



Wednesday
October 29, 1997

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 Federal Regulatory and Deregulatory Actions

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 require that the Department semiannually publish an agenda summarizing all rulemaking under development and indicating those regulatory actions being analyzed for impact on small businesses. The Department published its last such agenda on April 25, 1997.

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: The agenda set out below continues to reflect the Department's efforts to exemplify in its rulemaking practices and products the President's initiative to reinvent the Federal regulatory system so that it provides important benefits to the American people while creating fewer burdens. The agenda also reflects emerging policy mandates facing the Department in areas as diverse as welfare reform; health insurance reform; food safety; the combating of waste, fraud, and abuse in the health care system; and children's health.

The Balanced Budget Act (BBA) of 1997 alone includes numerous provisions requiring regulatory action substantially affecting the characteristics and administration of the Medicare Program. These actions will touch upon areas such as Medicare reimbursement rules for graduate medical education, revisions to payment procedures for hospice and home health services, and solvency standards for provider-sponsored organizations.

To address concerns about the integrity of services and quality of care delivered to beneficiaries in need of home health services, the Department will move quickly to implement the BBA requirement for surety bonds for Home Health Agencies. The requirement will help to assure that the agencies providing home health services to Medicare and Medicaid beneficiaries are sound and stable business concerns, legitimately providing protection to that vulnerable population in need of that care.

In addition, the Health Insurance Portability and Accountability Act of 1996, along with its health insurance reforms, gives the Department major new responsibilities concerning health data standards and health record privacy. These provisions require the Secretary to adopt a series of data standards to support electronic data interchange for health insurance and related transactions, such as claims processing and enrollment. The standards will apply to the entire health industry, not just Federal programs.

Underlying these initiatives in 1998 and beyond, there will remain the new focus and discipline that the principles articulated in the President's Executive Order 12866 brought to the Department's regulatory program. Comments are invited to assist the Department in continuing to pursue the President's purposes. Comments should be sent to the addresses listed below, depending on the specific agenda entry that is of interest. Comments may be sent to the Office of the Secretary if the responsible component of the Department is not apparent or if a comment covers subjects crossing agency lines.

For this edition of the Department's regulatory agenda, the most important significant regulatory actions are included in The Regulatory Plan, which appears in Part II of this issue of the **Federal Register**. The Regulatory Plan entries are listed in the Table of Contents below and are denoted by a bracketed bold reference, which directs the reader to the appropriate Sequence Number in Part II.

Health Care Financing Administration: Sue Brown, Director, Division of Regulations and Issuances, 7500 Security Boulevard, C5-09-27,

Baltimore, Maryland 21244; phone 410-786-4473.

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

Administration on Children and Families: Madeline Mocko, Director, Division of Policy and Legislation, 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, 2101 East Jefferson Street, Suite 603, Rockville, Maryland 20852; phone 301-594-1455.

Centers for Disease Control: Dana Weller, Policy Analyst, Office of Program and Planning and Evaluation, Office of the Director, 1600 Clifton Road, Building 16, Mail Stop D23, Atlanta, Georgia 30333; phone 404-639-7077.

Health Resource Services Administration: Dolores R. Etherith, 5600 Fishers Lane, Room 14-A-08, Rockville, Maryland 20857; phone 301-443-1786.

Indian Health Service: Betty Penn, 12300 Twinbrook Parkway, Suite 450, Rockville, Maryland 20857; phone 301-443-1116.

National Institutes of Health: Jerry Moore, 9000 Rockville Pike, Building 31, Room 1B25, Bethesda, Maryland 20892; 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.

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

William V. Corr,
Chief of Staff.

HHS

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1100	Revised OIG Exclusion Authorities Resulting From Public Law 104-191	0991-AA87
1101	Revised OIG Civil Money Penalties Resulting From Public Law 104-191	0991-AA90

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1102	Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute	0991-AA66
1103	Reproduction and Sale of Official Forms and Publications	0991-AA83
1104	Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
1105	Administrative Requirements for Grantees To Reflect Single Audit Act Amendments	0991-AA92
1106	Issuance of Advisory Opinions by the Inspector General	0991-AA94

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1107	Civil Money Penalties (CMPs) for Certain Hospital Physician Incentive Plans	0991-AA45
1108	Civil Money Penalties (CMPs) for Certain Practices Relating to Medicare Supplemental Policies	0991-AA53
1109	Civil Money Penalties for Referrals to Entities and for Prohibited Arrangements and Schemes	0991-AA65
1110	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
1111	Civil Money Penalties for False Information on Drug Manufacturer Price Surveys and Rebate Agreements	0991-AA80
1112	Senior Biomedical Research Services	0991-AA82

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1113	Revised PRO Sanctions for Failing To Meet Statutory Obligations	0991-AA86
1114	Indirect Cost Appeals	0991-AA88

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1115	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
1116	Block Grants for Prevention and Treatment of Substance Abuse	0930-AA01

HHS

Departmental Management—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1117	Implementation of the Equal Access to Justice Act in Agency Proceedings	0990-AA02

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
1118	Investigational New Drug Applications; Request for Information and Comments	0910-AA83
1119	Prescription Drug Compounding	0910-AB13
1120	Exports; Reporting and Recordkeeping Requirements	0910-AB16
1121	Requirements Pertaining to the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents; Use of Nontobacco Trade or Brand Names	0910-AB17

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1122	Over-the-Counter (OTC) Drug Review	0910-AA01
1123	Biological Product Reporting of Errors and Accidents in Manufacturing	0910-AA12
1124	Review of Warnings, Use Instructions, and Precautionary Information Under Section 314 of the National Childhood Vaccine Injury Act of 1986	0910-AA14
1125	Hearing Aids; Professional and Patient Labeling; Conditions for Sale (Reg Plan Seq. No. 24)	0910-AA39
1126	Development of Hazard Analysis Critical Control Points for Certain Unpasteurized Fruit and Vegetable Juices (Reg Plan Seq. No. 25)	0910-AA43
1127	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910-AA49
1128	Bioavailability and Bioequivalence Requirements	0910-AA51
1129	Drugs Used for Treatment of Narcotic Addicts	0910-AA52
1130	Investigational New Drug Applications; Clinical Holds	0910-AA73
1131	Parenteral Drug Products Containing Aluminum as an Ingredient or Contaminant; Labeling Requirements; Warning Statement	0910-AA74
1132	Debarment Certification Regulations for Drug Applications	0910-AA76
1133	Investigational New Drug Applications; Clinical Holds for Drugs for Life-Threatening Illnesses	0910-AA84
1134	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 Applications	0910-AA86
1135	Sterility Requirements for Inhalation Solution Products	0910-AA88
1136	Direct-to-Consumer Promotion Regulations	0910-AA90
1137	Labeling for Human Prescription Drugs; Revised Format	0910-AA94
1138	Adverse Drug Reaction Reporting Requirements for Human Drug and Biological Products; Expedited Reports	0910-AA97
1139	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Labeling of Drugs; Revision of Certain Labeling Controls	0910-AA98
1140	Chlorofluorocarbon Propellants in Self-Pressurized Containers; Determinations That Uses Are No Longer Essential	0910-AA99
1141	Radioactive Drugs for Basic Research	0910-AB00
1142	Investigational New Animal Drug Regulations	0910-AB02
1143	Establishment Registration and Listing of Human Cellular and Tissue-Based Products (Reg Plan Seq. No. 26)	0910-AB05
1144	Definition of Substantial Evidence	0910-AB08
1145	Veterinary Feed Directives: Distributor Notification	0910-AB09
1146	Use of Ozone-depleting Substances in Aerosol Products or Other Pressurized Dispensers; Determinations That Uses Are No Longer Essential	0910-AB10
1147	Clarification of the Scope of Treatment Uses With Investigational New Drugs That Can Be Authorized Under INDs and the Criteria for Charging for Investigational New Drugs Under INDs	0910-AB11
1148	New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification	0910-AB12
1149	Administrative Practices and Procedures; Advisory Opinions and Guidelines	0910-AB14
1150	Medicated Feed Mill Licenses	0910-AB18
1151	Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments; Group 1; Group 2	0910-AB19

