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Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Unified Agenda of Regulations

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual regulatory agenda.

SUMMARY: The President's September 30, 1993, Executive Order 12866 and the Regulatory Flexibility Act of 1980 require the Department semiannually to publish an agenda summarizing all current and projected rulemaking and indicating those regulatory actions that are being analyzed for their effect on small businesses. The Department published its last such agenda on November 28, 1995. The document reflects the Department's efforts to reinvent its rulemaking practices in accordance with the President's strategy and invites comments to assist the Department in reviewing its regulatory processes and products.

FOR FURTHER INFORMATION CONTACT: Ann White, Department of Health and Human Services, Washington, DC 20201, (202) 690-6824, or the contact person for a specific division or agency of the Department as listed below.

SUPPLEMENTARY INFORMATION: On September 30, 1993, President Clinton issued Executive Order 12866 to reform the Federal regulatory process. The Executive order and the Administration's effort to implement it have brought about substantial improvement in the Department's regulatory practices.

Building on this success, the President announced in March of 1995 an initiative involving more

comprehensive reform. The President directed each agency to undertake an exhaustive review of all existing regulations with a view to eliminating or modifying those that are obsolete, impose undue burden on the public, or are otherwise in need of reform. He directed each agency to change the way regulatory outcomes are measured—focusing on results, not process. The President asked senior executives to regularly convene grassroots-partnership meetings to allow greater collaboration and participation in reinventing the regulatory process on the part of those affected by it. He also directed that agencies expand their efforts to use newly emerging consensus-building techniques during the rulemaking process.

This agenda that follows constitutes the Department's most recent inventory of the regulatory actions to be taken in pursuit of the President's new approach to rulemaking. As we continue with this effort, we invite comments on the agenda entries and look forward to receiving suggestions for furthering the President's regulatory-reinvention strategy.

Comments should be sent to the addresses listed below, depending on the specific regulations under discussion. Comments may be sent to the Office of the Secretary if that is preferable or if a responsible division of the Department is not clear or when the comment covers subjects crossing agency lines.

Office of the Secretary: Jacquelyn Y. White, Deputy Executive Secretary, Office of the Executive Secretariat, Room 603H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Health Care Financing Administration: Mary Ann Troanovitch, Executive for Regulations Management, Health Care Financing Administration, Room 309G, Hubert H. Humphrey

Building, Washington, DC 20201; phone 202-690-7890.

Food and Drug Administration: Edwin V. Dutra, Jr., Director, Regulatory Policy and Management Staff, 5600 Fishers Lane, Rockville, Maryland 20857; phone 301-443-3480.

Administration on Children and Families: Madeline Mocko, Director, Office of Legislative Affairs and Budget, 7th Floor, 370 L'Enfant Promenade SW., Washington, DC 20447; phone 202-401-9223.

Administration on Aging: David Bunoski, Executive Secretariat, Room 4753, Wilbur H. Cohen Building, 330 Independence Avenue SW., Washington, DC 20201; phone 202-260-0669.

Agency for Health Care Policy and Research: Peggy Washburn, 6000 Executive Drive, Suite 603, Rockville, Maryland 20852; phone 301-594-1457.

Centers for Disease Control/Agency for Toxic Substances and Disease Registry: Galen Morris, 1600 Clifton Road NE., Mail Stop D-23, Atlanta, Georgia 30333; phone 404-639-7073.

Health Resource Services Administration: Alice Wallis, 5600 Fishers Lane, Room 14-A-12, Rockville, Maryland 20857; phone 301-443-1960.

Indian Health Service: Betty Penn, 5600 Fishers Lane, Twinbrook Building, Suite 450, Rockville, Maryland 20857; phone 301-443-1116.

National Institutes of Health: Jerry Moore, 9000 Rockville Pike, Building 31, Room 3B-11, Bethesda, Maryland 20205; phone 301-496-4606.

Substance Abuse and Mental Health Services Administration: Joe Faha, 5600 Fishers Lane, Room 12-A-17, Rockville, Maryland 20857; phone 301-443-4640.

Dated: April 4, 1996.

Claudia Cooley,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
936	Civil Money Penalties for Notifying a Home Health Agency, or a Home or Community-Based Health Care Center or Provider, of a Standard Survey	0991-AA79
937	Civil Money Penalties for False Information on Drug Manufacturer Price Surveys and Rebate Agreements	0991-AA80

HHS

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
938	Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute	0991-AA66

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
939	Civil Money Penalties (CMPs) for Certain Hospital Physician Incentive Plans	0991-AA45
940	Civil Money Penalties (CMPs) for Certain Practices Relating to Medicare Supplemental Policies	0991-AA53
941	Civil Money Penalties for Physician Ownership of and Referral to Certain Health Care Entities	0991-AA65
942	Senior Biomedical Research Services	0991-AA82

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
943	Uniform Administrative Requirements for Grants and Cooperative Agreements	0991-AA56
944	Safe Harbors for Protecting Health Plans	0991-AA69
945	Revisions to the PRO Sanctions Process	0991-AA73
946	Revisions to the Civil Money Penalty Provisions Relating to the Misuse of Certain Symbols and Emblems	0991-AA81

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
947	Protection and Advocacy for Individuals With Mental Illness	0930-AA02

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

Sequence Number	Title	Regulation Identifier Number
948	Block Grants for Prevention and Treatment of Substance Abuse	0930-AA01

Substance Abuse and Mental Health Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
949	Block Grants for Prevention and Treatment of Substance Abuse (Tobacco Provisions)	0930-AA03

Departmental Management—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
950	Implementation of the Equal Access to Justice Act in Agency Proceedings	0990-AA02

HHS

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
951	Medical Foods	0910-AA20
952	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals	0910-AA45
953	Reinventing FDA Food Regulations	0910-AA58
954	Food Standards of Identity, Quality, and Fill of Container; Common or Usual Name Regulations: Request for Comments on Existing Regulations	0910-AA67
955	Reinvention of Regulations	0910-AA69
956	Investigational New Drug Applications; Request for Information and Comments	0910-AA83

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
957	Over-the-Counter (OTC) Drug Review	0910-AA01
958	Infant Formula: Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910-AA04
959	Implementation of the Safe Medical Devices Act of 1990	0910-AA09
960	Reporting of Errors and Accidents	0910-AA12
961	Mammography Quality Standards Act of 1992	0910-AA24
962	Latex Condoms: Expiration Date Labeling	0910-AA32
963	Latex Warning	0910-AA34
964	Hearing Aids; Professional and Patient Labeling; Conditions for Sale	0910-AA39
965	Human Tissue Intended for Transplantation	0910-AA40
966	Animal Medicinal Drug Use Clarification Act of 1994; Extra-Label Use; Implementation	0910-AA47
967	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910-AA49
968	Bioavailability and Bioequivalence Requirements	0910-AA51
969	Consolidation of Regulations	0910-AA53
970	Name of Selling Agent or Distributor	0910-AA56
971	Changes to an Approved Application	0910-AA57
972	Dietary Supplement Regulations in Response to DSHEA	0910-AA59
973	Export Requirements for Drugs for Investigational Use in Other Countries	0910-AA61
974	Human Tissue Intended for Transplantation and Human Reproductive Tissue Intended for Fertilization, Implantation or Insemination	0910-AA70
975	Adverse Experience Reporting for Human Drug and Licensed Biological Products; Increased Frequency Reports	0910-AA72
976	Investigational New Drug Applications; Clinical Holds	0910-AA73
977	Parenteral Drug Products Containing Aluminum as an Ingredient or Contaminant; Labeling Requirements; Warning Statement	0910-AA74
978	Long-Term Contraceptive Drug Products and Medical Devices; Informed Consent Requirements	0910-AA75
979	Debarment Certification Regulations for Drug Applications	0910-AA76
980	Certification of Drugs Composed Wholly or Partly of Insulin	0910-AA77
981	Over-the-Counter Human Drugs; Labeling Requirements	0910-AA79
982	National Environmental Policy Act; Policies and Procedures	0910-AA80
983	Investigational New Drug Applications; Clinical Holds for Drugs for Life-Threatening Illnesses	0910-AA84
984	Adverse Experience Reporting, Recordkeeping, and Records Access Requirements for Marketed OTC Drugs That Are Now the Subjects of Approved New Drug or Abbreviated New Drug Apps	0910-AA86
985	Sterility Requirements for Inhalation Solution Products	0910-AA88
986	Informed Consent for Human Drugs and Biologics; Determination That Informed Consent Is Not Feasible	0910-AA89
987	Direct-to-Consumer Promotion Regulations	0910-AA90

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
988	New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTR)	0910-AA02

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
989	Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection	0910-AA05
990	Prescription Drug Marketing Act of 1987; Policy Information, Guidance, and Clarifications	0910-AA08
991	Food Labeling Review	0910-AA19
992	Disqualification of Clinical Investigators	0910-AA21
993	Investigational Device Exemption; Intraocular Lenses	0910-AA22
994	Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling	0910-AA25
995	Tamper-Evident Packaging Requirements for Over-the-Counter Human Drug Products	0910-AA26
996	Adverse Experience Expedited Reporting Requirements for Human Drug and Licensed Biological Products	0910-AA28
997	Electronic Signatures; Electronic Records	0910-AA29
998	Financial Disclosure by Clinical Investigators	0910-AA30
999	Effective Date of Requirement for Submission of Premarket Approval Applications	0910-AA31
1000	Prescription Drug Product Labeling; Medication Guide	0910-AA37
1001	Iron Containing Drugs and Supplements	0910-AA42
1002	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products To Protect Children and Adolescents	0910-AA48
1003	Revocation of Certain Regulations	0910-AA54
1004	Protection of Human Subjects; Informed Consent	0910-AA60
1005	Export Requirements for Medical Devices	0910-AA62
1006	Well-Characterized Biotechnology Products; Elimination of Establishment License Application	0910-AA71
1007	New Drug Applications; Drug Master File	0910-AA78
1008	Current Good Manufacturing Practice for Finished Pharmaceutical; Positron Emission Tomography	0910-AA81
1009	Investigational New Drug Applications and New Drug Applications	0910-AA82
1010	New Drugs for Human Use; Clarification of Requirements for Application Supplements	0910-AA87

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1011	Policies Concerning Uses of Sulfiting Agents	0910-AA03
1012	Lead in Foods	0910-AA06
1013	Fees for Certification Services; Insulin and Color Additive Certification Programs	0910-AA07
1014	Bottled Water	0910-AA11
1015	Review of Warnings, Use Instructions, and Precautionary Information Under Section 314 of the National Childhood Vaccine Injury Act of 1986	0910-AA14
1016	Dietary Supplement Label Review	0910-AA23
1017	Amalgam Ingredient Labeling	0910-AA33
1018	Classification of Computer Software Programs That Are Medical Devices	0910-AA41
1019	Development of Hazard Analysis Critical Control Points for the Food Industry; Request for Comments	0910-AA43
1020	Habit Forming Drugs	0910-AA50
1021	Drugs Used for Treatment of Narcotic Addicts	0910-AA52
1022	Substances Approved for Use in the Preparation of Meat and Poultry Products	0910-AA66
1023	Postmarketing Periodic Adverse Experience Reporting Requirements for Human Drug and Licensed Biological Products	0910-AA85

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1024	Final Regulation To Establish Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products	0910-AA10
1025	General Biological Product Standards; Alternative Procedures and Exceptions	0910-AA16
1026	Medical Devices; Protective Restraints; Revocation of Exemptions From 510(k) Premarket Notification Procedures and Current Good Manufacturing Practices Regulations	0910-AA17

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Food and Drug Administration—Completed Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
1027	Certification of Drugs Composed Wholly or Partly of Insulin; Fees for Certification of Drugs Composed Wholly or Partly of Insulin	0910-AA27
1028	Premarket Approval of Medical Devices; Supplemental Applications	0910-AA35
1029	Public Information; Communications With State and Foreign Government Officials	0910-AA46
1030	OTC Drug Labeling Review	0910-AA63
1031	Medical Device Exemptions From Premarket Notification	0910-AA65

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1032	Organ Procurement and Transplantation Network Rules	0906-AA32
1033	National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II	0906-AA36
1034	Removal of Obsolete Regulations of the Title VII Grant for the Construction of Teaching Facilities for Health Professions Personnel	0906-AA39

Health Resources and Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1035	Health Education Assistance Loan (HEAL) Program: Lenders'/ Holders' Performance Standards	0906-AA33

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1036	Technical Amendments to the Health Professions, Nursing, and Allied Health Training Grant Programs Under 42 CFR Parts 57 and 58	0906-AA38

Indian Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1037	Acquisition Under the Buy Indian Act	0917-AA00
1038	Indian Child Protection and Family Violence Prevention Act Minimum Standards of Character and Suitability for Employment	0917-AA02

Indian Health Service—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1039	Revision of Indian Self-Determination Regulations	0917-AA01

HHS

Agency for Health Care Policy and Research—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1040	Health Services Research, Evaluation, Demonstration, and Dissemination Projects; Peer Review of Grants and Contracts	0919-AA00

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1041	National Institutes of Health AIDS Research Loan Repayment Program	0925-AA02
1042	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925-AA09
1043	Undergraduate Scholarship Program Regarding Professions Needed by the NIH	0925-AA10
1044	Traineeships (Termination Policies)	0925-AA11
1045	Additional DHHS Protection for Pregnant Women and Human Fetuses Involved as Subjects for Research, and Pertaining to Human In Vitro Fertilization	0925-AA14
1046	National Research Service Awards	0925-AA16

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1047	Grants for Research Projects	0925-AA01
1048	Hazardous Substances Basic Research and Training Grants	0925-AA03
1049	National Institutes of Health Construction Grants	0925-AA04
1050	Training Grants	0925-AA05
1051	National Institutes of Health Center Grants	0925-AA06
1052	Grants for National Alcohol Research Centers	0925-AA08
1053	Removal of Obsolete Patent Regulations	0925-AA15
1054	Removal of National Cancer Institute Clinical Cancer Education Program	0925-AA17

Office of Assistant Secretary for Health—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1055	Standards of Compliance for Abortion-Related Services in Family Planning Service Projects	0937-AA00

Health Care Financing Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1056	Medicare Coverage of Outpatient Occupational Therapy Services (BPD-425-P)	0938-AD32
1057	Revisions to the Confidentiality and Disclosure Regulation (OPA-001-P)	0938-AD60
1058	"Without Fault" and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (BPD-719-P)	0938-AD95
1059	Protection of Income and Resources for Community Spouses of Institutionalized Individuals (MB-023-P)	0938-AE12
1060	Provider Reimbursement Determinations and Appeals Revisions (BPD-727-P)	0938-AF28
1061	Alternative Sanctions for Psychiatric Hospitals (HSQ-191-P)	0938-AF32
1062	Assessing Interest Against Medicare Secondary Payer (MSP) Debts (BPO-108-P)	0938-AF87
1063	Revisions to Rules on Health Care Prepayment Plans (OMC-016-P)	0938-AF97
1064	Conditions of Participation for Rural Health Clinics (BPD-764-P)	0938-AG05
1065	Appointment of Representatives for Medicare Appeals (BPO-120-P)	0938-AG30
1066	Enforcement Requirements for Renal Dialysis Facilities (HSQ-204-P)	0938-AG31
1067	General Criteria and Standards for Evaluating Performance of Contract Obligations (HSQ-207-NC)	0938-AG32

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Health Care Financing Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1068	Disclosure of Confidential PRO Information for Research Purposes (HSQ-208-P)	0938-AG33
1069	Effect of Change of Ownership on Provider and Supplier Penalties, Sanctions, and Overpayments (HSQ-215-P) ...	0938-AG59
1070	New Payment Methodology for Routine Extended Care Services Provider in a Swing Bed Hospital (BPD-805-P) ...	0938-AG68
1071	Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Pathology, and Occupational Therapy (BPD-808-PN)	0938-AG70
1072	Medicaid: Optional Coverage of TB-Related Services for Individuals Infected with Tuberculosis (MB-082-P)	0938-AG72
1073	Revision of Medicare Hospital Conditions of Participation (BPD-745-P)	0938-AG79
1074	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Expanded to Designated Health Services (BPD-809-P)	0938-AG80
1075	Home Health Agency (HHA) Conditions of Participation (BPD-819-P)	0938-AG81
1076	End-Stage Renal Disease (ESRD) Conditions for Coverage (BPD-818-P)	0938-AG82
1077	Wage Index Used To Adjust Payment Rates for Hospice Services Under the Medicare Program (BPD-820-P)	0938-AG93
1078	Liability for Third Parties To Pay for Care and Services (MB-080-P)	0938-AH01
1079	Definition of Skilled Nursing Facility (SNF) and Home Health Agency (HHA) for Coverage of Durable Medical Equipment (DME) (BPD-834-P)	0938-AH16
1080	Schedule of Limits for Skilled Nursing Facility Inpatient Routine Service Costs (BPD-837-NC)	0938-AH18
1081	Additional Supplier Standards (BPD-864-P)	0938-AH19
1082	State Plan Amendment (SPA) Reconsideration Process (MB-096-P)	0938-AH24
1083	Changes in Coverage and Payment Policies for Physician Assistant Services (BPD-829-P)	0938-AH26
1084	Hospice Care—Conditions of Participation (BPD-844-P)	0938-AH27
1085	Limitations on Payment for Home Oxygen Therapy Based on Inherent Reasonableness Criteria (BPD-845-PN)	0938-AH28
1086	Medicaid Eligibility Quality Control, Staffing and Training, and Utilization Control: Removal of Obsolete and Restrictive Requirements (MB-099-P)	0938-AH31
1087	Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 1997 Rates (BPD-847-P)	0938-AH34
1088	Medicare Coverage of Services of Speech-Language Pathologists and Audiologists (BPD-843-P)	0938-AH37
1089	Medicare Program: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule (BPD-846-PN)	0938-AH38
1090	Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1997 (BPD-852-P)	0938-AH40
1091	Privacy and Security Enforcement for the Medicare Transaction System (BPO-142-P)	0938-AH47
1092	Medicare: Amount of Payments If Customary Charges for Services Furnished Are Less Than Reasonable Costs (BPD-860-P)	0938-AH49
1093	Limitations on Liability (BPD-859-P)	0938-AH51

Health Care Financing Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1094	Deduction of Incurred Medical Expenses (Spenddown) (MB-020-F)	0938-AB07
1095	Effective Dates for Provider Agreements and Supplier Approvals (HSQ-139-F)	0938-AC88
1096	Changes Concerning Suspension of Medicare Payments and Determinations of Allowable Interest Expense (BPO-118-FC)	0938-AC99
1097	Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology (BPD-432-FC)	0938-AD07
1098	Prohibition on Unbundling of Hospital Outpatient Services (BPD-426-F)	0938-AD33
1099	Changes to Peer Review Organization Regulations (HSQ-135-F)	0938-AD38
1100	Omnibus Nursing Home Reform Requirements (BPD-488-F)	0938-AD81
1101	HMO Organizational Structure and Services (OMC-007-F)	0938-AE25
1102	Hospital Standard for HIV Infectious Blood and Blood Products (BPD-633-F)	0938-AE40
1103	Medicare, Medicaid, and CLIA Programs: Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (HSQ-226-F)	0938-AE47
1104	Conditions of Coverage for Organ Procurement Organizations (BPD-646-FC)	0938-AE48
1105	Resident Assessment in Long-Term Care Facilities (HSQ-180-F)	0938-AE61
1106	Post-Contract Beneficiary Protections and Other Provisions (OMC-003-F)	0938-AE63
1107	Employer Contributions to HMOs (OMC-004-F)	0938-AE64
1108	Payment for Nursing and Allied Health Science Education (BPD-685-F)	0938-AE79
1109	Coverage of Screening Pap Smears (BPD-705-F)	0938-AE98

HHS

Health Care Financing Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1110	Medicare Coverage of Clinical Psychologist, Other Psychologist, and Clinical Social Worker Services—Medicare (BPD-706-F)	0938-AE99
1111	OBRA '90 and Miscellaneous Managed Care Technical Amendments (OMC-018-FC)	0938-AF15
1112	Medicaid Payment for Covered Outpatient Drugs Under Rebate Agreements (MB-046-F)	0938-AF42
1113	Referral to Child Support Enforcement Agencies of Medicaid Families (MB-051-F)	0938-AF68
1114	Medicaid: Outstationed Intake Locations for Certain Low-Income Pregnant Women, Infants and Children Under Age 19 (MB-052-F)	0938-AF69
1115	Medicare and Medicaid Programs: Requirements for Physician Incentive Plans in Prepaid Health Care Organizations (OMC-010-FC)	0938-AF74
1116	Part B Advance Payments to Physicians/Suppliers or Other Entities Furnishing Items or Services Under Medicare Part B (BPO-105-F)	0938-AF85
1117	Retroactive Enrollment and Disenrollment in Risk Health Maintenance Organizations and Competitive Medical Plans (OMC-015-F)	0938-AF98
1118	Payment for Preadmission Services (BPD-731-F)	0938-AG00
1119	Change in Provider Agreement Regulations Related to Federal Employee Health Benefits (BPD-748-F)	0938-AG03
1120	Revised Medicaid Management Information Systems (MB-38-FN)	0938-AG10
1121	Medicare Program: Limitations on Medicare Coverage of Intermittent Positive Pressure Breathing Machine Therapy (BPD-781-FN)	0938-AG44
1122	Telephone and Electronic Requests for Review of Part B Initial Claim Determinations (BPO-121-F)	0938-AG48
1123	Medicare Program: Limitations on Medicare Coverage of Cataract Surgery (BPD-797-FN)	0938-AG65
1124	CLIA Program: Categorization of Waived Tests (HSQ-225-F)	0938-AG99
1125	Reporting of Interest From Zero Coupon Bonds (BPD-647-F)	0938-AH11
1126	Medicare Program: Uniform Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies (BPD-788-F)	0938-AH12
1127	Update of the Reasonable Compensation Equivalent Limits for Services Furnished by Physicians (BPD-816-N)	0938-AH14
1128	Criteria and Procedures for Extending Coverage to Certain Devices and Related Services (BPD-841-FC)	0938-AH21
1129	Delegation of Civil Money Penalties (BPO-135-FC)	0938-AH22
1130	Medicaid: Limitations on Aggregate Payments to Disproportionate Share Hospitals; Federal Fiscal Year 1996 (Preliminary) (MB-098-N)	0938-AH30
1131	Medicare Program; Special Enrollment Periods and Waiting Periods (BPD-752-FC)	0938-AH33
1132	Medicare Program: Physician Fee Schedule Update for Calendar Year 1996 and Physician Volume Performance Standard Rates of Increase for Federal Fiscal Year 1996 (BPD-853-FN)	0938-AH41
1133	Medicare Program: Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rates Beginning January 1, 1997 (OACT-052-N)	0938-AH42
1134	Medicaid: Limitations on Aggregate Payments to Disproportionate Share Hospitals; Federal Fiscal Year 1996 (Final) (MB-100-N)	0938-AH44
1135	Part A Premium for 1997 for the Uninsured Aged for Certain Disabled Individuals Who Have Exhausted Other Entitlement (OACT-053-N)	0938-AH45
1136	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1997 (OACT-054-N)	0938-AH46
1137	Requirements for Enrollment of Medicaid Recipients Under Cost Effective Employer-Based Group Health Plans (MB-047-F)	0938-AH48

Health Care Financing Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1138	Payment for Clinical Diagnostic Laboratory Tests (BPD-309-F)	0938-AB50
1139	Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care (BPD-393-F)	0938-AC58
1140	Medicare Secondary Payer for Disabled Individuals (BPD-482-F)	0938-AD73
1141	New Minimum Standards for Medicare Supplemental (Medigap) Policies (BPD-491-P)	0938-AD82
1142	Survey Requirements and Alternative Sanctions for Home Health Agencies (HSQ-169-F)	0938-AE39
1143	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services (MB-28-F)	0938-AE72
1144	Fire Safety Standards for Hospitals, Long-Term Care Facilities, Ambulatory Surgical Centers, Hospices, and Intermediate Care Facilities for the Mentally Retarded (BPD-650-FC)	0938-AE97
1145	Changes to the Long-Term Care Facility Survey Process (HSQ-175-FC)	0938-AF02

HHS

Health Care Financing Administration—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
1146	Case Management (MB-27-F)	0938-AF07
1147	Presumptive Limits on Payments to HMOs, CMPs, and HCPPs (OMC-006-F)	0938-AF16
1148	Partial Hospitalization Services in Community Mental Health Centers (BPD-736-F)	0938-AF53
1149	Intermediary and Carrier Functions (BPO-111-F)	0938-AG06
1150	End-Stage Renal Disease (ESRD) Payment Exception Requests and Organ Procurement Costs (BPD-763-F)	0938-AG20
1151	Noncoverage of Electrostimulation of Salivary Glands for the Treatment of Xerostomia (Dry Mouth) (BPD-782-FN)	0938-AG45
1152	Distinct Part Requirements for Nursing Homes and Prohibition of Financial Screening of Applicants for Nursing Home Admission (BPD-815-P)	0938-AG84
1153	Clinical Laboratory Improvement Amendment (CLIA) Fee Schedules (HSQ-219-FC)	0938-AG87
1154	Categorization and Certification Requirements for a New Subcategory of Moderate Complexity Testing (HSQ-222-F)	0938-AG98
1155	Medicaid Coverage of Personal Care Services (MB-071-F)	0938-AH00
1156	Ambulance Services (BPD-813-P)	0938-AH13
1157	Adjustment in Payment Amounts for New Technology Intraocular Lenses (BPD-831-P)	0938-AH15
1158	Medicare Coverage of Liver Transplantation (BPD-835-PN)	0938-AH17
1159	CLIA Program: Cytology Proficiency Testing (HSQ-233-P)	0938-AH35
1160	Limits on Actual Charges of Nonparticipating Physicians (BPD-862-P)	0938-AH50
1161	Medicare Secondary Payer Clarifications and Amendments (BPD-865-P)	0938-AH52
1162	Payment for Hospital Outpatient Radiology Services and Other Diagnostic Procedures (BPD-861-FC)	0938-AH53

Health Care Financing Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1163	Fee Schedule for Payment of Clinical Psychologist Services (BPD-495-P)	0938-AD84
1164	Coverage of Nurse Practitioner and Clinical Nurse Specialist Services (BPD-708-P)	0938-AF00
1165	Payment for Federally Qualified Health Center (FQHC) Services (BPD-728-F)	0938-AF14
1166	Federally Qualified Health Center Services (Medicaid) (MB-043-P)	0938-AF90
1167	Medicare Appeals of Individual Claims (BPD-453-P)	0938-AG18
1168	Withdrawal of Coverage of Diagnostic Nocturnal Penile Tumescence Testing (Impotence Testing) (BPD-780-FN)	0938-AG43
1169	Schedule of Limits on Home Health Agency Costs Per Visit (BPD-793-N)	0938-AG54
1170	Medicaid Program: Nurse-Midwife Services (MB-085-F)	0938-AG73
1171	Medicaid Program: Fees for Vaccine Administration Under Pediatric Immunization Program (MB-084-FN)	0938-AG77
1172	Medicaid: Nominal Copayments for Institutional Services for Medicaid Recipients (MB-090-FC)	0938-AG90
1173	Mandatory Rates of Increase for Federal Fiscal Year 1996 (BPD-811-P)	0938-AG94
1174	Medicare Program: Changes to the Inpatient Hospital Prospective Payment Systems and Fiscal Year 1996 Rates (BPD-825-FC)	0938-AG95
1175	Medicare Program: Revisions to Payment Policies and Adjustments to the Relative Value Units (RVUs) Under the Physician Fee Schedule for Calendar Year 1996 (BPD-827-FC)	0938-AG96
1176	Medicare Program: Coverage of Certified Nurse-Midwife Services (BPD-496-P)	0938-AH02
1177	Medicare Program: Physician Fee Schedule Update for Calendar Year 1996 & Physician Volume Performance Standard Rates of Increase for Federal Fiscal Year 1996 (BPD-828-FN)	0938-AH03
1178	Part A Premium for 1996 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (OACT-051-N)	0938-AH06
1179	Medicare Program: Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rates Beginning January 1, 1996 (OACT-050-N)	0938-AH07
1180	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1996 (OACT-049-N)	0938-AH08
1181	Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1995 (Medicaid Program) (MB-094-N)	0938-AH09
1182	Provisions That Allow Rural Primary Care Hospitals (RPCHs) To Enter Into Swing-Bed Agreements (BPD-839-P)	0938-AH20
1183	Transfer of Assets for Less Than Fair Market Value: Medicaid Program (MB-095-P)	0938-AH23
1184	Evidence of Lawful Permanent Residence (MB-097-P)	0938-AH25
1185	CLIA Program; Granting and Withdrawal of Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs; Technical Corrections (HSQ-205-FC)	0938-AH32

HHS

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1186	Foster Care, Adoption Assistance, and Child Welfare Services	0970-AA97
1187	Block Grant Programs (Low Income Home Energy Assistance Program —LIHEAP)—FY 1995 and FY 1996 Provisions	0970-AB47
1188	Administrative Flexibility Rule	0970-AB49
1189	Designation of Alternative Agency To Serve Indian Tribal Children	0970-AB52
1190	Construction of Head Start Facilities	0970-AB54
1191	Quality Standards for Early Head Start and Head Start Programs	0970-AB55
1192	Head Start Fellowship Program	0970-AB56
1193	On-Site Foster Care Eligibility Reviews	0970-AB60

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1194	Amendments to Developmental Disabilities Rules	0970-AB11
1195	Child Abuse and Neglect State Grant Program	0970-AB23
1196	Standards for Safe Transportation	0970-AB24
1197	Standards for Purchase of Facilities	0970-AB31
1198	National Voter Registration Act of 1993 Provisions Affecting Public Assistance Agencies	0970-AB32
1199	Child Care—Revised Regulations	0970-AB33
1200	Family Preservation and Support	0970-AB34
1201	Administration for Native Americans (ANA) 45 CFR Part 1336	0970-AB37
1202	Reduction of Reporting Requirements for the State Systems Advance Planning Document (APD) Process	0970-AB46
1203	Income Eligibility Criteria for Indian Tribes	0970-AB53
1204	Making Information Available to Consumer Reporting Agencies: Extension of Deadline for Certified Statewide Systems; and Revisions for the President's Reform Initiative	0970-AB57
1205	Income and Resource Disregards Related to Interests of Individual Indians in Trust or Restricted Lands	0970-AB59

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1206	Family Violence Prevention and Services	0970-AB18

Administration on Aging—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1207	Grants for State and Community Programs on Aging, Intrastate Funding Formulas; Training, Research and Discretionary Programs; Vulnerable Elder Rights; and Grants to Indians & Native Hawaiians	0985-AA00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Office of the Secretary (OS)

Proposed Rule Stage

936. CIVIL MONEY PENALTIES FOR NOTIFYING A HOME HEALTH AGENCY, OR A HOME OR COMMUNITY-BASED HEALTH CARE CENTER OR PROVIDER, OF A STANDARD SURVEY

Priority: Substantive, Nonsignificant
Legal Authority: PL 100-203, Sec 4022(a); PL 100-360, Sec 411(d)(2)(A); PL 100-485, Sec 608(d)(20)(A); PL 101-508, Sec 4711(b)(a)

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would set forth civil money penalties against any individual or entity that notifies, or causes to notify, a home health agency, or a home or community-based health care center or provider, of the time or date on which a standard survey is scheduled to be conducted by a State or local agency.

Timetable:

Action	Date	FR Cite
NPRM	10/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, OMP, 330 Independence Avenue SW., Washington, DC 20201
 Phone: 202 619-3270

RIN: 0991-AA79

937. CIVIL MONEY PENALTIES FOR FALSE INFORMATION ON DRUG MANUFACTURER PRICE SURVEYS AND REBATE AGREEMENTS

Priority: Substantive, Nonsignificant

Legal Authority: PL 101-508, Sec 4401(a)(3)

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would set forth civil money penalties against any wholesaler, manufacturer or seller of outpatient drugs that fails to respond to a request for information about charges or prices, or to knowingly

provide false information, in a survey by the Secretary to verify manufacturers' reported prices. In addition, this rule would set forth civil money penalties against any drug manufacturer doing business with Medicaid that, in accordance with section 1927(b)(3)(A) of the Social Security Act, fails to provide rebate agreement price information on a timely basis, and for knowingly providing false information.

Timetable:

Action	Date	FR Cite
NPRM	10/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, 330 Independence Avenue SW., Washington, DC 20201
 Phone: 202 619-3270

RIN: 0991-AA80

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Office of the Secretary (OS)

Final Rule Stage

938. CLARIFICATION OF THE INITIAL OIG SAFE HARBOR PROVISIONS AND ESTABLISHMENT OF ADDITIONAL SAFE HARBOR PROVISIONS UNDER THE ANTI-KICKBACK STATUTE

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: PL 100-93, Sec 2; PL 100-93, Sec 14

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This final rule serves both to clarify various aspects of the original safe harbor provisions and to add new

safe harbors as authorized under section 14 of PL 100-93. Specifically, this rule modifies the original set of final safe harbor provisions (56 FR 35952, 7/9/91) to give greater clarity to that rulemaking's original intent. In addition, this rule sets forth an expanded listing of safe harbor provisions designed to protect additional payment and business practices from criminal prosecution and civil sanctions under the anti-kickback statute.

Timetable:

Action	Date	FR Cite
NPRM	09/21/93	58 FR 49008
NPRM Comment Period End	11/22/93	
Final Action	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: This final rule incorporates the safe harbor clarification provisions previously addressed in RIN 0991-AA74 and set forth in proposed rulemaking (59FR37202, July 21, 1994).

Agency Contact: Joel Jay Schaer, Regulations Officer, Office of Inspector General, OMP, Department of Health and Human Services, Office of the Secretary, 330 Independence Avenue SW., Washington, DC 20201
 Phone: 202 619-3270

RIN: 0991-AA66

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Long-Term Actions

Office of the Secretary (OS)

939. CIVIL MONEY PENALTIES (CMPS) FOR CERTAIN HOSPITAL PHYSICIAN INCENTIVE PLANS**Priority:** Substantive, Nonsignificant**Legal Authority:** PL 99-509, Sec 9313(c); PL 101-239, Sec 6003(g)(3); PL 101-508, Sec 4204(a)(3); PL 101-508, Sec 4731(b)(1)**CFR Citation:** 42 CFR 1001; 42 CFR 1003**Legal Deadline:** None**Abstract:** This final rule will prohibit a hospital from knowingly making incentive payments to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the direct care of that physician. The rule would also set forth standards governing the imposition of CMPs for each such individual for whom payments are made.**Timetable:**

Action	Date	FR Cite
NPRM	12/01/94	59 FR 61571
NPRM Comment Period End	01/30/95	

Next Action Undetermined

Small Entities Affected: None**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, OMP, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-3270**RIN:** 0991-AA45**940. CIVIL MONEY PENALTIES (CMPS) FOR CERTAIN PRACTICES RELATING TO MEDICARE SUPPLEMENTAL POLICIES****Priority:** Substantive, Nonsignificant**Legal Authority:** PL 100-360, Sec 428(b); PL 101-508, Sec 4204(g)(1); PL 101-508, Sec 4351; PL 101-508, Sec 4354(a)(1)(E); PL 101-508, Sec 4354(a)(2); PL 101-508, Sec 4355(a); PL 101-508, Sec 4357**CFR Citation:** 42 CFR 1003**Legal Deadline:** None**Abstract:** This rule would authorize CMPs against any individual or entity who knowingly and willfully uses misleading or fraudulent practices in the advertisement, solicitation, offering

for sale or delivery of Medicare supplemental health insurance (Medigap) policies. Penalties would also be established for failure to (1) meet Medigap policy loss-ratio requirements, (2) comply with policy simplification standards, or (3) obtain Secretarial certification of Medigap policies in States with non-approved regulatory programs. In addition, this rule would also set forth CMPs for the failure of sellers or issuers to solicit information, and to provide notice, about Medicaid status and eligibility before selling or issuing Medigap policies.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined**Government Levels Affected:** Undetermined**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of the Secretary, Office of Inspector General, OMP, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089**RIN:** 0991-AA53**941. CIVIL MONEY PENALTIES FOR PHYSICIAN OWNERSHIP OF AND REFERRAL TO CERTAIN HEALTH CARE ENTITIES****Priority:** Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** PL 101-239, Sec 6204; PL 101-508, Sec 4207(e); PL 101-508, Sec 4207(m)(a); PL 103-66, Sec 13562**CFR Citation:** 42 CFR 1001; 42 CFR 1003**Legal Deadline:** None**Abstract:** This revised final rule is designed to implement civil money penalty authority for prohibited physician ownership and referral arrangements set forth in section 1877 of the Social Security Act. This rule addresses comments raised as a result of the final rule with comment period (60 FR 16580), and several technical changes to 42 CFR 1001 and 1003

resulting from Government reinvention efforts.

Timetable:

Action	Date	FR Cite
NPRM	10/20/93	58 FR 54096
NPRM Comment Period End	12/20/93	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaer, Regulations Officer, Office of Inspector General, OMP, Department of Health and Human Services, Office of the Secretary, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089**RIN:** 0991-AA65**942. • SENIOR BIOMEDICAL RESEARCH SERVICES****Priority:** Other**Legal Authority:** 42 USC 228**CFR Citation:** 42 CFR 24**Legal Deadline:** None**Abstract:** This regulation implements the Senior Biomedical Research Service (SBRS), a personnel system established in the Public Health Service by Section 304 of Public Law 101-509. The SBRS will consist of 500 members appointed by the Secretary without regard to the provisions of Title 5, U.S. Code, regarding appointment, who are outstanding in the field of biomedical research or clinical research evaluation. Appointments to the SBRS will be only to individuals with doctoral-level degrees in biomedicine or a related field. The regulation describes basic eligibility criteria, pay rates, performance appraisal system, optional retirement system, and procedure for removal from the SBRS.**Timetable:**

Action	Date	FR Cite
Interim Final Rule	02/21/96	61 FR 6557
Interim Final Rule Comment Period End	03/31/96	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** Federal**Agency Contact:** Rosemary Taylor, Personnel Management Specialist, Department of Health and Human Services, Office of the Secretary, 200

HHS—OS

Long-Term Actions

Independence Avenue SW., Room
522A, Washington, DC 20201

Phone: 202 690-7358

Fax: 202 690-6758

RIN: 0991-AA82

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Office of the Secretary (OS)**

Completed Actions

943. UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND COOPERATIVE AGREEMENTS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 74

Completed:

Reason	Date	FR Cite
Final Action	03/22/96	61 FR 11743

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Charles Gale
Phone: 202 690-6377

RIN: 0991-AA56

944. SAFE HARBORS FOR PROTECTING HEALTH PLANS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

CFR Citation: 42 CFR 1001

Completed:

Reason	Date	FR Cite
Final Action	01/25/96	61 FR 2122

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joel Jay Schaer
Phone: 202 619-3270

RIN: 0991-AA69

945. REVISIONS TO THE PRO SANCTIONS PROCESS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

CFR Citation: 42 CFR 1004

Completed:

Reason	Date	FR Cite
Final Action	12/12/95	60 FR 63634

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Joel Jay Schaer
Phone: 202 619-3270

RIN: 0991-AA73

946. REVISIONS TO THE CIVIL MONEY PENALTY PROVISIONS RELATING TO THE MISUSE OF CERTAIN SYMBOLS AND EMBLEMS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

CFR Citation: 42 CFR 1003

Completed:

Reason	Date	FR Cite
Final Action	11/27/95	60 FR 58239

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joel Jay Schaer
Phone: 202 619-3270

RIN: 0991-AA81

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)**

Final Rule Stage

947. PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 10801 et seq, as amended by PL 102-173

CFR Citation: 45 CFR 51

Legal Deadline: Final, Statutory, May 27, 1992.

