Citation: 42 CFR 408.200; 42 CFR 408.201; 42 CFR 408.202; 42 CFR 408.205; 42 CFR 408.207; 42 CFR 408.210; ...

Completed:

Reason	Date	FR Cite
Final Action	09/27/02	67 FR 60993

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local

Agency Contact: Sandy Clarke
Phone: 410 786-7451

RIN: 0938–AK42

1093. PAYMENT FOR UPGRADED DURABLE MEDICAL EQUIPMENT; WITHDRAWAL OF PROPOSED RULE (CMS-1084-WN)

Priority: Info./Admin./Other

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	05/01/02	67 FR 21617

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: William J. Long
Phone: 410 786-5655
Email: wlong@hcfa.gov

RIN: 0938–AK50

1094. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS FOR FY 2003 (CMS-1177-F)

Priority: Other Significant

CFR Citation: 42 CFR 412

Completed:

Reason	Date	FR Cite
Comment Period End	05/21/02	
Final Rule	08/30/02	67 FR 55954

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Local, Federal

Agency Contact: Judith H. Richter
Phone: 410 786-2590

RIN: 0938–AK69

1095. REVISIONS TO TRANSACTION AND CODE SET STANDARDS FOR ELECTRONIC TRANSACTIONS (CMS-0005-P)

Priority: Other Significant

CFR Citation: 45 CFR 162

Completed:

Reason	Date	FR Cite
Proposed Rule	05/31/02	67 FR 38051
Merged With 0938-AK64	09/12/02	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State, Local, Tribal, Federal

Agency Contact: Gladys Wheeler
Phone: 410 786-0273

RIN: 0938–AK76

1096. MODIFICATIONS TO MANAGED CARE RULES BASED ON PAYMENT PROVISIONS IN BIPA AND TECHNICAL CORRECTIONS (CMS-4040-F)

Priority: Economically Significant

CFR Citation: 42 CFR 417; 42 CFR 422

Completed:

Reason	Date	FR Cite
Final Action	03/22/02	67 FR 13278

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Alfred G. D'Alberto
Phone: 410 786-1100

RIN: 0938–AK90

1097. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR FY 2003 (CMS-1198-NC)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	06/28/02	67 FR 43616

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Susan Levy
Phone: 410 786-9364

RIN: 0938–AL16

1098. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2003 (CMS-1202-N)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 413.330 to 413.50

Completed:

Reason	Date	FR Cite
Notice	07/31/02	67 FR 49798

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: William Ullman
Phone: 401 786-5667

RIN: 0938–AL20

1099. INPATIENT REHABILITATION FACILITY PROSPECTIVE PAYMENT SYSTEM FOR FY 2003 (CMS-1205-N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 412.600 to 412.632

Completed:

Reason	Date	FR Cite
Notice	08/01/02	67 FR 49928

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Laurence Wilson
Phone: 410 786-4603

RIN: 0938–AL22

1100. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR FY 2003 (CMS-1203-F)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 405; 42 CFR 412; 42 CFR 413; 42 CFR 485; 42 CFR 489

Completed:

Reason	Date	FR Cite
NPRM	05/09/02	67 FR 31403
Final Action	08/01/02	67 FR 49982

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Stephen Phillips
Phone: 410 786-4548

RIN: 0938–AL23

1101. MEDICARE PROGRAM; MEDICARE-ENDORSED PRESCRIPTION DRUG DISCOUNT CARD ASSISTANCE INITIATIVE (CMS-4027-F)

Priority: Economically Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Comment Period End	05/26/02	
Final Rule	09/04/02	67 FR 56618

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Paula Stannard
Phone: 202 690-7741

Teresa Decaro
Phone: 410 786-6604
Email: tdecaro@cms.hhs.gov

RIN: 0938–AL28

1102. MEDICARE-ENDORSED PRESCRIPTION DRUG DISCOUNT CARD ASSISTANCE INITIATIVE FOR STATE SPONSORS (CMS-4032-P)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	03/06/02	67 FR 10293

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Teresa Decaro
Phone: 410 786-6604
Email: tdecaro@cms.hhs.gov