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Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1152	Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients (Reg Plan Seq. No. 27)	0910-AB20

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

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1153	New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	0910-AA02
1154	Prescription Drug Marketing Act of 1987; Policy Information, Guidance, and Clarifications	0910-AA08
1155	Mammography Quality Standards Act of 1992	0910-AA24
1156	Tamper-Evident Packaging Requirements for Over-the-Counter Human Drug Products	0910-AA26
1157	Financial Disclosure by Clinical Investigators	0910-AA30
1158	Prescription Drug Product Labeling; Medication Guide	0910-AA37
1159	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals	0910-AA45
1160	New Drug Applications; Drug Master File	0910-AA78
1161	Over-the-Counter Human Drugs; Labeling Requirements (Reg Plan Seq. No. 28)	0910-AA79
1162	Investigational New Drug Applications and New Drug Applications	0910-AA82
1163	Postmarketing Periodic Adverse Experience Reporting Requirements for Human Drug and Licensed Biological Products	0910-AA85
1164	New Drugs for Human Use; Clarification of Requirements for Application Supplements	0910-AA87
1165	Definition of Adequate and Well-Controlled Studies	0910-AB01

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

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1166	Infant Formula: Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910-AA04
1167	Fees for Certification Services; Insulin and Color Additive Certification Programs	0910-AA07
1168	Implementation of the Safe Medical Devices Act of 1990	0910-AA09
1169	Food Labeling Review	0910-AA19
1170	Medical Foods	0910-AA20
1171	Amalgam Ingredient Labeling	0910-AA33
1172	Classification of Computer Software Programs That Are Medical Devices	0910-AA41
1173	Habit-Forming Drugs	0910-AA50
1174	Revocation of Certain Regulations	0910-AA54
1175	Reinventing FDA Food Regulations	0910-AA58
1176	Dietary Supplement Regulations in Response to DSHEA	0910-AA59
1177	Export Requirements for Drugs for Investigational Use in Other Countries	0910-AA61
1178	Reinvention of Administrative Procedures Regulations	0910-AA69
1179	Long-Term Contraceptive Drug Products and Medical Devices; Informed Consent Requirements	0910-AA75
1180	Certification of Drugs Composed Wholly or Partly of Insulin	0910-AA77
1181	Informed Consent for Human Drugs and Biologics; Determination That Informed Consent Is Not Feasible	0910-AA89
1182	FDA Export Reform and Enhancement Act of 1996; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Later Export	0910-AB06
1183	Animal Drug Approvals for Minor Species and Minor Usage	0910-AB07

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Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1184	Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling	0910-AA25
1185	Adverse Experience Expedited Reporting Requirements for Human Drug and Licensed Biological Products	0910-AA28
1186	Latex Condoms: Expiration Date Labeling	0910-AA32
1187	Latex Warning	0910-AA34
1188	Human Tissue Intended for Transplantation	0910-AA40
1189	Changes to an Approved Application	0910-AA57
1190	Export Requirements for Medical Devices	0910-AA62
1191	Adverse Experience Reporting for Human Drug and Licensed Biological Products; Increased Frequency Reports ..	0910-AA72
1192	National Environmental Policy Act; Policies and Procedures	0910-AA80
1193	Current Good Manufacturing Practice for Finished Pharmaceutical; Positron Emission Tomography	0910-AA81
1194	Substances Prohibited From Use in Animal Food or Feed; Protein Derived From Ruminants Prohibited in Ruminant Feed	0910-AA91
1195	Treatment Use of Investigational Device Exemptions	0910-AA92
1196	Revision of the Requirements for a Responsible Head for Biological Establishments	0910-AA93
1197	Disqualification of a Clinical Investigator	0910-AA95
1198	Exemption from Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments	0910-AB03
1199	Content and Format of Labeling for Human Prescription Drugs; Pregnancy Labeling Section; Notice of Public Hearing; Request for Comments	0910-AB15

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1200	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Corporate Shield	0906-AA41
1201	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Charge for Self-Queries	0906-AA42
1202	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906-AA43
1203	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
1204	Health Care Fraud and Abuse	0906-AA46
1205	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Providers: Clarification and Modernization of Regulatory Terms	0906-AA48

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1206	Organ Procurement and Transplantation Network Rules (Reg Plan Seq. No. 29)	0906-AA32
1207	Grants for Residency Training and Advanced Education in the General Practice of Dentistry; Technical Amendments	0906-AA47

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

Health Resources and Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1208	Drug Pricing Program: Prime Vendor User Charge	0906-AA45

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Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1209	Health Education Assistance Loan (HEAL) Program: Lenders'/ Holders' Performance Standards	0906-AA33

Indian Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1210	Acquisition Under the Buy Indian Act	0917-AA00
1211	Indian Child Protection and Family Violence Prevention Act Minimum Standards of Character	0917-AA02

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1212	National Institutes of Health AIDS Research Loan Repayment Program	0925-AA02
1213	Undergraduate Scholarship Program Regarding Professions Needed by the NIH	0925-AA10
1214	Traineeships (Termination Policies)	0925-AA11
1215	Additional DHHS Protections for Pregnant Women and Human Fetuses Involved as Subjects in Research, and Pertaining to Human In Vitro Fertilization	0925-AA14
1216	National Research Service Awards	0925-AA16
1217	Removal of National Cancer Institute Clinical Cancer Education Program	0925-AA17
1218	National Institutes of Health Loan Repayment Program for Research	0925-AA18
1219	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925-AA19
1220	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	0925-AA20

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1221	National Institutes of Health Construction Grants	0925-AA04
1222	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925-AA09

Office of Assistant Secretary for Health—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1223	Standards of Compliance for Abortion-Related Services in Family Planning Service Projects	0937-AA00

Public Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1224	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0905-AE71

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Health Care Financing Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
1225	Medicare Program: Monthly Actuarial Rates and Monthly Supplementary Medicare Insurance Premium Rate Beginning January 1, 1998 (OACT-055-N)	0938-AI03
1226	Medicare Program; Physician Fee Schedule Update for Calendar Year 1998 and Physician Volume Performance Standard Rates of Increase For Federal Fiscal Year 1998 (BPD-893-FN)	0938-AI16
1227	Health Insurance Portability: Newborns' and Mothers' Health Protection (BPD-892-IFC)	0938-AI17