Section 9 of P.L. 102-173, enacted on 11/27/91, sets this deadline.

Abstract: Sets requirements for funding State and State-designated systems for protecting and advocating for

individuals with mental illness. By law, these requirements must be set out in regulations.

Timetable:

Action	Date	FR Cite
NPRM	12/14/94	59 FR 64367
NPRM Comment Period End	02/13/95	
Final Action	07/00/96	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local

Additional Information: Previously reported under RIN 0905-AD99.

Alternate Contact: Sue Martone, DLEA, SAMHSA, PHS; Room 12C-15, 5600 Fishers Lane, Rockville, MD 20857; 301-443-4640

Agency Contact: Joseph D. Faha, Director, DLEA, SAMHSA, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 12C-15, Rockville, MD 20857

Phone: 301 443-4640

RIN: 0930-AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Long-Term Actions
948. BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE

Priority: Other Significant

Legal Authority: 42 USC 300-x et seq, as amended by PL 102-321

CFR Citation: 45 CFR 96

Legal Deadline: Final, Statutory, August 25, 1992.

Awards to States after January 1, 1993 cannot be made until implementing regulations are published.

Abstract: Sets requirements for block grants for prevention and treatment of substance abuse. The requirements include criteria for approval of State plans which must by statute be prescribed in regulations. These

provisions would replace the existing interim final rule published March 31, 1993. Given the pending reauthorization of SAMHSA and the current Administration's FY 1996 legislative proposal to turn the block grant into a "Performance Partnership," publication of this regulation has been put on hold.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/31/93	58 FR 17062
Interim Final Rule Comment Period End	06/01/93	
Final Action	00/00/00	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Tribal

Additional Information: Previously reported under RIN 0905-AD98.

Alternate Contact: Sue Martone, DLEA, SAMHSA, PHS, 5600 Fishers Lane, Room 12C-15, Rockville, MD 20852; 301-443-4640

Agency Contact: Joseph D. Faha, Director, DLEA, SAMHSA, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 12C-15, Rockville, MD 20857

Phone: 301 443-4640

RIN: 0930-AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Completed Actions
949. BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE (TOBACCO PROVISIONS)

Priority: Other Significant

CFR Citation: 45 CFR 96

Completed:

Reason	Date	FR Cite
Final Action	01/19/96	61 FR 1492

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Agency Contact: Joseph D. Faha
Phone: 301 443-4640

RIN: 0930-AA03

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Departmental Management (HHSDM)
Final Rule Stage
950. 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 generally requires agencies to pay attorney fees to parties prevailing against the Government in certain types of administrative proceedings. It requires each agency to issue rules implementing the Act as it applies to these proceedings. As originally

enacted, the Act had a sunset clause. A statutory amendment eliminated the sunset provision and made other changes in the Act. The instant regulation would amend 45 CFR part 13 (HHS's regulation implementing the Act) to eliminate the corresponding sunset provision and to make other changes conforming with the statutory changes.

Timetable:

Action	Date	FR Cite
NPRM	06/19/87	52 FR 23311
NPRM Comment Period End	08/17/87	

Action	Date	FR Cite
Final Action	10/00/96	
Final Action Effective	11/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Leslie L. Clune, 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

RIN: 0990-AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Food and Drug Administration (FDA)

Prerule Stage

951. MEDICAL FOODS**Priority:** Other Significant**Legal Authority:** 21 USC 321; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 350; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360ee; 21 USC 371**CFR Citation:** Not yet determined**Legal Deadline:** None**Abstract:** The Food and Drug Administration is considering development of regulations for medical foods, as defined by the Orphan Drug Act Amendments of 1988 (21 USC 360ee(b)(3)) to assure, among other things, the safety and effectiveness of these products, proper labeling of the nutrient content and purported uses, including adequate and appropriate directions for use, and quality control and good manufacturing practices.**Timetable:**

Action	Date	FR Cite
ANPRM	10/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** State, Federal**Additional Information:** Previously reported under RIN 0905-AD91.**Agency Contact:** Robert Moore, Senior Regulatory Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-456), 200 C Street SW., Washington, DC 20204

Phone: 202 205-5372

RIN: 0910-AA20
952. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; PROPOSED AMENDMENT OF CERTAIN REQUIREMENTS FOR FINISHED PHARMACEUTICALS
Priority: Other Significant**Legal Authority:** 21 USC 321; 21 USC 351 to 352; 21 USC 355 to 357; 21 USC 360b; 21 USC 371; 21 USC 374**CFR Citation:** 21 CFR 210.3; 21 CFR 211.22; 21 CFR 211.68; 21 CFR 211.82; 21 CFR 211.84; 21 CFR 211.101; 21 CFR 211.103; 21 CFR 211.110; 21 CFR 211.111; 21 CFR 211.113; 21 CFR 211.115; 21 CFR 211.160; 21 CFR 211.166; 21 CFR 211.192; 21 CFR 211.220; ...**Legal Deadline:** None**Abstract:** FDA is proposing revisions to the current good manufacturing practice (CGMP) regulations at 21 CFR parts 210 and 211 regarding finished pharmaceuticals. The new regulations either codify current agency policies or current industry practices. Among other things, the proposal would create or clarify requirements for process and methods validation, appropriate laboratory testing procedures, and protection against contamination. The proposal is designed to update the CGMP regulations in response to technological changes and the Agency's experience with the regulations.**Timetable:**

Action	Date	FR Cite
ANPRM	05/00/96	

Small Entities Affected: None**Government Levels Affected:** Federal**Additional Information:** Previously reported under RIN 0905-AE63.**Agency Contact:** Thomas Kuchenberg, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1046
Fax: 301 827-0901**RIN:** 0910-AA45
953. REINVENTING FDA FOOD REGULATIONS
Priority: Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371**CFR Citation:** 21 CFR 101; 21 CFR 102; 21 CFR 103; 21 CFR 131; 21 CFR 133; 21 CFR 135; 21 CFR 136; 21 CFR 137; 21 CFR 139; 21 CFR 145; 21 CFR 146; 21 CFR 150; 21 CFR 152; 21 CFR 155; 21 CFR 156; ...**Legal Deadline:** None**Abstract:** In response to President Clinton's memorandum to heads of departments and agencies entitled

"Regulatory Reinvention Initiative," FDA will be initiating rulemaking to retain, revise, or revoke certain of its regulations for food. FDA will be proposing: (1) to establish a notification procedure for companies to use for independent GRAS determinations; (2) to request information on the need to retain, revise, or revoke its food standards of identity regulations and its common or usual name regulations; (3) to coordinate the food additive, GRAS, and color additive approval process with USDA when meat and poultry product uses are petitioned for; and (4) to increase the number of categorical exclusions from the requirements for environmental review.

Timetable:**Additional categorical exclusions for environmental impact**

NPRM 04/03/96 (61 FR 14922)

Food Additive and Other Regulations

Final Action 05/00/96

Food Labeling and Other Regulations

NPRM 05/00/96

Food Regulations; Plan for Revisions

ANPRM 05/00/96

Notification Procedures for Independent GRAS Determinations

NPRM 05/00/96

Revocation of Lower Fat Milk

NPRM 11/09/95 (60 FR 56541)

Comment Period End 01/23/96

Final Action 00/00/00

Revocation of Obsolete Regulations

NPRM 10/13/95 (60 FR 53480)

Comment Period End 01/11/96

Final Action 05/00/96

Small Entities Affected: Businesses**Government Levels Affected:** State**Agency Contact:** L. Robert Lake, Director, Office of Policy, Planning and Strategic Initiatives, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW., Washington, DC 20204

Phone: 202 205-4561

Fax: 202 401-7739

RIN: 0910-AA58
954. FOOD STANDARDS OF IDENTITY, QUALITY, AND FILL OF CONTAINER; COMMON OR USUAL NAME REGULATIONS; REQUEST FOR COMMENTS ON EXISTING REGULATIONS
Priority: Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in

HHS—FDA

Prerule Stage

the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 376

CFR Citation: 21 CFR 102 to 103; 21 CFR 130 to 131; 21 CFR 133; 21 CFR 135 to 137; 21 CFR 139; 21 CFR 145 to 146; 21 CFR 150; 21 CFR 152; 21 CFR 155 to 156; 21 CFR 158; 21 CFR 160 to 161; 21 CFR 163 to 166; 21 CFR 168 to 169

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is considering amending, revising, or revoking its food standards of identity, quality, and fill of container and its common or usual name regulations for nonstandardized foods to make them less burdensome on industry and more responsive to the needs of consumers. A notice of proposed rulemaking that published October 13, 1995, identified, among other obsolete or otherwise unnecessary regulations, 17 specific CFR sections on food standards for possible revocation. In addition, FDA published an advance notice of proposed rulemaking (ANPRM) in the Federal Register on December 29, 1995, requesting comments on other such standards from all interested parties, including consumers, consumer groups, academia, the regulated food industry, food distributors, importers, and exporters on these regulations. The agency is seeking comments on the benefits or lack of benefits of such regulations in facilitating domestic, as well as international, commerce and on their value to consumers, less costly alternative means of accomplishing the statutory objective of food standards, that is, to promote honesty and fair dealing in the interest of consumers, in the manufacture and sale of food products covered by these regulations.

Timetable:

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

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Federal

Agency Contact: F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS-150), 200 C St. SW., Washington, DC 20204
Phone: 202 205-4561

RIN: 0910-AA67

955. • REINVENTION OF REGULATIONS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 5 USC 504; 5 USC 551 to 558; 5 USC 701 to 721; 7 USC 138; 7 USC 2271; 15 USC 402; 15 USC 409; 15 USC 638; 15 USC 1261 to 1282; 15 USC 1451 to 1461; 15 USC 3701 to 3711; 21 USC 41 to 50; 21 USC 61 to 63; 21 USC 141 to 149; 21 USC 321 to 394

CFR Citation: 21 CFR 1 to 3; 21 CFR 5; 21 CFR 10; 21 CFR 12; 21 CFR 19 to 20; 21 CFR 56; 21 CFR 58; 21 CFR 70 to 71; 21 CFR 80; 21 CFR 101; 21 CFR 170; 21 CFR 172 to 175; 21 CFR 177 to 178; 21 CFR 184; 21 CFR 730 to 740; ...

Legal Deadline: None

Abstract: FDA is considering ways to further streamline certain regulations that are outdated or otherwise in need of reform. The agency is taking this action in response to President Clinton's March 4, 1995 directive to all Federal agencies to conduct a page-by-page review of their regulations as part of the "Reinventing Government" initiative. FDA plans to reinvent approximately 45 percent of its regulations to ease the burden on regulated industry and consumers without sacrificing public health protection. For those regulations requiring Congressional permission to reinvent, the Administration will seek legislative changes.

Timetable:

Action	Date	FR Cite
ANPRM	06/00/96	

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal, Federal

Agency Contact: Lisa M. Helmanis, Office of Policy (HF-26), Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-3480
Fax: 301 443-2946

RIN: 0910-AA69

956. • INVESTIGATIONAL NEW DRUG APPLICATIONS; REQUEST FOR INFORMATION AND COMMENTS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 56; 21 CFR 312

Legal Deadline: None

Abstract: The advance notice of proposed rulemaking would permit certain uses of investigational new drugs by individual investigators who are not included in a commercial sponsor's application provided that the drugs are in Phase 2 of commercial development.

Timetable:

Action	Date	FR Cite
ANPRM	05/00/96	
ANPRM Comment Period End	08/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. The agency has not yet determined whether there is a paperwork burden associated with this action.

Agency Contact: Murray Lumpkin, M.D., Deputy Center Director, (Review Management), Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-2), 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-5417
Fax: 301 594-6197

RIN: 0910-AA83

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Food and Drug Administration (FDA)

Proposed Rule Stage

**957. OVER-THE-COUNTER (OTC)
DRUG REVIEW**
Priority: Routine and Frequent

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 21 USC 321p; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360a; 21 USC 371a

CFR Citation: 21 CFR 310; 21 CFR 330; 21 CFR 333; 21 CFR 334; 21 CFR 335; 21 CFR 336; 21 CFR 337; 21 CFR 338; 21 CFR 339; 21 CFR 340; 21 CFR 341; 21 CFR 342; 21 CFR 343; 21 CFR 344; 21 CFR 345; ...

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. NOTE: NPRM for "Antidotes, Toxic Ingestion Products" was combined with NPRM for "Emetic Products" and repropose as "Poison Treatment Products." NPRM for "Astringent (Wet Dressings) Products" was included in the NPRM for "Skin Protectant Products." NPRM for "Diaper Rash Products" was included in NPRMs for "Antifungal," "Antimicrobial," "External Analgesic" and "Skin Protectant Products." NPRM for "Fever Blister/Cold Sore Products (External)" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Insect Bites and Stings (Relief) Products" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." "Poison Ivy/Oak/Sumac Prevention" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Mercurial (Topical) Products" was included in revised NPRM for "Antimicrobial Products." NPRM for "Alcohol (Topical) Products" was included in revised NPRM for "Antimicrobial Products." The NPRM for "Antimicrobial Products" was updated and split into two sections: First Aid Products and Health Care Products.

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:
Acne (Topical) Products

ANPRM 03/23/82 (47 FR 12430)
 NPRM 01/15/85 (50 FR 2172)
 NPRM (Amendment) 08/07/91 (56 FR 37622)
 Final Action 08/16/91 (56 FR 41008)

Alcohol (Oral) in OTC Drug Products

NPRM 10/21/93 (58 FR 54466)
 Final Action 03/13/95 (60 FR 13590)
 NPRM (Amendment) 05/00/96

Alcohol (Topical) Products (To be merged w/other rulemkg)

ANPRM 05/21/82 (47 FR 22324)

Anorectal Products

ANPRM 05/27/80 (45 FR 35576)
 NPRM 08/15/88 (53 FR 30756)
 Final Action 08/03/90 (55 FR 31776)
 Final Action (LYCD) 09/02/93 (58 FR 46746)
 Final Action (Witch Hazel) 06/03/94 (59 FR 28766)

Antacid Drug Products

ANPRM 04/05/73 (38 FR 8714)
 NPRM 11/12/73 (38 FR 31260)
 Final Action 06/04/74 (39 FR 9862)
 NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66754)
 Final Action (Amendment) (Warning) 08/26/93 (58 FR 45204)
 NPRM (Amendment) (Testing) 09/23/93 (58 FR 49826)
 NPRM (Amendment)(Sodium Bicarb.) 02/02/94 (59 FR 5060)
 Final Action (Technical Amendment) 11/25/94 (59 FR 60555)
 Final Action (Amendment) (Testing) 02/08/96 (61 FR 4822)

Anthelmintic Products

ANPRM 09/09/80 (45 FR 59541)
 NPRM 08/24/82 (47 FR 37062)
 Final Action 08/01/86 (51 FR 27756)

Antibiotic First Aid Products

ANPRM 04/01/77 (42 FR 17642)
 NPRM 07/09/82 (47 FR 29986)
 Final Action 12/11/87 (52 FR 47312)
 NPRM (Amendment) 08/18/89 (54 FR 34188)
 Final Action 03/15/90 (55 FR 9721)
 NPRM (Amendment) 05/11/90 (55 FR 19868)
 NPRM (Amendment) 06/08/90 (55 FR 23450)
 Final Action (Amendment) 10/03/90 (55 FR 40379)
 Final Action (Amendment) 12/05/90 (55 FR 50171)
 NPRM (Amendment) (Warning) 02/14/96 (61 FR 5918)

Anticaries Products

ANPRM 03/28/80 (45 FR 20666)
 NPRM 09/30/85 (50 FR 39854)
 NPRM 06/15/88 (53 FR 22430)
 Final Action 10/06/95 (60 FR 52474)

Antidiarrheal Products

ANPRM 03/21/75 (40 FR 12924)
 NPRM 04/30/86 (51 FR 16138)
 Final Action 08/00/96

Antidotes, Toxic Ingestion Prdts (New Poison Treatment Prdts)

ANPRM 01/05/82 (47 FR 444)

Antiemetic Products

ANPRM 03/21/75 (40 FR 12934)
 NPRM 07/13/79 (44 FR 41064)
 Final Action 04/30/87 (52 FR 15886)
 NPRM (Amendment) 08/26/93 (58 FR 45216)
 Final Action 04/11/94 (59 FR 16981)

Antiflatulent Drug Products

NPRM 11/12/73 (38 FR 31260)
 Final Action 06/04/74 (39 FR 19877)
 NPRM (Amendment) 01/29/88 (53 FR 2716)
 Final Action (Amendment) 03/05/96 (61 FR 8836)

Antifungal (Topical) Products

ANPRM 03/23/82 (47 FR 12480)
 NPRM 12/12/89 (54 FR 51136)
 NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25240)
 Final Action (Amdt.)(Diaper Rash) 12/18/92 (57 FR 60430)
 Final Action (Partial) 09/02/93 (58 FR 46744)
 Final Action 09/23/93 (58 FR 49890)

Antimicrobial Products

ANPRM 09/13/74 (39 FR 33103)
 NPRM 01/06/78 (43 FR 1210)
 NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25246)

Antiperspirant Products

ANPRM 10/10/78 (43 FR 46694)
 NPRM 08/20/82 (47 FR 36492)
 Final Action 00/00/00

Antiseptic First Aid

ANPRM 09/13/74 (39 FR 33103)
 NPRM 01/06/78 (43 FR 1210)
 NPRM (Revised) 07/22/91 (56 FR 33644)
 Final Action 00/00/00

Antiseptic Products (Professional Use)

ANPRM 09/13/74 (39 FR 33103)
 NPRM 01/06/78 (43 FR 1210)
 NPRM (Revised) 06/17/94 (59 FR 31402)

Aphrodisiac Products

ANPRM 10/01/82 (47 FR 43572)
 NPRM 01/15/85 (50 FR 2168)
 Final Action 07/07/89 (54 FR 28780)

Aspirin (Heart Labeling)

NPRM 10/20/93 (58 FR 54224)

Aspirin (Reye Syndrome)

NPRM 10/20/93 (58 FR 54228)

Astringent (Wet Dressings) Prdts (Merged w/other rulemkg)

ANPRM 09/07/82 (47 FR 39436)

Benign Prostatic Hypertrophy Products

ANPRM 10/01/82 (47 FR 43566)
 NPRM 02/20/87 (52 FR 5406)
 Final Action 02/27/90 (55 FR 6926)

Boil Ointments

ANPRM 06/29/82 (47 FR 28306)
 NPRM 01/26/88 (53 FR 2198)
 Final Action 11/15/93 (58 FR 60332)

Camphorated Oil Drug Products

ANPRM 09/26/80 (45 FR 63869)
 Final Action 09/21/82 (47 FR 41716)

HHS—FDA

Proposed Rule Stage

Cholecystokinetic Products

ANPRM 02/12/80 (45 FR 9286)
 NPRM 08/24/82 (47 FR 37068)
 Final Action 06/10/83 (48 FR 27004)
 NPRM (Amendment) 08/15/88 (53 FR 30786)
 Final Action (Amendment) 02/28/89 (54 FR 8320)

Corn and Callus Remover Products

ANPRM 01/05/82 (47 FR 522)
 NPRM 02/20/87 (52 FR 5412)
 Final Action 08/14/90 (55 FR 33258)

Cough/Cold (Anticholinergic) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 07/09/82 (47 FR 30002)
 Final Action 11/08/85 (50 FR 46582)

Cough/Cold (Antihistamine) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 01/15/85 (50 FR 2200)
 NPRM (Amendment) 08/24/87 (52 FR 31892)
 Final Action 12/09/92 (57 FR 58356)
 Final Action (Amendment)(Warning) 01/28/94 (59 FR 4216)

Cough/Cold (Antitussive) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 10/19/83 (48 FR 48576)
 Final Action 08/12/87 (52 FR 30042)
 NPRM (Amendment) 07/06/89 (54 FR 28442)
 NPRM (Amendment) 10/02/89 (54 FR 40412)
 Final Action (Amendment) 07/06/90 (55 FR 27806)
 Final Action (Amendment) 10/03/90 (55 FR 40381)
 NPRM (Amendment)(Warning) 06/19/92 (57 FR 27666)
 NPRM (Amendment)(Ingredients) 12/09/92 (57 FR 58378)
 Final Action (Amendment)(Warning) 10/20/93 (58 FR 54232)
 Final Action (Amdt.)(Ingredients) 06/03/94 (59 FR 29172)

Cough/Cold (Bronchodilator) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 10/26/82 (47 FR 47520)
 Final Action 10/02/86 (51 FR 35326)
 NPRM (Amendment)(Warning) 06/19/92 (57 FR 27662)
 Final Action (Amendment)(Warning) 10/20/93 (58 FR 54238)
 NPRM (Amendment)(MDI) 03/09/95 (60 FR 13014)
 NPRM (Amendment)(Ephedrine) 07/27/95 (60 FR 38643)
 Final Action (Amendment) (MDI) 05/00/96

Cough/Cold (Combination) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 08/12/88 (53 FR 30522)
 NPRM (Amendment)(DPH Combinations) 02/23/95 (60 FR 10286)
 Final Action Theophylline 07/27/95 (60 FR 38636)
 Final Action 09/00/96

Cough/Cold (Diphenhydramine) Products

Final Action/Enforcement Policy 04/09/96 (61 FR 15700)

Cough/Cold (Expectorant) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 07/09/82 (47 FR 30002)
 Final Action 02/28/89 (54 FR 8494)
 Final Action (Technical Changes) 06/30/92 (57 FR 29176)

Cough/Cold (Expectorant/Ipecac) Products

Final Action 09/14/92 (57 FR 41857)

Cough/Cold (Nasal Decongestant) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 01/15/85 (50 FR 2220)
 NPRM (Amendment) 06/19/92 (57 FR 27658)
 Final Action 08/23/94 (59 FR 43386)
 Final Action; Partial Stay 03/08/96 (61 FR 9570)
 NPRM (Phenylpropanolamine) 09/00/96

Dandruff, Seborrheic Dermatitis and Psoriasis Control Products

ANPRM 12/03/82 (47 FR 54646)
 NPRM 07/30/86 (51 FR 27346)
 Final Action 12/04/91 (56 FR 63554)
 NPRM (Amendment) 04/05/93 (58 FR 17554)
 Final Action 01/28/94 (59 FR 4000)

Daytime Sedatives

ANPRM 12/08/75 (40 FR 57292)
 NPRM 06/13/78 (43 FR 25544)
 Final Action 06/22/79 (44 FR 36378)

Diaper Rash Products (Merged w/other rulemkg)

ANPRM 09/07/82 (47 FR 39406)

Digestive Aid Products

ANPRM 01/05/82 (47 FR 454)
 NPRM 01/29/88 (53 FR 2706)
 Final Action 10/21/93 (58 FR 54450)

Eligibility Criteria for Additional Conditions

ANPRM 07/00/96

Emetic Products

ANPRM 03/21/75 (40 FR 12939)
 NPRM 09/05/78 (43 FR 39544)

Exocrine Pancreatic Insufficiency Products

ANPRM 12/21/79 (44 FR 75666)
 NPRM 11/08/85 (50 FR 46594)
 NPRM (Reproposed) 07/15/91 (56 FR 32282)
 Final Action 04/24/95 (60 FR 20162)

External Analgesic Products

ANPRM 12/04/79 (44 FR 69768)
 NPRM 02/08/83 (48 FR 5852)
 NPRM (Amendment) (Dandruff) 07/30/86 (51 FR 27360)
 NPRM (Amendment) (Anorectal) 08/25/88 (53 FR 32592)
 NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40818)
 NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3370)
 NPRM (Amendment) (1%Hydrocortisone) 02/27/90 (55 FR 6932)
 NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25234)
 Final Action (Diaper Rash) 12/18/92 (57 FR 60426)
 Final Action 00/00/00

Fever Blister Products (Internal)

ANPRM 01/05/82 (47 FR 502)
 NPRM 06/17/85 (50 FR 25156)
 Final Action 06/30/92 (57 FR 29166)

Fvr Blister/Cold Sore Prdts (Ext.) (To be merged w/other rulemkg)

ANPRM 09/07/82 (47 FR 39436)

Hair Grower and Hair Loss Prevention Products

ANPRM 11/07/80 (45 FR 73955)
 NPRM 01/15/85 (50 FR 2190)
 Final Action 07/07/89 (54 FR 28772)

Hormone (Topical) Products

ANPRM 01/05/82 (47 FR 430)
 NPRM 10/02/89 (54 FR 40618)
 Final Action 09/09/93 (58 FR 57608)

Hypo/Hyperphosphatemia Products

ANPRM 12/09/80 (45 FR 81154)
 NPRM 01/15/85 (50 FR 2160)
 Final Action 05/11/90 (55 FR 19852)

Ingrown Toenail Relief Products

ANPRM 10/17/80 (45 FR 69128)
 NPRM 09/03/82 (47 FR 39120)
 Final Action 09/09/93 (58 FR 47602)

Insect Bite & Sting (Relief) Prdts (Merged w/other rulemkg)

ANPRM 09/07/82 (47 FR 39412)

Insect Repellent Drug Products (Internal)

ANPRM 01/05/82 (47 FR 424)
 NPRM 06/10/83 (48 FR 26986)
 Final Action 06/17/85 (50 FR 25170)

Internal Analgesic Products

ANPRM 07/08/77 (42 FR 35346)
 NPRM 11/16/88 (53 FR 46204)
 NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66762)
 NPRM (Amdt.)(Sodium Bicarbonate) 02/02/94 (59 FR 5068)
 NPRM (Prof. Labeling)(Acute MI) 06/00/96
 Final Action (Cardio/Cerebrvasclar) 09/00/96
 NPRM (Amendment)(Alcohol Warning) 09/00/96
 NPRM (Labeling-revised indications) 09/00/96

Internal Analgesic Products (Overindulgence)

Final Action 00/00/00

Internal Deodorant Products

ANPRM 01/05/82 (47 FR 512)
 NPRM 06/17/85 (50 FR 25162)
 Final Action 05/11/90 (55 FR 19862)

Labeling of Drug Products for OTC Use

NPRM 04/05/93 (58 FR 17553)
 Final Action 01/28/94 (59 FR 3998)
 NPRM (Do not mix drugs) 08/03/94 (59 FR 39499)
 NPRM (Amendment) (Do not mix drugs) 10/04/95 (60 FR 52058)
 NPRM (Unless a doctor tells you) 03/04/96 (61 FR 8450)
 NPRM (Calcium/Magnesium/Potassium) 04/22/96 (61 FR 17807)
 NPRM (Format/Examples) 08/00/96

Laxative Products

ANPRM 03/21/75 (40 FR 12902)
 NPRM 01/15/85 (50 FR 2124)
 NPRM (Amendment) (Directions/Bulk) 10/01/86 (51 FR 35136)
 NPRM (Amendment) (Docusate Salts) 09/02/93 (58 FR 46589)
 NPRM (Amendment)(Sodium Phosphates) 03/31/94 (59 FR 15139)
 Final Action (Sodium Phosphates) 09/00/96
 NPRM (Amendment)(Phosphates Label.) 09/00/96
 Final Action 09/00/96

HHS—FDA

Proposed Rule Stage

Leg Muscle Cramps (Nocturnal Relief) Products

ANPRM 10/01/82 (47 FR 43562)
 NPRM 11/08/85 (50 FR 46588)
 Final Action 08/22/94 (59 FR 43234)

Male Genital Desensitizer Products

ANPRM 09/07/82 (47 FR 39412)
 NPRM 10/02/85 (50 FR 40260)
 Final Action 06/19/92 (57 FR 27654)

Menstrual Products

ANPRM 12/07/82 (47 FR 55075)
 NPRM 11/16/88 (53 FR 46194)

Mercurial (Topical) Products (To be merged w/other rulemkg)

ANPRM 01/05/82 (47 FR 436)

Nailbiting/Thumbsucking Deterrent Products

ANPRM 10/17/80 (45 FR 69122)
 NPRM 09/03/82 (47 FR 39096)
 Final Action 09/02/93 (58 FR 46749)

Nighttime Sleep Aid Products

ANPRM 12/08/75 (40 FR 57292)
 NPRM 06/13/78 (43 FR 25544)
 Final Action 02/14/89 (54 FR 6814)
 NPRM (Amendment) 08/26/93 (58 FR 45217)
 Final Action (Amendment) 04/11/94 (59 FR 16982)

NDA Labeling Exclusivity

NPRM 11/09/93 (58 FR 59622)

Ophthalmic Products

ANPRM 05/06/80 (45 FR 30002)
 NPRM 06/28/83 (48 FR 29788)
 Final Action 03/04/88 (53 FR 7076)
 Final Action (Anti-infective) 12/18/92 (57 FR 60416)

Oral Discomfort (Relief) Products

ANPRM 05/25/82 (47 FR 22712)
 NPRM 09/24/91 (56 FR 48302)

Oral Health Care Products

ANPRM 05/25/82 (47 FR 22760)
 NPRM 01/27/88 (53 FR 2436)
 NPRM (Amendment) (Antimicrobials) 02/09/94 (59 FR 6084)
 Final Action 00/00/00

Oral Mucosal Injury Products (Merged w/Oral Health Care)

ANPRM 11/02/79 (44 FR 63270)
 NPRM 07/26/83 (48 FR 33984)

Oral Wound Healing Products

ANPRM 11/02/79 (44 FR 63270)
 NPRM 07/26/83 (48 FR 33984)
 Final Action 07/18/86 (51 FR 26112)

Otic Products (Dry Water-Clogged Ears)

NPRM (Amendment) 07/00/96

Otic Products (Earwax)

NPRM 07/09/82 (47 FR 30012)
 Final Action 08/08/86 (51 FR 28656)

Otic Products (Swimmers Ear)

NPRM 07/30/86 (51 FR 27366)
 Final Action 02/15/95 (60 FR 8916)
 Final Action Partial Stay 08/16/95 (60 FR 42435)

Overindulgence Remedies

ANPRM 10/01/82 (47 FR 43540)
 NPRM 12/24/91 (56 FR 66742)
 NPRM (Amendment)(Warning) 05/05/93 (58 FR 26886)

Overindulgence Remedies/Prevention of Inebriation

ANPRM 10/01/82 (47 FR 43540)
 Final Action 07/19/83 (48 FR 32872)

Pediculicide Products

ANPRM 06/29/82 (47 FR 28312)
 NPRM 04/03/89 (54 FR 13480)
 Final Action 12/14/93 (58 FR 65452)

Phenylpropanolamine Products (Labeling)

NPRM 02/14/96 (61 FR 3912)

Poison Ivy/Oak/Sumac Prevention (Merged w/other rulemkg)

ANPRM 09/07/82 (47 FR 39412)

Poison Treatment Products

NPRM 01/15/85 (50 FR 2244)
 NPRM (Amendment) 07/00/96
 Final Action 09/00/96

Quinine for Malaria

NPRM 04/19/95 (60 FR 19650)
 Final Action 09/00/96

Reporting of Adverse Reactions

NPRM 07/00/96

Skin Bleaching Products

ANPRM 11/03/78 (43 FR 51546)
 NPRM 09/03/82 (47 FR 39108)
 NPRM (Reproposed) 09/00/96

Skin Protectant Products

ANPRM 08/04/78 (43 FR 34628)
 NPRM 02/15/83 (48 FR 6820)
 NPRM (Amendment) (Astringent) 04/03/89 (54 FR 13490)
 NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40808)
 NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3362)
 NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25204)
 Final Action (Astringent) 10/21/93 (58 FR 54466)
 Final Action (Witch Hazel) 06/03/94 (59 FR 28767)
 Final Action (Poison Ivy) 08/00/96
 Final Action 08/00/96

Smoking Deterrent Products

ANPRM 01/05/82 (47 FR 490)
 NPRM 07/03/85 (50 FR 27552)
 Final Action 06/01/93 (58 FR 31236)

Sodium Labeling

NPRM 04/25/91 (56 FR 19222)
 Final Action 04/22/96 (61 FR 17798)

Status of Certain Category II and III Ingredients

NPRM 05/16/90 (55 FR 20434)
 Final Action 11/07/90 (55 FR 46914)
 NPRM 08/25/92 (57 FR 38568)
 Final Action 05/10/93 (58 FR 27636)

Stimulant (Overindulgence) Products

NPRM (Amendment) 12/24/91 (56 FR 66758)

Stimulant Products

ANPRM 12/08/75 (40 FR 57292)
 NPRM 06/13/78 (43 FR 25544)
 Final Action 02/29/88 (53 FR 6100)

Stomach Acidifier Products

ANPRM 10/19/79 (44 FR 60316)
 NPRM 01/15/85 (50 FR 2184)
 Final Action 08/17/88 (53 FR 31270)

Sunscreen Products

ANPRM 08/25/78 (43 FR 38206)
 NPRM 05/12/93 (58 FR 28194)
 NPRM (Amendment) 06/08/94 (59 FR 29706)

Sweet Spirits of Nitre

ANPRM 02/22/80 (45 FR 11846)
 Final Action 06/27/80 (45 FR 43400)

Topical Drug Products Containing Benzoyl Peroxide (Labeling)

NPRM 02/17/95 (60 FR 9554)

Vaginal Contraceptive Products

ANPRM 12/12/80 (45 FR 82014)
 NPRM 02/03/95 (60 FR 6892)

Vaginal Drug Products

ANPRM 10/13/83 (48 FR 46694)
 Withdrawal 02/03/95 (60 FR 5226)

Vitamin/Mineral Products

ANPRM 03/16/79 (44 FR 16126)
 Withdrawal 11/27/81 (46 FR 57914)

Wart Remover Products

ANPRM 10/03/80 (45 FR 65609)
 NPRM 09/03/82 (47 FR 39102)
 NPRM (Amendment) 03/27/87 (52 FR 9992)
 Final Action 08/14/90 (55 FR 33246)
 NPRM (Amendment)(Directions) 01/28/94 (59 FR 4015)
 Final Action (Amdt.)(Directions) 11/23/94 (59 FR 60315)

Water Soluble Gums

NPRM 10/30/90 (55 FR 45782)
 Final Action 08/26/93 (58 FR 45194)

Weight Control Products

ANPRM 02/26/82 (47 FR 8466)
 NPRM 10/30/90 (55 FR 45788)
 Final Action 08/08/91 (56 FR 37792)
 NPRM (Amendment) 06/00/96

Small Entities Affected: None**Government Levels Affected: None****Additional Information: Previously reported under RIN 0905-AA06.**

NOTE: Reinventing government applies only to the Antacid Drug Products final action.

Agency Contact: William E. Gilbertson, Assoc. Commissioner for OTC Drug Monographs, Office of Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-105), 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 827-2304

RIN: 0910-AA01

958. INFANT FORMULA: GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, NOTIFICATION REQUIREMENTS, AND RECORDS AND REPORTS

Priority: Other Significant

Legal Authority: 21 USC 350a

CFR Citation: 21 CFR 107; 21 CFR 106

Legal Deadline: None

Abstract: The agency published on December 24, 1991, a final rule implementing certain aspects of the Infant Formula Act of 1986. The rule

HHS—FDA

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establishes infant formula record and record retention requirements. The agency is preparing a proposed rule that will establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and reports for the production of infant formulas.

Timetable:**Current Good Mfg. Practices; Qual Control Proc**

NPRM 07/00/96
NPRM (Comment Period End) 10/00/96

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)

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AC46.

Agency Contact: Carolyn W. Miles, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-456), 200 C Street SW., Washington, DC 20204
Phone: 202 205-5372

RIN: 0910-AA04

959. IMPLEMENTATION OF THE SAFE MEDICAL DEVICES ACT OF 1990

Priority: Other Significant

Legal Authority: PL 101-629 Safe Medical Devices Act of 1990

CFR Citation: 21 CFR 860; 21 CFR 820; 21 CFR 807; 21 CFR 803; 21 CFR 17; 21 CFR 812; 21 CFR 7; 21 CFR 814; 21 CFR 821; 21 CFR 861; 21 CFR 895

Legal Deadline:

NPRM, Statutory, August 28, 1991, for Medical Device Tracking.
Final, Statutory, November 28, 1991, for Exemption of Humanitarian Devices, etc.

Other, Statutory, December 1, 1991, for Classification of Transitional Devices Notice.

Final, Statutory, August 28, 1993, for Medical Device Tracking.

Abstract: The Safe Medical Devices Act of 1990 (SMDA), enacted November 28, 1990, was intended to assure marketed devices are safe and effective. FDA learns quickly of device problems, and has authority to remove defective devices from the market. The act directs or authorizes FDA to develop

these regulations: Medical Device Reporting--These rules require healthcare facilities and distributors to report deaths and serious injuries/illnesses related to medical devices. Medical Device Tracking--This regulation requires manufacturers to track certain devices to the user. Classification of Transitional Devices--FDA issued a notice to require submission of adverse safety and effectiveness data on transitional devices. FDA will now propose to keep each device in class III, or reclassify it in class I or II. Good Manufacturing Practices for Medical Devices--FDA proposed to add preproduction design validation in existing CGMP regulations. Exemption of Humanitarian Devices--The proposed rule gives procedures for applications for certain premarket review exemptions for humanitarian devices.

Summaries of Safety and Effectiveness for Premarket Notification--The final rule sets forth information to be included in data summaries on which substantial equivalence determinations are made. Recall of Medical Devices--A proposed rule sets forth procedures for using authority to order device recalls and notifications. Reports of Removal and Corrections--FDA proposed procedures for manufacturers to report to FDA health-related market removals and corrections of devices. Civil Money Penalties--A final rule established procedures for a hearing to which persons are entitled before the imposition of civil money penalties. Procedural Changes in Medical Device Regulations--This final rule made revisions in regulations necessary because of procedural changes made by the SMDA. Premarket Review of Combination Products--FDA published a final rule establishing procedures for determining which FDA center will review premarket approval applications for products that are a combination of a device and a drug or biologic.