RIN: 0938–AL30

1103. PEER REVIEW ORGANIZATIONS: NAME AND OTHER CHANGES—TECHNICAL AMENDMENTS (CMS-3088-FC)

Priority: Other Significant

CFR Citation: 42 CFR 400

Completed:

Reason	Date	FR Cite
Final Rule	05/24/02	67 FR 36539

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Valerie Mattison-Brown
Phone: 410 786-5958

RIN: 0938–AL38

1104. END-STAGE RENAL DISEASE—RESCISSION OF WAIVER OF CONDITIONS FOR COVERAGE UNDER A STATE OF EMERGENCY IN HOUSTON, TEXAS AREA (CMS-3074-F2)

Priority: Other Significant

CFR Citation: 42 CFR 405

Completed:

Reason	Date	FR Cite
Final Rule	07/26/02	67 FR 48800

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Lori Davis
Phone: 410 786-0710

RIN: 0938–AL39

1105. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITAL; CORRECTING AMENDMENT (CMS-1069-F2)

Priority: Info./Admin./Other

CFR Citation: 42 CFR 412; 42 CFR 413

Completed:

Reason	Date	FR Cite
Final Rule	07/01/02	67 FR 44073

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Robert Kuhl
Phone: 410 786-4597

RIN: 0938–AL40

1106. HOSPICE WAGE INDEX FOR FY 2003 (CMS-1211-N)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	08/30/02	67 FR 56092

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Lynn Riley
Phone: 410 786-1286

RIN: 0938–AL41

1107. PHYSICIAN FEE SCHEDULE FOR CY 2002: CORRECTION NOTICE (CMS-1169-CN)

Priority: Info./Admin./Other

CFR Citation: 42 CFR 405; 42 CFR 410; 42 CFR 411; 42 CFR 414; 42 CFR 415

Completed:

Reason	Date	FR Cite
Notice	04/26/02	67 FR 20681

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Diane Milstead
Phone: 410 786-3355

Related RIN: Related To 0938-AK57

RIN: 0938–AL48

1108. NOTICE OF MODIFICATION OF BENEFICIARY ASSESSMENT REQUIREMENTS FOR SKILLED NURSING FACILITIES (CMS-1209-N)

Priority: Info./Admin./Other

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	05/31/02	67 FR 38128

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Dana Burley
Phone: 410 786-4547

RIN: 0938–AL55

1109. REVISION OF THE PROCEDURES FOR REQUESTING EXCEPTIONS TO COST LIMITS FOR SKILLED NURSING FACILITIES AND ELIMINATION OF RECLASSIFICATIONS; CORRECTION (CMS-1883-F3)

Priority: Info./Admin./Other

CFR Citation: 42 CFR 413.30(d)

Completed:

Reason	Date	FR Cite
Final Rule	07/26/02	67 FR 48801

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Julie Stankivic
Phone: 410 786-5725

RIN: 0938–AL61

1110. NOTICE OF INTENT TO CONDUCT NEGOTIATED RULEMAKING FOR SPECIAL PAYMENT PROVISIONS AND STANDARDS FOR SUPPLIERS OF CUSTOM-FABRICATED ORTHOTICS AND PROSTHETICS (CMS-6012-N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	03/22/02	67 FR 13297

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Kathryn S Cox
Phone: 410 786-5954

RIN: 0938–AL68

1111. MEDICAID MANAGED CARE: WITHDRAWAL (CMS-2001-F4)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Rule	06/14/02	67 FR 40988

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Bruce Johnson
Phone: 410 786-0615

RIN: 0938–AL83

HHS—CMS **Completed Actions**

1112. FY 1999 SCHIP REALLOCATION NOTICE (CMS-2137-N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	04/26/02	67 FR 20794

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Richard Strauss
Phone: 410 786-2019
Email: rstrauss@hcfa.gov

RIN: 0938–AL86

1113. ● CRITERIA FOR ACCEPTANCE OF SUPPLEMENTAL PRACTICE EXPENSE SURVEY DATA (CMS-1223-IFC)