Health Care Financing Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1228	"Without Fault" and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (BPD-719-P)	0938-AD95
1229	Provider Reimbursement Determinations and Appeals (BPD-727-P)	0938-AF28
1230	Conditions of Participation for Rural Health Clinics (BPD-764-P)	0938-AG05
1231	Alternative Sanctions for Renal Dialysis Facilities (HSQ-204-P)	0938-AG31
1232	Effect of Change of Ownership on Provider and Supplier Penalties, Sanctions, Underpayments and Overpayments (HSQ-215-P)	0938-AG59
1233	Medicaid: Optional Coverage of TB-Related Services for Individuals Infected With Tuberculosis (MB-082-P)	0938-AG72
1234	Revision of Medicare Hospital Conditions of Participation (BPD-745-P) (Reg Plan Seq. No. 30)	0938-AG79
1235	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Expanded to Designated Health Services (BPD-809-P)	0938-AG80
1236	End Stage Renal Disease (ESRD) Conditions for Coverage (BPD-818-P) (Reg Plan Seq. No. 31)	0938-AG82
1237	Clinical Laboratory Improvement Amendment (CLIA) Fee Schedule Revision (HSQ-219-GNC)	0938-AG87
1238	Liability for Third Parties To Pay for Care and Services (MB-080-P)	0938-AH01
1239	Definition of Skilled Nursing Facility (SNF) for Coverage of Durable Medical Equipment (DME) (BPD-834-P)	0938-AH16
1240	Additional Supplier Standards (BPD-864-P) (Reg Plan Seq. No. 32)	0938-AH19
1241	State Plan Amendment (SPA) Reconsideration Process (MB-096-P)	0938-AH24
1242	Medicare Coverage of Services of Speech-Language Pathologists and Audiologists (BPD-843-P)	0938-AH37
1243	Payment Amount If Customary Charges Are Less Than Reasonable Costs (BPD-860-FC)	0938-AH49
1244	Supplier Participation Agreements and Limits on Actual Charges of Nonparticipating Physicians (BPD-862-P)	0938-AH50
1245	Revision to Accrual Basis of Accounting Policy (BPD-876-P)	0938-AH61
1246	Medicaid; Estate Recoveries (MB-083-P)	0938-AH63
1247	Medicaid Hospice Care (MB-007-P)	0938-AH65
1248	Provider and Supplier Billing When Medicare Is Secondary Payor to Liability Insurance (BPD-848-P)	0938-AH66
1249	Elimination of Certain Requirements for Peer Review Organizations in the Utilization and Quality Review Process and a Change in the Length of Peer Review Organization Contracts (HSQ-235-FC)	0938-AH68
1250	Update of Ratesetting Methodology, Payment Rates and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective for Calendar Year 1998 (BPD-885-P)	0938-AH81
1251	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (BPD-887-P)	0938-AH83
1252	Disclosure of Peer Review Organization Information in Response to Beneficiary Complaints (HSQ-241-P)	0938-AH85
1253	Medicare Program; Beneficiary Incentives Programs (BPO-144-P)	0938-AH86
1254	National Standard for Identifiers of Health Plans (BPO-145-P)	0938-AH87
1255	Medicare Coverage of Certified Nurse-Midwife Services (BPD-496-P)	0938-AH96
1256	National Standard Health Care Provider Identifier (BDM-45-P)	0938-AH99
1257	Medicare Program; Medicare Integrity Program (OFH-020-P) (Reg Plan Seq. No. 33)	0938-AI09
1258	Medicare Program; Improvements to the Appeals Process for Medicare Beneficiaries Enrolled in HMOs, CMPs, and HCPPs (OMC-024-P)	0938-AI11
1259	Mental Health Parity and Newborns' and Mothers' Health Protection	0938-AI13
1260	Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates (HCFA-1001-P) (Reg Plan Seq. No. 34)	0938-AI22
1261	Children's Health Insurance: Program Implementations; State Plan Approval; State Payment; Coordination With State Medicaid Program (Reg Plan Seq. No. 35)	0938-AI28

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

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Health Care Financing Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1262	Payment for Clinical Diagnostic Laboratory Tests (BPD-309-F)	0938-AB50
1263	Effective Dates for Provider Agreements and Supplier Approvals (HSQ-139-F)	0938-AC88
1264	Medicare Secondary Payer for Disabled Individuals (BPD-482-F)	0938-AD73
1265	Revisions to Regulations Implementing CLIA (HSQ-226-F) (Reg Plan Seq. No. 36)	0938-AE47
1266	Resident Assessment in Long-Term Care Facilities (HSQ-180-F)	0938-AE61
1267	Post-Contract Beneficiary Protections and Other Provisions (OMC-003-F)	0938-AE63
1268	Payment for Nursing and Allied Health Science Education (BPD-685-F)	0938-AE79
1269	Coverage of Screening Pap Smears (BPD-705-F)	0938-AE98
1270	Requirements for Certain Health Insuring Organizations and OBRA'90 Technical Amendments (OMC-018-F)	0938-AF15
1271	Medicaid Payment for Covered Outpatient Drugs Under Rebate Agreements (MB-046-FC)	0938-AF42
1272	Retroactive Enrollment and Disenrollment in Risk Health Maintenance Organizations and Competitive Medical Plans (OMC-015-F)	0938-AF98
1273	Payment for Preadmission Services (BPD-731-F)	0938-AG00
1274	Change in Provider Agreement Regulations Related to Federal Employee Health Benefits (BPD-748-F)	0938-AG03
1275	Medicare Program: Limitations on Medicare Coverage of Intermittent Positive Pressure Breathing Machine Therapy (BPD-781-FN)	0938-AG44
1276	Noncoverage of Electrostimulation of Salivary Glands for the Treatment of Xerostomia (Dry Mouth) (BPD-782-FN)	0938-AG45
1277	Telephone Requests for Review of Part B Initial Claim Determinations (BPO-121-F)	0938-AG48
1278	Home Health Agency (HHA) Conditions of Participation (BPD-819-F) (Reg Plan Seq. No. 37)	0938-AG81
1279	CLIA Program: Categorization of Waived Tests (HSQ-225-F) (Reg Plan Seq. No. 38)	0938-AG99
1280	Ambulance Services (BPD-813-P)	0938-AH13
1281	Adjustment in Payment Amounts for New Technology Intraocular Lenses (BPD-831-F)	0938-AH15
1282	CLIA Program: Cytology Proficiency Testing (HSQ-233-N)	0938-AH35
1283	Limitations on Liability (BPD-859-FC)	0938-AH51
1284	Terms, Definitions, and Addresses: Technical Amendments (BPD-877-FC)	0938-AH53
1285	Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 1998 Rates (BPD-878-F)	0938-AH55
1286	Home Health Agency Physician Certification Regulations (BPD-875-NC)	0938-AH59
1287	Medicare Program; Establishment of an Expedited Review Process for Medicare Beneficiaries Enrolled in HMOs, CMPs, and HCPPs (OMC-25-FC)	0938-AH62
1288	Utilization Control and Discontinued Review Activities; Medicaid (MB-101-FC)	0938-AH64
1289	Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies (HSQ-238-F) (Reg Plan Seq. No. 39)	0938-AH74
1290	Individual Market Health Ins. Reform Portability from Group to Indiv. Coverage; Federal Rules for Access in the Indiv. Market; State Alternative Mechanisms to Federal Rules (BPD-882-F)	0938-AH75
1291	Medicaid Program; Redeterminations of Medicaid Eligibility Due to Welfare Reform (MB-105-F)	0938-AH76
1292	CLIA Program; Simplifying CLIA Regulations to Accreditation Exemption of Laboratories Under a State Licensure Program, and Proficiency Testing and Inspection (HSQ-239-FC)	0938-AH82
1293	Final Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1997 (MB-110-N)	0938-AH93
1294	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule, Other Part B Payment Policies for Calendar Year 1998 (BPD-884-FC) (Reg Plan Seq. No. 40)	0938-AH94
1295	Revision to the Definition of an Unemployed Parent (MB-106-FC)	0938-AH98
1296	Health Insurance Reform: Parity in the Application of Certain Limits to Mental Health Benefits (BPD-891-IFC)	0938-AI05
1297	Portability and Nondiscrimination in the Group Health Insurance Market (BPD-890-F)	0938-AI08
1298	Part A Premium for 1998 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (OACT-056-N)	0938-AI10
1299	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1998 (OACT-057-N)	0938-AI12
1300	Medicare Program: Update of Ambulatory Surgical Center Payment Rates Effective for Services On or Before October 1, 1997 (BPD-897-N)	0938-AI18
1301	Schedule of Limits on Home Health Agency Cost Per Visit for Cost Reporting Periods Beginning On or After October 1, 1997 (BPD-904-FC)	0938-AI24
1302	Solvency Standards for Provider-Sponsored Organizations; Intent To Form Negotiated Rulemaking Committee	0938-AI25
1303	Medicare Program; Notice for the Solicitation for Proposals for a Demonstration Project for Congestive Heart Failure Case Management ORD-104-N	0938-AI26
1304	GME: Incentive Payments under Plans for Voluntary Reduction in Number of Residents (HCFA-1003-IFC)	0938-AI27
1305	Medicare + Choice Program; Regulatory Program to Implement Certain Medicare Provisions of the Balanced Budget Act of 1997 (OMC-030-IFC) (Reg Plan Seq. No. 41)	0938-AI29

HHS

Health Care Financing Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
1306	Surety Bond and Capitalization Requirements for Home Health Agencies (BPO-152-FC) (Reg Plan Seq. No. 42)	0938-AI31
1307	Health Insurance Portability and Accountability Act (HIPAA) of 1996: Administrative Simplification (Reg Plan Seq. No. 43)	0938-AI32