Timetable:

Action	Date	FR Cite
Final Action	00/00/00	

Assignment of Agency Component for Review of Premarket Applctns
Notice (Public Hearing) 07/12/91 (56 FR 31951)
Final Action 11/21/91 (56 FR 31951)

Civil Money Penalties
NPRM 05/26/93 (58 FR 30680)
Final Action 07/27/95 (60 FR 38612)

Classification of Transitional Devices

Notice 11/14/91 (56 FR 57960)
Notice(Extension of Comment Period) 03/10/92 (57 FR 8462)
Notice (Extension of Deadline) 11/30/92 (57 FR 56586)
Final Rule (Contact Lenses) 03/04/94 (59 FR 10283)

CGMPs for Medical Devices

ANPRM (Revisions;Request for Cmnts) 06/15/90 (55 FR 24544)
ANPRM (Suggested Changes;Availbty) 11/30/90 (55 FR 49644)
ANPRM (Extension of Comment Period) 02/14/91 (56 FR 5965)
Notice (Open Public Advsy Cmte Mtg) 04/17/91 (56 FR 15626)
NPRM 11/23/93 (58 FR 61952)
NPRM 07/24/95 (60 FR 37856)
Final Action 06/00/96

Distributor Reporting

NPRM 06/00/96

Exemption of Humanitarian Devices

NPRM 12/21/92 (57 FR 60491)
Final Action 06/00/96

Medical Device Recall Authority

NPRM 06/14/94 (59 FR 30656)
NPRM (Correction) 06/23/94 (59 FR 32489)
Final Action 06/00/96

Medical Device Reporting

Notice (Public Conf; Rqst for Info) 03/28/91 (56 FR 12934)
NPRM 11/26/91 (56 FR 60024)
Final Rule (Distributor Reporting) 09/01/93 (58 FR 46514)
Final Action 12/11/95 (60 FR 63578)
Final Action(Ext.Eff.Date-7/31/96) 04/11/96 (61 FR 16043)

Medical Device Tracking

NPRM 03/27/92 (57 FR 10702)
NPRM 05/29/92 (57 FR 22971)
Final Action 05/29/92 (57 FR 22966)
Final Action (Not Stat Eff Date 08/16/93) (58 FR 43442)

Miscellaneous Procedural Changes in Medical Device Regulations

Final Action 12/10/92 (57 FR 58400)

Pre-Amendment Class III Devices (merged with 0905-AE34)

Notice 05/06/94 (59 FR 23731)

Reports of Removals and Corrections of Medical Devices

NPRM 06/04/94 (59 FR 13828)
Final Action 06/00/96

Safe Medical Devices Act of 1990; Implementation Plans

Notice 04/05/91 (56 FR 14111)

Summaries of Safety & Effectiveness for Premarket Notification

Final Action 04/28/92 (57 FR 18062)
Notice (Stay of Effective Date) 06/01/92 (57 FR 23059)

Final Action 12/14/94 (59 FR 64287)

Temporary Suspension of a Premarket Approval Application

NPRM 10/12/93 (58 FR 52729)
Final Action 06/00/96

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

HHS—FDA

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Government Levels Affected: State, Local, Federal

Additional Information: Previously reported under RIN 0905-AD59.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850

Phone: 301 594-4765

RIN: 0910-AA09

960. REPORTING OF ERRORS AND ACCIDENTS

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 600; 21 CFR 606

Legal Deadline: None

Abstract: All licensed manufacturers are required to notify FDA promptly of errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any distributed biological product (21 CFR 600.14). The reporting of certain errors or accidents occurring in the manufacture of blood and blood components is necessary so that FDA can respond where the public health may be endangered and provide added assurance as to the continued safety, identity, quality, purported quality, and purity of blood and blood components. FDA has determined that errors and accidents that are detected and corrected before a finished unit is removed from the unprocessed inventory and made available for release and distribution do not affect the safety of the blood supply and need not be reported to the Agency. The proposed rule would require licensed establishments, unlicensed establishments, and transfusion services to report and keep records. The cost to licensed establishments would be minimal. Since they already are required to report, licensed establishments would only have to make some changes in standard operating procedures. Unlicensed establishments are already required to keep records and conduct investigations. Under the proposed rule they would have to establish reporting procedures and report to FDA. The

transfusion services would have to assure that their recordkeeping and investigation procedures are sufficient and establish reporting procedures.

Timetable:

Action	Date	FR Cite
NPRM	11/00/96	
NPRM Comment Period End	02/00/97	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD67.

Agency Contact: Paula S. McKeever, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-650), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 594-1077

RIN: 0910-AA12

961. MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992

Priority: Economically Significant

Legal Authority: PL 102-539 Mammography Quality Standards Act of 1992; 42 USC 263b

CFR Citation: 21 CFR 900

Legal Deadline: Final, Statutory, July 27, 1993.

Standards for accreditation bodies are required by July 27, 1993.

Abstract: The purpose of the Mammography Quality Standards Act of 1992 (MQSA), enacted October 27, 1992, is to assure quality in all aspects of the practice of mammography. The primary mechanism for this is oversight of all mammography facilities through a certification and inspection program. Only facilities certified by the Secretary are permitted to produce, process, or interpret mammographic images. The statute also required the establishment of an advisory committee to advise on appropriate quality standards and also provided for the establishment of surveillance systems to evaluate breast cancer screening programs.

The agency published interim regulations on December 21, 1993, which were drafted and implemented so as to maximize lawful operation by facilities under existing quality standards, and to ensure adequate examinee access to quality

mammography during the transition to more comprehensive national standards.

Concurrent with the implementation of the interim rules, FDA has proceeded with the development of proposed regulations to replace the interim rules. The agency recently issued proposed rules, with the advice and consultation of the National Mammography Quality Assurance Advisory Committee, on requirements for accreditation bodies, equipment and quality assurance requirements, facility requirements, and personnel requirements.

Timetable:

Alternative Approaches

NPRM 04/03/96 (61 FR 14856)

Approval of Accrediting Bodies

Interim Final Rule 12/21/93 (58 FR 67558)

Draft Proposed Quality Standards

Notice of Availability 01/26/95 (60 FR 5152)

Draft X-Ray and Medical Physicist

Standards Proposals

Notice of Availability; 12/30/94 (59 FR 67710)

General Facility Requirements

NPRM 04/03/96 (61 FR 14870)

Mammography Quality Standards Act of

1992; Inspection Fees

Notice 03/17/95 (60 FR 4584)

Personnel Requirements

NPRM 04/03/96 (61 FR 14898)

Quality Standards for Mammography

Equipment and QA

NPRM 04/03/96 (61 FR 14908)

Quality Standards for Mammography

Facilities

Interim Final Rule 12/21/93 (58 FR 67565)

Quality Standards/Certification Rqmts.

Interim Final Rule 09/30/94 (59 FR 49808)

Requirements for Accreditation Bodies and

Quality Standards

Notice (Advisory Committee) 12/21/94 (59 FR 65776)

NPRM 04/03/96 (61 FR 14884)

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AE07.

Agency Contact: Charles K. Showalter, Office of Health and Industry Programs, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-240), 1350 Piccard Drive Rockville, MD 20850
Phone: 301 594-3332

RIN: 0910-AA24

HHS—FDA

Proposed Rule Stage

962. LATEX CONDOMS: EXPIRATION DATE LABELING**Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 351; 21 USC 352**CFR Citation:** 21 CFR 801**Legal Deadline:** None

Abstract: Latex condoms are used as a barrier to transmission of diseases through bodily fluids, including AIDS. Latex deteriorates over time, reducing its utility as a barrier. The proposed rule would require manufacturers of these products to perform testing to establish an appropriate expiration date for their products and to place that date on their labeling.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE37.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850

Phone: 301 594-4765

RIN: 0910-AA32**963. LATEX WARNING****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 352**CFR Citation:** 21 CFR 801**Legal Deadline:** None

Abstract: Certain persons may be subject to severe adverse reaction upon contact with latex. Therefore, FDA would propose to require that devices containing latex have a warning in the labeling concerning the presence of latex and the potential risk. This will enable health professionals and consumers to make an informed choice concerning the use of a device.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE40.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850

Phone: 301 594-4765

RIN: 0910-AA34**964. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE****Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360d; 21 USC 371; 21 USC 360j(e)**CFR Citation:** 21 CFR 801.420; 21 CFR 801.421**Legal Deadline:** None

Abstract: FDA is considering revising its present regulation governing the labeling and conditions for sale of hearing aids. The present rule requires an examination by a physician before purchase of a hearing aid, but permits an informed adult to waive that requirement. There is some evidence that this waiver provision is being misused. FDA is reconsidering which types of health professionals are competent to perform hearing evaluations. FDA is also considering revisions to its professional and patient labeling to require updated information.

Timetable:

Action	Date	FR Cite
ANPRM	11/10/93	58 FR 59695
ANPRM Comment Period End	01/10/94	
NPRM	07/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** State**Additional Information:** Previously reported under RIN 0905-AE46.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850

Phone: 301 594-4765

RIN: 0910-AA39**965. HUMAN TISSUE INTENDED FOR TRANSPLANTATION****Priority:** Other Significant**Legal Authority:** 42 USC 216; 42 USC 243; 42 USC 264; 42 USC 271**CFR Citation:** 21 CFR 1270**Legal Deadline:** None

Abstract: FDA is issuing a final rule requiring certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of AIDS and hepatitis through human tissue used in transplantation. FDA is also clarifying and modifying those requirements previously promulgated by the interim rule. In addition, FDA is amending the regulations to require the registration of those establishments engaged in procurement, processing, storage, or distribution of human tissue intended for transplantation. Also, FDA will be proposing regulations to govern the recovery, processing, storage, or distribution of human reproductive tissue.

Timetable:

Action	Date	FR Cite
Interim Rule; Opport. for Comment	12/14/93	58 FR 65514
Interim Rule; Comment Period End	03/14/94	
NPRM	10/00/96	
NPRM Comment Period End	01/00/97	
Final Action	02/00/97	

Small Entities Affected: Businesses**Government Levels Affected:** Undetermined**Additional Information:** Previously reported under RIN 0905-AE49.

Agency Contact: Tracey Forfa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-630), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448

Phone: 301 594-3074

RIN: 0910-AA40

HHS—FDA

Proposed Rule Stage

966. ANIMAL MEDICINAL DRUG USE CLARIFICATION ACT OF 1994; EXTRA-LABEL USE; IMPLEMENTATION**Priority:** Substantive, Nonsignificant**Legal Authority:** PL 103-396**CFR Citation:** None**Legal Deadline:** Final, Statutory, October 22, 1996.

Two years after bill was signed into law (10/22/94).

Abstract: Upon promulgation of regulations, the Animal Drug Amendments of 1994 will allow licensed veterinarians to prescribe off-label use of approved animal and human drugs for animals under certain circumstances within limits set by FDA. If the Secretary finds there is a reasonable probability that a use may present a risk to the public, the Secretary may establish a safe level for residues of such use by order and require the development of analytical methods for detection of resultant residues. If the Secretary finds, after affording an opportunity for public comment, that a use presents a risk to public health or if no analytical method is developed, when called for, the Secretary may prohibit such use. The Secretary may also, by regulation, provide access to veterinarian records to ascertain any use or intended extra-label use that may present a risk to public health. The proposed rule will implement the statute by providing policies, procedures, and limitations on extra-label use and by setting the circumstances and conditions for Agency examination of veterinarian records.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
Final Action	10/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE66.

Agency Contact: Richard L. Arkin, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-238), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1737

RIN: 0910-AA47**967. REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION****Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 207**Legal Deadline:** None

Abstract: The proposed rule would revise and clarify the regulations under part 207 to reduce the burden on manufacturers, packers, and distributors, and to consolidate and streamline the requirements.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	
NPRM Comment	12/00/96	
Period End		

Small Entities Affected: None**Government Levels Affected:** None

Agency Contact: Howard Muller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA49**968. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS****Priority:** Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 357; 21 USC 371

CFR Citation: 21 CFR 320**Legal Deadline:** None

Abstract: The proposed rule would revise and clarify certain sections of part 320 to eliminate duplication and inconsistencies.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	
NPRM Comment	10/00/96	
Period End		

Small Entities Affected: None**Government Levels Affected:** None

Agency Contact: Christine Rogers, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1046
Fax: 301 827-0901

RIN: 0910-AA51**969. CONSOLIDATION OF REGULATIONS****Priority:** Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 21 USC 371

CFR Citation: 21 CFR 200.30; 21 CFR 200.31; 21 CFR 250.10; 21 CFR 250.103; 21 CFR 250.106; 21 CFR 310.502; 21 CFR 310.504-510; 21 CFR 310.513; 21 CFR 310.525; 21 CFR 310.526

Legal Deadline: None

Abstract: FDA is proposing to consolidate into one section a list of drugs previously determined to be new drugs. This document would also remove the section now providing for these drugs. This action, which will make the regulations more concise and efficient, is being taken in response to the President's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	04/00/96	
NPRM Comment	06/00/96	
Period End		

Small Entities Affected: None**Government Levels Affected:** None

Agency Contact: Mary E. Catchings, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-2041

HHS—FDA

Proposed Rule Stage

Fax: 301 827-0901

RIN: 0910-AA53

970. NAME OF SELLING AGENT OR DISTRIBUTOR**Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360i; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262 to 264**CFR Citation:** 21 CFR 610**Legal Deadline:** None**Abstract:** This proposed rule proposes to allow distributors' and selling agents' names to be prominently displayed on biological product containers, package labels, and labeling, while retaining current product manufacturer labeling information. The proposed rule modifies the current requirement giving precedence to the name of the manufacturer by deleting the requirement for prominence of the name of the manufacturer. The proposed rule is intended to remove an impediment to flexible manufacturing, packaging, and distribution arrangements and to harmonize with the drug regulations (21 CFR 201).**Timetable:**

Action	Date	FR Cite
NPRM	06/00/96	
NPRM Comment Period End	09/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** None**Agency Contact:** Gloria Hicks, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-630), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 594-3074

RIN: 0910-AA56

971. CHANGES TO AN APPROVED APPLICATION**Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing

Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 15 USC 1451 to 1461; 21 USC 321; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360u to 360j; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262 to 263**CFR Citation:** 21 CFR 601**Legal Deadline:** None**Abstract:** The Food and Drug Administration (FDA) is proposing to revise 21 CFR 601.12, which deals with proposed changes in the production of licensed biological products—for example, product labeling, production process, equipment, facilities, and responsible personnel. Currently, licenseholders must obtain FDA preapproval of all such changes through supplements to approved applications. In the proposed revision, FDA sets forth a process that is intended to reduce the burden on licenseholders by reducing the number of supplements submitted for changes and to result in more timely approval of changes in their products. The new process creates different mechanisms for reporting changes, based on their potential to affect adversely the safety, purity, potency, or effectiveness of the product. Proposed procedures for reporting changes in production include three categories:

No supplements to approved applications will be required. Firms would notify FDA of changes and dates of implementation in an annual report.

License holders would notify FDA not less than 30 days prior to implementing a change.

Changes would require FDA approval prior to implementation.

Timetable:

Action	Date	FR Cite
NPRM	01/29/96	61 FR 2739
NPRM Comment Period End	04/29/96	
Final Action	08/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** None**Agency Contact:** Tracey Forfa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center forBiologics Evaluation and Research (HFM-630), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 594-3074

RIN: 0910-AA57

972. DIETARY SUPPLEMENT REGULATIONS IN RESPONSE TO DSHEA**Priority:** Routine and Frequent**Legal Authority:** 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 371**CFR Citation:** 21 CFR 101**Legal Deadline:** None**Abstract:** On January 4, 1994, FDA published final rules relative to nutrition labeling, nutrient content claims and health claims for dietary supplements. The Dietary Supplement Health and Education Act (DSHEA) was enacted on October 25, 1995, modifying the provisions for labeling of dietary supplements. FDA is initiating rulemaking to modify its regulations for dietary supplements accordingly. One proposal would modify the nutrition labeling and ingredient declaration requirements. A second proposal would modify the provisions for nutrient content claims and health claims for the disclaimer to accompany statements of nutritional support. A third proposal would define the terms "high potency" and "antioxidant." These three proposals were published in the Federal Register on December 28, 1995.**Timetable:****High Potency and Antioxidant Terms; Dietary Supplements**NPRM 12/28/95 (60 FR 67184)
Comment Period End 06/10/96
Final Action 00/00/00**Nutrition Content and Health Claims; Dietary Supplements**NPRM 12/28/95 (60 FR 67176)
Comment Period End 06/10/96
Final Action 00/00/00**Nutrition Labeling and Ingredient Labeling; Dietary Supplements**NPRM 12/28/95 (60 FR 67194)
Comment Period End 06/10/96
Final Action 00/00/00**Small Entities Affected:** Businesses**Government Levels Affected:** State, Federal**Agency Contact:** F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and

HHS—FDA

Proposed Rule Stage

Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW. Washington, DC 20204
 Phone: 202 205-4561
 Fax: 202 205-4594
RIN: 0910-AA59

973. EXPORT REQUIREMENTS FOR DRUGS FOR INVESTIGATIONAL USE IN OTHER COUNTRIES

Priority: Substantive, Nonsignificant
Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 331; 21 USC 351 to 352; 21 USC 355 to 357; 21 USC 360; 21 USC 360b; 21 USC 360aa to 360dd; 21 USC 371 to 372; 21 USC 374; 21 USC 379e; 21 USC 379g; 21 USC 381 to 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 2421

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: FDA is proposing to amend its regulations on investigational new drug products to streamline requirements for exports of unapproved drugs for investigational use in other countries. The proposal would permit an unapproved new drug product to be exported without prior FDA approval if the product is to be exported for use in a clinical investigation in any country. Persons exporting such products would be required to report to FDA the country receiving the unapproved new drug product, the consignee in the foreign country, the name of the drug product, and the quantity being exported. Thus, the proposal would eliminate the need to submit a written request to FDA and to obtain FDA approval before exporting an unapproved new drug product for use in a clinical investigation in a foreign country. The proposal carries out the President's and Vice-President's "National Performance Review" for drugs and is consistent with recent Congressional initiatives.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Linda Horton, Director, International Policy Staff, Office of Policy (HF-23), Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 827-3344

RIN: 0910-AA61

974. ● HUMAN TISSUE INTENDED FOR TRANSPLANTATION AND HUMAN REPRODUCTIVE TISSUE INTENDED FOR FERTILIZATION, IMPLANTATION OR INSEMINATION

Priority: Other Significant

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

CFR Citation: 21 CFR 1270

Legal Deadline: None

Abstract: The proposed rule will propose the registration of all establishments engaged in the recovery, processing, storage, or distribution of human tissue intended for transplantation or human reproductive tissue intended for fertilization, implantation, or insemination (and extend the existing rule requirements testing, screening and recordkeeping to such tissue).

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Steven F. Falter, Director, Division of Regulations and Policy, Department of Health and Human Services, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852
 Phone: 301 594-3074
 Fax: 301 443-3874
 Email: Falter@A1.CBER.FDA.GOV

RIN: 0910-AA70

975. ● ADVERSE EXPERIENCE REPORTING FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS; INCREASED FREQUENCY REPORTS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 21 USC 216; 21 USC 262 to 264; 21 USC 300; 21 USC 321;

21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 371; 21 USC 374; 42 USC 262

CFR Citation: 21 CFR 310; 21 CFR 314; 21 CFR 600

Legal Deadline: None

Abstract: The proposed rule would revoke the requirement for increased frequency reports to FDA for postmarketing adverse experience reporting.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	

Small Entities Affected: None

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Audrey Thomas, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 594-1049
 Fax: 301 827-0901

RIN: 0910-AA72

976. ● INVESTIGATIONAL NEW DRUG APPLICATIONS; CLINICAL HOLDS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 312

Legal Deadline: None

Abstract: The proposed rule will revise existing regulations to state that FDA will issue, within five working days after imposing a clinical hold, a written explanation to the sponsor describing the reasons for imposing the clinical hold. The proposed rule would also state that a clinical study may resume 30 calendar days after FDA receives the sponsor's complete reply to all issues raised in the clinical hold, unless FDA

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Proposed Rule Stage

notifies the sponsor that it has reinstated the clinical hold.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
NPRM Comment Period End	08/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Murray Lumpkin, MD, Deputy Center Director (Review Management), Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-2), 1451 Rockville Pike Rockville, MD 20852
Phone: 301 594-5417
Fax: 301 594-6197

RIN: 0910-AA73

977. • PARENTERAL DRUG PRODUCTS CONTAINING ALUMINUM AS AN INGREDIENT OR CONTAMINANT; LABELING REQUIREMENTS; WARNING STATEMENT

Priority: Other Significant

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

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: The proposed rule would establish a maximum level of aluminum permitted in large volume parenterals used in total parenteral nutrition therapy; require that the maximum aluminum content present at the time of release be stated on the immediate container label of certain small volume parenterals and pharmacy bulk packages; require that the package insert of all parenterals include a warning statement describing the effects of aluminum toxicity in patients with impaired kidneys receiving total parenteral nutrition therapy; and require manufacturers to develop validated assay methods for determining the aluminum content.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	
NPRM Comment Period End	12/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Erica L. Keys, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA74

978. • LONG-TERM CONTRACEPTIVE DRUG PRODUCTS AND MEDICAL DEVICES; INFORMED CONSENT REQUIREMENTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379; 42 USC 216; 42 USC 241; ...

CFR Citation: 21 CFR 201; 21 CFR 801

Legal Deadline: None

Abstract: The proposed rule would require that patient labeling for long-acting contraceptive drugs and medical devices include an informed consent form that must be signed by the patient before any long-acting contraceptive is administered. The proposed rule would help ensure that patients receive adequate information to enable them to make an informed decision about whether or not to use a long-acting contraceptive.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	
NPRM Comment Period End	12/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Erica L. Keys, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA75

979. • DEBARMENT CERTIFICATION REGULATIONS FOR DRUG APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 15 USC 1451 to 1461; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379; 21 USC 381 to 382; 42 USC 216; 42 USC 241; 42 USC 262 to 263

CFR Citation: 21 CFR 314; 21 CFR 514; 21 CFR 601

Legal Deadline: None

Abstract: The proposed rule would amend the regulations to require applicants to certify that they did not and will not use in any capacity the services of a debarred person, and would require certain applicants to list certain Federal felony, Federal misdemeanor, or State felony convictions of the applicant and affiliated persons responsible for the development or submission of the application that have occurred within the preceding 5 years.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
NPRM Comment Period End	07/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is a statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Wayne Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA76

HHS—FDA

Proposed Rule Stage

980. • CERTIFICATION OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375

CFR Citation: 21 CFR 200; 21 CFR 429

Legal Deadline: None

Abstract: The proposed rule would revise part 429 to base insulin certification on compliance with an approved application and the U.S.P.; eliminate certain tests performed by manufacturers as well as packaging and labeling requirements; establish a new labeling system; and modify the requirement to submit samples.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	
NPRM Comment Period End	12/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Wayne Mitchell, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA77

981. • OVER-THE-COUNTER HUMAN DRUGS; LABELING REQUIREMENTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 330

Legal Deadline: None

Abstract: The proposed rule would provide standardized format and content requirements for OTC drug product labeling, including legibility and design features of such information as the uses for the drug, directions for use, warnings, drug interactions, precautions, active ingredients and other information that the consumer would need to know to use the product safely and effectively.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	
NPRM Comment Period End	12/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Melvin Lessing, Division of OTC Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-560), 9200 Corporate Blvd. Rockville, MD 20850
Phone: 301 827-2222

RIN: 0910-AA79

982. • NATIONAL ENVIRONMENTAL POLICY ACT; POLICIES AND PROCEDURES

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321 to 393; 42 USC 262; 42 USC 263b; 42 USC 264; 42 USC 4321; 42 USC 4332

CFR Citation: 21 CFR 25

Legal Deadline: None

Abstract: The proposed rule would amend the regulations governing compliance with the National Environmental Policy Act (NEPA) as implemented by the regulations of the Council on Environmental Quality. The proposed rule would increase the efficiency of FDA's implementation of NEPA and reduce the regulatory burden by providing for categorical exclusions

for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental impact statement nor an environmental assessment is required. The proposed rule would also amend the regulations to make the agency's NEPA procedures more concise and understandable to the public, and to reflect current FDA policy with respect to environmental considerations.

Timetable:

Action	Date	FR Cite
NPRM	04/03/96	61 FR 14922
NPRM Comment Period End	07/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Federal

Agency Contact: Nancy Sager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-4), 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 594-5413
Fax: 301 594-6197

RIN: 0910-AA80

983. • INVESTIGATIONAL NEW DRUG APPLICATIONS; CLINICAL HOLDS FOR DRUGS FOR LIFE-THREATENING ILLNESSES

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 312

Legal Deadline: None

Abstract: The proposed rule would prohibit the exclusion of women of childbearing potential from Phase 1 and early Phase 2 clinical trials of drugs used to treat life-threatening illnesses, when there is no evidence of reproductive toxicity resulting from such trials or when there is evidence of such toxicity but there are other methods available for preventing such exposure.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
NPRM Comment Period End	08/00/96	

Small Entities Affected: Businesses, Organizations

HHS—FDA

Proposed Rule Stage

Government Levels Affected:

Undetermined

Procurement: This is a procurement-related action for which there is no statutory requirement. The agency has not yet determined whether there is a paperwork burden associated with this action.

Agency Contact: Audrey Thomas, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA84

984. • ADVERSE EXPERIENCE REPORTING, RECORDKEEPING, AND RECORDS ACCESS REQUIREMENTS FOR MARKETED OTC DRUGS THAT ARE NOW THE SUBJECTS OF APPROVED NEW DRUG OR ABBREVIATED NEW DRUG APPS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379; 42 USC 216; ...

CFR Citation: 21 CFR 201; 21 CFR 211; 21 CFR 327; 21 CFR 330

Legal Deadline: None

Abstract: The proposed rule would require manufacturers, packers, and distributors of marketed nonprescription human drug products that are not the subjects of approved applications to report to FDA information they receive about adverse experiences associated with the use of their drug products; to maintain records of adverse drug experiences; and to permit access by FDA to adverse drug experience records.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	
NPRM Comment Period End	12/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Howard P. Muller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA86

985. • STERILITY REQUIREMENTS FOR INHALATION SOLUTION PRODUCTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 358; 21 USC 360; 21 USC 371; 21 USC 374 to 375

CFR Citation: 21 CFR 200

Legal Deadline: None

Abstract: The proposed rule would require that all inhalation solution products be manufactured to be sterile. Based on reports of adverse drug experiences from contaminated nonsterile inhalation solution products and recalls of these products, FDA is proposing to take this action to prevent future additional adverse health consequences.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
NPRM Comment Period End	08/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Tamar Nordernberg, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-2041
Fax: 301 827-0901

RIN: 0910-AA88

986. • INFORMED CONSENT FOR HUMAN DRUGS AND BIOLOGICS; DETERMINATION THAT INFORMED CONSENT IS NOT FEASIBLE

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 357; 21 USC 360; 21 USC 371; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262

CFR Citation: 21 CFR 50

Legal Deadline: None

Abstract: The Food and Drug Administration proposes an amendment to informed consent regulations. The proposal would replace the interim final rule regulation promulgated December 21, 1990. The proposal establishes requirements to allow agency approval for waiver of informed consent in use of investigational drugs or biologics in certain military combat circumstances. Findings required that obtaining consent is not feasible and withholding treatment would be contrary to the best interests of military personnel. Individual waivers are required for each product and circumstance, with one year maximum extendable duration. Each waiver request from the Department of Defense must justify need for waiver, reasons use is the best preventive or therapeutic treatment, and verify that such use was approved by a properly constituted institutional review board.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Brian J. Malkin, Associate Director for Patents and Hearings, Health Assessment Policy Staff (HFY-20), Department of Health and Human Services, Food and Drug Administration, Office of Health Affairs, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-1698
Fax: 301 443-0232
Email: bmalkin@fdaem.ssw.dhhs.gov

RIN: 0910-AA89

HHS—FDA

Proposed Rule Stage

987. • DIRECT-TO-CONSUMER PROMOTION REGULATIONS**Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 334; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 358; 21 USC 360e to 360i; 21 USC 360k; 21 USC 361; 21 USC 362; 21 USC 371; ...**CFR Citation:** 21 CFR 200; 21 CFR 800**Legal Deadline:** None**Abstract:** The Food and Drug Administration will issue proposed

regulations for direct-to-consumer promotion of human and animal prescription drugs, biologics, and restricted devices. The regulations will set forth the requirements for what information shall be contained in the consumer directed advertisements for these products and how the information shall be presented.

Timetable:

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected: None**Government Levels Affected:** None

Agency Contact: Nancy Ostrove, Public Health Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation Research, (HFD-40), Room 17B-04, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-3882

RIN: 0910-AA90

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Food and Drug Administration (FDA)

988. NEW ANIMAL DRUG APPROVAL PROCESS; IMPLEMENTATION OF TITLE I OF THE GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT (GADPTRA)**Priority:** Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 21 USC 360b; 21 USC 371**CFR Citation:** 21 CFR 514**Legal Deadline:** Final, Statutory, November 16, 1989.

The deadline applies to the GADPTRA sections. There is no deadline relating to the other sections.

Abstract: On December 17, 1991, the Agency published a proposed revision of the existing regulations that is consistent with the current procedural regulations for human drugs where appropriate. The New Animal Drug Application (NADA) revisions articulate general requirements in regulations containing performance standards and would complement them through detailed guidelines on, among other matters, appropriate ways of meeting requirements for submission of chemistry, pharmacology, and statistical data that would better address the intricate scientific issues involved. A separate proposed rule for reporting requirements for marketed animal drugs also was published on that date. The agency intends to repropose the NADA proposed rule to incorporate some recent changes in

procedure. The Agency also proposes to amend its regulations to implement Title I of the Generic Animal Drug and Patent Term Restoration Act, which established new standards for marketing approval of generic copies of animal drugs approved after 1962.

Timetable:**New Animal Drug Approval Process**

NPRM 12/17/91 (56 FR 65544)

NPRM 10/00/96

Reporting Requirements for Marketed**Animal Drugs**

NPRM 12/17/91 (56 FR 65581)

Final Action 06/00/96

Small Entities Affected: Businesses**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AA96.

For information concerning reporting requirements for marketed animal drugs, contact William C. Keller, Director, Division of Surveillance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, (301) 594-1722. For further information concerning generic animal drugs, contact Lonnie W. Luther, Chief, Generic Animal Drug and Quality Control Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, (301) 594-1623.

Agency Contact: Andrew J. Beaulieu, Deputy Director, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-101), 7500 Standish Place, Rockville, MD 20855

Phone: 301 594-1620

RIN: 0910-AA02**989. CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS; NOTIFICATION OF CONSIGNEES RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK FOR TRANSMITTING HIV INFECTION****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 351 to 360k; 21 USC 374; 42 USC 262 to 264**CFR Citation:** 21 CFR 606; 21 CFR 610**Legal Deadline:** None

Abstract: The agency currently requires that all blood and blood components intended for transfusion or for the manufacture of any product be tested for antibody to human immunodeficiency virus (HIV). In instances when the blood of a donor is found to contain antibodies to HIV, some blood centers have initiated a program of voluntary "look-back" to determine the suitability of previous donations and to notify consignees of blood and blood components obtained from the donor's prior donations. Consignees may withdraw or destroy such blood and blood products, and may trace and notify recipients. A well-conducted look-back program can provide an effective mechanism for quarantine of products and for identifying, testing, and counseling recipients of transfusions determined to be at increased risk of HIV infection—those who receive blood from a donor later found to be infected with HIV. The agency is publishing a final rule

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to establish a mandatory look-back program. The final rule will require blood collection facilities to develop a procedure to identify and quarantine products from prior collections and to notify consignees promptly whenever a blood donor who has previously donated blood or source plasma is found to be positive for the antibody to HIV; and to keep appropriate records when such notification has been made. In addition, the final rule will require hospital transfusion services to notify recipients of blood products at increased risk for transmitting HIV and to keep appropriate records of the notification process. The purpose of the rulemaking is to ensure the notification of consignees and blood transfusion recipients and that prompt and appropriate action is taken.

Timetable:

Action	Date	FR Cite
NPRM	06/30/93	58 FR 34962
Final Action	06/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected:

Undetermined

Additional Information: Previously reported under RIN 0905-AC90.

Agency Contact: Sharon Carayiannis, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-630), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 594-3074

RIN: 0910-AA05

990. PRESCRIPTION DRUG MARKETING ACT OF 1987; POLICY INFORMATION, GUIDANCE, AND CLARIFICATIONS

Priority: Other Significant

Legal Authority: PL 100-293
Prescription Drug Marketing Act of 1987

CFR Citation: 21 CFR 203

Legal Deadline: None

Abstract: The Prescription Drug Marketing Act of 1987 (PDMA) amended the Federal Food, Drug, and Cosmetic Act to: (1) require State licensing of wholesale distributors of prescription human drugs under Federal guidelines including minimum standards for storage, handling, and

recordkeeping; (2) ban the reimportation of prescription human drugs produced in the United States, except when reimported by the manufacturer or for emergency use; (3) ban the sale, trade, or purchase of drug samples; (4) ban trafficking in or counterfeiting of drug coupons; (5) mandate storage, handling, and recordkeeping requirements for drug samples; (6) require licensed practitioners to request drug samples in writing; (7) prohibit, with certain exceptions, the resale of prescription human drugs purchased by hospitals or health care facilities; and (8) set forth criminal and civil penalties for violations of these provisions. In the Federal Register of September 14, 1990 (55 FR 38012), FDA issued a final rule setting forth Federal guidelines for State licensing of wholesale drug distributors. The final rule would provide information, guidance, and clarification of those sections of PDMA that are not related to State licensing of wholesale distributors.

Timetable:

Action	Date	FR Cite
NPRM	03/14/94	59 FR 11842
NPRM Comment Period End	08/01/94	
Final Action	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AD44.

Agency Contact: Lee D. Korb, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA08

991. FOOD LABELING REVIEW

Priority: Routine and Frequent

Legal Authority: 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

CFR Citation: 21 CFR 100; 21 CFR 101; 21 CFR 102; 21 CFR 161

Legal Deadline: None

Abstract: The Nutrition Labeling and Education Act of 1990 (NLEA) requires that most foods bear nutrition labeling. The agency issued final rules implementing most of the provisions contained in the NLEA on January 6, 1993. Subsequently, however, the agency has identified additional areas that should be the subject of rulemaking. FDA issued a proposal on January 6, 1993, to establish requirements for the identification of certain ingredients on food labels. FDA proposed on June 15, 1993, to amend its January 6, 1993, final rules on nutrient content and health claims to remove the provisions that exempted restaurant menus from the requirements for how nutrient content claims and health claims are to be made. FDA also proposed to modify the provisions that delay the effective date of these regulations for small restaurant firms for one year. The agency proposed January 4, 1994, to establish reference daily intakes based on the 9th and 10th editions of the National Research Council's Recommended Dietary Allowances. On March 14, 1994, FDA published a proposal describing the provisions for exemptions for low-volume food products of small businesses that were established by the Nutrition Labeling and Education Act Amendments of 1993. On August 18, 1993, FDA published a proposal concerning the placement of the nutrition facts panel on food labels. Finally, on July 18, 1994, FDA published proposed revised guidelines for the voluntary declaration of nutrition labeling for raw produce and fish. A final rule concerning the placement of the nutrition facts panel was published on April 5, 1995. A final rule establishing reference daily intakes based on the 9th and 10th editions of Recommended Dietary Allowances was published on December 28, 1995.

Timetable:

Amend Standard of Identity for Grain Products (Folic Acid)

NPRM 10/14/93 (58 FR 53305)
Final Action 03/05/96 (61 FR 8781)

Health Claims and Label Statements

NPRM Folic Acid and Neural Tube Def
10/14/93 (58 FR 53254)

Final Action 03/05/96 (61 FR 8752)

Misleading Containers; Nonfunctional Slack Fill

NPRM 01/06/93 (58 FR 2957)
Final Action 12/06/93 (58 FR 64123)

HHS—FDA

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Nutrient Content Claims and Health Claims;**Restaurant Foods**

NPRM 06/15/93 (58 FR 33055)

Final Action 00/00/00

Nutrient Content, Definition of the Term,**Healthy**

NPRM 01/06/93 (58 FR 2944)

Final Action 05/10/94 (59 FR 24232)

Placement of Nutrition Facts Panel

NPRM 08/18/93 (58 FR 44091)

Final Action 04/05/95 (60 FR 17202)

Final Action Effective 05/05/95

Final Action Correction 06/12/95 (60 FR 30788)

Protein Hydrolysates; Broth in Tuna; and/or Labeling

NPRM (Declaration of Ingredients)

01/06/93 (58 FR 2950)

Final Action (Dec. of Ingredients) 00/00/00

Reference Daily Intakes

NPRM 01/04/94 (59 FR 427)

Final Action 12/28/95 (60 FR 67164)

Small Business Exemption, Nutrition**Labeling**

NPRM 03/14/94 (59 FR 11872)

Final Action 07/00/96

Voluntary Guidelines for Nutrition Labeling**Produce**

NPRM 07/18/94 (59 FR 36379)

Final Action 08/00/96

Small Entities Affected: Businesses**Government Levels Affected:** State, Federal**Additional Information:** Previously reported under RIN 0905-AD89.**Agency Contact:** F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4561
Fax: 202 205-4594**RIN:** 0910-AA19**992. DISQUALIFICATION OF CLINICAL INVESTIGATORS****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 360j(g)**CFR Citation:** 21 CFR 812**Legal Deadline:** None**Abstract:** The rule would amend the investigational device exemption (IDE) regulations to provide for a procedure for disqualification of clinical investigators in cases of fraud or other serious violations of the regulations. Persons whose disqualification is proposed would be entitled to an opportunity for hearing.**Timetable:**

Action	Date	FR Cite
NPRM	10/06/93	58 FR 52144
Final Action	06/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AD94.**Agency Contact:** Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765**RIN:** 0910-AA21**993. INVESTIGATIONAL DEVICE EXEMPTION; INTRAOCULAR LENSES****Priority:** Other**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.**Legal Authority:** 21 USC 360j(g)**CFR Citation:** 21 CFR 813; 21 CFR 812**Legal Deadline:** None**Abstract:** The rule would revoke the separate investigational device exemption regulation for intraocular lenses (IOLs). IOLs would then be subject to the same IDE regulation (21 CFR part 812) as all other devices. The IOL-IDE regulation was originally created as an interim measure.**Timetable:**

Action	Date	FR Cite
NPRM	10/06/93	58 FR 52142
Final Action	06/00/96	

Small Entities Affected: None**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AD95.**Agency Contact:** Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765**RIN:** 0910-AA22**994. SPECIFIC REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS; ADDITION OF "GERIATRIC USE" SUBSECTION IN THE LABELING****Priority:** Other Significant**Legal Authority:** 21 USC 352; 21 USC 355; 42 USC 262**CFR Citation:** 21 CFR 201**Legal Deadline:** None**Abstract:** On November 1, 1990 (55 FR 46134), the Agency proposed to amend its regulations governing the content and format of labeling for human prescription drug products to require a subsection in the labeling that would include information on the use of a drug in the elderly. This proposal reflects growing recognition by FDA and others of the special concerns associated with prescription drug use in this age group. FDA believes that providing access to this information is necessary for the safe and effective use of prescription drugs in older populations. The final rule would finalize these proposed revisions based on the comments received.**Timetable:**

Action	Date	FR Cite
NPRM	11/01/90	55 FR 46134
NPRM Comment Period End	12/31/90	
Final Action	09/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE26.**Agency Contact:** Thomas Kuchenberg, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1046
Fax: 301 827-0901**RIN:** 0910-AA25**995. TAMPER-EVIDENT PACKAGING REQUIREMENTS FOR OVER-THE-COUNTER HUMAN DRUG PRODUCTS****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 371**CFR Citation:** 21 CFR 211**Legal Deadline:** None

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Abstract: On January 18, 1994 (59 FR 2542), the Agency proposed to amend its tamper-resistant packaging regulations to require that all over-the-counter (OTC) human drug products marketed in two-piece, hard gelatin capsules be sealed. The proposal also solicited public comments on whether additional regulatory changes, such as packaging performance standards, may be necessary. FDA has required tamper-resistant packaging features for OTC drug products since 1982. The tamper-resistant packaging regulations were revised in 1989 in response to continuing tampering incidents. Despite the regulatory protection provided by the regulations, two-piece, hard gelatin capsules remain vulnerable to malicious tampering and were implicated in tampering incidents in 1991. This regulatory action is in response to the 1991 tampering incidents.