Priority: Other Significant

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871; Social Security Act, sec 1881(b); 42 USC 1302; 42 USC 1395(hh); 42 USC 1395rr(b)(1)

CFR Citation: 42 CFR 414

Legal Deadline: None

Abstract: This interim final rule with comment period modifies the criteria for physicians and non-physicians specialty groups for submitting supplemental practice expense survey data for use in determining payments under the physician fee schedule.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/28/02	67 FR 43555
Interim Final Rule Effective	06/28/02	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Marc Hartstein, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4539

Related RIN: Related To 0938-AL21

RIN: 0938–AL99

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

Proposed Rule Stage

1114. SAFEGUARDING CHILD SUPPORT AND EXPANDED FPLS INFORMATION

Priority: Substantive, Nonsignificant

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/03	

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
Phone: 202 401-5369
TDD Phone: 800 877-8339
Fax: 202 401-4054
Email: ebrooks@acf.hhs.gov

RIN: 0970–AC01

1115. 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	FR Cite
NPRM	03/00/03	

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

1116. ● CHILD SUPPORT ENFORCEMENT PROGRAM; CUSTOMER SERVICE ANNUAL STATE SELF-ASSESSMENT

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 654(15)(A)

CFR Citation: 45 CFR 308.2; 45 CFR 308.3

HHS—ACF

Proposed Rule Stage

Legal Deadline: None

Abstract: This proposed rule will revise existing regulations on State child support self-assessments to add customer service as one of the required program compliance criteria.

Timetable:

Action	Date	FR Cite
NPRM	06/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

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

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RIN: 0970–AC10

1117. ● 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	FR Cite
NPRM	06/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

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

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RIN: 0970–AC11

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

Final Rule Stage

1118. 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	FR Cite
NPRM	02/08/99	64 FR 6013
NPRM Comment Period End	04/09/99	
Final Action	12/00/02	

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
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RIN: 0970–AB54

1119. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES

Priority: Other Significant

Legal Authority: 42 USC 655(f)

CFR Citation: 45 CFR 309

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/21/00	65 FR 50800
Final Action	06/00/03	

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

1120. 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

HHS—ACF **Final Rule Stage**

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

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

1121. FAMILY CHILD CARE PROGRAM OPTION FOR HEAD START PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1304; 45 CFR 1306

Legal Deadline: None

Abstract: This rule would allow Head Start programs to choose Family Child Care as a Head Start program option.

Timetable:

Action	Date	FR Cite
NPRM	08/29/00	65 FR 52394
Final Action	12/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal

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RIN: 0970–AB90

1122. 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 correct several Head Start regulations that define Head Start programs as ''nonprofit'' agencies. Recent statutory changes now allow ''for-profit'' agencies to receive Head Start grant funds.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/00/03	

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
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RIN: 0970–AC00

1123. ● CHILD SUPPORT ENFORCEMENT PROGRAM; FEDERAL TAX REFUND OFFSET

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 303.72

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/00/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

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

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

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

Completed Actions

1124. PROGRAM PERFORMANCE STANDARDS FOR THE OPERATION OF HEAD START PROGRAMS

Priority: Other Significant

CFR Citation: 45 CFR 1304

Completed:

Reason	Date	FR Cite
Withdrawn	08/30/02	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Douglas Klafehn
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RIN: 0970–AB99

Department of Health and Human Services (HHS)

Proposed Rule Stage

Administration on Aging (AOA)

1125. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, TRAINING, RESEARCH, AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; AND 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 recent reauthorization of the Older Americans Act, Public Law 106-501, the Administration on Aging (AoA) proposes to issue a notice of proposed rulemaking by winter of 2002-03.

Timetable:

Action	Date	FR Cite
NPRM	01/00/03	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Federalism: Undetermined

Additional Information: Incorrectly reported as under Section 610 Review in April 2001.

Agency Contact: Edwin Walker, Deputy Assistant Secretary for Policy and Programs, Department of Health and Human Services, Administration on Aging, Room 4733, 330 Independence Avenue SW., Cohen Building, Washington, DC 20201 Phone: 202 619-0011

RIN: 0985–AA00

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