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

Health Care Financing Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1308	Deduction of Incurred Medical Expenses (Spenddown) (MB-020-F)	0938-AB07
1309	Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care (BPD-393-F)	0938-AC58
1310	Criteria and Procedures for Developing Medical Services Coverage Policy (BPD-432-F)	0938-AD07
1311	Medicare Coverage of Outpatient Occupational Therapy Services (BPD-425-P)	0938-AD32
1312	Prohibition on Unbundling of Hospital Outpatient Services (BPD-426-F)	0938-AD33
1313	Changes to Peer Review Organization Regulations (HSQ-135-F)	0938-AD38
1314	Omnibus Nursing Home Reform Requirements (BPD-488-F)	0938-AD81
1315	Protection of Income and Resources for Community Spouses of Institutionalized Individuals (MB-023-P)	0938-AE12
1316	Survey Requirements and Alternative Sanctions for Home Health Agencies (HSQ-169-F)	0938-AE39
1317	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services (MB-28-F)	0938-AE72
1318	Medicare Coverage of, and Application of the Outpatient Mental Health Treatment Limitation to, Clinical Psychologist and Clinical Social Worker Services (BPD-706-F)	0938-AE99
1319	Changes to the Long-Term Care Facility Survey Process (HSQ-175-FC)	0938-AF02
1320	Case Management (MB-27-F)	0938-AF07
1321	Alternative Sanctions for Psychiatric Hospitals (HSQ-191-P)	0938-AF32
1322	Referral to Child Support Enforcement Agencies of Medicaid Families (MB-051-F)	0938-AF68
1323	Medicaid: Outstationed Intake Locations for Certain Low-Income Pregnant Women, Infants, and Children Under Age 19 (MB-052-F)	0938-AF69
1324	Assessing Interest Against Medicare Secondary Payer (MSP) Debts (BPO-108-P)	0938-AF87
1325	Revisions to Rules on Health Care Prepayment Plans (OMC-016-P)	0938-AF97
1326	Revised Medicaid Management Information Systems (MB-38-FN)	0938-AG10
1327	Description of HCFA's Evaluation Methodology for the Peer Review Organizations Fifth Scope of Work Contracts (HSQ-207-NC)	0938-AG32
1328	Disclosure of Confidential PRO and ESRD Network Organization Information for Research Purposes (HSQ-208-P)	0938-AG33
1329	Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Pathology, and Occupational Therapy (BPD-808-F)	0938-AG70
1330	Distinct Part Requirements for Nursing Homes and Prohibition of Financial Screening of Applicants for Nursing Home Admission (BPD-815-P)	0938-AG84
1331	Categorization and Certification Requirements for a New Subcategory of Moderate Complexity Testing (HSQ-222-F)	0938-AG98
1332	Medicare Coverage of Organ Transplantation (BPD-835-PN)	0938-AH17
1333	Criteria and Procedures for Extending Coverage to Certain Devices and Related Services (BPD-841-F)	0938-AH21
1334	Delegation of Civil Money Penalties (BPO-135-FC)	0938-AH22
1335	Hospice Care—Conditions of Participation (BPD-844-P)	0938-AH27
1336	Requirements for Enrollment of Medicaid Recipients Under Cost Effective Employer-Based Group Health Plans (MB-047-FC)	0938-AH48
1337	Medicare Secondary Payer Clarifications and Amendments (BPD-865-P)	0938-AH52
1338	Conditions for Certification of Community Mental Health Centers and Coverage Requirements for Partial Hospitalization Services (BPD-871-P)	0938-AH58
1339	Medicare Technical Conforming Amendments (BPD-858-FC)	0938-AH67
1340	Determination of Substandard Care in SNFs and NFs (HSQ-240-P)	0938-AH69
1341	Waiver of Staffing Requirements for End Stage Renal Disease (ESRD) Facilities Participating in an Experiment (HSQ-236-GNC)	0938-AH72
1342	Information Requirements for Medicare Professional Suppliers Billing Privileges (BPO-143-P)	0938-AH73
1343	Medicaid Program; Amendment to the Preadmission Screening and Annual Resident Review Program (MB-107-P)	0938-AH89
1344	Allocation of Enhanced Federal Matching Funds for Increased Administrative Costs (MB-103-N)	0938-AH90
1345	Medically Needy Determinations Under Welfare Reform (MB-109-IFC)	0938-AH92

HHS

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

Sequence Number	Title	Regulation Identifier Number
1346	Medicaid Program; Coverage and Payment for Federally Qualified Health Center Services (MB-43-P)	0938-AH95
1347	Medicaid Program: Charges for Vaccine Administration Under the Vaccines for Children (VCF) Program (MB-84-N)	0938-AI20
1348	Medicaid: Medical Child Support (MB-081-P)	0938-AI21

Health Care Financing Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1349	Fire Safety Standards for Hospitals, Long-Term Care Facilities, and Intermediate Care Facilities for the Mentally Retarded (BPD-650-FC)	0938-AE97
1350	Presumptive Limits on Payments to HMOs, CMPs, and HCPPs (OMC-006-F)	0938-AF16
1351	End-Stage Renal Disease (ESRD) Payment Exception Requests and Organ Procurement Costs (BPD-763-F)	0938-AG20
1352	Wage Index Used To Adjust Payment Rates for Hospice Services Under the Medicare Program (BPD-820-F)	0938-AG93
1353	Medicaid Coverage of Personal Care Services (MB-071-F)	0938-AH00
1354	Update of the Reasonable Compensation Equivalent Limits for Services Furnished by Physicians (BPD-816-N)	0938-AH14
1355	Changes in Coverage and Payment Policies for Physician Assistant Services (BPD-829-P)	0938-AH26
1356	Limitations on Payment for Home Oxygen Therapy Based on Inherent Reasonableness Criteria (BPD-845-FN)	0938-AH28
1357	Designation of Independent Rural Primary Care Hospitals (RPCHs) (BPD-784-N)	0938-AH60
1358	Initiative To Recognize Hemodialysis Facilities of Achievement (HSQ-232-N)	0938-AH71
1359	Clinical Laboratory Requirements—Extension of Certain Effective Dates for Clinical Laboratory Requirements Under CLIA (HSQ-237-F)	0938-AH84
1360	Medicare Program; Schedule of Limits on Home Health Agency Cost Per Visit for Cost Reporting Periods Beginning On or After July 1, 1997 (BPD-889-N)	0938-AH88
1361	Medicare Appeals of Individual Claims (BPD-453-FC)	0938-AH97
1362	Medicare Program; Adjustments to Cost Limits for SNF Inpatient Routine Service Costs (BPD-896-PN)	0938-AI14
1363	Medicare Program; Schedules of Limits and Prospectively Determined Rates for SNF Inpatient Routine Service Costs (BPD-895-NC)	0938-AI15
1364	Medicaid Program: Limitation on Provider-Related Donations and Health Care-Related Taxes; Revision on Waiver Criteria for Tax Programs Based Exclusively on Regional Variations; Correction	0938-AI30

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1365	Title IV-E Foster Care Eligibility Reviews and Child and Family Services State Plan Reviews	0970-AA97
1366	Designation of Alternative Agency To Serve Indian Tribal Children	0970-AB52
1367	Construction of Head Start Facilities	0970-AB54
1368	Methodology for Determining Child Poverty Rates	0970-AB65
1369	Bonus to Reward High Performance States Under the Temporary Assistance for Needy Families Block Grant	0970-AB66
1370	Quarterly Wage and Unemployment Compensation Claims Reporting to the National Directory of New Hires	0970-AB67
1371	State Case Registry and Expansion of the Federal Parent Locator Service (FPLS)	0970-AB68
1372	State Law Concerning Paternity Establishment	0970-AB69
1373	Automated Data Processing Requirements	0970-AB70
1374	Automated Data Processing Funding Limitation	0970-AB71
1375	Grants to States for Access and Visitation Programs	0970-AB72
1376	Child Support Enforcement for Indian Tribes	0970-AB73
1377	Temporary Assistance for Needy Families (TANF) (Reg Plan Seq. No. 44)	0970-AB77
1378	Requirements for the Tribal Programs	0970-AB78
1379	Bonus to Reward Decrease in Out-of-Wedlock Birth Ratio	0970-AB79
1380	Case Closure	0970-AB82
1381	Refugee Resettlement Program: Responding and Conforming to TANF Replacing AFDC	0970-AB83
1382	Child Support Non-Performance Penalty	0970-AB85
1383	Child Abuse and Neglect Prevention and Treatment	0970-AB86
1384	Head Start Appeal Timelines	0970-AB87