Timetable:

Action	Date	FR Cite
NPRM	01/18/94	59 FR 2542
NPRM Comment Period End	03/21/94	
Final Action	05/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE27.

Agency Contact: Tamar S. Nordenberg, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA26

996. ADVERSE EXPERIENCE EXPEDITED REPORTING REQUIREMENTS FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 371; 21 USC 374; 21 USC 216; 21 USC 262; 21 USC 263; 21 USC 263a; 21 USC 264; 21 USC 300aa-25

CFR Citation: 21 CFR 20; 21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 600

Legal Deadline: None

Abstract: The final rule would amend the adverse experience expedited reporting regulations for human drug and licensed biological products to make the requirements consistent with a new unified agency form (FDA Form 3500A) and require the use of this new reporting form. The new form was announced as part of FDA's MedWatch program. The final rule will also revise certain definitions and reporting periods and formats as recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the World Health Organization's Council for International Organizations of Medical Sciences (CIOMS). In addition, the rule will amend the regulations governing the expedited reporting of data from clinical studies.

Timetable:

Action	Date	FR Cite
NPRM	10/27/94	59 FR 54046
NPRM Comment Period End	01/25/95	
Final Action	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Additional Information: Previously reported under RIN 0905-AE29.

Agency Contact: Audrey Thomas, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA28

997. ELECTRONIC SIGNATURES; ELECTRONIC RECORDS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 301 et seq; 21 USC 201 et seq

CFR Citation: 21 CFR 11

Legal Deadline: None

Abstract: FDA is preparing regulations to set forth criteria for agency acceptance of electronic records and electronic signatures in lieu of paper records and handwritten signatures. The new rules would apply to any records requirements in chapter I of title 21 (all program areas and industries), unless specifically exempted by future regulations. For documents required to be maintained, but not submitted to FDA, persons could use electronic records and signatures upon the effective date of a final rule. For documents submitted to FDA, persons could use electronic records and signatures if FDA has stated, in a public docket to be maintained for that purpose, that the intended receiving organization is prepared to accept the submission in electronic form. (The proposed rule does not require use of electronic records and signatures, but permits their use under certain circumstances.) This action was taken as a follow-up to the Agency's 7/21/92 advance notice of proposed rulemaking. The intended effect is to permit and foster use of new technologies in a manner that is consistent with FDA's overall mission and that preserves the integrity of the Agency's enforcement activities.

Timetable:

Action	Date	FR Cite
ANPRM	07/21/92	57 FR 32185
ANPRM Comment Period End	10/19/92	
NPRM	08/31/94	59 FR 45160
NPRM Comment Period End	11/29/94	
Final Action	05/00/96	

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal

Additional Information: Previously reported under RIN 0905-AE31.

Agency Contact: Paul J. Motise, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-323), 7500 Standish Place, Rockville, MD 20855
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Email: Motise@FDA.CD.BITNET

RIN: 0910-AA29

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998. FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

Priority: Other Significant

Legal Authority: 42 USC 262; 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 360; 21 USC 371; 21 USC 372; 21 USC 373; 21 USC 374; 21 USC 375; ...

CFR Citation: 21 CFR 54; 21 CFR 312.53; 21 CFR 312.57; 21 CFR 312.64; 21 CFR 314.50; 21 CFR 314.60; 21 CFR 314.94; 21 CFR 314.200; 21 CFR 314.300; 21 CFR 320.36; 21 CFR 330.10; 21 CFR 601.2; 21 CFR 807.31; 21 CFR 807.87; 21 CFR 807.100; ...

Legal Deadline: None

Abstract: This final regulation would address the problem of certain financial arrangements and interests of clinical investigators that have the potential to bias the outcome of clinical trials. The problem is significant because clinical research data provide the basis for FDA's evaluation of drugs, biologics and devices for marketing. The regulation would require the sponsor of a product that is the subject of a marketing application to submit either a statement certifying that the clinical investigator is not a party to any problematic financial interests and arrangements or a statement disclosing problematic interests and arrangements to which the investigator is a party. This information would enable FDA to subject the relevant clinical research data to an appropriate level of scrutiny to test its reliability. Alternatives to the regulation would be to prohibit investigators from holding certain financial interests altogether or to require divestiture by the investigator of a prohibited interest. The estimated costs to industry associated with preparation, submission, and retention of the information required by this final rule are well below the \$100 million threshold that defines a significant regulatory action. The final rule is not expected to impose a significant resource burden on FDA because the submission of statements is limited to clinical data submitted in support of marketing applications, ruling out data from the large number of studies that do not lead to applications, and FDA estimates that sponsors will be able to certify for the majority of their clinical investigators, so that most submitted data will not require intensified scrutiny. The final rule will strengthen the FDA review process.

Timetable:

Action	Date	FR Cite
NPRM	09/22/94	59 FR 47807
NPRM Comment Period End	12/21/94	
Final Action	12/00/96	

Small Entities Affected: None

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Additional Information: Previously reported under RIN 0905-AE32.

Agency Contact: Mary Gross, Department of Health and Human Services, Food and Drug Administration, Office of External Affairs (HF-24) 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-3440
Fax: 301 594-0113

RIN: 0910-AA30

999. EFFECTIVE DATE OF REQUIREMENT FOR SUBMISSION OF PREMARKET APPROVAL APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360e

CFR Citation: 21 CFR 868; 21 CFR 870; 21 CFR 872; 21 CFR 878; 21 CFR 882; 21 CFR 888

Legal Deadline: Final, Statutory, December 1, 1995.

Abstract: Class III devices which were on the market before 1976 are exempt from premarket approval until FDA issues a rule requiring the submission of premarket approval applications. The Safe Medical Devices Act of 1990 directed FDA to review the classification of pre-1976 class III devices for which premarket approval is not yet required, and either reclassify them into class I or class II or require premarket approval for those devices remaining in class III. There are approximately 125 pre-1976 class III devices not yet addressed. The devices covered by this final rule are devices which FDA believes may no longer be commercially viable.

Timetable:

Action	Date	FR Cite
Notice	05/06/94	59 FR 23731
NPRM	09/07/95	60 FR 46718

Action	Date	FR Cite
NPRM Comment Period End	01/05/96	
Final Action	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE34.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20857
Phone: 301 594-4765

RIN: 0910-AA31

1000. PRESCRIPTION DRUG PRODUCT LABELING; MEDICATION GUIDE

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 352; 21 USC 371; 21 USC 355; 42 USC 262

CFR Citation: 21 CFR 201; 21 CFR 208; 21 CFR 314; 21 CFR 600

Legal Deadline: None

Abstract: Inadequate access to appropriate patient information is a major cause of inappropriate use of prescription medications, resulting in serious personal injury and related costs to the health care system. The Food and Drug Administration (FDA) believes that it is essential that patients receive information accompanying dispensed prescription drugs. This information needs to be widely distributed and be of sufficient quality to promote the proper use of prescription drugs. Therefore, FDA is proposing performance standards that would define acceptable levels of information distribution and quality, and to assess supplied information according to these standards. In accordance with the Administration's philosophy of fairly assessing a voluntary approach before imposing requirements through regulations, FDA is proposing that this information be disseminated through voluntary private-sector initiatives. Preliminary evidence suggests recent increases in the distribution of privately produced patient medication information with dispensed prescriptions; however, estimated distribution rates indicate that significant numbers of patients still

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do not receive information with their medications. FDA analyses also indicate that there is a high variability in the quality of this information. FDA believes that, with greater encouragement and clear objectives, the private sector will substantially improve the quality and distribution of patient information. Therefore, in concert with Healthy People 2000, FDA is proposing that private-sector initiatives meet the goal of distributing useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent of individuals receiving new prescriptions by the year 2006. FDA is proposing two alternative approaches to help ensure that these goals (performance standards) are achieved. FDA would periodically evaluate and report on achievement of these goals. If the goals are not met in the specified timeframes, FDA would either (a) implement a mandatory comprehensive Medication Guide program, or (b) seek public comment on whether the comprehensive program should be implemented or whether, and what, other steps should be taken to meet patient information goals.

Regardless of the approach chosen, a mandatory Medication Guide program would initially be limited to instances where a product poses a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. FDA believes that substantial health care cost savings can be realized by ensuring that consumers obtain the inherent benefits of proper use of prescription drugs, and by reducing the potential for harm caused by inappropriate drug use by the patient.

Timetable:

Action	Date	FR Cite
NPRM	08/24/95	60 FR 44182
Final Action	06/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** State, Federal**Additional Information:** Previously reported under RIN 0905-AE43.

Agency Contact: Louis A. Morris, Chief, Marketing Practices & Communication Branch, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-240), 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 594-6828

RIN: 0910-AA37

1001. IRON CONTAINING DRUGS AND SUPPLEMENTS**Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 342; 21 USC 343; 21 USC 351; 21 USC 352**CFR Citation:** 21 CFR 101; 21 CFR 111; 21 CFR 310**Legal Deadline:** None

Abstract: On October 6, 1994, FDA published a proposal responding to three citizen petitions that were submitted in response to an increase in deaths and poisonings in small children due to accidental ingestion of iron-containing drugs and dietary supplements. The petitions requested that FDA require label warning statements for these products and special packaging to ensure the safe use of these products. Because of recent changes in the laws regulating dietary supplements brought about by the Dietary Supplement Health and Education Act (Pub. L. 103-417), FDA published a supplemental proposal on February 16, 1995, that set forth its revised legal authority a supplemental proposal that sets forth its revised legal authority.

Timetable:

Action	Date	FR Cite
NPRM	10/06/94	59 FR 51030
NPRM Correction	11/14/94	59 FR 56573
NPRM Comment Period End	12/20/94	
Supplemental NPRM	02/16/95	60 FR 8989
Supplemental NPRM Comment Period End	04/17/95	
Final Action	08/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE59.

Agency Contact: Linda Kahl, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-206), 200 C Street SW., Washington, DC 20204

Phone: 202 418-3101

RIN: 0910-AA42

1002. REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS TO PROTECT CHILDREN AND ADOLESCENTS**Priority:** Economically Significant**Legal Authority:** 21 USC 351; 21 USC 360; 21 USC 360j; 21 USC 371; 21 USC 374**CFR Citation:** 21 CFR 801; 21 CFR 803; 21 CFR 804; 21 CFR 897**Legal Deadline:** None

Abstract: The Food and Drug Administration is proposing new regulations governing the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents, in order to address the serious public health problems caused by the use of and addiction to these products. The proposed rule would reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and would significantly decrease the amount of positive imagery that makes these products so appealing to them. The proposed rule would not restrict the use of tobacco products by adults.

The objective of the proposed rule is to meet the goal of the report "Healthy People 2000" by reducing roughly by half children's and adolescents' use of tobacco products. If this objective is not met within 7 years of the date of publication of the final rule, the agency would take additional measures to help achieve the reduction in the use of tobacco products by young people. In the proposed rule, the agency is requesting comment regarding the type of additional measures that would be most effective.

Timetable:

Action	Date	FR Cite
NPRM	08/11/95	60 FR 41314
NPRM Comment Period Extended to	10/16/95	60 FR 53560
01/02/96		
NPRM Comment Period End	11/09/95	
NPRM Comment Period Reopened for Specific Documents to	03/20/96	61 FR 11349
04/19/96		
Final Action	00/00/96	

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Jurisdictional Analysis

Notice 08/11/95 (60 FR 41453)
 Notice Com. Per. Ext. to 01/02/96
 10/16/95 (60 FR 53620)
 Reopened for Spec. Docs. to 4/19/96
 03/20/96 (61 FR 11419)

Small Entities Affected: Businesses**Government Levels Affected:** State

Agency Contact: Philip L. Chao, Policy Analyst, Office of Policy (HF-23), Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 827-3380

RIN: 0910-AA48**1003. REVOCATION OF CERTAIN REGULATIONS****Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 21 USC 321 to 394; 21 USC 41 to 50; 21 USC 141 to 149; 21 USC 467F; 21 USC 679; 21 USC 821; 21 USC 1034; 42 USC 202; 42 USC 262; 42 USC 263B; 42 USC 264; 15 USC 1451 to 1461; 5 USC 551 to 558; 5 USC 701 to 721; 28 USC 2112; ...

CFR Citation: 21 CFR 100 to 101; 21 CFR 103 to 105; 21 CFR 109; 21 CFR 137; 21 CFR 161; 21 CFR 163; 21 CFR 182; 21 CFR 186; 21 CFR 197; 21 CFR 505; 21 CFR 507 to 508; 21 CFR 601; 21 CFR 620; 21 CFR 630; 21 CFR 640 to 660; ...

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to revoke certain regulations that either do not achieve public health goals or do not need to be codified as regulations to do so. These regulations include regulations that are actually statements of policy or guidance, that are duplicative, that are obsolete, or that have been made inaccurate by changes in legislation and technology.

FDA is taking this action in response to President Clinton's directive of March 4, 1995, to all Federal agencies to conduct a page-by-page review of their regulations and to eliminate or revise those that are outdated or otherwise in need of reform. As a result of its regulations review, FDA is proposing to eliminate 36 percent of its regulations that it has determined are

obsolete or no longer necessary to achieve public health goals (735 pages of which will first require Congressional action). In addition, FDA plans to revise or modify an additional 45 percent of its remaining regulations to ease the burden on regulated industry and the consumer without sacrificing public health protection. For those regulations requiring Congressional permission to eliminate or reform, the Administration is seeking legislation. This proposal contains deletions that can be accomplished administratively. Examples include regulations that refer to substances no longer used in product formulations or to products that are no longer marketed; and regulations that codify product standards that can be more flexibly handled and updated within the context of the review process. FDA is providing a 90-day period for public comment on these proposed deletions.

Timetable:

Action	Date	FR Cite
NPRM	10/13/95	60 FR 53480
NPRM Comment Period End	01/11/96	
Final Action	06/00/96	
Revocation of Certain Regulations; General		
	NPRM 01/25/96 (61 FR 2192)	
	Final Rule 00/00/00	

Small Entities Affected: Businesses**Government Levels Affected:** Federal

Agency Contact: Lisa M. Helmanis, Office of Policy (HF-26), Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857
 Phone: 301 443-3480
 Fax: 301 443-2946

RIN: 0910-AA54**1004. PROTECTION OF HUMAN SUBJECTS; INFORMED CONSENT****Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 352; 21 USC 353; 21 USC 355 to 357; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 381

CFR Citation: 21 CFR 50; 21 CFR 56; 21 CFR 312; 21 CFR 314; 21 CFR 601; 21 CFR 812; 21 CFR 814

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its current informed consent regulations to permit harmonization of FDA and National Institutes of Health (NIH) policies on emergency research, and to reduce confusion as to when such research can proceed without obtaining informed consent. The regulation provides a narrow exception to the requirement for obtaining and documenting informed consent from each human subject prior to initiation of an experimental treatment. The exception would apply to a limited class of research activities involving human subjects who, because of their life-threatening medical condition and the unavailability of legally authorized persons to represent them, are in need of emergency medical intervention and cannot provide legally effective informed consent.

The proposed rule would permit an Institutional Review Board (IRB) to approve an emergency research protocol if the IRB finds and documents that (a) the human subjects will be in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine what particular treatment is most beneficial; (b) obtaining informed consent is not feasible; (c) the opportunity for the subjects to participate in the research is in the interest of the subjects because treatment is required, and the risk is "reasonable" given what is known about the risks and benefits of experimental treatment, the current therapy, and the medical condition; (d) the research could not practically be carried out without the waiver; (e) additional protection of the rights and welfare of the subjects will be provided; and, (f) the IRB has reviewed and approved an informed consent document for use with subjects for whom consent is possible.

The proposed rule provided that, when possible and at the earliest possible opportunity, each subject will be informed about the details of the study and permitted to discontinue participation at any time without penalty. The rule also incorporates additional patient protections,

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including: FDA review of the protocol; consultation with representatives of the communities from which the subjects will be drawn; public disclosure prior to the study sufficient to describe the study and its risks and benefits; the establishment of an independent data and safety monitoring board; and public disclosure following completion of the study sufficient to apprise the community and researchers of the study and its results.

FDA, in coordination with NIH, developed this proposal because of concerns expressed by the research community and patient advocacy groups that emergency research is at a virtual halt pending a revision of both FDA's informed consent regulations and a waiver of HHS regulations for the protection of research subjects. HHS intends to bring both policies into harmony on this matter at the time this rule is made final.

Timetable:

Action	Date	FR Cite
NPRM	09/21/95	60 FR 49086
NPRM Comment Period End	11/06/95	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Glen D. Drew, Department of Health and Human Services, Food and Drug Administration, Office of Health Affairs (HFY-20) 5600 Fishers Lane Rockville, MD 20857

Phone: 301 443-1382

RIN: 0910-AA60

1005. EXPORT REQUIREMENTS FOR MEDICAL DEVICES

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 393; 42 USC 216; 42 USC 241; 42 USC 2421; ...

CFR Citation: 21 CFR 812.18

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations for investigational devices to describe streamlined requirements for exports of unapproved medical devices. Under the proposed rule, an approved investigational device exemption (IDE) would constitute an agency determination that the export of the unapproved device is not contrary to the public health or safety. Countries could notify FDA that they do not object to the importation of unapproved devices with an approved IDE into their countries. Thus, for devices with an FDA-approved IDE, the proposal would eliminate the need for FDA to make independent determinations either that exportation is not contrary to the public health or safety or that an importing country does not object to the importation of a specific device. The proposed rule is intended to codify and to simplify export requirements for certain unapproved devices pursuant to the President's and Vice-President's "National Performance Review," as reflected in the April 1995 report titled, "Reinventing Drug & Medical Device Regulations." It is also consistent with recent Congressional initiatives.

Timetable:

Action	Date	FR Cite
NPRM	11/27/95	60 FR 58308
Final Action	08/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Linda Horton, Director, International Policy Staff, Office of Policy (HF-23), Department of Health and Human Services, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-3344

RIN: 0910-AA62

1006. • WELL-CHARACTERIZED BIOTECHNOLOGY PRODUCTS; ELIMINATION OF ESTABLISHMENT LICENSE APPLICATION

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 15 USC 1451 to 1461; 21 USC 321; 21 USC 351 to 353; 21

USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360j to 360u; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262 to 263

CFR Citation: 21 CFR 601.2

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is amending the biologics regulations to eliminate the establishment license application (ELA) requirement for well-characterized biotechnology products licensed under the Public Health Service Act (PHS Act). The final rule will exempt well-characterized biotechnology products licensed under the PHS Act from certain biologics' regulations and harmonize the requirements applicable to these products with those applicable to similar drug products which are approved under the Federal Food, Drug, and Cosmetic Act.

Timetable:

Action	Date	FR Cite
NPRM	01/29/96	61 FR 2733
Final Action	05/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Sharon Carayiannis, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-630), 1401 Rockville Pike Suite 200N, Rockville, MD 20852-1448

Phone: 301 594-3074

Fax: 301 443-3874

RIN: 0910-AA71

1007. • NEW DRUG APPLICATIONS; DRUG MASTER FILE

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 371; 21 USC 374; 21 USC 379

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: The final rule would eliminate Type I Drug Master Files,

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which contain information about manufacturing sites, facilities, operating procedures, and personnel, because these files contain outdated information, duplicate information contained in marketing applications, and are not used by application review divisions or field inspectors.

Timetable:

Action	Date	FR Cite
NPRM	07/03/95	60 FR 34486
NPRM Comment Period End	10/02/95	
Final Action	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is no paperwork burden associated with this action.

Agency Contact: Thomas Kuchenburg, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
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RIN: 0910-AA78

1008. • CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICAL; POSITRON EMISSION TOMOGRAPHY

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 360; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 211

Legal Deadline: None

Abstract: The final rule would permit manufacturers of positron emission tomography radiopharmaceuticals to apply to the agency for approval of an exception or alternative to the requirements of the current good manufacturing practice regulations.

Timetable:

Action	Date	FR Cite
NPRM	02/27/95	60 FR 10517
NPRM Comment Period End	03/29/95	
Final Action	07/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Thomas Kuchenberg, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA81

1009. • INVESTIGATIONAL NEW DRUG APPLICATIONS AND NEW DRUG APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 371; 21 USC 374; 21 USC 379; 42 USC 262

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

Abstract: The final rule would define in the NDA format and content requirements the need to present effectiveness and safety data for important demographic subgroups, specifically gender, age, and racial subgroups, and would require IND sponsors to characterize in their annual reports the number of subjects in a clinical study according to age group, gender, and race.

Timetable:

Action	Date	FR Cite
NPRM	09/08/95	60 FR 46794
NPRM Comment Period End	12/07/95	
Final Action	08/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Audrey Thomas, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA82

1010. • NEW DRUGS FOR HUMAN USE; CLARIFICATION OF REQUIREMENTS FOR APPLICATION SUPPLEMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 357; 21 USC 371; 21 USC 374; 21 USC 379

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: The final rule would clarify the scope of certain reporting obligations imposed on holders of approved applications permitting an applicant to make certain changes in an approved application without submitting a supplemental application if the changes are made to comply with an official compendium.

Timetable:

Action	Date	FR Cite
NPRM	06/04/86	51 FR 20310
Final Action	07/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Erica L. Keys, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
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RIN: 0910-AA87

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Long-Term Actions

Food and Drug Administration (FDA)

1011. POLICIES CONCERNING USES OF SULFITING AGENTS**Priority:** Other Significant**Legal Authority:** 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371**CFR Citation:** 21 CFR 182.3616; 21 CFR 182.3637; 21 CFR 182.3739; 21 CFR 182.3766; 21 CFR 182.3798; 21 CFR 182.3862; 21 CFR 100.100; 21 CFR 130.9**Legal Deadline:** None

Abstract: Acceptable evidence and information exist to show that a subgroup of asthmatics is at moderate to severe risk for a severe reaction upon exposure to sulfites. The agency's primary tool for handling a situation where population subgroups may be at increased risk from a food ingredient that is safe for most people is to use labeling to inform those persons who need or want to avoid the ingredient. The agency issued a final rule, effective January 9, 1987, that requires that when a sulfiting agent is present in a finished food at 10 parts per million or greater, the sulfiting agent must be declared on the label. In addition, FDA issued a final rule, effective August 8, 1986, prohibiting the use of sulfiting agents on raw fruits and vegetables intended to be served or sold raw to consumers (e.g., in salad bars). On December 10, 1987, FDA announced its tentative conclusion that there is no longer a basis to find that the use of sulfiting agents on "fresh" potatoes served or sold unpackaged to consumers is GRAS. On December 19, 1988, FDA proposed to affirm, with specific limitations, that certain other uses of sulfiting agents are GRAS and to establish labeling requirements for sulfiting agents in standardized foods. On March 15, 1990 (55 FR 9826), FDA issued a final rule prohibiting the use of sulfiting agents on "fresh" potatoes (55 FR 9826) and requested data and information concerning the use of sulfiting agents on frozen potatoes (55 FR 9834).

On August 3, 1990, the United States District Court for the Middle District of Pennsylvania declared the final rule concerning "fresh" potatoes to be null and void on procedural grounds. The Government appealed the district court's decision. On May 22, 1991, the U.S. Court of Appeals for the Third Circuit en banc split equally. Therefore, the decision of the district court

invalidating on procedural grounds FDA's final rule revoking the GRAS status of the use of sulfiting agents on fresh potatoes was left in place. On December 22, 1994 (59 FR 65938), FDA withdrew the invalidated rule.

FDA's repropoed rule will address the regulatory status of sulfiting agents on both minimally processed ("fresh") and frozen potatoes. FDA also plans to issue a tentative final rule regarding the use of sulfiting agents in shrimp.

Timetable:**Food Labeling; Declaration of Sulfiting Agents**

NPRM 04/03/85 (50 FR 13306)
Final Action 07/09/86 (51 FR 25012)
Final Action Effective 01/09/87

GRAS Status of the Use of Sulfiting Agents on Fresh Potatoes

NPRM-To be Merged w/Frozen Potatoes
12/10/87 (52 FR 46968)
Final Action 03/15/90 (55 FR 9826)

GRAS Status of Certain Other Food Uses of Sulfiting Agents, Etc.

NPRM 12/19/88 (53 FR 51065)
Final Action 00/00/00

Revoking Use of Sulfiting Agents on Fruits & Vegetables, Etc.

NPRM 08/14/85 (50 FR 32836)
Final Action 07/09/86 (51 FR 25021)
Final Action Effective 08/09/86

Use of Sulfiting Agents on Minimally Processed & Frozen Potatoes

NPRM 00/00/00
Use of Sulfiting Agents on Shrimp
NPRM 12/19/88 (53 FR 51065)
Tentative Final Rule 00/00/00

Small Entities Affected: Undetermined**Government Levels Affected:** Undetermined**Additional Information:** Previously reported under RIN 0905-AB52.

Agency Contact: JoAnn Ziyad, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-207), 200 C Street SW., Washington, DC 20204
Phone: 202 418-3116

RIN: 0910-AA03**1012. LEAD IN FOODS****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 336; 21 USC 342(a); 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 371**CFR Citation:** 21 CFR 109; 21 CFR 182; 21 CFR 189**Legal Deadline:** None**Abstract:** In light of the public health concerns raised by continuing findings

concerning the effects of low levels of exposure to lead, particularly exposure by pregnant women, infants, and children, the agency is undertaking a comprehensive effort to further reduce lead levels in food where controllable or avoidable sources of lead addition to food can be identified. The goal of FDA is to reduce consumers' exposure to lead in the diet to the lowest level that can be practicably obtained.

Timetable:

Action	Date	FR Cite
Final Action	02/08/96	
Final Action Effective	02/08/96	
Lead From Ceramic Pitchers		
NPRM	06/01/89 (54 FR 23485)	
NPRM Comment Period End	07/31/89	
Withdrawal of NPRM	00/00/00	
Prohibit Use of Lead-Soldered Food Cans		
NPRM	06/21/93 (58 FR 33860)	
Final Action	06/27/95 (60 FR 33106)	
Prohibit Use of Tin-Coated Lead Foil Capsules on Wine Bottles		
NPRM	11/25/92 (57 FR 55485)	
Final Rule	02/08/96 (61 FR 4816)	

Small Entities Affected: None**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AC91.

Agency Contact: Michael E. Kashtock, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-306), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4681

RIN: 0910-AA06**1013. FEES FOR CERTIFICATION SERVICES; INSULIN AND COLOR ADDITIVE CERTIFICATION PROGRAMS****Priority:** Routine and Frequent

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 356; 21 USC 371; 21 USC 379e(e)**CFR Citation:** 21 CFR 80; 21 CFR 429**Legal Deadline:** None**Abstract:** Insulin Certification Program:

In the Federal Register of October 4, 1991 (56 FR 50248), FDA issued an interim rule effective on November 4,

HHS—FDA

Long-Term Actions

1991, with opportunity for public comment, revising the fee schedule for insulin certification services. In the Federal Register of November 9, 1995 (60 FR 56515), FDA issued an interim final rule, which was effective December 11, 1995. This interim final rule decreased the fees charged for insulin certification services due to lower program and administrative costs. The public had the opportunity to submit written comments to FDA by February 7, 1996.

Color Certification Program:

In the Federal Register of November 29, 1994, FDA issued an interim rule effective December 29, 1994, which amended the color additive regulations by increasing the fees for certification services. In the Federal Register of February 1, 1996 (61 FR 3571), FDA issued a final rule, effective March 4, 1996, which incorporated comments FDA received from the International Association of Color Manufacturers (IACM) on an interim rule FDA published in the Federal Register of November 29, 1994 (59 FR 60808). FDA received an objection from IACM to an annual escalator provision which would have allowed FDA to increase the fees for color certification services by a rate proportional with Federal salary increases. After considering the objection, FDA decided not to implement this provision.

Timetable:**Color Additives**

Interim Final Rule 11/29/94 (59 FR 60898)
Final Action 02/01/96 (61 FR 3571)

Insulin

Interim Final Rule 10/04/91 (56 FR 50248)
Interim Final Rule 11/09/95 (60 FR 56515)
Next Action Undetermined

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD34 and RIN 0910-AA27.

Agency Contact: David R. Petak, Director, Division of Accounting, Department of Health and Human Services, Food and Drug Administration, Office of Management (HFA-120), 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-1766
Fax: 301 443-6242

RIN: 0910-AA07

1014. BOTTLED WATER

Priority: Routine and Frequent

Legal Authority: 21 USC 341; 21 USC 343(g); 21 USC 343(h); 21 USC 349; 21 USC 371(a)

CFR Citation: 21 CFR 103; 21 CFR 165

Legal Deadline: Other, Statutory. Other deadline is for publication of NPRM or Notice within 180 days of EPA final action.

Abstract: In fulfillment of its mandate under the Safe Drinking Water Act, EPA is currently in the midst of reviewing and establishing standards for contaminants in public drinking water such as pathogenic bacteria, pesticides, and organic chemicals. When EPA establishes such standards for public drinking water, FDA is required to take appropriate action to amend its regulations for bottled drinking water or to state its reasons for not doing so. FDA also establishes identity standards for a food when it has determined that the standard will promote honesty and fair dealing in the interest of consumers.

Timetable:**Beverages; Bottled Water**

NPRM 01/05/93 (58 FR 393)
Final Action 11/13/95 (60 FR 57132)

Microbiological Quality Standard

NPRM 10/06/93 (58 FR 25042)
Final Action 00/00/00

Quality Standard for Lead and Copper

NPRM 01/05/93 (58 FR 389)
Final Action 05/25/94 (59 FR 26933)

Quality Standards for 24 Contaminants

NPRM 08/04/93 (58 FR 41612)
Final Action 03/26/96 (61 FR 13258)

Quality Standards for 35 Contaminants

NPRM 01/05/93 (58 FR 382)
Final Action 12/01/94 (59 FR 61529)

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD65.

Agency Contact: Michael E. Kashtock, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-306), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4681

RIN: 0910-AA11

1015. REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION UNDER SECTION 314 OF THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

Priority: Other Significant

Legal Authority: PL 99-660, sec 314

CFR Citation: None

Legal Deadline: Final, Statutory, June 22, 1989.

Abstract: Section 314 of the National Childhood Vaccine Injury Act of 1986 mandated that the warnings, use instructions, and precautionary information of specified childhood vaccines be reviewed and that their adequacy in warning health care professionals of the nature and extent of dangers posed by such vaccines be determined. This precautionary information is contained in the package insert of each vaccine licensed by the agency. FDA held a public meeting to receive public comment on the adequacy of these package inserts.

Timetable:

Action	Date	FR Cite
Notice of Public Meeting; Public Comment on Package Inserts	07/31/92	57 FR 33915
NPRM	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: Previously reported under RIN 0905-AD72.

A public meeting was held on 9/18/92 on section 314 Labeling Review. Presentations were made by FDA, CDC, manufacturers, parents groups, and the public on the adequacy of the current labeling.

Agency Contact: Tracey Forfa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-630), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 594-3074

RIN: 0910-AA14

1016. DIETARY SUPPLEMENT LABEL REVIEW

Priority: Routine and Frequent

Legal Authority: 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21

HHS—FDA

Long-Term Actions

USC 342; 21 USC 343; 21 USC 348;
21 USC 371

CFR Citation: 21 CFR 101

Legal Deadline: NPRM, Statutory, June 15, 1993. Final, Statutory, December 31, 1993.

If final regulations on labeling of Dietary Supplements are not published by 12/31/93, the proposed regulations shall be considered the final regulations.

Abstract: With the publication of various final rules on January 6, 1993, the Agency completed action on its food labeling initiative under the Nutrition Labeling and Education Act of 1990. Rulemaking on nutrition labeling of dietary supplements was delayed due to requirements of the Dietary Supplement Act of 1992 (DSA), which amended the law to provide that the Agency would issue proposed regulations for dietary supplements by June 15, 1993, and final regulations by December 31, 1993. Three proposed regulations were developed and published on June 18, 1993: Health Claims for Dietary Supplements, Nutrient Content Claims for Dietary Supplements, and Mandatory Nutrition Labeling for Dietary Supplements. On October 14, 1993, FDA published a proposal to not authorize health claims on the labels of dietary supplements of five nutrient/disease relationships: (1) Dietary fiber and cancer, (2) Dietary fiber and CVD, (3) Antioxidants and cancer, (4) Omega-3 fatty acids and CHD, and (5) Zinc and immune function in the elderly. In addition, FDA also published a proposed rule to authorize the use of health claims about the relationship of folates and neural tube defects. On January 4, 1994, FDA published notices stating that the proposed health claim regulations be final by operation of law. However, the notices also stated that FDA considers the October 14, 1993, rulemakings to be ongoing. The Agency intends to continue rulemaking with respect to folates and to issue a final rule as quickly as possible. FDA is also considering new scientific information that may support health claims for some of the nutrient-disease relationships given above. If this information is sufficient to support claims, the Agency will repropose to allow those claims.

Timetable:

Health Claims; Diet. Fiber/Cancer, CHD; Antioxidant/CVD; Omega-3

NPRM 10/14/93 (58 FR 53296)
Final Action 00/00/00

Health Claims; Dietary Supplements

NPRM 06/18/93 (58 FR 33700)
Final Action 01/04/94 (59 FR 395)

Health Claims; Folate and Neural Tube Defects

Final Action 01/04/94 (59 FR 433)
Final Action Effective 07/01/95

Nutrient Content Claims; Dietary Supplements

NPRM 06/18/93 (58 FR 33731)
Final Action 01/04/94 (59 FR 378)

Nutrition Labeling; Dietary Supplements

NPRM 06/18/93 (58 FR 33715)
Final Action 01/04/94 (59 FR 354)

Regulation of Diet. Supp.

ANPRM 06/18/93 (58 FR 33690)
Withdrawal of ANPRM 12/06/94 (59 FR 62644)

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AD96.

Agency Contact: F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4561

RIN: 0910-AA23

1017. AMALGAM INGREDIENT LABELING

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 352

CFR Citation: 21 CFR 801

Legal Deadline: None

Abstract: Certain dental amalgams may contain ingredients which may cause some persons severe adverse reactions. Therefore, FDA would propose that labeling for dental amalgams must include the ingredients so that health professionals may choose the appropriate amalgam for the patient.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE39.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850

Phone: 301 594-4765

RIN: 0910-AA33

1018. CLASSIFICATION OF COMPUTER SOFTWARE PROGRAMS THAT ARE MEDICAL DEVICES

Priority: Other Significant

Legal Authority: 21 USC 321(h); 21 USC 351; 21 USC 352; 21 USC 360(c)

CFR Citation: None

Legal Deadline: None

Abstract: FDA is announcing its intention to classify stand-alone computer software products that fit the definition of a medical device under the Federal Food, Drug, and Cosmetic Act. The Agency anticipates classifying these devices by using a risk-based approach as required under the Medical Device Amendments to the act. Under this approach low risk medical software devices would be subject only to the adulteration and misbranding provisions of the act. Moderate risk devices would additionally be subject to the registration, listing, and good manufacturing practice requirements for adverse events and complaints. High risk devices would be the only products to require premarket submissions or premarket approval. FDA is also seeking comment on potential criteria related to the intended uses of medical software devices that might be used in determining the level of risk.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE58.

Agency Contact: Chuck Furfine, Regulatory Review Scientist/Software Expert, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA41

HHS—FDA

Long-Term Actions

1019. DEVELOPMENT OF HAZARD ANALYSIS CRITICAL CONTROL POINTS FOR THE FOOD INDUSTRY; REQUEST FOR COMMENTS

Priority: Other Significant

Legal Authority: 21 USC 321 et seq; 21 USC 342(a)(4); 21 USC 371(a); 42 USC 264

CFR Citation: None

Legal Deadline: None

Abstract: FDA announced on April 4, 1994, its plans to consider developing regulations that would establish requirements for a new comprehensive food safety assurance program for both domestically produced and imported foods that would be based on the principles of Hazard Analysis Critical Control Points (HACCP). The new food safety program would respond to new challenges, such as new food processing and packaging technologies, new food distribution and consumption patterns, exposure to industrial chemicals and chemical waste, the increasing importation of foods, new microbial pathogens, and resource constraints. The most serious of these challenges is presented by food pathogens. The number of recognized food-borne pathogens has broadened considerably, as has awareness of long-term complications from certain food-borne illnesses--such as arthritis, heart disease, and kidney and neurological damage. To meet such challenges, FDA intends to shift the focus of its food safety assurance program away from periodic visual inspection and end-product testing and toward prevention of food safety risks and problems, utilizing the HACCP state-of-the-art preventive approach.

Timetable:

Action	Date	FR Cite
ANPRM	08/04/94	59 FR 39888
ANPRM Comment Period End	12/02/94	
NPRM	00/00/00	
NPRM Comment Period End	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AE60.

Agency Contact: John E. Kvenberg, Strategic Manager, Department of Health and Human Services, Food and Drug Administration, Center for Food

Safety and Applied Nutrition (HFS-10), 200 C Street SW., Washington, DC 20204

Phone: 202 205-4010

RIN: 0910-AA43

1020. HABIT FORMING DRUGS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 329

Legal Deadline: None

Abstract: The proposed rule would revise and clarify the regulations under part 329 to be consistent with the Drug Enforcement Administration regulations and the Controlled Substances Act.

Timetable: Next Action Undetermined

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA50

1021. DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 241; 42 USC 257; 42 USC 290; 42 USC 300

CFR Citation: 21 CFR 291

Legal Deadline: None

Abstract: The proposed rule would revise the regulations under part 291 to reduce burden, to streamline requirements, to consolidate various sections.

Timetable: Next Action Undetermined

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA52

1022. SUBSTANCES APPROVED FOR USE IN THE PREPARATION OF MEAT AND POULTRY PRODUCTS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 348; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 262

CFR Citation: 21 CFR 71; 21 CFR 170; 21 CFR 171

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the review of petitions for the approval of food and color additives and substances generally recognized as safe (GRAS) to provide for simultaneous review of such petitions by the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), when meat or poultry product uses are proposed. By agreement between USDA and FDA, such listings would eliminate the need for a separate FSIS rulemaking to allow the use in meat and poultry products of FDA-approved substances.

Timetable:

Action	Date	FR Cite
NPRM	12/29/95	60 FR 67490
NPRM Comment Period End	03/14/96	

Next Action Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal

HHS—FDA

Long-Term Actions

Agency Contact: George Pauli, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-200) 200 C Street SW., Washington, DC 20204 Phone: 202 418-3090

RIN: 0910-AA66

1023. • POSTMARKETING PERIODIC ADVERSE EXPERIENCE REPORTING REQUIREMENTS FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS

Priority: Other Significant

Legal Authority: 21 USC 216; 21 USC 262; 21 USC 263; 21 USC 264; 21 USC 300; 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC

355; 21 USC 356; 21 USC 357; 21 USC 371; 21 USC 374; ...

CFR Citation: 21 CFR 314; 21 CFR 600

Legal Deadline: None

Abstract: The final rule would amend the periodic adverse experience reporting requirements to provide new definitions and to revise reporting periods and formats as recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization's Council for International Organizations of Medical Sciences.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is no statutory requirement. There is a paperwork burden associated with this action.

Agency Contact: Audrey Thomas, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 7500 Standish Place, Rockville, MD 20855 Phone: 301 594-1049 Fax: 301 827-0901

RIN: 0910-AA85

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Food and Drug Administration (FDA)**

Completed Actions

1024. FINAL REGULATION TO ESTABLISH PROCEDURES FOR THE SAFE AND SANITARY PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS

Priority: Economically Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

CFR Citation: 21 CFR 123; 21 CFR 1240

Completed:

Reason	Date	FR Cite
Final Action	12/18/95	60 FR 65096
Final Action Effective	12/18/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Philip Spiller
Phone: 202 418-3133

RIN: 0910-AA10

1025. GENERAL BIOLOGICAL PRODUCT STANDARDS; ALTERNATIVE PROCEDURES AND EXCEPTIONS

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 610; 21 CFR 640; 21 CFR 630

Completed:

Reason	Date	FR Cite
Withdrawn	02/12/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Stephen Ripley
Phone: 301 594-3074

RIN: 0910-AA16

1026. MEDICAL DEVICES; PROTECTIVE RESTRAINTS; REVOCATION OF EXEMPTIONS FROM 510(K) PREMARKET NOTIFICATION PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES REGULATIONS

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 880.6760; 21 CFR 890.3910

Completed:

Reason	Date	FR Cite
Final Action	03/04/96	61 FR 8432

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Joseph M. Sheehan
Phone: 301 594-4765

RIN: 0910-AA17

1027. CERTIFICATION OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN; FEES FOR CERTIFICATION OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

Completed:

Reason	Date	FR Cite
Withdrawn - Duplicate of RIN 0910-AA07	02/13/96	

RIN: 0910-AA27

1028. PREMARKET APPROVAL OF MEDICAL DEVICES; SUPPLEMENTAL APPLICATIONS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

CFR Citation: 21 CFR 814.39

Completed:

Reason	Date	FR Cite
Withdrawn - The agency has determined this regulation is unnecessary.	02/12/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joseph M. Sheehan

HHS—FDA

Completed Actions

Phone: 301 594-4765

RIN: 0910-AA35

1029. PUBLIC INFORMATION; COMMUNICATIONS WITH STATE AND FOREIGN GOVERNMENT OFFICIALS

Priority: Other

CFR Citation: 21 CFR 20

Completed:

Reason	Date	FR Cite
Final Action	12/08/95	60 FR 63372
Final Action Effective	01/08/96	

Small Entities Affected: None

Government Levels Affected: State, Local, Federal

Agency Contact: Linda Horton
Phone: 301 827-3344

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Email: LHorton@Bangate.FDA.GOV

RIN: 0910-AA46

1030. OTC DRUG LABELING REVIEW

Completed:

Reason	Date	FR Cite
Withdrawn - Duplicate of RIN 0910-AA79	03/20/96	

RIN: 0910-AA63

1031. MEDICAL DEVICE EXEMPTIONS FROM PREMARKET NOTIFICATION

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or

duplication, or streamline requirements.

CFR Citation: 21 CFR 862; 21 CFR 866; 21 CFR 868; 21 CFR 870; 21 CFR 872; 21 CFR 874; 21 CFR 876; 21 CFR 878; 21 CFR 880; 21 CFR 882; 21 CFR 884; 21 CFR 886; 21 CFR 888; 21 CFR 890; 21 CFR 892

Completed:

Reason	Date	FR Cite
Final Action	01/16/96	61 FR 1117
Final Action Effective	02/15/96	

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Joseph M. Sheehan
Phone: 301 594-4765

RIN: 0910-AA65

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Health Resources and Services Administration (HRSA)

1032. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK RULES

Priority: Other Significant

Legal Authority: 42 USC 1320b-8 sec 1138 of the Social Security Act; 42 USC 274 sec 372 of the Public Health Service Act

CFR Citation: 42 CFR 121

Legal Deadline: None

Abstract: Section 1138 of the Social Security Act requires Medicare and Medicaid participating hospitals that perform organ transplants to be members of and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) as established by section 372 of the Public Health Service Act. Section 1138 also requires that for organ procurement costs attributable to payments to an Organ Procurement Organization (OPO) to be paid by Medicare or Medicaid, the OPO must be a member of and abide by the rules and requirements of the OPTN. No other entity (for example, a histocompatibility laboratory) is required to be a member of or abide by the rules of the OPTN under the provisions of the statute. It is the Department's position that no rule, requirement, policy, or other issuance of the OPTN will be considered to be a "rule or requirement" of the Network

within the meaning of section 1138 unless the Secretary has formally approved that rule. The OPTN is currently in operation and these rules will impose no further cost or provide any benefit other than that which now exists.

Timetable:

Action	Date	FR Cite
NPRM	09/08/94	59 FR 46482
NPRM Comment Period End	12/07/94	
Final Action	06/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD26.

Agency Contact: Judy Braslow, Director, Division of Transplantation, Bureau of Health Resources Development, Department of Health and Human Services, Health Resources and Services Administration, Room 7-18 Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-7577

RIN: 0906-AA32

1033. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE—II

Priority: Other Significant

Legal Authority: 42 USC 216; 42 USC 300aa-14; 42 USC 300aa-1 note.

CFR Citation: 42 CFR 100

Legal Deadline: None

Abstract: The Secretary has made findings as to the illnesses and conditions that can reasonably be determined in some circumstances to be caused or significantly aggravated by certain vaccines. Based on these findings, the Secretary amends the Vaccine Injury Table by regulation pursuant to section 313 of the National Childhood Vaccine Injury Act of 1986 and section 2114(c) of the Public Health Service Act. This final rule would have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the final regulations become effective.

Timetable:

Action	Date	FR Cite
NPRM	11/08/95	60 FR 56289
Final Action	02/00/97	

Small Entities Affected: None

Government Levels Affected: None

HHS—HRSA

Final Rule Stage

Additional Information: Previously reported under RIN 0905-AE52.

Agency Contact: Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation Program, BHP, Department of Health and Human Services, Health Resources and Services Administration, Room 8A-35, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-6593

RIN: 0906-AA36

1034. REMOVAL OF OBSOLETE REGULATIONS OF THE TITLE VII GRANT FOR THE CONSTRUCTION OF TEACHING FACILITIES FOR HEALTH PROFESSIONS PERSONNEL

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 42 USC 292 et seq

CFR Citation: 42 CFR 57.101 to 57.108; 42 CFR 57.110 to 57.112

Legal Deadline: None

Abstract: The purpose of this action is to remove regulations rendered obsolete by P.L. 102-408, which rescinded the authority for a health professions

training facilities construction grant program that the now obsolete regulations governed.

Timetable:

Action	Date	FR Cite
Final Action	06/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Charlotte Pascoe, Chief, Division of Facilities Compliance and Recovery, Department of Health and Human Services, Health Resources and Services Administration, Room 7-31 Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-6512

RIN: 0906-AA39

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Resources and Services Administration (HRSA)**

Long-Term Actions

1035. HEALTH EDUCATION ASSISTANCE LOAN (HEAL) PROGRAM: LENDERS'/ HOLDERS' PERFORMANCE STANDARDS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 292 to 292o

CFR Citation: 42 CFR 60

Legal Deadline: NPRM, Statutory, October 13, 1993.

Abstract: This Final rule amends the existing regulations governing the HEAL Program to establish standards for lenders and holders as required by

the Health Professions Education Extension Amendments of 1992 (Pub. L. 102-408). These standards would provide lenders and holders a greater incentive to work to maintain low HEAL default rates and, thus, improve the long-term solvency of the Student Loan Insurance Fund.

Timetable:

Action	Date	FR Cite
NPRM	11/16/94	59 FR 50103
NPRM Comment Period End	12/16/94	
Next Action	Undetermined	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD87.

Agency Contact: Michael Heningburg, Director, Division of Student Assistance, Bureau of Health Professions, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Bldg. Room 8-48, Rockville, MD 20857
Phone: 301 443-1173

RIN: 0906-AA33

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Resources and Services Administration (HRSA)**

Completed Actions

1036. TECHNICAL AMENDMENTS TO THE HEALTH PROFESSIONS, NURSING, AND ALLIED HEALTH TRAINING GRANT PROGRAMS UNDER 42 CFR PARTS 57 AND 58

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing

Government effort. It will eliminate existing text in the CFR.

CFR Citation: 42 CFR 57; 42 CFR 58

Completed:

Reason	Date	FR Cite
Final Action	02/16/96	61 FR 6118
Final Action Effective	02/16/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jennifer Burks
Phone: 301 443-1590

RIN: 0906-AA38

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Proposed Rule Stage

Indian Health Service (IHS)

1037. ACQUISITION UNDER THE BUY INDIAN ACT

Priority: Substantive, Nonsignificant

Legal Authority: 25 USC 47

CFR Citation: 48 CFR ch 3, app A

Legal Deadline: None

Abstract: This regulation will update and standardize existing regulations for the Buy Indian Act to coincide with the Department of Interior regulations at 48 CFR Chapter 14. There are no costs associated with these revised regulations. These revisions will increase competition among Indian economic enterprises and facilitate economic development of Indian reservations by increasing opportunities for Indian businesses.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
NPRM Comment Period End	07/00/96	

Small Entities Affected: None

Government Levels Affected: Tribal

Procurement: This is a procurement-related action for which there is a statutory requirement. The agency has

not yet determined whether there is a paperwork burden associated with this action.

Additional Information: Previously reported under RIN 0905-AE09.

Agency Contact: Myrna Mooney, Small and Disadvantaged Business Utilization Specialist, Department of Health and Human Services, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852
Phone: 301 443-1480

RIN: 0917-AA00

1038. • INDIAN CHILD PROTECTION AND FAMILY VIOLENCE PREVENTION ACT MINIMUM STANDARDS OF CHARACTER AND SUITABILITY FOR EMPLOYMENT

Priority: Other

Legal Authority: 5 USC 301; 25 USC 3201 et seq; 42 USC 13041

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, P.L. 101-630, 25 U.S.C.

3201-3211, that prescribes minimum standards of character and suitability of employment for individuals whose duties and responsibilities involve regular contact with, or control over, Indian children. These regulations also incorporate suitability of employment criteria required by section 231 of the Crime Control Act of 1990, P.L. 101-647, 42 U.S.C. 13041, which applies to each agency of the federal government and contractors with the federal government which hires individuals to provide child care services.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	
NPRM Comment Period End	07/00/96	

Small Entities Affected: None

Government Levels Affected: Tribal

Agency Contact: Ramona D. Williams, Child Protection Coordinator, Department of Health and Human Services, Indian Health Service, 5300 Homestead Road NE., Albuquerque, NM 87110
Phone: 505 837-4245

RIN: 0917-AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Indian Health Service (IHS)

1039. REVISION OF INDIAN SELF-DETERMINATION REGULATIONS

Priority: Other Significant

Legal Authority: PL 93-638; PL 100-202; PL 100-446; PL 100-472; PL 100-581; PL 101-301; PL 103-413; 25 USC 450

CFR Citation: 42 CFR 36; 48 CFR 380.4; 48 CFR 352.280-4

Legal Deadline: Final, Statutory, June 1996.

Abstract: Public Law 93-638, passed in 1975, requires the Indian Health Service (IHS) to turn over administrative responsibility for service delivery programs to tribes so requesting, using the mechanism of contracting. Public Law 93-638 also authorizes the IHS to make grants to tribes for the planning, development, and/or operations of health programs. Public Law 100-472, enacted October 5, 1988, made significant changes to the

statute and required that regulations implementing the amendments be promulgated in final within 10 months of enactment. The NPRM was published on January 20, 1994. The 120-day comment period was extended until August 20, 1994. On October 26, 1994, Public Law 103-413 was enacted. These amendments superseded the published NPRM and authorized the Secretaries of Interior and Health and Human Services to publish joint regulations only in specified areas. These regulations would be developed using the negotiated rulemaking procedure and are to be published within 18 months of enactment of the authorizing legislation.

Timetable:

Action	Date	FR Cite
NPRM	01/24/96	61 FR 2037

Action	Date	FR Cite
NPRM Comment Period End	03/25/96	
Final Action	06/00/96	

Small Entities Affected: None

Government Levels Affected: Tribal

Additional Information: Previously reported under RIN 0905-AE68. Future action undetermined because statutory deadline and end of comment period differ by 30 days. Legislation to change statutory deadline to June 25, 1996, has been introduced in both houses of Congress.

Agency Contact: Betty J. Penn, Chief, Regulations Branch, DLR, Department of Health and Human Services, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852
Phone: 301 443-1116

RIN: 0917-AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Agency for Health Care Policy and Research (AHCPR)

Final Rule Stage

1040. HEALTH SERVICES RESEARCH, EVALUATION, DEMONSTRATION, AND DISSEMINATION PROJECTS; PEER REVIEW OF GRANTS AND CONTRACTS
Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 299c-1(e)**CFR Citation:** 42 CFR 67**Legal Deadline:** None

Abstract: This final rule revises the regulations under 42 CFR part 67 to establish updated regulations for the administration of grants and peer review of grants and contracts for health services research projects

supported by the Agency for Health Care Policy and Research. These grants and contracts are under authority of Title IX of the PHS Act and section 1142 of the Social Security Act, as amended by P.L. 101-239 and P.L. 102-410. Public Comment was solicited on an NPRM on November 16, 1993. The final rule will also remove an existing subpart, which is obsolete.

Timetable:

Action	Date	FR Cite
NPRM	11/16/93	58 FR 60510
NPRM Comment Period End	01/18/94	
Final Action	08/00/96	

Small Entities Affected: None**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AD30.

Agency Contact: Phyllis Zucker, Dir., Off. of Planning and Evaluation, Department of Health and Human Services, Agency for Health Care Policy and Research, Suite 603, 2101 East Jefferson Street, Rockville, MD 20852
Phone: 301 594-2453

RIN: 0919-AA00
DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
National Institutes of Health (NIH)

Proposed Rule Stage

1041. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM
Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 288-1**CFR Citation:** 42 CFR 68**Legal Deadline:** None

Abstract: Section 634 of PL 100-607 creates a new program through which health professionals can obtain federally funded repayment of educational loans by conducting AIDS research as NIH employees. The new regulations will cover this program.

Timetable:

Action	Date	FR Cite
NPRM	04/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** Undetermined**Additional Information:** Previously reported under RIN 0905-AD18.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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RIN: 0925-AA02
1042. NATIONAL INSTITUTES OF HEALTH CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS
Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 288-5**CFR Citation:** 42 CFR 68a**Legal Deadline:** None

Abstract: Regulations would be issued to govern the awarding of educational loan repayments under the NIH Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds authorized by section 487E of the Public Health Service Act, as added by provisions of the NIH Revitalization Act of 1993.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	

Small Entities Affected: None**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE56.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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RIN: 0925-AA09
1043. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NIH
Priority: Other**Legal Authority:** 42 USC 288-4; 42 USC 216**CFR Citation:** 42 CFR 68b**Legal Deadline:** None

Abstract: Section 487D of the PHS Act, as added by the NIH 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 ten consecutive weeks of service (employment) at the NIH during which the individual is attending the institution and receiving the NIH scholarship. The proposed new regulations will cover this program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: None**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AE57.

HHS—NIH

Proposed Rule Stage

Agency Contact: Jerry Moore, NIH Regulations Officer, Program, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892
Phone: 301 402-4606

RIN: 0925-AA10

1044. TRAINEESHIPS (TERMINATION POLICIES)

Priority: Other

Legal Authority: 42 USC 216; 42 USC 283g(d); 42 USC 284(b)(1)(C); 42 USC 286b-3; 42 USC 287c(b)

CFR Citation: 42 CFR 63

Legal Deadline: None

Abstract: Regulations governing NIH traineeships will be amended to set forth additional conditions under which awards may be terminated.

Timetable:

Action	Date	FR Cite
NPRM	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE62.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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Fax: 301 402-0169
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RIN: 0925-AA11

1045. ADDITIONAL DHHS PROTECTION FOR PREGNANT WOMEN AND HUMAN FETUSES INVOLVED AS SUBJECTS FOR RESEARCH, AND PERTAINING TO HUMAN IN VITRO FERTILIZATION

Priority: Other

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46, subpart B

Legal Deadline: None

Abstract: Current regulations which have been in effect for two decades will be revised to reflect provisions of Public Law 103-43 and recent changes in NIH and FDA policies on the involvement of women in research.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: F. William Dommel, Jr., J.D., Senior Policy Advisor, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, 6100 Executive Blvd., Ste. 3801, MSC 7507, Rockville, MD 20892-7507
Phone: 301 496-7005
Fax: 301 402-2071
Email: WD3U@NIH.GOV

RIN: 0925-AA14

1046. • NATIONAL RESEARCH SERVICE AWARDS

Priority: Other

Legal Authority: 42 USC 216; 42 USC 288

CFR Citation: 45 CFR 66

Legal Deadline: None

Abstract: Current HHS regulations will be amended to reflect provisions of the ADAMHA Reorganization Act and the NIH Revitalization Act and the NIH Revitalization Act of 1993. New language concerning the service payback obligation will set forth that a service payback obligation is incurred only during the first twelve months of postdoctoral support and individuals may pay back this service obligation by engaging in an equal period of health-related teaching, or if the individual finished the first twelve months of support, by engaging in a second year of NRSA supported research training.

Timetable:

Action	Date	FR Cite
NPRM	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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RIN: 0925-AA16

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

National Institutes of Health (NIH)

1047. GRANTS FOR RESEARCH PROJECTS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 52

Legal Deadline: None

Abstract: Regulations covering grants for research projects will be amended to show changes necessitated by enactment of Public Laws 99-158, 99-660, 100-607, 101-549, 101-613, 102-222, 102-321, and 102-588, and to show their applicability to various programs administered by the Centers for Disease Control and Prevention and the Food and Drug Administration previously omitted from the regulations.

Timetable:

Action	Date	FR Cite
NPRM	08/02/94	59 FR 39312

Action	Date	FR Cite
NPRM Comment Period End	10/03/94	
Final Action	04/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AC02.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075

HHS—NIH

Final Rule Stage

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 RIN: 0925-AA01

1048. HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

Priority: Other

Legal Authority: 42 USC 9660; 42 USC 216

CFR Citation: 42 CFR 65a

Legal Deadline: None

Abstract: Regulations will be promulgated concerning grants for research and training made for the purpose of understanding, assessing, and reducing the adverse effect on human health of exposure to hazardous substances. The grants are authorized by section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as added by section 209 of the Superfund Amendments and Reauthorization Act (SARA) of 1986, P.L. 99-499.

Timetable:

Action	Date	FR Cite
NPRM	03/07/95	60 FR 12525
NPRM Comment Period End	05/08/95	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD46.

Agency Contact: Dr. William A. Suk, Program Administrator, Division of Extramural Research and Training, Department of Health and Human Services, National Institutes of Health, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709
 Phone: 919 541-0797

RIN: 0925-AA03

1049. NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 216; 42 USC 285a-2; 42 USC 285a-3; 42 USC 285b-

3; 42 USC 285b-4; 42 USC 285d-6; 42 USC 285i; 42 USC 285m-3; 42 USC 287a-2; 42 USC 287a-3; 42 USC 300cc-41

CFR Citation: 42 CFR 52b

Legal Deadline: None

Abstract: Regulations concerning NCI construction grants will be amended to more clearly show their general applicability to all NIH extramural programs with construction grant authority. Additionally, the regulations will be amended to show new administrative and technical requirements, add new procedures for the recovery of grant funds for facilities no longer used for biomedical research, show new PHS Act section numbers, and update the listing of other HHS regulations relevant to construction grants.

Timetable:

Action	Date	FR Cite
NPRM	07/06/95	60 FR 35266
NPRM Comment Period End	09/05/95	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD49.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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RIN: 0925-AA04

1050. TRAINING GRANTS

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 216; 42 USC 2421(b)(3); 42 USC 284(b)(1)(C); 42 USC 287c(b); 42 USC 300cc-15(a)(1); 42 USC 300cc-41(a)(3)(C); 42 USC 7403(h)(2)

CFR Citation: 42 CFR 63a

Legal Deadline: None

Abstract: New regulations concerning non-NRSA training grants authorized

by various PHS Act sections and training activities authorized by section 103(h)(2) of the Clean Air Act, as amended by section 901 of the Clean Air Act Amendments of 1990, P.L. 101-549. The regulations are intended to serve as a standing set of regulations that could be adapted for future training grant programs.

Timetable:

Action	Date	FR Cite
NPRM	01/24/95	60 FR 4742
NPRM Comment Period End	03/27/95	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD56.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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RIN: 0925-AA05

1051. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 216; 42 USC 285a-3; 42 USC 285b-4; 42 USC 285c-5; 42 USC 285d-6; 42 USC 285e-2; 42 USC 285e-3; 42 USC 285f-1; 42 USC 285g-5; 42 USC 285g-7; 42 USC 285m-3; 42 USC 285o-2; 42 USC 300cc-16; 42 USC 285a-6(c)(1)(E); 42 USC 285c-8

CFR Citation: 42 CFR 52a

Legal Deadline: None

Abstract: NIH Center Grants regulations will be amended to show their applicability to the Drug Abuse Research Centers Program authorized by PHS Act, section 464N, as added by section 123 of the ADAMHA Reorganization Act, P.L. 102-321, and several new centers authorized under the NIH Revitalization Act of 1993. Additionally, in accordance with the

HHS—NIH

Final Rule Stage

President's Reinventing Government effort, NIH is merging the regulations governing Grants for National Alcohol Research Centers codified at 42 CFR Part 54a with the Center Grants regulations and removing 42 CFR Part 54a from the CFR.

Timetable:

Action	Date	FR Cite
NPRM	02/17/95	60 FR 9560
NPRM Comment Period End	04/18/95	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE00. NIH plans to modify the National Alcohol Research Centers regulations to set forth changes necessitated by enactment of the ADAMHA Reorganization Act, Public Law 102-321, and other changes to update the regulations previously reported under RIN 0905-AE08. Additional Legal Authorities: 42 USC 286a-7(c)(1)(G)

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2975
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RIN: 0925-AA06

1052. GRANTS FOR NATIONAL ALCOHOL RESEARCH CENTERS

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 42 USC 216; 42 USC 285n-2

CFR Citation: 42 CFR 54a

Legal Deadline: None

Abstract: In accordance with the President's Reinventing Government effort, regulations governing grants for alcohol abuse and alcoholism prevention, treatment, and rehabilitation services, and National Alcohol Research Centers are being

merged with the regulations governing NIH center grants codified at 42 CFR Part 52. Part 54a is being removed from the CFR.

Timetable:

Action	Date	FR Cite
NPRM	08/19/94	59 FR 42793
NPRM Comment Period End	10/18/94	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE08. Merging of the National Alcohol Research Center grants regulations with the NIH center grant regulations is also reported under RIN 0925-AA06.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
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RIN: 0925-AA08

1053. • REMOVAL OF OBSOLETE PATENT REGULATIONS

Priority: Other

Legal Authority: 42 USC 216

CFR Citation: 45 CFR 6; 45 CFR 8

Legal Deadline: None

Abstract: Currently HHS regulations relating to inventions and patents generally, and inventions resulting from research grants and contracts and fellowships awards are being rescinded because those regulations are obsolete. The current regulations were superseded by the Bayh-Dole Act and implementing regulations issued by the Department of Commerce at 37 CFR Part 401 that provide for the transfer of Government-funded technology to the private sector through the elimination of Government control over inventions made under Federal grants and contracts.

Timetable:

Action	Date	FR Cite
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606
Fax: 301 402-0169
Email: moorej@od31em.nih.gov

RIN: 0925-AA15

1054. • REMOVAL OF NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 52d

Legal Deadline: None

Abstract: Current regulations relating to the National Cancer Institute Clinical Cancer Education Program will be rescinded because the regulations are obsolete. Current guidelines communicated by NCI with respect to the care of cancer patients no longer reflect the type of program described in the current regulations. This action will not affect the authority of the Director, NCI, to support appropriate programs of education and training, including clinical research training set forth in section 414 of the Public Health Service Act.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Building 31, Room 1B-25, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606
Fax: 301 402-0169
Email: moorej@od31em1.nih.gov

RIN: 0925-AA17

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Office of Assistant Secretary for Health (OASH)
Long-Term Actions
1055. STANDARDS OF COMPLIANCE FOR ABORTION-RELATED SERVICES IN FAMILY PLANNING SERVICE PROJECTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 300a-4

CFR Citation: 42 CFR 59

Legal Deadline: None

Abstract: This rule would return the Family Planning Service Program, funded under title X of the Public Health Service Act, to the compliance

standards operative prior to February 2, 1988, with regard to the statutory provision prohibiting abortion as a method of family planning in projects funded under that title.

Timetable:

Action	Date	FR Cite
NPRM	02/05/93	58 FR 7464
NPRM Comment Period End	08/09/93	58 FR 34024
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: Previously reported under RIN 0905-AE03.

Agency Contact: Felicia Stewart, M.D., Deputy Assistant Secretary for Population Affairs, Department of Health and Human Services, Office of Assistant Secretary for Health, East-West Towers, Suite 200, West Bldg., 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 594-4000

RIN: 0937-AA00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)
Proposed Rule Stage
1056. MEDICARE COVERAGE OF OUTPATIENT OCCUPATIONAL THERAPY SERVICES (BPD-425-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395k; 42 USC 1395l; 42 USC 1395w-4; 42 USC 1395x(s); 42 USC 1395x(p); 42 USC 1395cc(e)

CFR Citation: 42 CFR 410; 42 CFR 485; 42 CFR 486

Legal Deadline: None

Abstract: This rule would implement section 9337 of OBRA '86 which provides Medicare coverage for outpatient occupational therapy services furnished by providers and independent practitioners, identical to the coverage for outpatient physical therapy. It also would implement section 6133(a) of OBRA '89 which increased the payment limit for outpatient occupational therapy services provided by independent practitioners.

Timetable:

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sheridan Gladhill, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-03-18, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-1782

RIN: 0938-AD32

1057. REVISIONS TO THE CONFIDENTIALITY AND DISCLOSURE REGULATION (OPA-001-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 5 USC 552; 5 USC 552a; PL 99-570, Sec 1801; PL 99-570, Sec 1802; PL 99-570, Sec 1803; PL 99-570, Sec 1804; 42 USC 1306; EO 12600

CFR Citation: 42 CFR 401.101 to 401.102; 42 CFR 401.110; 42 CFR 401.120 to 401.123; 42 CFR 401.124 to 401.125; 42 CFR 401.105 to 401.108; 42 CFR 401.115 to 401.116

Legal Deadline: None

Abstract: This proposed rule would supplement the existing Department of Health and Human Services (HHS) Freedom of Information Act (FOIA) and Privacy Act regulations by establishing rules specific to HCFA. The rule would also revise existing HCFA regulations to delete language that reiterates or conflicts with HHS-FOIA or Privacy Act regulations or that pertains to the Social Security Act. This proposed rule is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Melody Hardy, Freedom of Information & Privacy

Office, Department of Health and Human Services, Health Care Financing Administration, C2-01-11, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5358

RIN: 0938-AD60

1058. "WITHOUT FAULT" AND BENEFICIARY WAIVER OF RECOVERY AS IT APPLIES TO MEDICARE OVERPAYMENT LIABILITY (BPD-719-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395gg

CFR Citation: 42 CFR 405; 42 CFR 401; 42 CFR 466.94; 42 CFR 411.23; 42 CFR 411.28; 42 CFR 466.86; 42 CFR 473.14; 42 CFR 413.20; 42 CFR 413.153

Legal Deadline: None

Abstract: This rule would amend the Medicare regulations to clarify our interpretation of "without fault" as it applies to physician, provider, supplier and beneficiary liability for overpayments. This definition would result in greater uniformity of determinations by carriers and intermediaries. Additionally, this rule would amend the Medicare regulations governing liability for overpayments to eliminate application of certain regulations of the Social Security Administration and to replace them with HCFA regulations more specific to

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circumstances involving Medicare overpayments. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David Walczak, Health Insurance Specialist, Office of Chronic Care & Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4475

RIN: 0938-AD95

1059. PROTECTION OF INCOME AND RESOURCES FOR COMMUNITY SPOUSES OF INSTITUTIONALIZED INDIVIDUALS (MB-023-P)

Priority: Other Significant

Legal Authority: 42 USC 1396r-5; 42 USC 1302

CFR Citation: 42 CFR 435.650 to 674; 42 CFR 435.750 to 754

Legal Deadline: None

Abstract: These regulations would interpret section 303(a) of MCCA '88, as amended by section 608(d)(16) of the FSA (PL 100-485), section 6411(e)(3) of OBRA '89, section 4714 of OBRA '90 and 513611(d) and 513643(c) of OBRA '93 (PI 103-66). Section 303(a) allocates income and resources between a spouse who is institutionalized and the spouse remaining in the community. It also provides special post-eligibility rules for institutionalized individuals who have spouses in the community. The revision would allow the community spouse to retain more income to meet living expenses.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: State, Local

Agency Contact: Jennifer Ryan, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-23-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4459

RIN: 0938-AE12

1060. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS REVISIONS (BPD-727-P)

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g(a); 42 USC 1395i; 42 USC 1395x(u); 42 USC 1395hh; 42 USC 1395jj; 42 USC 1395oo; 42 USC 1395ww

CFR Citation: 42 CFR 405.1801; 42 CFR 405.1889

Legal Deadline: None

Abstract: Under section 1878 of the Social Security Act, the Provider Reimbursement Review Board (PRRB) has the authority to adjudicate substantial reimbursement disputes between providers and intermediaries. This proposed rule would revise, update, and clarify various provisions of the regulations pertaining to provider appeals before intermediaries and the PRRB. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	08/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Morty Marcus, Office of Chronic Care & Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4477

RIN: 0938-AF28

1061. ALTERNATIVE SANCTIONS FOR PSYCHIATRIC HOSPITALS (HSQ-191-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395cc; 42 USC 1396a

CFR Citation: 42 CFR 488

Legal Deadline: None

Abstract: This proposed rule would provide an alternative to terminating a psychiatric hospital's participation in the Medicare and Medicaid programs for facilities found to be out of compliance with participation requirements. The alternative sanctions could be imposed instead of, or in addition to, terminating a psychiatric hospital's participation in the Medicare and Medicaid programs where deficiencies do not present immediate jeopardy to the health and safety of psychiatric hospital patients. These amendments are necessary to conform HCFA regulations to changes made by section 6020 of OBRA '89 and section 4755 of OBRA '90. The statutory and regulatory revisions are intended to encourage correction of deficiencies that do not jeopardize patient health and safety before termination becomes necessary.

Timetable:

Action	Date	FR Cite
NPRM	11/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: State, Federal

Agency Contact: Frank Sololik, Center for Hospital and Community Care, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-13-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7089

RIN: 0938-AF32

1062. ASSESSING INTEREST AGAINST MEDICARE SECONDARY PAYER (MSP) DEBTS (BPO-108-P)

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 3711; 31 USC 3717; 42 USC 1395y(b)(2)(B)

CFR Citation: 42 CFR 411.40; 42 CFR 405.376

Legal Deadline: None

Abstract: This proposal would establish in HCFA rules provisions concerning interest charges on amounts owed to the Federal government when an overpayment occurs because Medicare was billed and made payment as the primary payer, rather than as the secondary payer. We also propose to clarify the date of determination that an overpayment has occurred so that

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all parties would have a clear understanding of the period subject to payment of interest charges.

Timetable:

Action	Date	FR Cite
NPRM	03/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information:

TIMETABLE: Pending revisions resulting from PL 103-432.

Agency Contact: John Albert, Health Insurance Specialist, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S3-02-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7457

RIN: 0938-AF87

1063. REVISIONS TO RULES ON HEALTH CARE PREPAYMENT PLANS (OMC-016-P)

Priority: Other Significant

Legal Authority: 42 USC 1395l; 31 USC 9701

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This regulation would impose a range of requirements on Health Care Prepayment Plans corresponding to certain provisions for prepaid health plans under section 1876 of the Social Security Act. The expanded regulatory requirements would increase beneficiary protections and strengthen Federal oversight of the HCFA program.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Tim Love, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1094

RIN: 0938-AF97

1064. CONDITIONS OF PARTICIPATION FOR RURAL HEALTH CLINICS (BPD-764-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395l(a); 42 USC 1395l(d); 42 USC 1395x(aa); 42 USC 1395ww(a)(4); 42 USC 1396a(a)(13)(E); 42 USC 263a

CFR Citation: 42 CFR 405; 42 CFR 410; 42 CFR 491

Legal Deadline: None

Abstract: This rule would update our regulations to incorporate several health care coverage and payment provisions contained in OBRAs '87, '89, and '90 and would propose administrative changes that clarify policy related to sharing space between rural health centers and other entities, such as physician offices, the replacement of the provider-based cost basis system with the all-inclusive rate payment system, and the allowance of separate payment under Part B for more complex laboratory services. (This rule is part of HCFA's regulatory reform initiative.)

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Helen Klein, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-06-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4641

RIN: 0938-AG05

1065. APPOINTMENT OF REPRESENTATIVES FOR MEDICARE APPEALS (BPO-120-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395ff; 42 USC 1302; 42 USC 1320(c); 42 USC 1395hh; 42 USC 1395ii; 42 USC 1395pp; 42 USC 1395u

CFR Citation: 42 CFR 405.870; 42 CFR 405.701(c); 42 CFR 405.801(c); 42 CFR 405.871; 42 CFR 405.872

Legal Deadline: None

Abstract: This rule would clarify current regulations concerning: who can be appointed as representatives at Medicare appeal proceedings; the appointment procedure for representatives; whether a representative may be paid for his or her services; and the representative's specific responsibilities. These changes would improve the administration of the claims appeal process.

Timetable:

Action	Date	FR Cite
NPRM	03/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Betsy Horn, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S1-05-15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0973

RIN: 0938-AG30

1066. ENFORCEMENT REQUIREMENTS FOR RENAL DIALYSIS FACILITIES (HSQ-204-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395rr(g)

CFR Citation: 42 CFR 405; 42 CFR 405.2181; 42 CFR 405.2182; 42 CFR 405.2184

Legal Deadline: None

Abstract: This rule would implement section 12 of PL 100-93, which amended section 1881 of the Social Security Act by adding a new paragraph (h). Paragraph (h) (redesignated as (g) by section 4036(d)(5)(D) of OBRA '87) broadens the Secretary's authority to impose alternative sanctions on suppliers of end-stage renal disease services when the noncompliance of the supplier with the conditions of coverage does not immediately jeopardize patient health and safety. Alternative sanctions provide HCFA with a more flexible response to facility deficiencies short of termination. This rule is part of HCFA's regulatory reform initiative.

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Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Debbie Schoenemann, Office of Survey & Certification, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6771

RIN: 0938-AG31

1067. GENERAL CRITERIA AND STANDARDS FOR EVALUATING PERFORMANCE OF CONTRACT OBLIGATIONS (HSQ-207-NC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1320c; 42 USC 132c-2

CFR Citation: 42 CFR 462

Legal Deadline: None

Abstract: This notice provides general criteria and standards that will be used to evaluate the effective and efficient performance of Utilization and Quality Control Peer Review Organizations (PROs) for new contracts entered into on or after April 1, 1996.

Timetable:

Action	Date	FR Cite
Notice With Comment Period	08/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Heidi Gelzer, Health Standards & Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S1-08-24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9352

RIN: 0938-AG32

1068. DISCLOSURE OF CONFIDENTIAL PRO INFORMATION FOR RESEARCH PURPOSES (HSQ-208-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320c-9; 42 USC 1302

CFR Citation: 42 CFR 476.144

Legal Deadline: None

Abstract: This rule would allow Peer Review Organizations (PROs) to disclose confidential information to researchers without the consent of the individuals who would be identified. Currently, PROs can only disclose to the public nonconfidential aggregate data where no one is specifically identified. The statute, however, provides for limited disclosure in cases where there are circumstances to assure adequate protection of the rights established by regulation, and interest of patients, health care practitioners, or providers. HCFA is now emphasizing the sharing of PRO data for educational and research purposes as evidenced by the implementation of the Uniform Clinical Data Set and the Health Care Quality Improvement Initiative. This regulatory revision will make confidential PRO information accessible to researchers while still protecting the identities of beneficiaries and practitioners from unwarranted disclosure. PRO flexibility to share information with researchers is comparable with the revised requirements in the PRO's Fourth Scope of Work contract.