HHS

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

Sequence Number	Title	Regulation Identifier Number
1385	Title IV-B Planning Requirements for Tribes	0970-AB88
1386	Title IV-E Training	0970-AB89
1387	Designation of Family Child Care as a Program Option for Head Start Programs	0970-AB90

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

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1388	Standards for Safe Transportation	0970-AB24
1389	Standards for Purchase of Facilities	0970-AB31
1390	Income Eligibility Criteria for Indian Tribes	0970-AB53
1391	Income and Resource Disregards Related to Interests of Individual Indians in Trust or Restricted Lands	0970-AB59
1392	Child Care and Development Fund	0970-AB74
1393	Child Support Enforcement Program Omnibus Conforming Regulation	0970-AB81
1394	Personal Responsibility and Work Opportunity Reconciliation Act of 1996 Conforming Regulation	0970-AB84
1395	Data Collection and Reporting for the Welfare to Work Program	0970-AB92

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1396	Data Collection and Reporting Under the Temporary Assistance for Needy Families Block Grant	0970-AB64
1397	TANF Penalties and Administrative Costs	0970-AB76

Administration on Aging—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1398	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)

Proposed Rule Stage

Office of the Secretary (OS)

1100. REVISED OIG EXCLUSION AUTHORITIES RESULTING FROM PUBLIC LAW 104-191

Priority: Substantive, Nonsignificant

Legal Authority: PL 104-191, sec 211; PL 104-191, sec 212; PL 104-191, sec 213

CFR Citation: 42 CFR 1000; 42 CFR 1001; 42 CFR 1002; 42 CFR 1005

Legal Deadline: None

Abstract: This proposed rule addresses revisions to the OIG's sanction authorities in conjunction with sections 211, 212, and 213 resulting from the

Health Insurance Portability and Accountability Act of 1996, along with other technical and conforming changes to the OIG exclusion authorities. The revisions are specifically designed to expand the protection of certain basic fraud authorities and revise and strengthen the current legal authorities pertaining to exclusions from the Medicare and State health care programs.

Timetable:

Action	Date	FR Cite
NPRM	09/08/97	62 FR 47182

Action	Date	FR Cite
NPRM Comment Period End	11/07/97	
Final Action	06/00/98	

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, OCIG, 330 Independence Avenue SW., Washington, DC 20201

HHS—OS

Proposed Rule Stage

Phone: 202 619-0089

RIN: 0991-AA87

1101. REVISED OIG CIVIL MONEY PENALTIES RESULTING FROM PUBLIC LAW 104-191

Priority: Substantive, Nonsignificant

Legal Authority: PL 104-191, sec 231(a); PL 104-191, sec 231(b); PL 104-191, sec 231(c); PL 104-191, sec 231(d); PL 104-191, sec 231(e); PL 104-191, sec 231(h); PL 104-191, sec 232

CFR Citation: 42 CFR 1003; 42 CFR 1005; 42 CFR 1006

Legal Deadline: None

Abstract: This proposed rule would revise the OIG's civil money penalty provisions in conjunction with new and revised authorities set forth in the Health Insurance Portability and Accountability Act of 1996. Among other provisions this proposed rulemaking would codify new civil money penalties for (1) excluded individuals retaining ownership or control interest in an entity; (2) upcoding and claims for medically unnecessary services; (3) offering inducements to beneficiaries; and (4) false certification of eligibility for home health services.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	
NPRM Comment Period End	02/00/98	

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 the Inspector General, OCIG, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA90

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

Final Rule Stage

1102. 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, 7/29/91) to give greater clarity to the 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	04/00/98	

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, OCIG, Department of Health and Human Services, Office of the Secretary, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA66

1103. REPRODUCTION AND SALE OF OFFICIAL FORMS AND PUBLICATIONS

Priority: Info./Admin./Other

Legal Authority: PL 103-296, sec 312 (42 USC 1320b-10)

CFR Citation: 45 CFR 101

Legal Deadline: None

Abstract: This interim final rule with comment period will establish procedures for implementation of section 312 of the Social Security Independence Act. That section amends existing prohibitions against "misuse of symbols, emblems, or names in reference to Social Security or Medicare." Section 312 newly prohibits the "unauthorized reproduction, reprinting, or distribution for fee" of a "form, application, or other publication

of the Social Security Administration or of the Department of Health and Human Services". It requires prior authorization for any such activity in accordance with the Secretary's regulations. The Department plans to distinguish between forms and publications that potentially involve misuse in contrast to benign or desirable reproductions and distributions, and to provide pre-authorization for the latter. The rule will be developed in consultation with the Social Security Administration.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Walton Francis, Senior Advisor, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 690-8291

RIN: 0991-AA83

1104. • SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS

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

HHS—OS

Final Rule Stage

duplication, or streamline requirements.

Legal Authority: PL 104-191, sec 216

CFR Citation: 41 CFR 1001

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

Abstract: This interim final rule would establish a new statutory exception for risk-sharing arrangements under the Federal health care programs anti-kickback provisions. The rule would set forth an exception from liability for remuneration between an eligible organization under section 1876 of the Social Security Act and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule would also allow remuneration between an organization and an individual or entity if a written agreement places the individual or entity at "substantial financial risk" for the cost or utilization of the items or services which the individual or entity is obligated to provide.

Timetable:

Action	Date	FR Cite
ANPRM	05/23/97	62 FR 28410
ANPRM Comment Period End	06/09/97	
Interim Final Rule	04/00/98	

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, OIG, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA91

1105. • ADMINISTRATIVE REQUIREMENTS FOR GRANTEES TO REFLECT SINGLE AUDIT ACT AMENDMENTS

Priority: Info./Admin./Other

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

Legal Authority: 5 USC 301; 42 USC 300 w et seq

CFR Citation: 45 CFR 74; 45 CFR 92; 45 CFR 96

Legal Deadline: None

Abstract: This interim final rule implements the Single Audit Act Amendments of 1996 and OMB Circular A-133 for HHS grantees.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/29/97	62 FR 45937
Interim Final Rule Effective	09/29/97	
Interim Final Rule Comment Period End	10/28/97	

Small Entities Affected: None

Government Levels Affected: State, Local, Tribal

Agency Contact: Charles Gale, Director, Office of Grants Management, Department of Health and Human Services, Office of the Secretary, Room 517-D, 200 Independence Ave. SW., Washington, DC 20201
Phone: 202 690-6377
TDD: 202 690-6902
Fax: 202 690-6415

RIN: 0991-AA92

1106. • ISSUANCE OF ADVISORY OPINIONS BY THE INSPECTOR GENERAL

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 800

CFR Citation: 42 CFR 1008

Legal Deadline: Final, Statutory, February 21, 1997.

Abstract: This final rule sets forth the specific procedures by which the OIG, in consultation with the Department of Justice, will issue advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the Medicare and State health care programs.

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/19/97	62 FR 7350
Final Action	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joel 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: 202 619-0089

RIN: 0991-AA94

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

Long-Term Actions

1107. 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	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joel Jay Schaer, Regulations Officer, Department of Health and Human Services, Office of

HHS—OS

Long-Term Actions

the Secretary, Office of Inspector General, OCIG, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA45

1108. 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, OCIG, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA53

1109. CIVIL MONEY PENALTIES FOR REFERRALS TO ENTITIES AND FOR PROHIBITED ARRANGEMENTS AND SCHEMES

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)(2); 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 referrals as 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, OCIG, Department of Health and Human Services, Office of the Secretary, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA65

1110. 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	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, OCIG, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089

RIN: 0991-AA79

1111. 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 wholesale or manufacturer of covered outpatient drugs that fails to respond to a request for information about charges or prices, or knowingly provides false information, in a survey by the Secretary to verify manufacturers' reported prices under the Medicaid drug rebate program. In addition, this rule would set forth civil money penalties against any drug manufacturer 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.