Timetable:

Action	Date	FR Cite
NPRM	02/00/97	

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Mike Rappaport, Director, Division of Systems Management, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S1-09-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6759

RIN: 0938-AG33

1069. EFFECT OF CHANGE OF OWNERSHIP ON PROVIDER AND SUPPLIER PENALTIES, SANCTIONS, AND OVERPAYMENTS (HSQ-215-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395g(a); 42 USC 1395x; 42 USC 1395z; 42 USC 1395cc(a); 42 USC 1395ii; 42 USC 1396a(a)(28); 42 USC 1396r(a) to (f); 42 USC 1302; 42 USC 1395i-3(a) to (f); 42 USC 1395x(j)and (l); 42 USC 1395aa;

42 USC 1395hh; 42 USC 1395oo; 42 USC 1395d(a) and (c) and (d)

CFR Citation: 42 CFR 405.1803; 42 CFR 405.1811; 42 CFR 405.1835; 42 CFR 405.1843; 42 CFR 405.1805; 42 CFR 483.151; 42 CFR 484.36; 42 CFR 489.2; 42 CFR 489.18

Legal Deadline: None

Abstract: This rule would amend the regulations on provider agreements by clarifying the effect a change of ownership has on penalties and sanctions incurred by Medicare providers. It would provide that all Medicare penalties and sanctions are automatically assigned to a new owner. It would also extend the same principle to suppliers; i.e., we would require the new owner of a supplier to be liable for any Medicare overpayments, penalties, and sanctions incurred by or imposed on the previous owner.

Timetable:

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected: None

Government Levels Affected: Undetermined

Additional Information: Legal Authority (Continued) 42 USC 1395f(b) 42 USC 1395l 42 USC 1395x(v) 42 USC 1395cc 42 USC 1395ww

Agency Contact: Mike Goldman, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-14-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6768

RIN: 0938-AG59

1070. NEW PAYMENT METHODOLOGY FOR ROUTINE EXTENDED CARE SERVICES PROVIDER IN A SWING BED HOSPITAL (BPD-805-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395tt

CFR Citation: 42 CFR 413.53; 42 CFR 413.114

Legal Deadline: None

Abstract: This proposed rule would revise the regulations governing the methodology for payment of routine extended care services provided in a swing bed hospital. Medicare payment for such services would be determined prospectively based on the average rate

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per patient day paid by Medicare for routine care services provided in a free standing skilled nursing facility in the region where the hospital is located. This rule would also provide that payment for these services will be the higher of the payment cost rate in effect for the current calendar year or for the payment rate received by the swing-bed hospital for the prior calendar year. In addition, this rule would revise the regulations concerning the method used to allocate hospital general routine inpatient service costs for purposes of determining payment to swing-bed hospitals.

Timetable:

Action	Date	FR Cite
NPRM	04/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Katie Walker, Office of Hospital Policy, Department of Health and Human Services, Health Care Financing Administration, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7278

RIN: 0938-AG68

1071. SALARY EQUIVALENCY GUIDELINES FOR PHYSICAL THERAPY, RESPIRATORY THERAPY, SPEECH PATHOLOGY, AND OCCUPATIONAL THERAPY (BPD-808-PN)

Priority: Other Significant

Legal Authority: 42 USC 1395x(v)(5)

CFR Citation: 42 CFR 413.106

Legal Deadline: None

Abstract: This notice proposes revisions to the salary equivalency guidelines for Medicare payment for the reasonable costs of physical and respiratory therapy services furnished by providers under arrangements with an outside contractor. The notice also proposes initial salary equivalency guidelines for speech language pathology and occupational therapy services furnished by providers under arrangements with an outside contractor. The guidelines would be used by Medicare fiscal intermediaries to determine the maximum allowable costs of those services.

Timetable:

Action	Date	FR Cite
Proposed Notice	10/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Jacqueline Gordon, Health Insurance Specialist, Division of Home Care and Therapy, Department of Health and Human Services, Health Care Financing Administration, C4-07-14, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4517

RIN: 0938-AG70

1072. MEDICAID: OPTIONAL COVERAGE OF TB-RELATED SERVICES FOR INDIVIDUALS INFECTED WITH TUBERCULOSIS (MB-082-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(10)(A)(ii); PL 103-66, Sec 13603; 42 USC 1396a(2)

CFR Citation: 42 CFR 435.219; 42 CFR 435.201; 42 CFR 440.250; 42 CFR 436.201; 42 CFR 436.219; 42 CFR 440.164

Legal Deadline: None

Abstract: This rule would amend the existing Medicaid regulations to provide for optional Medicaid coverage of low-income individuals infected with tuberculosis (TB). These individuals would be eligible only for specified TB-related services. The rule would incorporate and interpret provisions of section 13603 of OBRA '93.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Jennifer Ryan, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-20-14, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4459

RIN: 0938-AG72

1073. REVISION OF MEDICARE HOSPITAL CONDITIONS OF PARTICIPATION (BPD-745-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

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

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care and the outcomes of that care, reflect a cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are necessary to reflect advances in health care practices since the requirements were last revised in 1986. This regulation is part of the Administration's reinventing government and regulatory reform initiatives.

Timetable:

Action	Date	FR Cite
NPRM	04/00/96	
Final Action	06/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Charles Booth, Director, Office of Hospital Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-02-23, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4487

RIN: 0938-AG79

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1074. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—EXPANDED TO DESIGNATED HEALTH SERVICES (BPD-809-P)**Priority:** Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh; 42 USC 1395nn**CFR Citation:** 42 CFR 411**Legal Deadline:** None

Abstract: This proposed rule would provide that a physician who has (or has a family member who has) a financial relationship with a health care entity may not make referrals to that entity for certain services (designated health services) under the Medicare program, except under specified circumstances. This proposed rule would also deny payment to a State for expenditures for designated health services furnished on the basis of a physician referral that, all things being equal, would result in denial of payment under Medicare. The provisions of the proposed rule are based on sections 13562 and 13624 of the OBRA '93, as amended by SSA '94.

Timetable:

Action	Date	FR Cite
NPRM	10/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** State

Agency Contact: Betty Burrier, Office of Chronic Care Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0191

RIN: 0938-AG80

1075. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (BPD-819-P)**Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

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

CFR Citation: 42 CFR 484**Legal Deadline:** None

Abstract: This proposed rule would revise home health agency conditions of participation to center on the patient, using outcome-oriented measures. Most of the current HHA conditions of participation have remained unchanged since home health services became a Medicare benefit in 1966. Some limited modifications have been made over the years to comply with legislative changes. As a result, most of the conditions of participation continue to be structure and process oriented. They do not effectively support the mandate of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) to develop a patient-centered, outcome-oriented survey process that focuses on the organization and delivery of quality care services. This proposed rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: Businesses, Organizations**Government Levels Affected:** Undetermined

Agency Contact: Susan Levy, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-9364

RIN: 0938-AG81

1076. END-STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (BPD-818-P)**Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395rr

CFR Citation: 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 489; 42 CFR 492

Legal Deadline: None

Abstract: This proposed rule would revise current conditions of coverage for end-stage renal disease (ESRD) services covered by Medicare. It would

update the conditions to reflect new developments in outcome-oriented standards technology and equipment, emphasize the total patient experience with dialysis and develop performance expectations for the facility that result in quality, comprehensive care for the dialysis patient. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: Undetermined**Government Levels Affected:** Undetermined

Agency Contact: Lynn Merritt-Nixon, Office of Hospital Policy, Department of Health and Human Services, Health Care Financing Administration, C5-05-15, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4652

RIN: 0938-AG82

1077. WAGE INDEX USED TO ADJUST PAYMENT RATES FOR HOSPICE SERVICES UNDER THE MEDICARE PROGRAM (BPD-820-P)**Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395f(i); 5 USC 561 to 590

CFR Citation: 42 CFR 418**Legal Deadline:** None

Abstract: The Medicare hospice benefit has been in effect since 1983. This proposed rule would update the wage index used to adjust payment rates to reflect local differences in area wage levels. The proposed is the successful result of a "negotiated rulemaking" proceeding under the Negotiated Rulemaking Act of 1990, and is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
Notice of Intent	10/14/94	59 FR 52129
NPRM	06/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** None

HHS—HCFA

Proposed Rule Stage

Agency Contact: Janice Flaherty, Director, Division of Home Care & Therapy, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4637
RIN: 0938-AG93

1078. LIABILITY FOR THIRD PARTIES TO PAY FOR CARE AND SERVICES (MB-080-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(25)(A); 42 USC 1396b(o)

CFR Citation: 42 CFR 433.135 to 433.152

Legal Deadline: None

Abstract: This rule would incorporate the provisions of OBRA '93 by amending the regulations governing third party liability. It would add ERISA plans, service benefit plans and health maintenance organizations to the definition of liable third parties. It would require States to prohibit any health insurer from taking into account when enrolling or making payments, that an individual is eligible for or receiving Medicaid. It would also require States to enact a law under which the State is deemed to have acquired a recipient's right to payment by a third party.

Timetable:

Action	Date	FR Cite
NPRM	03/00/97	

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: Robert Nakielny, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-21-01, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4466

RIN: 0938-AH01

1079. DEFINITION OF SKILLED NURSING FACILITY (SNF) AND HOME HEALTH AGENCY (HHA) FOR COVERAGE OF DURABLE MEDICAL EQUIPMENT (DME) (BPD-834-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing

Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1495x(n)

CFR Citation: 42 CFR 409; 42 CFR 410

Legal Deadline: None

Abstract: This proposed rule would define skilled nursing facilities (SNFs) for purposes of Medicare coverage of durable medical equipment (DME) and home health services. A Medicare SNF (as defined under section 1819 of the Act) can not be considered a home under Medicare Part B for DME and home health coverage. This proposed rule would presume that all Medicaid nursing facilities are section 1819(a) facilities and thus would not be considered a home for DME and home health coverage. This rule would identify non-Medicare nursing homes as skilled facilities based upon the receipt of skilled care by a proportion of its resident population that is at least comparable to the proportion typically found in participating Medicare SNFs. This proposed rule is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Thomas Hoyer, Director, Office of Chronic Care and Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4605

RIN: 0938-AH16

1080. SCHEDULE OF LIMITS FOR SKILLED NURSING FACILITY INPATIENT ROUTINE SERVICE COSTS (BPD-837-NC)

Priority: Other Significant

Legal Authority: 42 USC 1395f(b); 42 USC 1395x(v)(1); 42 USC 1395yy; 42 USC 1302; 42 USC 1395cc(a); 42 USC 1395hh

CFR Citation: 42 CFR 413

Legal Deadline: Final, Statutory, October 1, 1995.

Abstract: This final notice with comment period will set forth an updated schedule of limits on skilled nursing facility (SNF) routine service costs for which payment may be made under the Medicare program. Section 1888(a) of the Social Security Act requires that for cost reporting periods, beginning on or after October 1, 1995 and every 2 years thereafter, the Secretary will update the per diem cost limits for SNF routine service costs.

Timetable:

Action	Date	FR Cite
Notice With Comment Period	10/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Robert Kuhl, Technical Advisor, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4597

RIN: 0938-AH18

1081. ADDITIONAL SUPPLIER STANDARDS (BPD-864-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395(cc); 42 USC 1395m; 42 USC 1395pp(h); 42 USC 1395u(b) and (p); 42 USC 1395cc(d); 42 USC 1302; 42 USC 1395x; 42 USC 1395hh; 42 USC 1395ii

CFR Citation: 42 CFR 424.57

Legal Deadline: None

Abstract: This rule would establish additional standards for entities seeking to qualify as Medicare suppliers for purposes of submitting claims for medical equipment and supplies. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

HHS—HCFA

Proposed Rule Stage

Agency Contact: Larry Bonander, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-24, 7500 Security Boulevard, Baltimore, MD 21214
Phone: 410 786-4479

RIN: 0938-AH19

1082. STATE PLAN AMENDMENT (SPA) RECONSIDERATION PROCESS (MB-096-P)

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1396a(a)

CFR Citation: 42 CFR 430.18; 42 CFR 430.60

Legal Deadline: None

Abstract: This proposed rule would revise and streamline the State Plan Amendment (SPA) reconsideration process. Currently, when a State requests reconsideration of a denied SPA, a hearing is held in all cases, even when the only dispute is over the interpretation of the statute. Under the proposed regulation, the State and HCFA could avoid the cost and delay of the hearing process when the only issue is interpretation of the statute and by permitting the State to take the issue directly to court. The reconsidered decision would then be made without a hearing. This rule is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Robert Tomlinson, Office of Beneficiary Services, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-20-21, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4463

RIN: 0938-AH24

1083. CHANGES IN COVERAGE AND PAYMENT POLICIES FOR PHYSICIAN ASSISTANT SERVICES (BPD-829-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395k; 42 USC 1395u(b)(2); 42 USC 1395u(b)(12); 42 USC 1395x(s)

CFR Citation: 42 CFR 410.10; 42 CFR 410.74; 42 CFR 410.150; 42 CFR 414.1; 42 CFR 414.52; 42 CFR 491.2

Legal Deadline: None

Abstract: This proposed rule concerns the coverage and payment policies for services performed by physician assistants and services furnished as incident to these services. It would conform Medicare regulations to the provisions in section 6114 of OBRA '89. It would also provide consistent qualification requirements for physician assistants.

Timetable:

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Pat Moore, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-8098

RIN: 0938-AH26

1084. HOSPICE CARE—CONDITIONS OF PARTICIPATION (BPD-844-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395x(dd)

CFR Citation: 42 CFR 418

Legal Deadline: None

Abstract: This proposed rule would revise the Medicare conditions of participation for hospices to help ensure the provision of quality care through an emphasis on patient-centered outcomes. Areas of change would include, among others, assessment of patient needs, clarification of physician roles, coordination of care for hospice

patients residing in nursing homes, clarification of nursing roles, patient rights, and provision of services. This rule is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	11/30/96	

Small Entities Affected: Businesses

Government Levels Affected: State, Local

Agency Contact: Thomas Saltz, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4480

RIN: 0938-AH27

1085. LIMITATIONS ON PAYMENT FOR HOME OXYGEN THERAPY BASED ON INHERENT REASONABLENESS CRITERIA (BPD-845-PN)

Priority: Economically Significant

Legal Authority: 42 USC 1395m(a); 42 USC 1395u(b)(8) and (9)

CFR Citation: 42 CFR 405.502(g); 42 CFR 414.210(d)

Legal Deadline: None

Abstract: This proposed notice sets forth our rationale for determining that Medicare's Part B payment allowances for home oxygen are grossly excessive and specifies the proposed change in our charge or methodology for determining home oxygen payment amounts.

Timetable:

Action	Date	FR Cite
Proposed Notice	08/00/96	

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: William J. Long, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-04-05, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5655

RIN: 0938-AH28

HHS—HCFA

Proposed Rule Stage

1086. MEDICAID ELIGIBILITY QUALITY CONTROL, STAFFING AND TRAINING, AND UTILIZATION CONTROL: REMOVAL OF OBSOLETE AND RESTRICTIVE REQUIREMENTS (MB-099-P)**Priority:** Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.**Legal Authority:** 42 USC 1302; 42 USC 1396a(a)(4); 42 USC 1396a(a)(26); 42 USC 1396b(g) and (i); 42 USC 1396b(u); 42 USC 1396d(a)(16); 42 USC 1396d(h); 42 USC 1396a(a)(31)**CFR Citation:** 42 CFR 431.861; 42 CFR 431.862; 42 CFR 431.863; 42 CFR 431.864; 42 CFR 432.10; 42 CFR 456**Legal Deadline:** None**Abstract:** This rule would remove several obsolete sections of the Medicaid regulations that specify rules and procedures for disallowing Federal financial participation for erroneous medical assistance payments due to eligibility and beneficiary liability errors as detected through the Medicaid eligibility quality control (MEQC) program for assessment periods from 1980 through June 1990. The rule would eliminate certain regulations that specify Federal standards for personnel administration and training programs to allow States more flexibility and reduce burden. In addition, the rule would remove most of the regulations that prescribe requirements concerning control of the utilization of all Medicaid services, including specific requirements for control of utilization in institutions. The statutory requirements for utilization control remain in effect. This effort is part of our initiative to reinvent health care regulations.**Timetable:**

Action	Date	FR Cite
NPRM	06/00/96	

Small Entities Affected: Businesses, Organizations**Government Levels Affected:** State, Local**Agency Contact:** Robert Weaver, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5914

RIN: 0938-AH31

1087. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1997 RATES (BPD-847-P)**Priority:** Other Significant**Legal Authority:** 42 USC 1395ww**CFR Citation:** 42 CFR 412; 42 CFR 413**Legal Deadline:** NPRM, Statutory, May 1, 1996. Final, Statutory, September 1, 1996.**Abstract:** Medicare pays for hospital inpatient services under a prospective payment system (PPS) in which payment is made at a predetermined specific rate for the operating and capital-related costs associated with each discharge. These rules will announce the prospective payment rates for operating and capital-related costs for FY 1997. We will also revise the Medicare hospital inpatient prospective payment systems for operating costs and capital-related costs to implement necessary changes arising from our continuing experience with the system. In addition, we will set forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the prospective payment systems. These changes are applicable to discharges occurring on or after October 1, 1996.**Timetable:**

Action	Date	FR Cite
NPRM	05/00/96	
Interim Final Rule	09/00/96	

Small Entities Affected: Businesses, Organizations**Government Levels Affected:** State, Federal**Agency Contact:** Charles Booth, Director, Office of Hospital Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-02-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4487

RIN: 0938-AH34

1088. • MEDICARE COVERAGE OF SERVICES OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS (BPD-843-P)**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1395x; 42 USC 1395x(cc)(1); 42 USC 1395x(ll)**CFR Citation:** 42 CFR 484; 42 CFR 485**Legal Deadline:** None**Abstract:** This proposed rule would implement SSA '94 to provide coverage for speech-language provision pathology services furnished by a qualified pathologist.**Timetable:**

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Jackie Gordon, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-07-14, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4517

RIN: 0938-AH37

1089. • MEDICARE PROGRAM: FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE (BPD-846-PN)**Priority:** Other Significant**Legal Authority:** 42 USC 1395w-4(c)(2)(B)(i)**CFR Citation:** None**Legal Deadline:** Final, Statutory, January 1, 1997.**Abstract:** This proposed notice discusses changes to work relative value units (RVUs) affecting payment for physician services. Section 1848(c)(2)(B)(i) of the Social Security Act requires that we review all work RVUs no less often than every 5 years. Since we implemented the physician fee schedule effective for services furnished beginning January 1, 1992, we have initiated the 5-year review of work RVUs that will be effective for services furnished beginning January 1, 1997.

HHS—HCFA

Proposed Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Terrance Kay, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-10-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4497

RIN: 0938-AH38

1090. • MEDICARE PROGRAM: REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1997 (BPD-852-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395w-4

CFR Citation: 42 CFR 414

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

Abstract: This proposed rule involves several policy changes affecting payment for physician services under the Medicare Physician Fee Schedule for calendar year 1997. The proposed rule will discuss changes concerning Medicare payment for drugs and comprehensive locality changes.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Shana Olshan, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-10-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5246

RIN: 0938-AH40

1091. • PRIVACY AND SECURITY ENFORCEMENT FOR THE MEDICARE TRANSACTION SYSTEM (BPO-142-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302; 42 USC 1320a-3; 42 USC 1320a-5; 42 USC 1395l(e); 42 USC 1395cc; 42 USC 1395hh; 42 USC 1320a-3a

CFR Citation: 42 CFR 401; 42 CFR 420

Legal Deadline: None

Abstract: The Medicare transaction system will rely heavily on highly sophisticated electronic technology, thus requiring changes in privacy and security enforcement provisions.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Gerald Waters, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S2-25-13, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1009

RIN: 0938-AH47

1092. • MEDICARE: AMOUNT OF PAYMENTS IF CUSTOMARY CHARGES FOR SERVICES FURNISHED ARE LESS THAN REASONABLE COSTS (BPD-860-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: 42 USC 1395f(b); 42 USC 1395l(a); 42 USC 1395m(a)

CFR Citation: 42 CFR 413.13

Legal Deadline: None

Abstract: A provider whose charges are lower than its reasonable costs for those services in any cost reporting period beginning January 1, 1974 but before April 28, 1988 may carry forward costs

that are unreimbursed for two succeeding cost reporting periods. Sufficient time has passed since the publication of this provision to warrant the deletion in the CFR of any reference to the carryover provision. Since payment for DME is no longer based on the lesser of the reasonable cost or reasonable charges but based on 80% for the lesser of the actual charge or the DME fee schedule amount and 80% of the fee schedule amount for nominal charge; HHAs the lesser of costs or charges (LCC) provision no longer applies and should be deleted from the CFR. This rulemaking is part of the reinventing Government effort. It will eliminate existing text in the CFR.

Timetable:

Action	Date	FR Cite
NPRM	09/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Ward Pleinas, Office of Hospital Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4528

RIN: 0938-AH49

1093. • LIMITATIONS ON LIABILITY (BPD-859-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302 and 1395hh; 42 USC 1395pp

CFR Citation: 42 CFR 411.404

Legal Deadline: None

Abstract: This proposed rule would implement section 1879 of the Social Security Act, which limits beneficiary liability for certain durable medical equipment. This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

HHS—HCFA

Proposed Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Denis Garrison,
Division of Beneficiary and Insurance
Issues, Department of Health and
Human Services, Health Care Financing

Administration, C4-06-21, 7500
Security Boulevard, Baltimore, MD
21244

Phone: 410 786-5643

RIN: 0938-AH51

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)

Final Rule Stage

**1094. DEDUCTION OF INCURRED
MEDICAL EXPENSES (SPENDDOWN)
(MB-020-F)**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 42 CFR 435.831; 42 CFR
436.831

Legal Deadline: None

Abstract: This final rule amends and responds to comments on a final rule with comment period published in the Federal Register on January 12, 1994. That rule permits States flexibility to revise the process by which incurred medical expenses are considered to reduce an individual's or a family's income in order for the individual or family to become Medicaid eligible. Only States that cover the medically needy, and States that use more restrictive criteria to determine eligibility of the aged, blind, and disabled than the criteria used to determine eligibility for Supplemental Security Income (SSI) benefits, have a spenddown.

Timetable:

Action	Date	FR Cite
NPRM	09/02/83	48 FR 39959
NPRM Comment Period End	11/16/83	
Interim Final Rule	01/12/94	59 FR 1659
Final Rule With Comment Period	01/12/94	59 FR 1659
Comment Period End	03/14/94	
Effective Date	03/14/94	
Final Action	08/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Roy Trudel, Health
Insurance Specialist, Medicaid Bureau,
Department of Health and Human
Services, Health Care Financing
Administration, C4-25-02, 7500
Security Boulevard, Baltimore, MD
21244

Phone: 410 786-3417

RIN: 0938-AB07

**1095. EFFECTIVE DATES FOR
PROVIDER AGREEMENTS AND
SUPPLIER APPROVALS (HSQ-139-F)**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC
1395hh

CFR Citation: 42 CFR 431; 42 CFR 442;
42 CFR 488; 42 CFR 489; 42 CFR 498

Legal Deadline: None

Abstract: This rule will establish uniform criteria for determining the effective dates of Medicare and Medicaid provider agreements and of the approval of Medicare suppliers when the provider or supplier is subject to survey as a basis for determining participation in those programs.

Timetable:

Action	Date	FR Cite
NPRM	10/08/92	57 FR 46362
NPRM Comment Period End	12/07/92	
Final Action	11/00/96	

Small Entities Affected: Businesses

Government Levels Affected: State,
Federal

Agency Contact: Irene Gibson, Depty
Dir., Office of Survey & Certification,
Health Standards and Quality Bureau,
Department of Health and Human
Services, Health Care Financing
Administration, S2-14-17, 7500
Security Blvd., Baltimore, MD 21244
Phone: 410 786-6768

RIN: 0938-AC88

**1096. CHANGES CONCERNING
SUSPENSION OF MEDICARE
PAYMENTS AND DETERMINATIONS
OF ALLOWABLE INTEREST EXPENSE
(BPO-118-FC)**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320b-4; 42
USC 1395g; 42 USC 1395x(v)(1)(A); 42
USC 1395l; 42 USC 1395gg

CFR Citation: 42 CFR 405.370 to
405.378; 42 CFR 413.5; 42 CFR 413.90;
42 CFR 413.153

Legal Deadline: None

Abstract: This rule will change the Medicare regulations to provide for the following: (1) elimination of the requirement that in case of overpayments to health care providers, the contractor make a determination that a suspension of payment is needed to protect the program against financial loss before the payment can be suspended; (2) clarification of procedures and roles of contractors, HCFA, and the DHHS Office of Inspector General relating to suspension of payment; (3) elimination of the requirement that investment income of providers from gifts, grants, and endowments be offset against allowable interest expenses if that investment income is commingled with other funds; and (4) extension of the list of exceptions to the interest expense investment income offset provision to include investment income from deferred compensation plans and self-insurance funds.

Timetable:

Action	Date	FR Cite
NPRM	08/22/88	53 FR 31888
NPRM Comment Period End	10/21/88	
Final Rule With Comment Period	06/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Lisa Vriezen,
Overpayment & Medicare Secondary
Payer Collection Unit, Bureau of
Program Operations, Department of
Health and Human Services, Health
Care Financing Administration, S3-05-
07, 7500 Security Blvd., Baltimore, MD
21244

Phone: 410 786-1492

RIN: 0938-AC99

HHS—HCFA

Final Rule Stage

1097. CRITERIA AND PROCEDURES FOR MAKING MEDICAL SERVICES COVERAGE DECISIONS THAT RELATE TO HEALTH CARE TECHNOLOGY (BPD-432-FC)**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395y**CFR Citation:** 42 CFR 400.200; 42 CFR 405.201; 42 CFR 405.203; 42 CFR 405.205; 42 CFR 405.207; 42 CFR 405.209**Legal Deadline:** None

Abstract: The final rule with comment period will establish generally applicable criteria and procedures for determining whether a service is "reasonable and necessary" under the Medicare program; set forth the coverage decisionmaking process; and summarize and provide an analysis of the public comments that we received in response to the January 30, 1989 proposed rule. The objective of the criteria and procedures set forth in this rule is to ensure that Federal funds are expended only for medical services that are appropriate to meet an individual's medical needs.

Timetable:

Action	Date	FR Cite
NPRM	01/30/89	54 FR 4302
NPRM Comment Period End	03/31/89	
Final Rule With Comment Period	10/00/96	

Small Entities Affected: None**Government Levels Affected:** None

Agency Contact: Ron Milhorn, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-10-07, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-5663

RIN: 0938-AD07**1098. PROHIBITION ON UNBUNDLING OF HOSPITAL OUTPATIENT SERVICES (BPD-426-F)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395y(a)(14); 42 USC 1395cc(a)(1)(H); 42 USC 1395cc(g); 42 USC 1395x(w)(1)**CFR Citation:** 42 CFR 409; 42 CFR 410; 42 CFR 411; 42 CFR 412; 42 CFR 489; 42 CFR 1003**Legal Deadline:** None

Abstract: This final rule, to be issued jointly by HCFA and the OIG, will prohibit Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than the hospital, unless the services are furnished under an arrangement with the hospital. The hospital is obligated by its provider agreement to furnish the services directly or under an arrangement. These regulations will also authorize the OIG to impose a civil money penalty, not to exceed \$2,000, against any individual who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for items or services furnished under Medicare, that is inconsistent with an arrangement under section 1866(a)(1)(H) of the Social Security Act or is in violation of the requirements for an arrangement. These regulations implement section 9343(c) of OBRA '86, section 4085(i)(17) of OBRA '87, and section 4157 of OBRA '90.

Timetable:

Action	Date	FR Cite
NPRM	08/05/88	53 FR 29486
NPRM Comment Period End	10/04/88	
Final Action	08/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** None

Agency Contact: Carolyn Mullen, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-16, 7500 Security Blvd., Baltimore, MD 21244

RIN: 0938-AD33**1099. CHANGES TO PEER REVIEW ORGANIZATION REGULATIONS (HSQ-135-F)****Priority:** Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395y(a); 42 USC 1320c; 42 USC 1396a(a)(30); 42 USC 1395cc(a)**CFR Citation:** 42 CFR 400.200; 42 CFR 411.15; 42 CFR 431.630; 42 CFR 433.15; 42 CFR 462.1; 42 CFR 462.101; 42 CFR

462.102; 42 CFR 462.106; 42 CFR 462.107; 42 CFR 466.1; 42 CFR 466.71; 42 CFR 466.76; 42 CFR 466.78; 42 CFR 466.83

Legal Deadline: None

Abstract: This rule will set forth several changes to regulations that govern Peer Review Organizations (PROs) and is based on statutory changes contained in COBRA '85 and OBRA '86. In addition, several technical changes will be included as a result of experience gained with the PRO program by HCFA. This rule also implements the new quality review requirements for certain Medicaid Health Maintenance Organization contracts.

Timetable:

Action	Date	FR Cite
NPRM	03/16/88	53 FR 8654
NPRM Comment Period End	05/16/88	
Final Action	01/00/97	

Small Entities Affected: None**Government Levels Affected:** Undetermined

Agency Contact: Harvey Brook, Office of Quality Improvement Programs, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S1-13-07, 7500 Security Blvd., Baltimore, MD 21244

RIN: 0938-AD38**1100. OMNIBUS NURSING HOME REFORM REQUIREMENTS (BPD-488-F)****Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395i-3; 42 USC 1395x; 42 USC 1396r; 42 USC 1302**CFR Citation:** 42 CFR 418; 42 CFR 440; 42 CFR 441; 42 CFR 482; 42 CFR 483; 42 CFR 431; 42 CFR 405; 42 CFR 413; 42 CFR 430; 42 CFR 434 to 436; 42 CFR 447; 42 CFR 466; 42 CFR 498**Legal Deadline:** None**Abstract:** This final rule will implement several provisions of OBRA

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'87 that concern services to residents of nursing homes. This rule will implement provisions that include Federal standards for evaluating State waivers of nursing facility nurse staffing requirements, use of physical and chemical restraints in nursing facilities, qualifications of facility administrators, notice of Medicaid rights to be given to persons admitted to nursing facilities, and other technical changes. This rule is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	02/05/92	57 FR 4516
NPRM Comment Period End	04/06/92	
Final Action	10/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bill Ullman, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5667

RIN: 0938-AD81

1101. HMO ORGANIZATIONAL STRUCTURE AND SERVICES (OMC-007-F)

Priority: Other Significant

Legal Authority: 42 USC 300e

CFR Citation: 42 CFR 417.100; 42 CFR 417.101; 42 CFR 417.103; 42 CFR 417.104; 42 CFR 417.107; 42 CFR 417.120; 42 CFR 417.122; 42 CFR 417.123; 42 CFR 417.124; 42 CFR 417.126; 42 CFR 417.143; 42 CFR 417.152

Legal Deadline: None

Abstract: This final rule will provide organizations operating health maintenance organizations (HMOs) that are federally qualified under title XIII of the Public Health Service Act with greater flexibility in operating other health benefit plans. It will also authorize, with certain limitations, federally qualified HMOs to offer out-of-plan physician services and require a reasonable deductible for those services. Further, this final rule will permit the HMO to use assets of the parent organization to meet fiscal

soundness and insolvency protection requirements.

Timetable:

Action	Date	FR Cite
NPRM	07/15/93	58 FR 38170
Correction Notice	09/03/93	58 FR 46925
NPRM Comment Period End	09/13/93	58 FR 38170
Final Action	09/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Maureen Miller, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1097

RIN: 0938-AE25

1102. HOSPITAL STANDARD FOR HIV INFECTIOUS BLOOD AND BLOOD PRODUCTS (BPD-633-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(e)(9)

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule will require hospitals to notify the patient's attending physician whenever potentially HIV infectious blood has been administered, and to ask the physician to inform the patient of the need for HIV testing and counseling. If the physician is unavailable or declines to inform the patient, the hospital must notify the patient. This rule implements a recommendation of the President's Commission on AIDS.

Timetable:

Action	Date	FR Cite
NPRM	06/30/93	58 FR 34977
NPRM Comment Period End	08/30/93	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Janet Samen, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-13-07, 7500 Security Blvd., Baltimore, MD 21244

RIN: 0938-AE40

1103. MEDICARE, MEDICAID, AND CLIA PROGRAMS: REGULATIONS IMPLEMENTING THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA '88) (HSQ-226-F)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 263a

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: Historically the Department regulated by "location," rather than by the types of tests they performed. CLIA changes this approach. CLIA requires that the Department "regulate by test," using what is commonly referred to as the "complexity model." A final rule with comment period was published February 28, 1992, that set forth standards for all laboratories, based on complexity, and responded to public comments on the proposed standards. The regulation was revised by rules with comment period published on January 19, 1993, December 6, 1994, and April 24, 1995. A final rule, which will respond to these public comments, will be issued.

Timetable:

Action	Date	FR Cite
NPRM	05/21/90	55 FR 20896
NPRM Comment Period End	09/21/90	
Final Rule With Comment Period	02/28/92	57 FR 7002
Comment Period End	04/28/92	
Effective Date	09/01/92	
Effective Date	01/19/93	58 FR 5215
Final Rule With Comment Period	01/19/93	58 FR 5215
Comment Period End	03/22/93	
Final Action	11/00/96	

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: Anthony J. Tirone, Director, Office of Survey & Certification, Health Standardss and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Boulevard, Baltimore, MD 21244

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Phone: 410 786-6763

RIN: 0938-AE47

1104. CONDITIONS OF COVERAGE FOR ORGAN PROCUREMENT ORGANIZATIONS (BPD-646-FC)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1320b-8

CFR Citation: 42 CFR 485; 42 CFR 405; 42 CFR 482

Legal Deadline: Final, Statutory, November 16, 1991.

Abstract: This final rule with comment period will respond to comments on the final rule with comment period which set forth changes to the conditions of coverage for organ procurement organizations (OPOs). It deals with the definition of an OPO service area; qualifications of the board of directors; establishment of qualification and performance criteria for OPOs; clarification of operational policy for certification and recertification of OPOs, competition for open areas, and, appeals of the Secretary's decisions. This rule contains provisions that are part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	06/21/91	56 FR 28513
NPRM Comment Period End	08/21/91	
Interim Final Rule With Comment Period	09/08/94	59 FR 46500
Effective Date	10/11/94	
Comment Period End	11/07/94	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Claude Mone, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5666

RIN: 0938-AE48

1105. RESIDENT ASSESSMENT IN LONG-TERM CARE FACILITIES (HSQ-180-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395i-3; 42 USC 1396r; 42 USC 1302

CFR Citation: 42 CFR 483; 42 CFR 456.1; 42 CFR 456.600; 42 CFR 456.601; 42 CFR 456.602; 42 CFR 456.603; 42 CFR 456.608; 42 CFR 456.609; 42 CFR 456.610; 42 CFR 456.612; 42 CFR 456.651; 42 CFR 456.654; 42 CFR 483.20; 42 CFR 483.315

Legal Deadline: Final, Statutory, January 1, 1989.

Abstract: Sections 1819(b)(3) and 1919(b)(3) of the Social Security Act, as amended by PL 100-203, require skilled nursing facilities in the Medicare program (and before October 1, 1990, nursing facilities in the Medicaid program) to conduct a comprehensive, standardized assessment of each resident's capability to perform daily life functions. The assessment must also describe significant impairments in the resident's functional capacity and be based on a uniform minimum data set specified by the Secretary. Sections 1819(f)(6)(A) and 1919 (f)(6)(A) of the Act require the Secretary to specify a minimum data set of core elements and common definitions for use by nursing facilities in conducting the assessments. This rule will specify this minimum data set and establish guidelines for using it.

Timetable:

Action	Date	FR Cite
NPRM	12/28/92	57 FR 61614
NPRM Comment Period End	02/26/93	
Final Action	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sue Nonemaker, Health Standards Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6825

RIN: 0938-AE61

1106. POST-CONTRACT BENEFICIARY PROTECTIONS AND OTHER PROVISIONS (OMC-003-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395mm

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This rule will require health maintenance organizations (HMO) or competitive medical plans (CMP) that cease to contract with HCFA under section 1876 to provide Medicare beneficiaries with certain coverage for pre-existing conditions under supplemental insurance; provide a 30-day open enrollment period for individuals who would otherwise lose prepaid Medicare coverage as a result of termination, non-renewal or reduction in service area of a risk contract; accelerate the deadline for risk contracting HMOs and CMPs to submit adjusted community rate proposals; require all HMOs and CMPs to furnish a copy of an executed enrollment application form to Medicare applicants; and, require HCPPs to comply with HMO/CMP beneficiary application procedures.

Timetable:

Action	Date	FR Cite
NPRM	03/11/94	59 FR 11230
NPRM Comment Period End	05/09/94	
Final Action	08/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tracy Jensen, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1033

RIN: 0938-AE63

1107. EMPLOYER CONTRIBUTIONS TO HMOS (OMC-004-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 300e(c); 42 USC 300e-1(l); 42 USC 300e-9

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This rule would conform existing regulations to sections 5(b) and 7 of the Health Maintenance Organization (HMO) Amendments of

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1988 (PL 100-517). It would prohibit employers from financially discriminating against HMO enrollees in setting the contributions the employers make to employees' health plans.

Timetable:

Action	Date	FR Cite
NPRM	07/05/91	56 FR 30723
Comment Period End	09/03/91	
Final Action	04/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Marty Abeln, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1096

RIN: 0938-AE64

1108. PAYMENT FOR NURSING AND ALLIED HEALTH SCIENCE EDUCATION (BPD-685-F)

Priority: Other Significant

Legal Authority: PL 101-239, Sec 6205; PL 101-508, Sec 4004; PL 101-508, Sec 4159; 42 USC 1395x

CFR Citation: 42 CFR 413

Legal Deadline: NPRM, Statutory, July 1, 1990.

Abstract: This rule will set forth our policy for the payment of the costs of approved nursing and allied health science programs, as directed by section 6205(b)(2) of OBRA '89. For the most part, the provisions set forth in this rule restate or clarify our current policies governing these costs, which were previously set forth in the provider reimbursement manual and other documents, but have never been included in the regulations. In addition, we are amending the list of approved programs and clarifying payment rules for certified registered nurse anesthetist programs. This rule will also implement section 4004 of OBRA '90 which provides that, effective with cost reporting periods beginning on or after October 1, 1990, under certain conditions, costs incurred by a hospital or educational institution related to the hospital for clinical training are treated as pass-through costs and paid on the basis of reasonable cost even though the hospital does not operate the education programs.

Timetable:

Action	Date	FR Cite
NPRM	09/22/92	57 FR 43659
NPRM Comment Period End	11/23/92	
Final Action	12/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director, Division of Hospital Services, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-1850

RIN: 0938-AE79

1109. COVERAGE OF SCREENING PAP SMEARS (BPD-705-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(s)(14); 42 USC 1395x(nn); 42 USC 1395y(a)(1)(F)

CFR Citation: 42 CFR 410.10; 42 CFR 410.15; 42 CFR 410.56

Legal Deadline: None

Abstract: This rule will establish regulations under section 6115 of OBRA '89 to govern Medicare Part B coverage of screening pap smears (including a physician's interpretation of the test results) provided to a woman for the early detection of cervical cancer.