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

HHS—OS

Long-Term Actions

Health and Human Services, Office of the Secretary, Office of Inspector General, OCIG, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0089
RIN: 0991-AA80

1112. SENIOR BIOMEDICAL RESEARCH SERVICES

Priority: Info./Admin./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

Action	Date	FR Cite
Interim Final Rule	03/31/96	
Comment Period End		
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 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)

Completed Actions

Office of the Secretary (OS)

1113. REVISED PRO SANCTIONS FOR FAILING TO MEET STATUTORY OBLIGATIONS

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	04/29/97	62 FR 23140

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: Joel Jay Schaer
Phone: 202 619-0089

RIN: 0991-AA86

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

CFR Citation: 45 CFR 16; 45 CFR 74; 45 CFR 75; 45 CFR 95

Completed:

Reason	Date	FR Cite
Final Action	07/17/97	62 FR 38217

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ronald Speck
Phone: 202 401-2751
TDD: 202 690-6415

RIN: 0991-AA88

1114. INDIRECT COST APPEALS

Priority: Info./Admin./Other

Reinventing Government: This rulemaking is part of the Reinventing

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Substance Abuse and Mental Health Services Administration (SAMHSA)

1115. 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 PL 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	12/00/97	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local

Additional Information: Previously reported under RIN 0905-AD99.

Alternate Contact: Lorinda Daniel, 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,

HHS—SAMHSA

Final Rule Stage

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)

Long-Term Actions

Substance Abuse and Mental Health Services Administration (SAMHSA)

1116. 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: Jim Sayers, DSP, C SAT SAMHSA, 5515 Security Lane, Suite 800, Rockville, MD 20852; 301-443-3820.

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)

Proposed Rule Stage

Departmental Management (HHSDM)

1117. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS

Priority: Substantive, Nonsignificant

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

CFR Citation: 45 CFR 13

Legal Deadline: None

Abstract: The Equal Access to Justice Act requires agencies to pay fees to parties prevailing against the government in certain administrative proceedings. The Act has been amended several times since its 1980 enactment, most recently by the

Contract with America Advancement Act of 1996, which increased the amount of the hourly fees payable. The proposed rule revises 45 CFR Part 13 (HHS' regulation implementing the Equal Access to Justice Act) to conform with statutory changes.

Timetable:

Action	Date	FR Cite
NPRM	06/19/87	52 FR 23311
NPRM Comment Period End	08/17/87	
Second NPRM	11/00/97	
Final Action	12/00/97	

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)

Prerule Stage

Food and Drug Administration (FDA)

1118. INVESTIGATIONAL NEW DRUG APPLICATIONS; REQUEST FOR INFORMATION AND COMMENTS

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

Unfunded Mandates: Undetermined

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, among other things, the drugs are in Phase 2 of commercial development.

HHS—FDA

Prerule Stage

Timetable:

Action	Date	FR Cite
ANPRM	01/00/98	
ANPRM Comment	04/00/98	
Period End		

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

1119. ● PRESCRIPTION DRUG COMPOUNDING

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 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; 42 USC 264

CFR Citation: 21 CFR 201; 21 CFR 207; 21 CFR 211; 21 CFR 310; 21 CFR 314

Legal Deadline: None

Abstract: This advance notice of proposed rulemaking would describe proposed regulatory requirements and policies that FDA is considering and seek public input concerning prescription drug compounding practices, including delineating those compounding practices subject to state oversight and those subject to FDA regulations

Timetable:

Action	Date	FR Cite
ANPRM	03/00/98	
ANPRM Comment	06/00/98	
Period End		

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Lana Ogram, Office of Compliance, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-330), 7500 Standish Place, Rockville, MD 208552
Phone: 301 594-0101
Fax: 301 594-5998

RIN: 0910-AB13

1120. ● EXPORTS; REPORTING AND RECORDKEEPING REQUIREMENTS

Priority: Routine and Frequent

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 243; 42 USC 262

CFR Citation: 21 CFR 1

Legal Deadline: None

Abstract: The proposed rule would establish the recordkeeping and notification requirements for persons exporting human drugs, animal drugs, biologics, and devices under the FDA Export Reform and Enhancement Act.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health

and Human Services, Food and Drug Administration, Office of Policy (HF-23), 5600 Fishers Lane, Room 15-74, Rockville, MD 20857
Phone: 301 827-3380
Fax: 301 443-6906
Email: pchao@bangate.fda.gov

RIN: 0910-AB16

1121. ● REQUIREMENTS PERTAINING TO THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS; USE OF NONTOBACCO TRADE OR BRAND NAMES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 352; 21 USC 360; 21 USC 360(j); 21 USC 371; 21 USC 372

CFR Citation: 21 CFR 897

Legal Deadline: None

Abstract: The proposed rule would clarify the restrictions on the use of nontobacco product names and other identification on tobacco products and would modify the list of established names for smokeless tobacco products.

Timetable:

Action	Date	FR Cite
ANPRM	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy (HF-23), 5600 Fishers Lane, Room 15-74, Rockville, MD 20857
Phone: 301 827-3380
Fax: 301 443-6906
Email: pchao@bangate.fda.gov

RIN: 0910-AB17

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Proposed Rule Stage

Food and Drug Administration (FDA)

1122. 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

HHS—FDA

Proposed Rule Stage

drug application, may be legally marketed. NOTE: NPRM for "Antidotes, Toxic Ingestion Products" was combined with NPRM for "Emetic Products" and repropoed 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 Antiseptic 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) 05/10/96 (61 FR 21392)
Final Action (Amendment) 11/18/96 (61 FR 58629)

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)
Final Action (Amendment)(Sodium B.) 05/00/98

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)
Final Action (Amendment)(Warning) 11/15/96 (61 FR 58471)

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)
Final Action (Technical Amendment) 10/07/96 (61 FR 52285)

Antidiarrheal Products

ANPRM 03/21/75 (40 FR 12924)
NPRM 04/30/86 (51 FR 16138)
NPRM (Amendment)(Trav. Diar.) 06/00/98
Final Action 06/00/98

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)
NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)

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 08/00/98

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)
 NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)

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)
 NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
 NPRM (Amendment)(Warning) 03/00/98

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) 05/20/96 (61 FR 25142)

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 03/00/99

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) 00/00/00**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 10/03/96 (61 FR 51625)
 NPRM 04/00/98

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)
 NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
 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) 06/13/96 (61 FR 30002)
 NPRM (Amendment)(Alcohol Warning) 11/00/97
 Final Action (Professional Labeling) 04/00/98
 NPRM (Labeling-revised indications) 10/00/98

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 Human 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 (Unless a doc. tells you)(Wi.) 02/27/97 (62 FR 9024)
 Final Action (Ca/Mg/K) 06/00/98
 Final Action (Format/Examples) 07/00/98

HHS—FDA

Proposed Rule Stage

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)
 NPRM (Phenolphthalein) 09/02/97 (62 FR
 46223)
 Final Action (Phenolphthalein) 11/00/97
 Final Action (Sodium Phosphates)
 02/00/98
 NPRM (Amendment)(Phosphates Label)
 02/00/98
 Final Action 08/00/98

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 (Active/Inactive)

NPRM 02/00/98

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)
 NPRM (Amendment) (Warning) 08/29/97
 (62 FR 45767)

NDA Labeling Exclusivity

NPRM 11/09/93 (58 FR 59622)
 Final Action 03/00/98

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) 02/00/98

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)
 Final Action (Amendment) (Warning)
 06/00/98

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)
 Final Action 00/00/00

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) 07/00/98
 Final Action 12/00/98

Quinine for Malaria

NPRM 04/19/95 (60 FR 19650)
 Final Action 02/00/98

Reporting of Adverse Reactions

NPRM 01/00/98

Skin Bleaching Products

ANPRM 11/03/78 (43 FR 51546)
 NPRM 09/03/82 (47 FR 39108)
 NPRM (Reproposed) 06/00/98

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) 01/00/98
 Final Action 01/00/98

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)
 Final Action (Technical Amendment)
 06/00/98

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)
 NPRM 02/00/98

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)
 NPRM (Amendment)(Avobenzone)
 09/16/96 (61 FR 48645)
 Final Action (Avobenzone Enf. Pol.)
 04/30/97 (62 FR 23350)

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) 10/00/97

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AA06.