Timetable:

Action	Date	FR Cite
NPRM	11/26/93	58 FR 62312
NPRM Comment Period End	01/24/94	
Final Action	09/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joyce Eng, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4619

RIN: 0938-AE98

1110. MEDICARE COVERAGE OF CLINICAL PSYCHOLOGIST, OTHER PSYCHOLOGIST, AND CLINICAL SOCIAL WORKER SERVICES—MEDICARE (BPD-706-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395l(c); 42 USC 1395x(hh)(2); 42 USC 1395x(ii)

CFR Citation: 42 CFR 410; 42 CFR 417; 42 CFR 424

Legal Deadline: None

Abstract: This rule will address provisions of section 6113 of OBRA '89 and section 4157 of OBRA '90. Section 6113 of OBRA '89 provides coverage for the services of clinical psychologists (CPs) and clinical social workers. It will require CPs to agree to consult with the patient's primary care or attending physician. Also, it will eliminate the dollar limitation that previously applied to mental health services although the 62.5 percent limitation still applies. OBRA '89 also provides coverage for clinical social worker services, but places two limitations on separate payment, which apply to services provided to inpatients of hospitals and skilled nursing facilities that are Medicare participating. Section 4157 of OBRA '90 unbundled CP services from the definition of "inpatient hospital services." It also implements sections 104 (psychology services in hospitals) and 147 (consultation by social workers) of the Social Security Act Amendments of 1994.

Timetable:

Action	Date	FR Cite
NPRM	12/29/93	58 FR 68829
NPRM Comment Period End	02/28/94	
Final Action	09/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Regina Walker, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-08-16, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6735

RIN: 0938-AE99

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1111. OBRA '90 AND MISCELLANEOUS MANAGED CARE TECHNICAL AMENDMENTS (OMC-018-FC)**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1396b(m); 42 USC 1396a(e)(2)(A)**CFR Citation:** 42 CFR 434.20 to 44; 42 CFR 435.212; 42 CFR 435.362**Legal Deadline:** None

Abstract: This rule will require certain health insuring organizations to be subject to the regulations governing prepaid health plans. This rule will also allow State-only funds to be paid to Medicaid contracting entities. These funds will not be considered when computing the rate at which Federal financial participation is made. Further, this rule will incorporate several technical amendments from section 4732 of OBRA '90.

Timetable:

Action	Date	FR Cite
NPRM	05/09/94	59 FR 23820
NPRM Comment Period End	07/08/94	
Final Action	08/00/96	

Small Entities Affected: None**Government Levels Affected:** None

Agency Contact: Jane McClard, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-4460

RIN: 0938-AF15

1112. MEDICAID PAYMENT FOR COVERED OUTPATIENT DRUGS UNDER REBATE AGREEMENTS (MB-046-F)**Priority:** Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1396a(a); 42 USC 1396b(i); 42 USC 1396r-8; 42 USC 1396b(a); 42 USC 1302**CFR Citation:** 42 CFR 447; 42 CFR 441**Legal Deadline:** None**Abstract:** This rule will incorporate section 4401 of OBRA '90 to add

specific requirements for Medicaid payment for covered outpatient drugs. The requirements concern: denial of Federal financial participation unless rebate agreements and drug use review are in effect; prohibiting some State plan drug access limitations for drugs covered under a rebate agreement; and, the content of the rebate agreements. The drug rebate agreement was previously published in the Federal Register on February 21, 1991 (56 FR 7049). This rule will also reflect statutory revisions mandated by the Veteran's Health Care Act of 1992 and OBRA '93. The revision of the drug rebate dispute resolution process is part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	09/19/95	60 FR 48442
NPRM Comment Period End	11/20/95	
Final Action	08/00/96	

Small Entities Affected: Businesses**Government Levels Affected:** State

Agency Contact: Estelle Chisholm, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-15-26, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-3286

RIN: 0938-AF42

1113. REFERRAL TO CHILD SUPPORT ENFORCEMENT AGENCIES OF MEDICAID FAMILIES (MB-051-F)**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1396k**CFR Citation:** 42 CFR 433.160; 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.151**Legal Deadline:** None

Abstract: This rule will require State Medicaid agencies to refer Medicaid families with an absent parent to child support enforcement (CSE) agencies. Section 9142 of OBRA '87 required CSE agencies to provide all CSE services to such Medicaid families who have assigned to the State their rights to medical support. The purpose of these rules is to require States to make this referral to State CSE agencies to ensure that those recipients requiring CSE services receive them.

Timetable:

Action	Date	FR Cite
NPRM	09/22/93	58 FR 49272
NPRM Comment Period End	11/22/93	
Final Action	10/00/96	

Small Entities Affected: None**Government Levels Affected:** State

Agency Contact: Randy Graydon, Director, Division of Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, C4-22-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4451

RIN: 0938-AF68

1114. MEDICAID: OUTSTATIONED INTAKE LOCATIONS FOR CERTAIN LOW-INCOME PREGNANT WOMEN, INFANTS AND CHILDREN UNDER AGE 19 (MB-052-F)**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1396a(a)(55)**CFR Citation:** 42 CFR 435.901; 42 CFR 435.902; 42 CFR 435.903; 42 CFR 435.904; 42 CFR 435.907; 42 CFR 436.2; 42 CFR 436.3**Legal Deadline:** None

Abstract: This rule implements a statutory requirement that State Medicaid agencies must provide for receipt and initial processing of Medicaid applications filed by certain low-income pregnant women, infants, and children under age 19, at locations which are other than those used for receipt and processing of Aid to Families with Dependent Children (AFDC) applications. The statutory requirement also provides that the application form for these individuals must not be the AFDC application form.

The rule is based on section 1902(a)(55) of the Social Security Act as added by section 4602 of OBRA '90, PL 101-508.

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/23/94	59 FR 48805
Interim Final Rule With Comment Period	09/23/94	59 FR 48805
Effective Date	10/24/94	
Comment Period End	11/22/94	
Final Action	10/00/96	

Small Entities Affected: None**Government Levels Affected:** None

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Agency Contact: Robert Tomlinson, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-07-22, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4531
RIN: 0938-AF69

1115. MEDICARE AND MEDICAID PROGRAMS: REQUIREMENTS FOR PHYSICIAN INCENTIVE PLANS IN PREPAID HEALTH CARE ORGANIZATIONS (OMC-010-FC)

Priority: Other Significant

Legal Authority: 42 USC 1395mm(i); 42 USC 1396b

CFR Citation: 42 CFR 417.01; 42 CFR 417.409; 42 CFR 417.495; 42 CFR 434.67; 42 CFR 1003.100 to 1003.103

Legal Deadline: None

Abstract: This rule will amend the regulations governing federally qualified health maintenance organizations (HMOs) and competitive medical plans (CMPs) contracting with the Medicare program, and certain HMOs and health insuring organizations (HIOs) contracting with States under the Medicaid program, by implementing changes made by sections 4204(a) and 4731(a) of OBRA '90 concerning physician incentive plans. The changes are intended to allow HMOs, CMPs, and HIOs the flexibility to provide reasonable financial incentives to their physicians and physician groups in order to eliminate unnecessary care while still protecting enrollees from reduced quality of care or reduced access to care.

Timetable:

Action	Date	FR Cite
NPRM	12/14/92	57 FR 59024
Comment Period End	04/13/93	58 FR 8568
Final Rule	03/27/96	61 FR 13430
Final Rule Effective Date	04/26/96	
Final Rule Comment Period End	05/28/96	
Final Action	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Tony Hausner, Office of Managed Care, Department of Health and Human Services, Health Care

Financing Administration, S-3-23-24, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1093
RIN: 0938-AF74

1116. PART B ADVANCE PAYMENTS TO PHYSICIANS/SUPPLIERS OR OTHER ENTITIES FURNISHING ITEMS OR SERVICES UNDER MEDICARE PART B (BPO-105-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395u

CFR Citation: 42 CFR 421.214

Legal Deadline: None

Abstract: This rule will amend Medicare regulations to provide advance payment to physicians, suppliers, or entities that furnish items or services under Medicare Part B. These payments will be made only when claims processing is so delayed that interest payments alone are insufficient to adequately compensate the provider, in light of cash flow needs. This change will result in more efficient and economical administration of the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	07/18/94	59 FR 36415
NPRM Comment Period End	09/16/94	
Final Action	04/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Bob Shaw, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S2-01-23, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3312
RIN: 0938-AF85

1117. RETROACTIVE ENROLLMENT AND DISENROLLMENT IN RISK HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS (OMC-015-F)

Priority: Other Significant

Legal Authority: 42 USC 1395mm

CFR Citation: 42 CFR 417.448; 42 CFR 417.450; 42 CFR 417.456; 42 CFR 417.460; 42 CFR 417.461; 42 CFR 417.462; 42 CFR 417.464; 42 CFR 417.584

Legal Deadline: None

Abstract: This rule implements section 4204(e) of OBRA '90. It permits HCFA to make retroactive payments for up to 90 days when there is a delay in notifying HCFA that a beneficiary has enrolled under a section 1876 risk contract through an employer health plan. In addition, the rule will permit the Secretary to authorize retroactive disenrollment in specific cases.

Timetable:

Action	Date	FR Cite
NPRM	12/27/93	58 FR 68366
Comment Period End	02/25/94	
Final Action	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Anne Manley, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1096
RIN: 0938-AF98

1118. PAYMENT FOR PREADMISSION SERVICES (BPD-731-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395ww(a)(4)

CFR Citation: 42 CFR 412.2(c); 42 CFR 413.40

Legal Deadline: None

Abstract: This rule confirms the provisions published in an interim final rule with comment period on January 12, 1994, and responds to comments received on that rule. The interim final rule implemented section 4003 of OBRA '90, entitled "Expansion of DRG Payment Window," which amended the statutory definition of "inpatient operating cost" to include certain preadmission services.

Timetable:

Action	Date	FR Cite
Effective Date	01/12/94	59 FR 1654
Interim Final Rule With Comment Period	01/12/94	59 FR 1654
Comment Period End	03/14/94	
Final Action	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Nancy Edwards, Director, Division of Prospective Payment System, Department of Health

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and Human Services, Health Care Financing Administration, C5-06-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4531
RIN: 0938-AG00

1119. CHANGE IN PROVIDER AGREEMENT REGULATIONS RELATED TO FEDERAL EMPLOYEE HEALTH BENEFITS (BPD-748-F)

Priority: Substantive, Nonsignificant
Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 5 USC 8904(b)

CFR Citation: 42 CFR 489

Legal Deadline: None

Abstract: This final rule will amend current Medicare regulations to require that payment limitations apply to hospitals that furnish inpatient hospital services to retired Federal workers, aged 65 or older, who are enrolled in a Federal Employee Health Benefits (FEHB) plan but not covered under Medicare Part A (Hospital Insurance). The payment amount will approximate the Medicare diagnosis-related group payment rates established under the inpatient hospital Medicare prospective payment rate. This rule will also amend current Medicare regulations to authorize HCFA to consider terminating or nonrenewing a hospital's Medicare provider agreement if the hospital repeatedly fails to accept the Medicare rate as payment in full for inpatient hospital services provided to retired Federal workers enrolled in a fee-for-service from a FEHB plan who do not have Medicare Part A coverage. This rule will implement section 7002(f) of OBRA '90, enacted November 5, 1990. It will clarify that an institutional provider may not discriminate against Medicare patients in providing services because it is dissatisfied with the level of Medicare payment.

Timetable:

Action	Date	FR Cite
NPRM	02/10/94	59 FR 6228
NPRM Comment Period End	04/11/94	
Final Action	09/00/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Paul Olenick, Director, Division of Beneficiary and Insurance Issues, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4472

RIN: 0938-AG03

1120. REVISED MEDICAID MANAGEMENT INFORMATION SYSTEMS (MB-38-FN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396b(r)

CFR Citation: None

Legal Deadline: None

Abstract: This notice sets forth revised general functional requirements for the Medicaid Management Information System (MMIS). The MMIS consists of software and hardware used to process Medicaid claims and to retrieve and produce utilization and management information about services that are required by the Medicaid agency or Federal Government for administrative or audit purposes. The revised requirements allow States more flexibility to exercise variations in the implementation.

Timetable:

Action	Date	FR Cite
Proposed Notice	11/22/93	58 FR 61692
Comment Period End	01/21/94	
Final Action	09/00/96	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Richard Friedman, Director, Div. of Systems Data and Analysis, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-17-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3292

RIN: 0938-AG10

1121. MEDICARE PROGRAM: LIMITATIONS ON MEDICARE COVERAGE OF INTERMITTENT POSITIVE PRESSURE BREATHING MACHINE THERAPY (BPD-781-FN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(n); 42 USC 1395y(a)(1)(A)

CFR Citation: None

Legal Deadline: None

Abstract: Intermittent positive pressure breathing (IPPB) machine therapy is currently covered under Medicare as durable medical equipment for patients whose ability to breathe is severely impaired. Based on an Office of Health Technology Assessment recommendation, we will place limitations on Medicare coverage of IPPB machine therapy.

Timetable:

Action	Date	FR Cite
Proposed Notice	06/29/94	59 FR 33520
Comment Period End	08/29/94	
Final Action	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Francine Spencer, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-04-05, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4614

RIN: 0938-AG44

1122. TELEPHONE AND ELECTRONIC REQUESTS FOR REVIEW OF PART B INITIAL CLAIM DETERMINATIONS (BPO-121-F)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395hh; 42 USC 1395ff

CFR Citation: 42 CFR 405.807

Legal Deadline: None

Abstract: Current Medicare regulations allow a Medicare beneficiary to appeal, in writing, decisions to deny payment for a claim under supplementary medical insurance. This rule will allow a beneficiary to appeal an initial payment determination either in writing or by telephone. This rule will allow beneficiaries to more easily pursue appeals.

Timetable:

Action	Date	FR Cite
NPRM	07/10/95	60 FR 35544

HHS—HCFA

Final Rule Stage

Action	Date	FR Cite
NPRM Comment Period End	09/08/95	
Final Action	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Rosalind Little, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S1-05-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6972

RIN: 0938-AG48

1123. MEDICARE PROGRAM: LIMITATIONS ON MEDICARE COVERAGE OF CATARACT SURGERY (BPD-797-FN)

Priority: Other Significant

Legal Authority: 42 USC 1395x(s)(1); 42 USC 1395y(a)(1)(A)

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the Medicare program's definition of medical necessity with respect to Medicare coverage of preoperative testing for cataracts, cataract surgery, and Nd:YAG capsulotomy.

Timetable:

Action	Date	FR Cite
Proposed Notice	10/06/95	60 FR 52396
NPRM Comment Period End	12/05/95	60 FR 52396
Final Action	11/00/96	

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Karen McVeary, Technology & Special Analysis Staff, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-10-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4643

RIN: 0938-AG65

1124. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HSQ-225-F)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing

Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 263a

CFR Citation: 42 CFR 493.2; 42 CFR 493.7; 42 CFR 493.9; 42 CFR 493.15; 42 CFR 493.20; 42 CFR 493.25; 42 CFR 493.35; 42 CFR 493.37; 42 CFR 493.39; 42 CFR 493.45; 42 CFR 493.47; 42 CFR 493.49; 42 CFR 493.53; 42 CFR 493.1775

Legal Deadline: None

Abstract: This rule would revise our current process of evaluating tests against generic criteria. A waiver would be granted to any test that meets the statutory criteria, provided that scientifically valid data were submitted verifying that the criteria were met.

Timetable:

Action	Date	FR Cite
NPRM	09/13/95	60 FR 47534
NPRM Comment Period End	11/13/95	
Final Action	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Anthony Tirone, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Blvd., Baltimore, MD 21244

RIN: 0938-AG99

1125. REPORTING OF INTEREST FROM ZERO COUPON BONDS (BPD-647-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(v)

CFR Citation: 42 CFR 413.153

Legal Deadline: None

Abstract: This final rule requires Medicare providers to report all interest expense and income from zero coupon bonds in the cost reporting period in which the interest was accrued.

Timetable:

Action	Date	FR Cite
NPRM	12/13/93	58 FR 65150
Final Action	05/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ann Pash, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-03-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4615

RIN: 0938-AH11

1126. MEDICARE PROGRAM: UNIFORM ELECTRONIC COST REPORTING FOR SKILLED NURSING FACILITIES AND HOME HEALTH AGENCIES (BPD-788-F)

Priority: Other Significant

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

CFR Citation: 42 CFR 413.24

Legal Deadline: None

Abstract: This rule will add the requirement that, for cost reporting periods beginning on or after October 1, 1995 all skilled nursing facilities and home health agencies must submit cost reports currently required under Medicare regulations in a uniform electronic format. This rule will also allow a delay or waiver of this requirement where implementation would result in financial hardship for a provider.

Timetable:

Action	Date	FR Cite
NPRM	12/05/95	60 FR 62237
NPRM Comment Period End	02/05/96	
Final Action	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas Talbott, Auditor, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-01-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4592

RIN: 0938-AH12

1127. UPDATE OF THE REASONABLE COMPENSATION EQUIVALENT LIMITS FOR SERVICES FURNISHED BY PHYSICIANS (BPD-816-N)

Priority: Other Significant

Legal Authority: 42 USC 1395xx

CFR Citation: 42 CFR 405.482(f)

HHS—HCFA

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Legal Deadline: None

Abstract: This notice sets forth updated payment limits on the amount of allowable compensation for services furnished by physicians to providers that are not covered by the prospective payment system or per resident payments for graduate medical education. These services are paid by Medicare on a reasonable cost basis. The revised reasonable compensation equivalent limits are based on updated economic index data and replace the limits that were published in the Federal Register on February 20, 1985.

Timetable:

Action	Date	FR Cite
Final Action	08/00/96	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ward Pleines, Health Insurance Specialist, Office of Hospital Policy, Department of Health and Human Services, Health Care Financing Administration, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4528

RIN: 0938-AH14

1128. CRITERIA AND PROCEDURES FOR EXTENDING COVERAGE TO CERTAIN DEVICES AND RELATED SERVICES (BPD-841-FC)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395y(a)(1)(A)

CFR Citation: 42 CFR 405; 42 CFR 411

Legal Deadline: None

Abstract: This final rule will provide that certain medical devices with an investigational device exemption (IDE) approved by the Food and Drug Administration (FDA) may be covered under Medicare. Specifically, it will set forth the process by which the FDA will assist HCFA in identifying nonexperimental investigational devices that may be potentially covered under Medicare. It is intended to provide Medicare beneficiaries with greater access to advances in medical technology.

Timetable:

Action	Date	FR Cite
Final Rule With Comment Period	08/19/95	60 FR 48417
Comment Period End	10/20/95	
Effective Date	11/01/95	
Final Action	09/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sharon Hippler, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-04, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4633

RIN: 0938-AH21

1129. DELEGATION OF CIVIL MONEY PENALTIES (BPO-135-FC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 405(a); 42 USC 1302; 42 USC 1320; 42 USC 1395cc; 42 USC 1395u(j)(2); 42 USC 1395hh; 42 USC 1395ii

CFR Citation: None

Legal Deadline: None

Abstract: This rule will contain the processes and procedures to be undertaken in the imposition of civil money penalties and in the appeals process.

Timetable:

Action	Date	FR Cite
Final Action	07/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joel Cohen, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S3-14-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3349

RIN: 0938-AH22

1130. MEDICAID: LIMITATIONS ON AGGREGATE PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS; FEDERAL FISCAL YEAR 1996 (PRELIMINARY) (MB-098-N)

Priority: Other Significant

Legal Authority: 42 USC 1396r-4

CFR Citation: 42 CFR 447.297; 42 CFR 447.298; 42 CFR 447.299

Legal Deadline: Final, Statutory, October 1995.

Abstract: This notice announces the preliminary Federal fiscal year 1996 national target and individual State allotments for Medicaid payments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs.

Timetable:

Action	Date	FR Cite
Notice	05/00/96	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Richard Strauss, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-18-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-2019

RIN: 0938-AH30

1131. MEDICARE PROGRAM; SPECIAL ENROLLMENT PERIODS AND WAITING PERIODS (BPD-752-FC)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302; 42 USC 1395

CFR Citation: 42 CFR 406; 42 CFR 407; 42 CFR 408; 42 CFR 416

Legal Deadline: None

Abstract: This rule reflects statutory changes made by OBRA's 1987, 1989, 1990, 1993 and the Social Security Act Amendments of 1994. These changes will provide an additional way for certain disabled individuals to qualify for special enrollment periods (SEPs); extend through 1998 the period during which certain disabled individuals under age 65 may take advantage of SEPs if they are covered under large group health plans; and provide that a second 24-month waiting period is not required for disability-based reentitlement if the current impairment is the same as or directly related to the impairment on which the previous period of entitlement was based. The

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rule ensures clear understanding of these rights for applicants and recipients. This rule also reflects several technical and clarifying changes.

Timetable:

Action	Date	FR Cite
Final Rule With Comment Period	05/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Margaret Jefferson, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-07-22, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4482

RIN: 0938-AH33

1132. • MEDICARE PROGRAM: PHYSICIAN FEE SCHEDULE UPDATE FOR CALENDAR YEAR 1996 AND PHYSICIAN VOLUME PERFORMANCE STANDARD RATES OF INCREASE FOR FEDERAL FISCAL YEAR 1996 (BPD-853-FN)

Priority: Other Significant

Legal Authority: 42 USC 1395w-4

CFR Citation: None

Legal Deadline: Final, Statutory, October 31, 1996.

Abstract: This notice announces the calendar year 1997 updates to the Medicare physician fee schedule and the Federal fiscal year 1997 performance standard rates of increase for expenditures and volume of physicians' services under the Medicare Supplementary Medical Insurance (Part B) program as required by sections 1848(d) and (f) of the Social Security Act.

Timetable:

Action	Date	FR Cite
Final Notice	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Terrence Kay, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-10-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4497

RIN: 0938-AH41

1133. • MEDICARE PROGRAM: MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATES BEGINNING JANUARY 1, 1997 (OACT-052-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395r

CFR Citation: None

Legal Deadline: Final, Statutory, September 30, 1996.

Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in the Medicare Supplementary Insurance (SMI) program for the 12 months beginning January 1, 1997. It also announces the monthly SMI premium rate to be paid by all enrollees during the 12 months beginning January 1, 1997.

Timetable:

Action	Date	FR Cite
Final Notice	09/30/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Carter Warfield, Director, Division of Supplementary Medical Insurance, Office of the Actuary, Department of Health and Human Services, Health Care Financing Administration, N3-26-00, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6396

RIN: 0938-AH42

1134. • MEDICAID: LIMITATIONS ON AGGREGATE PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS; FEDERAL FISCAL YEAR 1996 (FINAL) (MB-100-N)

Priority: Other Significant

Legal Authority: 42 USC 1396r-4

CFR Citation: 42 CFR 447.297; 42 CFR 447.298; 42 CFR 447.299

Legal Deadline: Final, Statutory, April 1, 1996.

Abstract: This notice announces the final Federal fiscal year 1996 national target and individual State allotments for Medicaid payments made to hospitals that serve a disproportionate

number of Medicaid recipients and low-income patients with special needs.

Timetable:

Action	Date	FR Cite
Notice	06/00/96	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Richard Strauss, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-18-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-2019

RIN: 0938-AH44

1135. • PART A PREMIUM FOR 1997 FOR THE UNINSURED AGED FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (OACT-053-N)

Priority: Other Significant

Legal Authority: 42 USC 1395i-2; 42 USC 1395i-20

CFR Citation: None

Legal Deadline: Final, Statutory, September 30, 1995.

Abstract: This notice announces the hospital insurance premium for calendar year 1997 under the Medicare's hospital insurance program (Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. The uninsured aged are those individuals who are not insured under the Social Security or Railroad Retirement Acts and do not otherwise meet the requirements for entitlement to Medicare Part A. The disabled beneficiaries are those who lose monthly Social Security cash payments because they returned to work even though their disability continues. Section 1818(d) of the Social Security Act specifies the method to be used to determine this amount.

Timetable:

Action	Date	FR Cite
Final Notice	09/00/96	

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: John Wandishin, Office of the Actuary, Department of Health and Human Services, Health

HHS—HCFA

Final Rule Stage

Care Financing Administration, N3-36-24, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-6389
RIN: 0938-AH45

1136. • INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR 1997 (OACT-054-N)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1395e
CFR Citation: None

Legal Deadline: Final, Statutory, September 15, 1996.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1997 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulas to be used to determine these amounts.

Timetable:

Action	Date	FR Cite
Final Notice	09/00/96	

Small Entities Affected: None

Government Levels Affected: None
Agency Contact: John Wandishin, Office of the Actuary, Department of Health and Human Services, Health Care Financing Administration, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-6389
RIN: 0938-AH46

1137. • REQUIREMENTS FOR ENROLLMENT OF MEDICAID RECIPIENTS UNDER COST EFFECTIVE EMPLOYER-BASED GROUP HEALTH PLANS (MB-047-F)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1396a(a)10; 42 USC 1396a(u)(1); 42 USC 1396d(a); 42 USC 1396a(a)(25); 42 USC 1396a(e); 42 USC 1396e

CFR Citation: 42 CFR 435.2; 42 CFR 435.3; 42 CFR 435.10; 42 CFR 435.186; 42 CFR 435.188

Legal Deadline: None

Abstract: This rule will amend our regulations to provide for continuation of payment of health insurance premiums for individuals who are entitled to elect COBRA continuation coverage under a group health plan

provided by an employer with 75 or more employees; require Medicaid recipients to apply for enrollment in employer-based cost effective group health plans as a condition of Medicaid eligibility; require State agencies to pay for premiums, deductibles, coinsurances and other cost sharing obligations under employer-based cost effective group health plans, and define "COBRA continuation coverage" and "COBRA beneficiaries."

Timetable:

Action	Date	FR Cite
NPRM	06/04/94	59 FR 31569
NPRM Comment Period End	08/19/94	
Final Action	10/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Mark Ross, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-20-20, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-5855

RIN: 0938-AH48

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Health Care Financing Administration (HCFA)

Long-Term Actions

1138. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (BPD-309-F)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395k; 42 USC 1395m(b); 42 USC 1395u(b)and(h); 42 USC 1395w(4); 42 USC 1395x(b)and(s)and(v); 42 USC 1395y(a)(14); 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395ww; 42 USC 1395xx; 42 USC 1395zz

CFR Citation: 42 CFR 414.1; 42 CFR 414.2; 42 CFR 414.5; 42 CFR 405.556; 42 CFR 431.54; 42 CFR 447.342

Legal Deadline: None

Abstract: This rule will incorporate provisions of the Deficit Reduction Act of 1984, COBRA '85, OBRA '86, OBRA '87, TMRA '88, OBRA '89, and OBRA '90 regarding payment and "assignment" for diagnostic clinical laboratory tests establishing in

regulations the methods for implementing fee schedules. This rule would set forth the methods by which the fee schedules would be updated and would allow certain adjustments for exceptions to the fee schedule. It will also reflect a statutory revision mandated by OBRA '93.

Timetable:

Action	Date	FR Cite
NPRM	08/18/93	58 FR 43156
NPRM Comment Period End	10/18/93	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Charles Spalding, Division of Ambulatory Care Services, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-05-24, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-4496
RIN: 0938-AB50

1139. PARTICIPATION IN CHAMPUS AND CHAMPVA, HOSPITAL ADMISSIONS FOR VETERANS, DISCHARGE RIGHTS NOTICE, AND HOSPITAL RESPONSIBILITY FOR EMERGENCY CARE (BPD-393-F)

Priority: Other Significant

Legal Authority: 42 USC 1395x; 42 USC 1395cc; 42 USC 1395dd

CFR Citation: 42 CFR 488.18; 42 CFR 489.20; 42 CFR 489.24; 42 CFR 489.25; 42 CFR 489.26; 42 CFR 489.27; 42 CFR 489.53; 42 CFR 1003

Legal Deadline: None

Abstract: This final rule will require Medicare participating hospitals with emergency departments to provide upon request medical examinations and treatments for individuals with emergency medical conditions and

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Long-Term Actions

women in labor. A participating hospital that has specialized capabilities or facilities (such as burn, shock trauma, or neonatal intensive care units) must accept an appropriate transfer if they have the capacity to treat the individual. Hospitals failing to meet those requirements may have their Medicare provider agreements terminated, and hospitals and responsible physicians may be subject to civil money penalties. Under section 9122 of OBRA '85, Medicare participating hospitals are required to accept CHAMPUS and CHAMPVA payment as payment in full for services provided to CHAMPUS and CHAMPVA beneficiaries. These regulations also implement section 9305(b) of OBRA '86, which requires Medicare hospitals to give patients a notice of their discharge rights.

Timetable:

Action	Date	FR Cite
NPRM	06/16/88	53 FR 22513
NPRM Comment Period End	08/15/88	
Final Rule With Comment Period	06/22/94	59 FR 32086
Effective Date	07/22/94	
Comment Period End	08/22/94	
Final Action	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director, Division of Hospital Service, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-1304

RIN: 0938-AC58

1140. MEDICARE SECONDARY PAYER FOR DISABLED INDIVIDUALS (BPD-482-F)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395y(b)

CFR Citation: 42 CFR 411

Legal Deadline: None

Abstract: This rule will implement the Medicare secondary payer (MSP) provision for disabled individuals who

are covered under large group health plans (LGHPs). Under this provision LGHPs may not take into account that such individuals are entitled to Medicare. The rule contains procedures under which a plan can appeal a determination of nonconformance which could lead to an excise tax. It reflects statutory revisions mandated by OBRA '86, OBRA '89, and OBRA '93, some of which also affect the MSP provisions for persons who are entitled on the basis of age or end-stage renal disease.

Timetable:

Action	Date	FR Cite
NPRM	03/08/90	55 FR 8491
NPRM Comment Period End	05/08/90	
Final Rule With Comment Period	08/31/95	60 FR 45344
Effective Date	10/02/95	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Herbert Pollock, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-08-14, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4474

RIN: 0938-AD73

1141. NEW MINIMUM STANDARDS FOR MEDICARE SUPPLEMENTAL (MEDIGAP) POLICIES (BPD-491-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1395ss

CFR Citation: 42 CFR 403.200; 42 CFR 403.205; 42 CFR 403.206; 42 CFR 403.210; 42 CFR 403.215; 42 CFR 403.216; 42 CFR 403.220; 42 CFR 403.222; 42 CFR 403.232; 42 CFR 403.239; 42 CFR 403.250 to 403.258

Legal Deadline: None

Abstract: This rule would organize and codify in regulations the statutory changes to Medigap provisions made in 1987, 1988, 1989, 1990 and 1994. It will contain specific procedures for review of State regulatory plans (and

individual policies) as required in OBRA '90. The new standards were enacted by OBRA '87, and '90, the Medicare Catastrophic Coverage Act of 1988, the Medicare Catastrophic Coverage Repeal Act of 1989, and the Social Security Act Amendments of 1994. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Julie Walton, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-08-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4622

RIN: 0938-AD82

1142. SURVEY REQUIREMENTS AND ALTERNATIVE SANCTIONS FOR HOME HEALTH AGENCIES (HSQ-169-F)

Priority: Other Significant

Legal Authority: 42 USC 1395w-2; 42 USC 1395bbb; 42 USC 1395hh

CFR Citation: 42 CFR 488; 42 CFR 489; 42 CFR 498

Legal Deadline: None

Abstract: These rules will establish periodic, unannounced surveys of home health agencies (HHAs) and other survey requirements and also will specify a number of sanctions that could be used, when an HHA is out of compliance with Federal requirements, as an alternative or in addition to terminating an HHA's participation in the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	08/02/91	56 FR 37054
NPRM Comment Period End	10/01/91	
Final Action	00/00/00	

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Local, Federal

Agency Contact: Frank Sokolik, Center for Hospital and Community Care,

HHS—HCFA

Long-Term Actions

Health Standards and Quality Bureau,
Department of Health and Human
Services, Health Care Financing
Administration, S2-13-23, 7500
Security Blvd., Baltimore, MD 21244
Phone: 410 786-7089

RIN: 0938-AE39

**1143. EARLY AND PERIODIC
SCREENING, DIAGNOSTIC, AND
TREATMENT (EPSDT) SERVICES (MB-
28-F)**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a(a)(43);
42 USC 1396d(r)

CFR Citation: 42 CFR 441.50; 42 CFR
440.40

Legal Deadline: None

Abstract: Section 1905(r) of the Social Security Act, added by section 6403 of OBRA '89 defines the following EPSDT services: screening services, vision services, dental services and hearing services. EPSDT services also are defined to include such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects, illnesses and conditions discovered by the screening services whether or not the services are covered under the State plan. Section 1902(a)(43) of the Act requires States to report to the Secretary certain information about EPSDT services provided under the plan during each fiscal year. This rule would set forth requirements to implement these statutory provisions.

Timetable:

Action	Date	FR Cite
NPRM	10/01/93	58 FR 51288
NPRM Comment Period End	11/30/93	
Final Action	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: State,
Local

Agency Contact: Robert Wardwell,
Director, Office of Medical & Remedial
Care Services, Medicaid Bureau,
Department of Health and Human
Services, Health Care Financing
Administration, C4-14-17, 7500
Security Boulevard, Baltimore, MD
21244

Phone: 410 786-3254

RIN: 0938-AE72

**1144. FIRE SAFETY STANDARDS FOR
HOSPITALS, LONG-TERM CARE
FACILITIES, AMBULATORY
SURGICAL CENTERS, HOSPICES,
AND INTERMEDIATE CARE
FACILITIES FOR THE MENTALLY
RETARDED (BPD-650-FC)**

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

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

CFR Citation: 42 CFR 482.41(b)(1); 42
CFR 483.70(a); 42 CFR
483.470(j)(2)(i)(C); 42 CFR 416.44(b); 42
CFR 418.100(d); 42 CFR 483.470(j)(1)

Legal Deadline: None

Abstract: This final rule with comment period will revise the fire safety standards for hospitals, long term care facilities participating in Medicare and Medicaid, intermediate care facilities for the mentally retarded, ambulatory surgical centers and hospices. It deletes references to the 1967 and 1973, 1981, and 1985 editions of the Life Safety Code (LSC) of the National Fire Protection Association and requires compliance with only the 1994 edition of the LSC. This is a part of the Department's regulatory reinvention initiative.

Timetable:

Action	Date	FR Cite
NPRM	08/01/90	55 FR 31196
NPRM Comment Period End	10/01/90	
Final Action	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: James Kenton,
Division of Skilled Nursing Care,
Bureau of Policy Development,
Department of Health and Human
Services, Health Care Financing
Administration, C4-11-06, 7500
Security Blvd., Baltimore, MD 21244
Phone: 410 786-5629

RIN: 0938-AE97

**1145. CHANGES TO THE LONG-TERM
CARE FACILITY SURVEY PROCESS
(HSQ-175-FC)**

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority: PL 101-239, Sec
6901(a); 42 USC 1395i-3; 42 USC
1395aa(d); 42 USC 1396r

CFR Citation: 42 CFR 442; 42 CFR 488

Legal Deadline: None

Abstract: This final rule with comment period will amend the Medicare and Medicaid regulations by removing obsolete long-term care survey forms, guidelines, and procedures used by State agencies when they evaluate a Medicare skilled nursing facility or a Medicaid nursing facility for compliance with Federal certification requirements. Effective October 1, 1990, the application of new Federal participation requirements for these facilities with an increased focus on actual or potential resident outcomes has made the survey forms and process in existing regulations outdated. Retention of the outdated items can cause confusion in connection with directions State survey agencies must follow in determining facility compliance.

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective Date	10/19/94	
Interim Final Rule Comment Period End	11/18/94	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information:

TIMETABLE: This regulation may be published only with the concurrence of the U.S. District Court in the Smith v. Shalala suit.