HHS—FDA

Proposed Rule Stage

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

Agency Contact: William E. Gilbertson, Assoc. Director for OTC Drug Monographs, Office of Drug Evaluation V, 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

1123. BIOLOGICAL PRODUCT REPORTING OF ERRORS AND ACCIDENTS IN MANUFACTURING

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: FDA is proposing to amend the regulations that require licensed manufacturers of biological products to report errors and accidents in manufacturing that may affect the safety, purity, or potency of a product. FDA proposes to define terms used; establish a reporting period for all licensed biological products; and amend the current good manufacturing practice (CGMP) regulations for blood and blood components to require error and accident reporting by registered blood establishments and transfusion services currently reporting on a voluntary basis. The proposed reporting requirements will expedite reporting of errors and accidents in manufacturing of biological products; provide FDA with a more accurate surveillance of the Nation's blood supply, enabling FDA to monitor actions taken in response to the errors and accidents detected for all establishments involved in the manufacture of blood and blood components; and facilitate a rapid response where public health may be at risk. The cost to licensed establishments would be minimal, since they already are required to report. Unlicensed 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	09/23/97	62 FR 49642
NPRM Comment Period End	12/22/97	
Final Action	12/00/98	

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-17), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 827-6210

RIN: 0910-AA12

1124. 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: 21 CFR 601

Legal Deadline: Final, Statutory, February 1, 1991.

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	03/00/98	

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: Dano B. Murphy, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-17), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 301 827-6210

RIN: 0910-AA14

1125. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE

Regulatory Plan: This entry is Seq. No. 24 in Part II of this issue of the **Federal Register**.
RIN: 0910-AA39

1126. DEVELOPMENT OF HAZARD ANALYSIS CRITICAL CONTROL POINTS FOR CERTAIN UNPASTEURIZED FRUIT AND VEGETABLE JUICES

Regulatory Plan: This entry is Seq. No. 25 in Part II of this issue of the **Federal Register**.
RIN: 0910-AA43

1127. REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

Priority: Other Significant. Major status under 5 USC 801 is undetermined.
Unfunded Mandates: Undetermined
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—FDA

Proposed Rule Stage

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 substantially revise the regulations under part 207 to clarify the burden on manufacturers packers, and distributors, and to consolidate, reorganize, and streamline the requirements.

Timetable:

Action	Date	FR Cite
NPRM	04/00/98	
NPRM Comment Period End	07/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Lee D. Korb, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA49

1128. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

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

Unfunded Mandates: Undetermined

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 and eliminate duplication and inconsistencies.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Action	Date	FR Cite
NPRM Comment Period End	03/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
RIN: 0910-AA51

1129. DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

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

Unfunded Mandates: Undetermined

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; 21 USC 823; 42 USC 241; 42 USC 257; 42 USC 290; 42 USC 300

CFR Citation: 21 CFR 291

Legal Deadline: None

Abstract: The proposed rule will revise the regulations under part 291 to provide for the certification of narcotic treatment programs as a basis for fulfilling the Department's requirements of the Narcotic Addict Treatment Act of 1974. Certification will be based on accreditation by non-profit accrediting bodies. This new system will replace the current system which relies solely on direct FDA approval and inspection for determining whether narcotic treatment programs comply with Federal treatment standards. The proposed rule will provide for a transition period for programs operating under the existing regulatory system.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Nicholas Reuter, Associate Director for International and Domestic Drug Control, Department of Health and Human Services, Food and Drug Administration, Office of Health Affairs (HFY-20), 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-1696
Fax: 301 443-0232
Email: nreuter@bangate.fda.gov
RIN: 0910-AA52

1130. INVESTIGATIONAL NEW DRUG APPLICATIONS; CLINICAL HOLDS

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

Unfunded Mandates: Undetermined

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 would revise existing regulations to reduce the timeframe within which FDA will issue a written explanation to a sponsor describing the reasons for imposing the clinical hold. The proposed rule would also state that a clinical study may resume within a specified timeframe after FDA receives the sponsor's complete reply to all issues raised in the clinical hold, unless FDA notifies the sponsor that it has reinstated the clinical hold.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	
NPRM Comment Period End	04/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

HHS—FDA

Proposed Rule Stage

Fax: 301 594-6197

RIN: 0910-AA73

1131. PARENTERAL DRUG PRODUCTS CONTAINING ALUMINUM AS AN INGREDIENT OR CONTAMINANT; LABELING REQUIREMENTS; WARNING STATEMENT

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 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 on 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	12/00/97	
NPRM Comment Period End	03/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Leanne Cusumano, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AA74

1132. DEBARMENT CERTIFICATION REGULATIONS FOR DRUG APPLICATIONS

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

Unfunded Mandates: Undetermined

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	02/00/98	
NPRM Comment Period End	05/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Leanne Cusumano, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AA76

1133. INVESTIGATIONAL NEW DRUG APPLICATIONS; CLINICAL HOLDS FOR DRUGS FOR LIFE-THREATENING ILLNESSES

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 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 final rule amends the provisions governing investigational new drug applications to permit FDA to place a clinical hold on one or more studies under an IND involving a drug that is intended to treat a life-threatening disease affecting both genders if men or women with reproductive potential who have the disease are excluded from eligibility in any phase of the investigation because of a risk or potential risk of reproductive or developmental toxicity from use of the investigational drug.

Timetable:

Action	Date	FR Cite
NPRM	09/24/97	62 FR 49946
NPRM Comment Period End	12/23/97	
Final Action	07/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Nancy E. Derr, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-5), 1451 Rockville Pike, Suite 6027, Rockville, MD 20852

Phone: 301 594-5400

Fax: 301 594-6197

RIN: 0910-AA84

1134. 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 APPLICATIONS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 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

HHS—FDA

Proposed Rule Stage

Abstract: The proposed rule would require applicants and manufacturers, packers, and distributors of marketed nonprescription human drug products 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	02/00/98	
NPRM Comment Period End	05/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA86

1135. STERILITY REQUIREMENTS FOR INHALATION SOLUTION PRODUCTS

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 200

Legal Deadline: None

Abstract: The final rule requires 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 taking this action to prevent future additional adverse health consequences.

Timetable:

Action	Date	FR Cite
NPRM	09/23/97	62 FR 49638
NPRM Comment Period End	12/22/97	
Final Action	07/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Carol Drew, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA88

1136. DIRECT-TO-CONSUMER PROMOTION REGULATIONS

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

Unfunded Mandates: Undetermined

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	06/00/98	
NPRM Comment Period End	09/00/98	

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

1137. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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

Unfunded Mandates: Undetermined

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 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: The proposed rule would revise existing regulations governing the format of prescription drug labeling directed toward prescribers and other health care professionals to increase the usefulness of this labeling. The revisions to part 201.57 would reorder the content areas of the labeling; add an introductory section of highlights and an index; and institute an identification system to enhance accessibility to detailed information.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	
NPRM Comment Period End	05/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Nancy Ostrove, Division of Drug Marketing, Advertising and Communications, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-40), 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-2828
Fax: 301 594-6759

RIN: 0910-AA94

HHS—FDA

Proposed Rule Stage

1138. ADVERSE DRUG REACTION REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS; EXPEDITED REPORTS

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

Unfunded Mandates: Undetermined

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

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

Legal Deadline: None

Abstract: The proposed rule would amend the expedited safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonization and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to make other revisions to these regulations to enhance the quality of adverse drug reaction reports received by FDA.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	
NPRM Comment Period End	05/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA97

1139. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR LABELING OF DRUGS; REVISION OF CERTAIN LABELING CONTROLS

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 210; 21 CFR 211

Legal Deadline: None

Abstract: The final rule amends the labeling control provisions in the current good manufacturing practice regulations to make the provisions less burdensome while still reducing the frequency of drug product mislabeling and associated drug product recalls associated with cut labeling.