Agency Contact: Helene Fredeking,
Codirector, Center for Long Term Care,
Health Standards and Quality Bureau,
Department of Health and Human
Services, Health Care Financing
Administration, S2-21-27, 7500
Security Boulevard, Baltimore, MD
21244

Phone: 410 786-7304

RIN: 0938-AF02

HHS—HCFA

Long-Term Actions

1146. CASE MANAGEMENT (MB-27-F)**Priority:** Other Significant**Legal Authority:** 42 USC 1396d; 42 USC 1396n**CFR Citation:** 42 CFR 431.51(c); 42 CFR 440.169; 42 CFR 440.250; 42 CFR 441.10; 42 CFR 441.18; 42 CFR 447.327; 42 CFR 431.54**Legal Deadline:** None**Abstract:** This rule will place into our regulations provisions of COBRA '85, OBRA '86, TEFRA '86, OBRA '87 and TMRA '88 dealing with case management services. These regulations will provide for optimal Medicaid coverage of case management services furnished to specific groups in specific geographic areas or political subdivisions within a State.**Timetable:**

Action	Date	FR Cite
NPRM	10/15/93	58 FR 53481
NPRM Comment Period End	12/14/93	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** State, Local**Agency Contact:** Robert Wardwell, Office of Medical and Remedial Care Services, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-25-07, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-5659

RIN: 0938-AF07

1147. PRESUMPTIVE LIMITS ON PAYMENTS TO HMOS, CMPS, AND HCPPS (OMC-006-F)**Priority:** Other Significant**Legal Authority:** 42 USC 1395mm(h); 42 USC 1395x(v)(1)(A)**CFR Citation:** 42 CFR 417.532(a)(3); 42 CFR 417.802; 42 CFR 417.800(c)**Legal Deadline:** None**Abstract:** This rule will establish presumptive limits for Medicare cost payments to Health Maintenance Organizations and Competitive Medical Plans, and to Health Care Prepayment Plans (HCPPs) that furnish inpatient hospital care. It will also revise the criteria that HCFA uses to determine reasonable costs for HCPPs that do not furnish inpatient hospital care. This

rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	02/22/94	59 FR 8435
NPRM Comment Period End	04/25/94	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** A. G. D'Albarto, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1100

RIN: 0938-AF16

1148. PARTIAL HOSPITALIZATION SERVICES IN COMMUNITY MENTAL HEALTH CENTERS (BPD-736-F)**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395k(a)(2)(J); 42 USC 1395x(ff); 42 USC 1395cc(e)(2)**CFR Citation:** 42 CFR 400; 42 CFR 410; 42 CFR 413; 42 CFR 489; 42 CFR 498**Legal Deadline:** None**Abstract:** In accordance with section 4162 of OBRA '90, this rule sets forth the coverage criteria and payment methodology for partial hospitalization services furnished in community mental health centers. Also in accordance with the law, the rule will specify the requirements a community mental health center must meet in order to enter into a Medicare provider agreement to furnish partial hospitalization services. This final rule will respond to public comments to the interim rule published on February 2, 1994.**Timetable:**

Action	Date	FR Cite
Interim Final Rule	02/11/94	59 FR 6570
Effective Date	03/13/94	
Comment Period End	04/12/94	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Janet Samen, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-08-15, 7500

Security Boulevard, Baltimore, MD 21244

Phone: 410 786-9161

RIN: 0938-AF53

1149. INTERMEDIARY AND CARRIER FUNCTIONS (BPO-111-F)**Priority:** Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 42 USC 1395h; 42 USC 1395u**CFR Citation:** 42 CFR 421.100; 42 CFR 421.200**Legal Deadline:** None**Abstract:** Current regulations list functions that intermediaries and carriers must perform. All intermediaries and all carriers must perform all the enumerated functions. This rule changes the regulations to bring them into greater conformance with the Medicare statute, which gives the Health Care Financing Administration flexibility to move some functions from one contractor to another to reduce inefficiency, lower cost or achieve better program administration. This rule is part of HCFA's regulatory reform initiative.**Timetable:**

Action	Date	FR Cite
NPRM	02/22/94	59 FR 8446
NPRM Comment Period End	04/25/94	
Notice to Reopen Comment Period	07/17/94	59 FR 35664
Comment Period End	10/11/94	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Alan Bromberg, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S2-01-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7441

RIN: 0938-AG06

HHS—HCFA

Long-Term Actions

1150. END-STAGE RENAL DISEASE (ESRD) PAYMENT EXCEPTION REQUESTS AND ORGAN PROCUREMENT COSTS (BPD-763-F)**Priority:** Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 42 USC 1395rr**CFR Citation:** 42 CFR 413.170; 42 CFR 413.172; 42 CFR 413.174; 42 CFR 413.176; 42 CFR 413.178; 42 CFR 413.179; 42 CFR 413.180; 42 CFR 413.182; 42 CFR 413.184; 42 CFR 413.186; 42 CFR 413.188; 42 CFR 413.190; 42 CFR 413.192; 42 CFR 413.194; 42 CFR 413.196; ...**Legal Deadline:** None**Abstract:** This final rule will specify the criteria HCFA will use to determine if a facility furnishing dialysis services to patients with end-stage renal disease qualifies for a higher payment under an exception to the prospectively determined payment rate; and the procedures used to evaluate ESRD payment exceptions requests. The rule will also revise the way HCFA computes acquisition costs for organs that are transplanted into Medicare beneficiaries. The rule is part of the Department's regulatory reinvention initiative.**Timetable:**

Action	Date	FR Cite
NPRM	08/26/94	59 FR 44097
NPRM Comment Period End	10/25/94	
Final Action	00/00/00	

Small Entities Affected: Businesses**Government Levels Affected:** State**Additional Information:** CFR CITATIONS (CONTINUED) 42 CFR 412.113 42 CFR 413.202 42 CFR 413.203**Agency Contact:** Michael Powell, Health Insurance Specialist, Division of End-Stage Renal Disease, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4557**RIN:** 0938-AG20**1151. NONCOVERAGE OF ELECTROSTIMULATION OF SALIVARY GLANDS FOR THE TREATMENT OF XEROSTOMIA (DRY MOUTH) (BPD-782-FN)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395y(a)(1)(A)**CFR Citation:** None**Legal Deadline:** None**Abstract:** This notice announces the Medicare program's intent to exclude from coverage electrostimulation of the salivary glands in the treatment of xerostomia secondary to Sjogren's Syndrome. Public Health Service (PHS) studies show that there is insufficient data to establish the clinical utility of electrostimulation to evaluate its long-term effectiveness, or to identify those xerostomia patients who would benefit from this procedure. Also, PHS reports that electrostimulation is not widely accepted as a treatment for xerostomia secondary to Sjogren's Syndrome.**Timetable:**

Action	Date	FR Cite
Proposed Notice	05/23/94	59 FR 26653
Comment Period End	07/22/94	
Final Action	00/00/00	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Francina Spencer, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-04-05, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4614**RIN:** 0938-AG45**1152. DISTINCT PART REQUIREMENTS FOR NURSING HOMES AND PROHIBITION OF FINANCIAL SCREENING OF APPLICANTS FOR NURSING HOME ADMISSION (BPD-815-P)****Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 42 USC 1395i-3; 42 USC 1396f**CFR Citation:** 42 CFR 409; 42 CFR 483; 42 CFR 413**Legal Deadline:** None**Abstract:** In this proposed rule we would define "distinct part" by specifying that a distinct part is a physically identifiable unit of an institution (that is, an entire ward wing, floor, or building) including all beds in the unit. In conjunction with this change we propose an alternative approach for calculating Medicare payments to a skilled nursing facility (SNF). This new "distinct costing" procedure would enable a participating SNF to establish a distinct costing area within the SNF for its relatively high intensity residents so that it can isolate and fully capture the routine cost of their care without resorting to the use of arbitrary certification boundaries to achieve this result. This proposed rule would also prohibit nursing homes from financially screening private pay applicants for admission. Instead, nursing homes would be permitted to charge up to a 2-month deposit before admission to ensure that sufficient funds are available to pay for care to which the individual may be entitled.**Timetable:**

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** William Ullman, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-13-15, 7500 Security Blvd, Baltimore, MD 21244
Phone: 401 786-5667**RIN:** 0938-AG84**1153. CLINICAL LABORATORY IMPROVEMENT AMENDMENT (CLIA) FEE SCHEDULES (HSQ-219-FC)****Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 42 USC 263a(m)**CFR Citation:** 42 CFR 493.638; 42 CFR 493.649**Legal Deadline:** None

HHS—HCFA

Long-Term Actions

Abstract: The preamble to this final rule with comment period announces updated fees that laboratories must pay as required by CLIA '88. Fee increases are necessary to meet the costs of program administration, which are to be borne by the laboratories. In addition, technical conforming changes are made to the regulations to ensure consistent and complete references. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Judy Yost, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-09-28, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786-3531

RIN: 0938-AG87

1154. CATEGORIZATION AND CERTIFICATION REQUIREMENTS FOR A NEW SUBCATEGORY OF MODERATE COMPLEXITY TESTING (HSQ-222-F)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 263a

CFR Citation: 42 CFR 493.2; 42 CFR 493.3; 42 CFR 493.5; 42 CFR 493.18; 42 CFR 493.20; 42 CFR 493.21; 42 CFR 493.25; 42 CFR 493.43; 42 CFR 493.45; 42 CFR 493.48; 42 CFR 493.49; 42 CFR 493.51; 42 CFR 493.53; 42 CFR 493.638

Legal Deadline: None

Abstract: This rule would develop criteria for simple and easy-to-use test systems that have demonstrated accuracy and precision through scientific studies. It would waive the routine 2-year survey of users of accurate and precise technology (APT) tests, conducting surveys only if there are indications of problems or complaints. A small number of surveys would be conducted to validate the

criteria for determining APT and to assure quality.

Timetable:

Action	Date	FR Cite
NPRM	09/15/95	60 FR 47982
NPRM Comment Period End	11/14/95	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Anthony Tirone, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6810

RIN: 0938-AG98

1155. MEDICAID COVERAGE OF PERSONAL CARE SERVICES (MB-071-F)

Priority: Other Significant

Legal Authority: 42 USC 1396d(a)(24)

CFR Citation: 42 CFR 440.70; 42 CFR 440.167; 42 CFR 440.170

Legal Deadline: None

Abstract: This rule would revise the Medicaid regulations to incorporate the provisions of OBRA '93 relating to coverage of personal care services. Personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded or an institution for mental disease are an optional Medicaid benefit, effective October 1, 1994. The services may be furnished both in the home and in other locations.

Timetable:

Action	Date	FR Cite
NPRM	03/08/96	61 FR 9405
NPRM Comment Period End	05/07/96	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Terese Klitenic, Office of Long Term Care Services, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-25-02, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-5942

RIN: 0938-AH00

1156. AMBULANCE SERVICES (BPD-813-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1861(s)(7)

CFR Citation: 42 CFR 410.40

Legal Deadline: None

Abstract: This proposed rule would revise HCFA's policy on Medicare coverage of ambulance services. It focuses on the medical necessity for ambulance service, redefines an ambulance as an "emergency vehicle" and revises the policy on coverage of non-emergency ambulance transportation for beneficiaries with end-stage renal disease. These changes would prevent use of non-emergency vehicles and the use of ambulance transportation in non-emergency situations where the medical need has not clearly been determined. These changes require the use of emergency vehicles as ambulances and would focus on the medical treatment rather than transportation as the primary concern for furnishing ambulance services, as required by Title XVIII, Section 1861(s)(7) of the Social Security Act. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Margot Blige, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4642

RIN: 0938-AH13

1157. ADJUSTMENT IN PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES (BPD-831-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

HHS—HCFA

Long-Term Actions

Legal Authority: 42 USC 1395k(a)(2); 42 USC 1395l; 42 USC 1395z; 42 USC 1395aa; 42 USC 2630

CFR Citation: 42 CFR 416

Legal Deadline: NPRM, Statutory, October 31, 1995.

Abstract: This rule would establish a process under which interested parties could request, with respect to a class of new technology intraocular lenses (IOLs), a review of the appropriateness of the current payment amount for IOLs furnished by Medicare-participating ASCs. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Cathaleen Ahern, Office of Physician & Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-09-24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4515

RIN: 0938-AH15

1158. MEDICARE COVERAGE OF LIVER TRANSPLANTATION (BPD-835-PN)

Priority: Other Significant

Legal Authority: 42 USC 1395y(a)(1)(A)

CFR Citation: None

Legal Deadline: None

Abstract: This proposed notice would announce changes in Medicare's national coverage policy for liver transplantations. Currently, Medicare coverage for liver transplantation in adults is limited to seven diagnoses. This notice proposes to expand the diagnoses for which Medicare would cover a liver transplant to include all end stage liver disease except malignancies, hepatitis B, and hemochromatosis. We are also proposing a change in the criteria for approval of a facility to perform liver transplants.

Timetable: Next Action Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Lana Price, Director, Division of End Stage Renal Disease, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4533

RIN: 0938-AH17

1159. • CLIA PROGRAM: CYTOLOGY PROFICIENCY TESTING (HSQ-233-P)

Priority: Other Significant

Legal Authority: 42 USC 263a(f)(4)(B)(IV)

CFR Citation: 42 CFR 493.855

Legal Deadline: None

Abstract: In this proposal, HHS is complying with a court order requiring publication of a proposed rule to require that cytology proficiency testing be conducted to the extent practicable, under normal working conditions. We propose to revise regulations to require that proficiency testing be conducted at a pace corresponding to the maximum workload rate for individuals examining slides. We also solicit comments on the use of computer facsimile representations of cytology specimens, as an alternative to glass-slide proficiency testing.

Timetable:

Action	Date	FR Cite
NPRM	11/30/95	60 FR 61509
NPRM Comment Period End	01/29/96	60 FR 61509
Final Action	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Rhonda Whalen, Senior Health Scientist, Department of Health and Human Services, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS F 11, Atlanta, GA 30341-3724

Phone: 770 488-7670

RIN: 0938-AH35

1160. • LIMITS ON ACTUAL CHARGES OF NONPARTICIPATING PHYSICIANS (BPD-862-P)

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in

the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395rr(b)(1)

CFR Citation: 42 CFR 414.48

Legal Deadline: None

Abstract: This proposed rule would reflect provisions of OBRA '93 as to the suppliers subject to the charge limits, and provisions of SSA '94 as to administrative procedures for enforcing the charge limits. This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Anita Heygster, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-04-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4486

RIN: 0938-AH50

1161. • MEDICARE SECONDARY PAYER CLARIFICATIONS AND AMENDMENTS (BPD-865-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 411

Legal Deadline: None

Abstract: This regulation is necessary to clarify and amend various Medicare secondary payer regulations. For instance, we wish to incorporate in regulations, policies with respect to liability insurance issues, such as structured liability settlements, future medical expenses, provider malpractice, wrongful death, and Federal tort claims policy. Also, we wish to clarify the rules dealing with group health plan bankruptcies, religious orders, and foreign group health plans, and make numerous other changes.

HHS—HCFA

Long-Term Actions

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Dave Holstein, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-08-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4476

RIN: 0938-AH52

1162. • PAYMENT FOR HOSPITAL OUTPATIENT RADIOLOGY SERVICES AND OTHER DIAGNOSTIC PROCEDURES (BPD-861-FC)

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

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

CFR Citation: 42 CFR 413.122

Legal Deadline: None

Abstract: The rule revises section 413.133 to remove references to payment blend effective prior to

January 1, 1991. This rulemaking is part of the Reinventing Government effort. It will eliminate text in the CFR to reduce burden or duplication, or streamline requirements.

Timetable: Next Action Undetermined

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Janet Wellham, Health Policy Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-13-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4510

RIN: 0938-AH53

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Health Care Financing Administration (HCFA)

1163. FEE SCHEDULE FOR PAYMENT OF CLINICAL PSYCHOLOGIST SERVICES (BPD-495-P)

Priority: Other Significant

CFR Citation: 42 CFR 414

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Elisa Tunanidas
Phone: 410 786-4505

RIN: 0938-AD84

1164. COVERAGE OF NURSE PRACTITIONER AND CLINICAL NURSE SPECIALIST SERVICES (BPD-708-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 410; 42 CFR 413; 42 CFR 414; 42 CFR 491

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During this Semiannual Period.	03/25/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Roberta Epps
Phone: 410 786-4503

RIN: 0938-AF00

1165. PAYMENT FOR FEDERALLY QUALIFIED HEALTH CENTER (FQHC) SERVICES (BPD-728-F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 405.2401; 42 CFR 405.2430; 42 CFR 405.2446; 42 CFR 405.2448; 42 CFR 405.2450; 42 CFR 405.2463; 42 CFR 405.2466; 42 CFR 405.2468; 42 CFR 491.5; 42 CFR 491.8

Completed:

Reason	Date	FR Cite
Final Action	04/03/96	61 FR 14640
Final Action Effective	05/03/96	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Bernadette Schumaker
Phone: 410 786-4568

RIN: 0938-AF14

1166. FEDERALLY QUALIFIED HEALTH CENTER SERVICES (MEDICAID) (MB-043-P)

Priority: Other Significant

CFR Citation: 42 CFR 440; 42 CFR 447

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David Worgo
Phone: 410 786-5919

RIN: 0938-AF90

1167. MEDICARE APPEALS OF INDIVIDUAL CLAIMS (BPD-453-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 405.732; 42 CFR 405.801; 42 CFR 405.837; 42 CFR 405.838; 42 CFR 405.839; 42 CFR 405.840

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Paul Olenick
Phone: 410 786-4472

RIN: 0938-AG18

HHS—HCFA

Completed Actions

1168. WITHDRAWAL OF COVERAGE OF DIAGNOSTIC NOCTURNAL PENILE TUMESCENCE TESTING (IMPOTENCE TESTING) (BPD-780-FN)**Priority:** Substantive, Nonsignificant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Withdrawn	02/07/96	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Bob Ulikowski
Phone: 410 786-5721**RIN:** 0938-AG43**1169. SCHEDULE OF LIMITS ON HOME HEALTH AGENCY COSTS PER VISIT (BPD-793-N)****Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Final Action	02/14/95	60 FR 8389

Small Entities Affected: Businesses**Government Levels Affected:** None**Agency Contact:** Michael Bussacca
Phone: 410 786-4602**RIN:** 0938-AG54**1170. MEDICAID PROGRAM: NURSE-MIDWIFE SERVICES (MB-085-F)****Priority:** Other Significant**CFR Citation:** 42 CFR 440**Completed:**

Reason	Date	FR Cite
Final Action	11/30/95	60 FR 61483

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Linda Sizelove
Phone: 410 786-3255**RIN:** 0938-AG73**1171. MEDICAID PROGRAM: FEES FOR VACCINE ADMINISTRATION UNDER PEDIATRIC IMMUNIZATION PROGRAM (MB-084-FN)****Priority:** Other Significant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: Governmental Jurisdictions**Government Levels Affected:** State**Agency Contact:** Marge Sciulli
Phone: 410 786-0691**RIN:** 0938-AG77**1172. MEDICAID: NOMINAL COPAYMENTS FOR INSTITUTIONAL SERVICES FOR MEDICAID RECIPIENTS (MB-090-FC)****Priority:** Other Significant**CFR Citation:** 42 CFR 447.54; 42 CFR 447.55**Completed:**

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: None**Government Levels Affected:** State**Agency Contact:** Ingrid Osburne
Phone: 410 786-4461**RIN:** 0938-AG90**1173. MANDATORY MEDIGAP CROSSOVER CLAIMS TRANSMITTAL REQUIREMENTS (BPD-811-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 403.206; 42 CFR 403.212; 42 CFR 403.222; 42 CFR 403.232; 42 CFR 403.204; 42 CFR 424.68**Completed:**

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During this Semi-annual Period.	03/25/96	

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Thomas Hoyer,
Director
Phone: 410 786-5661**RIN:** 0938-AG94**1174. MEDICARE PROGRAM: CHANGES TO THE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1996 RATES (BPD-825-FC)****Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**CFR Citation:** 42 CFR 412; 42 CFR 413**Completed:**

Reason	Date	FR Cite
Final Action	09/01/95	60 FR 45778

Small Entities Affected: Businesses, Organizations**Government Levels Affected:** State, Federal**Agency Contact:** Nancy Edwards
Phone: 410 786-4531**RIN:** 0938-AG95**1175. MEDICARE PROGRAM: REVISIONS TO PAYMENT POLICIES AND ADJUSTMENTS TO THE RELATIVE VALUE UNITS (RVUS) UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996 (BPD-827-FC)****Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**CFR Citation:** 42 CFR 400; 42 CFR 405; 42 CFR 410; 42 CFR 411; 42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 415; 42 CFR 417; 42 CFR 489**Completed:**

Reason	Date	FR Cite
Final Action	12/08/95	60 FR 63124

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Terrence Kay

HHS—HCFA

Completed Actions

Phone: 410 786-4497

RIN: 0938-AG96

1176. MEDICARE PROGRAM: COVERAGE OF CERTIFIED NURSE-MIDWIFE SERVICES (BPD-496-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 405; 42 CFR 410; 42 CFR 486

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Roberta Epps
Phone: 419 786-4503

RIN: 0938-AH02

1177. MEDICARE PROGRAM: PHYSICIAN FEE SCHEDULE UPDATE FOR CALENDAR YEAR 1996 & PHYSICIAN VOLUME PERFORMANCE STANDARD RATES OF INCREASE FOR FEDERAL FISCAL YEAR 1996 (BPD-828-FN)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	12/08/95	60 FR 63358

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Terrence Kay
Phone: 410 786-4497

RIN: 0938-AH03

1178. PART A PREMIUM FOR 1996 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (OACT-051-N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	10/16/95	60 FR 53631

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Wandishin
Phone: 410 786-6389

RIN: 0938-AH06

1179. MEDICARE PROGRAM: MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATES BEGINNING JANUARY 1, 1996 (OACT-050-N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	10/16/95	60 FR 53626

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Carter Warfield
Phone: 410 786-6396

RIN: 0938-AH07

1180. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR 1996 (OACT-049-N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	10/16/95	60 FR 53625

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Wandishin
Phone: 410 786-6389

RIN: 0938-AH08

1181. LIMITATIONS ON AGGREGATE PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS: FEDERAL FISCAL YEAR 1995 (MEDICAID PROGRAM) (MB-094-N)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 447.297; 42 CFR 447.298; 42 CFR 447.299

Completed:

Reason	Date	FR Cite
Final Action	09/08/95	60 FR 46838

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Richard Strauss
Phone: 410 786-2019

RIN: 0938-AH09

1182. PROVISIONS THAT ALLOW RURAL PRIMARY CARE HOSPITALS (RPCHS) TO ENTER INTO SWING-BED AGREEMENTS (BPD-839-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 485.645

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During this Semi-annual Period.	03/25/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: George Morey
Phone: 410 786-4653

RIN: 0938-AH20

1183. TRANSFER OF ASSETS FOR LESS THAN FAIR MARKET VALUE: MEDICAID PROGRAM (MB-095-P)

Priority: Other Significant

CFR Citation: 42 CFR 435; 42 CFR 436

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During this Semi-annual Period.	03/25/96	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Roy Trudel
Phone: 410 786-3417

RIN: 0938-AH23

1184. EVIDENCE OF LAWFUL PERMANENT RESIDENCE (MB-097-P)

Priority: Other

CFR Citation: 42 CFR 435.406; 42 CFR 435.408

Completed:

Reason	Date	FR Cite
Withdrawn - Publication Not Expected During This Semiannual Period	04/01/96	

Small Entities Affected: None

HHS—HCFA

Completed Actions

Government Levels Affected: State, Local

Agency Contact: Robert Tomlinson
Phone: 410 786-4463

RIN: 0938-AH25

1185. CLIA PROGRAM; GRANTING AND WITHDRAWAL OF AUTHORITY TO PRIVATE NONPROFIT ACCREDITATION ORGANIZATIONS AND OF CLIA EXEMPTION UNDER STATE LABORATORY PROGRAMS; TECHNICAL CORRECTIONS (HSQ-205-FC)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

CFR Citation: 42 CFR 493.501; 42 CFR 493.506; 42 CFR 493.513; 42 CFR 493.515; 42 CFR 493.521

Completed:

Reason	Date	FR Cite
Withdrawn - To Be Merged Into RIN 0938-AE47 (HSQ-226-F)	02/12/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Josephine Simmons
Phone: 410 786-3409

RIN: 0938-AH32

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Proposed Rule Stage

Administration for Children and Families (ACF)

1186. FOSTER CARE, ADOPTION ASSISTANCE, AND CHILD WELFARE SERVICES

Priority: Other Significant

Legal Authority: 42 USC 627; 42 USC 671; 42 USC 1320

CFR Citation: 45 CFR 1355; 45 CFR 1356; 45 CFR 1357

Legal Deadline: NPRM, Statutory, July 1, 1995.

Abstract: This NPRM will propose requirements that implement the statutory provisions of the Social Security Act Amendments of 1994 on review of State programs under Parts B and E of the Social Security Act for conformity with State Plan requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: This action was previously reported under RIN 0980-AA08.

Agency Contact: Daniel H. Lewis, Deputy Associate Commissioner, Children's Bureau, Adm. on Children, Youth & Families, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8594

RIN: 0970-AA97

1187. BLOCK GRANT PROGRAMS (LOW INCOME HOME ENERGY ASSISTANCE PROGRAM —LIHEAP)—FY 1995 AND FY 1996 PROVISIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 8621

CFR Citation: 45 CFR 96

Legal Deadline: None

Abstract: This Notice of Proposed Rulemaking will amend the DHHS block grant regulations to implement changes to the Low Income Home Energy Assistance Program (LIHEAP) statute which were made by the Human Services Amendments of 1994 (Pub. L. 103-252). Several of the provisions in the new law are self-implementing, but a few require implementing regulations. The major provisions requiring implementing regulations are: (1) Inclusion of new Assurance 16, to require grantees to submit as a part of their annual application a description of their "self-sufficiency" activities and to submit a report to DHHS on the effect of these activities; (2) Inclusion of allowable uses of DOE rules for weatherization services provided with LIHEAP funds; (3) Inclusion for requirements for submission of data on households served. In addition, other related amendments to the regulations will be included, concerning the following issues: (1) Consideration of different weighting of factors under the allocation formula for the leveraging incentive program; (2) Hearing requirements for audit disallowances; and (3) Allotments for territories.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: None

Government Levels Affected: State, Tribal

Agency Contact: Janet M. Fox, Director, Division of Energy Assistance, Office of Community Services, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9351

RIN: 0970-AB47

1188. ADMINISTRATIVE FLEXIBILITY RULE

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 205.31

Legal Deadline: None

Abstract: This proposed rule adds a new section 205.31 which will provide a simple administrative process for requesting waivers of certain AFDC regulatory provisions.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

HHS—ACF

Proposed Rule Stage

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Mack Storrs, Director, Division of AFDC Program, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9289

RIN: 0970-AB49

1189. DESIGNATION OF ALTERNATIVE AGENCY TO SERVE INDIAN TRIBAL CHILDREN

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801, et seq

CFR Citation: 45 CFR 1302

Legal Deadline: None

Abstract: This NPRM will specify a process by which an Indian tribe may identify and establish an alternative agency to provide Head Start Services if the agency previously serving the tribe is terminated.

Timetable:

Action	Date	FR Cite
NPRM	07/00/96	

Small Entities Affected: Organizations

Government Levels Affected: Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB52

1190. CONSTRUCTION OF HEAD START FACILITIES

Priority: Other Significant

Legal Authority: 42 USC 9801, et seq

CFR Citation: 45 CFR 1309

Legal Deadline: None

Abstract: This NPRM will establish procedures to be used by Head Start agencies in requesting to use Head Start grant funds to construct or renovate a Head Start facility.

Timetable:

Action	Date	FR Cite
NPRM	08/00/96	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB54

1191. QUALITY STANDARDS FOR EARLY HEAD START AND HEAD START PROGRAMS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 9801

CFR Citation: 45 CFR 1301; 45 CFR 1302; 45 CFR 1305; 45 CFR 1306; 45 CFR 1308; 45 CFR 1309

Legal Deadline: NPRM, Statutory, May 18, 1995.

Legal deadline only pertains to performance standards.

Abstract: The NPRM will establish performance standards with respect to services provided to children 0 to 5 years old by Early Head Start and Head Start Programs, including health, education, parent involvement, nutritional, social and transitional services, administrative and financial management standards and condition and location of facilities used to carry out activities.

Timetable:

Action	Date	FR Cite
NPRM	04/22/96	61 FR 17754
NPRM Comment Period End	06/21/96	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB55

1192. HEAD START FELLOWSHIP PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801

CFR Citation: 45 CFR 1311

Legal Deadline: None

Abstract: This NPRM will establish the policies and procedures to be used in selecting individuals to be part of the Head Start Fellowship Program.

Timetable:

Action	Date	FR Cite
NPRM	05/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB56

1193. ON-SITE FOSTER CARE ELIGIBILITY REVIEWS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 1356

Legal Deadline: None

Abstract: This NPRM will propose requirements that govern on-site eligibility reviews that the Administration for Children and Families conducts to assure State agencies' compliance with the statutory requirements under Title IV-E of the Social Security Act for eligibility of foster care providers and eligibility of the children in foster care.

Timetable:

Action	Date	FR Cite
NPRM	10/00/96	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Daniel H. Lewis, Deputy Associate, Commissioner, Children's Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8594

RIN: 0970-AB60

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Administration for Children and Families (ACF)

Final Rule Stage

1194. AMENDMENTS TO DEVELOPMENTAL DISABILITIES RULES
Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 6000 et seq**CFR Citation:** 45 CFR 1385; 45 CFR 1386; 45 CFR 1387; 45 CFR 1388**Legal Deadline:** Final, Statutory, April 29, 1991.

Final, Statutory, October 3, 1994.

Abstract: This rule updates current rules with clarifications and new requirements to implement recent changes in the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1990 (Pub. L. 101-496) and 1994 (Pub. L. 103-230).**Timetable:**

Action	Date	FR Cite
NPRM	05/18/95	60 FR 26774
Final Action	07/00/96	

Small Entities Affected: None**Government Levels Affected:** State**Additional Information:** This action was previously reported under RIN 0980-AA48.**Agency Contact:** John Doyle, Director, Administration and Planning Staff, Administration on Developmental Disabilities, Department of Health and Human Services, Administration for Children and Families, 200 Independence Avenue SW., Room 315D, Washington, DC 20201
Phone: 202 690-6590**RIN:** 0970-AB11
1195. CHILD ABUSE AND NEGLECT STATE GRANT PROGRAM
Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 5101**CFR Citation:** 45 CFR 1340**Legal Deadline:** None**Abstract:** The primary purpose of this rule is to revise existing regulations at 45 CFR 1340 in order to implement recent amendments to the Child Abuse Prevention and Treatment Act with respect to confidentiality requirements.**Timetable:**

Action	Date	FR Cite
NPRM	05/18/94	59 FR 26046
Final Action	08/00/96	

Small Entities Affected: None**Government Levels Affected:** State**Agency Contact:** Emily Cooke, Acting Director, National Center on Child Abuse and Neglect, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013

Phone: 202 205-8586

RIN: 0970-AB23
1196. STANDARDS FOR SAFE TRANSPORTATION
Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1310**Legal Deadline:** None**Abstract:** This rule establishes Head Start Performance Standards for the safe transportation of Head Start children, including vehicle requirements, driver qualifications and training and safety rules for children and staff while en route and loading and unloading of vehicles.**Timetable:**

Action	Date	FR Cite
NPRM	08/14/95	60 FR 31612
Final Action	01/00/97	

Small Entities Affected: Organizations**Government Levels Affected:** None**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569**RIN:** 0970-AB24
1197. STANDARDS FOR PURCHASE OF FACILITIES
Priority: Other Significant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1309**Legal Deadline:** None**Abstract:** This regulation establishes standards for the purchase of facilities as required by the Head Start Improvement Act of 1992.**Timetable:**

Action	Date	FR Cite
NPRM	12/01/94	59 FR 61575
Final Action	08/00/96	

Small Entities Affected: Organizations**Government Levels Affected:** None**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013

Phone: 202 205-8569

RIN: 0970-AB31
1198. NATIONAL VOTER REGISTRATION ACT OF 1993 PROVISIONS AFFECTING PUBLIC ASSISTANCE AGENCIES
Priority: Other Significant**Legal Authority:** PL 103-31**CFR Citation:** 45 CFR 205.50 (a)(4); 42 CFR 431.307(a); 42 CFR 431.307 (b)**Legal Deadline:** None**Abstract:** Incorporates general guidance for public assistance agencies regarding registration procedures to be carried out by State Public Assistance offices. It removes former prohibitions from distributing such materials in these offices.**Timetable:**

Action	Date	FR Cite
NPRM	11/22/94	59 FR 60109
Final Action	07/00/96	

Small Entities Affected: Governmental Jurisdictions**Government Levels Affected:** State, Local**Agency Contact:** Mack Storrs, Director, Division of AFDC Program, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447

Phone: 202 401-9289

RIN: 0970-AB32
1199. CHILD CARE—REVISED REGULATIONS
Priority: Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 42 USC 1302**CFR Citation:** 45 CFR 98.255; 45 CFR 98.256; 45 CFR 98.257**Legal Deadline:** None**Abstract:** The Administration for Children and Families will amend

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existing regulations which govern the administration of child care programs under Title IV-A of the Social Security Act (AFDC Child Care, Transitional Child Care, At-Risk Child Care) and the Child Care and Development Block Grant. Based on recent legislative changes, as well as comments from state and tribal program administrators, child care advocates and other interested parties, we are examining a number of specific regulatory provisions. The purpose of this regulatory package will be to implement legislative changes, reduce program differences, and promote better program coordination. We do not expect these changes to result in significant program costs; administrative savings may result.

Timetable:

Action	Date	FR Cite
NPRM	05/11/94	59 FR 24510
Final Action	09/00/96	

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: Olivia M. Golden, Commissioner, Administration on Children, Youth and Families, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8572

RIN: 0970-AB33

1200. FAMILY PRESERVATION AND SUPPORT

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 430 to 435

CFR Citation: 45 CFR 1355; 45 CFR 1356; 45 CFR 1357

Legal Deadline: None

Abstract: This rule will amend the requirements under title IV-B subpart 1 for the Child and Family Services State plan and set forth the requirements the State must adhere to in the development and submission of its comprehensive five year plan under title IV-B, subpart 2, family preservation and support services. The

submission of this jointly developed plan is required in order to receive both child and family services funds under subpart 1 and family preservation and support services funds under subpart 2 for fiscal years 1995 and following.

Timetable:

Action	Date	FR Cite
NPRM	10/04/94	59 FR 50646
Final Action	07/00/96	

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Tribal

Agency Contact: Daniel H. Lewis, Deputy Associate Commissioner, Children's Bureau, ACYF, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8618

RIN: 0970-AB34

1201. ADMINISTRATION FOR NATIVE AMERICANS (ANA) 45 CFR PART 1336

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 2991, et seq

CFR Citation: 45 CFR 1336

Legal Deadline: Final, Statutory, March 29, 1993.

Abstract: This regulation amends 45 CFR part 1336. It will incorporate an appeals procedure affording applicants the opportunity to appeal ANA ineligibility determinations to the HHS Departmental Appeals Board. Native American organizations are expected to welcome these procedural changes.

Timetable:

Action	Date	FR Cite
NPRM	04/21/95	60 FR 19994
Final Action	07/00/96	

Small Entities Affected: Organizations

Government Levels Affected: Tribal

Agency Contact: R. Denise Rodriguez, J.D., Program Specialist, Department of Health and Human Services, Administration for Children and Families, 200 Independence Ave SW., Washington, DC 20201
Phone: 202 690-6265

RIN: 0970-AB37

1202. REDUCTION OF REPORTING REQUIREMENTS FOR THE STATE SYSTEMS ADVANCE PLANNING DOCUMENT (APD) PROCESS

Priority: Other Significant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 95.600

Legal Deadline: None

Abstract: These rules decrease the reporting burden on States and increase their flexibility within the State systems APD process by increasing the threshold under which APDs and related procurement documents need not be submitted for Federal approval. Additionally, States will no longer be required to submit biennial security plans for Federal review and approval.

Timetable:

Action	Date	FR Cite
NPRM	07/24/95	60 FR 34858
NPRM Comment Period End	09/22/95	
Final Action	07/00/96	

Small Entities Affected: Undetermined

Government Levels Affected: None

Procurement: This is a procurement-related action for which there is a statutory requirement. There is no paperwork burden associated with this action.

Agency Contact: Bill Davis, Management Analyst, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-6404

RIN: 0970-AB46

1203. INCOME ELIGIBILITY CRITERIA FOR INDIAN TRIBES

Priority: Substantive, Nonsignificant

Legal Authority: 45 USC 9801, et seq

CFR Citation: 45 CFR 1305

Legal Deadline: None

Abstract: This Final Rule will revise the income eligibility criteria used in enrolling Head Start children and families to allow Indian tribes, in certain situations, to enroll more

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children whose families do not meet Head Start's income criteria than would otherwise be possible.

Timetable:

Action	Date	FR Cite
NPRM	10/25/95	60 FR 54648
NPRM Comment Period End	12/26/95	
Final Action	09/00/96	

Small Entities Affected: Organizations

Government Levels Affected: Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB53

1204. MAKING INFORMATION AVAILABLE TO CONSUMER REPORTING AGENCIES: EXTENSION OF DEADLINE FOR CERTIFIED STATEWIDE SYSTEMS; AND REVISIONS FOR THE PRESIDENT'S REFORM INITIATIVE

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: PL 103-432; PL 104-35

CFR Citation: 45 CFR 301; 45 CFR 302; 45 CFR 303; 45 CFR 304; 45 CFR 306; 45 CFR 307

Legal Deadline: None

Abstract: This rule contains provisions regarding required State laws for reporting information concerning unpaid child support obligations to consumer reporting agencies. These provisions implement the requirements of section 212 of the Social Security Act Amendments of 1994, which amend title IV-D of the Social Security Act. These provisions require States to adopt procedures for periodic reporting of information to consumer reporting agencies. This rule implements PL 104-35; enacted October 12, 1995, which revises section 454(24) of the Social Security Act. This rule also includes technical changes to other child support regulations to support the President's Regulatory Reinvention Initiative.

Timetable:

Action	Date	FR Cite
NPRM	01/29/96	61 FR 2774
NPRM Comment Period End	03/29/96	
Final Action	12/00/96	

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Local

Agency Contact: Marianne Upton, Branch Chief, Policy Division, Office of Child Support Enforcement, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-5373

RIN: 0970-AB57

1205. INCOME AND RESOURCE DISREGARDS RELATED TO INTERESTS OF INDIVIDUAL INDIANS IN TRUST OR RESTRICTED LANDS

Priority: Substantive, Nonsignificant

Legal Authority: PL 103-66

CFR Citation: 45 CFR 233

Legal Deadline: None

Abstract: These rules incorporate statutory disregards in the AFDC program and the Adult Assistance programs in Guam, Puerto Rico and the Virgin Islands. The first provides that up to \$2,000 per year of income derived from interests of individual Indians in trust or restricted lands shall not be considered in determining assistance. The second is a provision requiring that interests of individual Indians in trust or restricted lands shall not be considered a resource in determining eligibility for assistance.

Timetable:

Action	Date	FR Cite
NPRM	10/25/94	59 FR 51536
Final Action	08/00/96	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Mack A. Storrs, Director, Division of AFDC Program, Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9289

RIN: 0970-AB59

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Administration for Children and Families (ACF)

1206. FAMILY VIOLENCE PREVENTION AND SERVICES

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1370

Completed:

Reason	Date	FR Cite
Final Action	02/22/96	61 FR 6791

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local

Agency Contact: Margaret Washnitzer
Phone: 202 401-2333

RIN: 0970-AB18

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Administration on Aging (AOA)
Long-Term Actions
1207. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, INTRASTATE FUNDING FORMULAS; TRAINING, RESEARCH AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; AND GRANTS TO INDIANS & NATIVE HAWAIIANS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority: PL 102-375, sec 202(a)(10); PL 102-375, sec 202(a)(14); PL 102-375, sec 305(a); PL 102-375, sec 305(a)(1); PL 102-375, sec 305(a)(2)(c); PL 102-375, sec 305(a)(2); PL 102-375, sec 305(a)(2)(D); PL 102-375, sec 305(a)(1)(E); PL 102-375, sec 305(a)(2)(E); PL 102-375, secs 305(d)(1) to 305(d)(4); PL 102-375, sec 305(a)(A)(i); PL 102-375, sec 306(a)(6)(O)(i); PL 102-375, sec

306(a)(13); PL 102-375, sec 307(a)(1); PL 102-375, sec 307(a)(C)(i)

CFR Citation: 45 CFR 1321; 45 CFR 1324; 45 CFR 1326; 45 CFR 1327; 45 CFR 1328

Legal Deadline: None
Unknown until law is reauthorized.

Abstract: The Administration on Aging (AoA) anticipates revising current rules to reflect the changes resulting from the pending reauthorization of the Older Americans Act which incorporates greater flexibility for the States.

PURPOSE: The purpose of these revisions is to implement the newly enacted law in the development and provision of community-based services.

Timetable:

OAA Amendments in FY '96
NPRM 08/00/97

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Additional Information: The Administration on Aging, in

consultation with the Office of Management and Budget, has determined that it is no longer necessary to pursue final action on rules earlier proposed to implement the 1992 amendments to the Older Americans Act. The provisions of the Act remain in force and need no further regulations to implement them. AoA anticipates promulgating rules in the latter part of 1997 to implement the provisions to the next reauthorization of the Older Americans Act, if necessary.

Agency Contact: Edwin Walker, Director, Office of Program Development and Operations, Department of Health and Human Services, Administration on Aging, 330 Independence Avenue SW., Room 4733, Cohen Bldg., Washington, DC 20201
Phone: 202 619-0011

RIN: 0985-AA00

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