Timetable:

Action	Date	FR Cite
NPRM	07/29/97	62 FR 40489
NPRM Comment Period End	10/27/97	
Final Action	06/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA98

1140. CHLOROFLUOROCARBON PROPELLANTS IN SELF-PRESSURIZED CONTAINERS; DETERMINATIONS THAT USES ARE NO LONGER ESSENTIAL

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

Unfunded Mandates: Undetermined

Legal Authority: 15 USC 402; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 357; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 2

Legal Deadline: None

Abstract: The proposed rule presents the policy FDA is proposing to adopt on making and implementing determinations that uses of chlorofluorocarbons (CFCs) currently designated essential will no longer be deemed essential under section 610 of

the Clean Air Act due to the availability of safe and effective medical product technology that does not use CFCs.

Timetable:

Action	Date	FR Cite
ANPRM	03/06/97	62 FR 10242
ANPRM Comment Period End	05/05/97	
NPRM	03/00/98	
NPRM Comment Period End	06/00/98	

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA99

1141. RADIOACTIVE DRUGS FOR BASIC RESEARCH

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

Unfunded Mandates: Undetermined

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 353; 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 361

Legal Deadline: None

Abstract: The proposed rule would update FDA's regulations on the use of radioactive drugs for basic research to reflect technological changes in the field of radiopharmaceuticals. The proposed rule would also clarify and correct certain provisions.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	
NPRM Comment Period End	04/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

HHS—FDA

Proposed Rule Stage

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
 Phone: 301 594-2041
 Fax: 301 827-5562
RIN: 0910-AB00

1142. INVESTIGATIONAL NEW ANIMAL DRUG REGULATIONS

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

Unfunded Mandates: Undetermined

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 353; 21 USC 360b; 21 USC 371; 21 USC 381

CFR Citation: 21 CFR 511; 21 CFR 512

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
ANPRM	11/21/96	61 FR 59209
ANPRM Comment Period End	01/21/97	
NPRM	06/00/98	

Small Entities Affected: Undetermined
Government Levels Affected: Undetermined

Agency Contact: Marty Schoenemann, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-120), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 827-0220

RIN: 0910-AB02

1143. ESTABLISHMENT REGISTRATION AND LISTING OF HUMAN CELLULAR AND TISSUE-BASED PRODUCTS

Regulatory Plan: This entry is Seq. No. 26 in Part II of this issue of the **Federal Register**.

RIN: 0910-AB05

1144. • DEFINITION OF SUBSTANTIAL EVIDENCE

Priority: Other Significant

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

CFR Citation: 21 CFR 514.4

Legal Deadline: NPRM, Statutory, October 9, 1997. Final, Statutory, October 9, 1998.

Abstract: The ADAA requires FDA to issue within 12 months after the date of its enactment proposed regulations to encourage dose range labeling and to further define the term "substantial evidence," as the term is defined in section 512(d)(3) of the Federal Food, Drug, and Cosmetic Act, as amended by the ADAA, in a manner that encourages the submission of applications and supplemental applications.

Timetable:

Action	Date	FR Cite
ANPRM	11/21/96	61 FR 59209
NPRM	11/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Gail Schmerfeld, Special Assistant, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-100), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 827-0205
 Fax: 301 594-2297

RIN: 0910-AB08

1145. • VETERINARY FEED DIRECTIVES: DISTRIBUTOR NOTIFICATION

Priority: Other Significant

Legal Authority: PL 104-250

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: The Animal Drug Availability Act (ADAA) amended the Federal Food, Drug, and Cosmetic Act (the act) to create a new section 504, Veterinary Feed Directive Drugs (VFD Drugs). VFD drugs are animal drugs intended for use in or on animal feed which are limited by an approved application filed pursuant to section 512(b) of the act to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice. This section requires, among other things, that the labeling, distribution and use of a VFD drug be consistent with its approval; persons involved in the distribution and use of a VFD drug maintain copies of the VFD; and, persons distributing animal feed must provide a one time notice upon first engaging in the distribution of VFD drugs. The proposed rule will provide guidance to the industry about how to comply with section 504 of the act and will serve as a basis for enforcement action.

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: George Graber, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-228), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 594-1733
 Fax: 301 594-1512

RIN: 0910-AB09

1146. • USE OF OZONE-DEPLETING SUBSTANCES IN AEROSOL PRODUCTS OR OTHER PRESSURIZED DISPENSERS; DETERMINATIONS THAT USES ARE NO LONGER ESSENTIAL

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

Unfunded Mandates: Undetermined

HHS—FDA

Proposed Rule Stage

Legal Authority: 15 USC 402; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 357; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 2

Legal Deadline: None

Abstract: FDA is proposing to amend its regulations governing use of ozone-depleting substances to provide stricter scrutiny of proposed new essential uses that seek exemption from the general ban on the use of ozone-depleting substances. FDA is also proposing to amend the regulations to better conform to other statutes and regulations relating to ozone-depleting substances to eliminate potential confusion and conflicts. FDA is proposing to eliminate out-of-date transitional provisions and make other nonsubstantive housekeeping changes to its regulations on ozone-depleting substances.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	
NPRM Comment Period End	04/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 827-5562

RIN: 0910-AB10

1147. • CLARIFICATION OF THE SCOPE OF TREATMENT USES WITH INVESTIGATIONAL NEW DRUGS THAT CAN BE AUTHORIZED UNDER INDs AND THE CRITERIA FOR CHARGING FOR INVESTIGATIONAL NEW DRUGS UNDER INDs

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 312

Legal Deadline: None

Abstract: The proposed rule would revise 21 CFR part 312 to describe types of treatment uses that can be authorized under INDs in addition to those treatment uses that meet the criteria for a treatment IND under 21 CFR 312.34. The proposed rule would also amend 21 CFR 312.7(d) (charging for and commercialization of investigational drugs) to clarify criteria for charging for investigational drugs in a controlled clinical trial or under a treatment IND, and to set forth criteria for authorizing charging for drugs for treatment use under an established access protocol or a continuation protocol.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	
NPRM Comment Period End	04/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Joseph Griffin, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB11

1148. • NEW DRUGS FOR HUMAN USE; CLARIFICATION OF REQUIREMENTS FOR PATENT HOLDER NOTIFICATION

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: This proposed rule would clarify the methods by which application holders may provide notice to patent holders.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Action	Date	FR Cite
NPRM Comment Period End	03/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Leanne Cusumano, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB12

1149. • ADMINISTRATIVE PRACTICES AND PROCEDURES; ADVISORY OPINIONS AND GUIDELINES

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

Unfunded Mandates: Undetermined

Legal Authority: 15 USC 1451 to 1461; 21 USC 41 to 50; 21 USC 141 to 149; 21 USC 321 to 394; 21 USC 467f; 21 USC 679; 21 USC 821; 21 USC 1034; 42 USC 201; 42 USC 262; 42 USC 263b; 42 USC 264

CFR Citation: 21 CFR 10; 21 CFR 808

Legal Deadline: None

Abstract: This proposed rule would amend FDA regulations in 21 CFR part 10 concerning advisory opinions and guidelines to provide consistency with the agency's Good Guidance Practices and applicable case law.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	
NPRM Comment Period End	05/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Andrea Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

Phone: 301 594-5648

RIN: 0910-AB14

HHS—FDA

Proposed Rule Stage

1150. • MEDICATED FEED MILL LICENSES**Priority:** Substantive, Nonsignificant**Legal Authority:** PL 104-250**CFR Citation:** 21 CFR 5; 21 CFR 207; 21 CFR 225; 21 CFR 510; 21 CFR 514; 21 CFR 515; 21 CFR 558**Legal Deadline:** None

Abstract: The Animal Drug Availability Act of 1996 (ADAA) amends sections 512(a) and 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) to require a single facility license for the manufacture of feeds containing approved new animal drugs, rather than multiple medicated feed applications (MFAs) for each feed mill, as previously required by the act. Prior to the passage of the ADAA, an approved medicated feed application was required by the act for the manufacture of medicated feed. The ADAA eliminates the requirement that a feed mill submit a separate medicated feed application for the manufacture of each type of medicated feed and instead provides for feed mills to be licensed and allows a licensed facility to manufacture any feed containing an approved new animal drug. Additionally, the act as amended by the ADAA provides the agency with the authority to exempt facilities that manufacture certain types of medicated feed from the requirement of a medicated feed mill license.

The Food and Drug Administration published on July 30, 1997, a proposed rule to amend the animal drug regulations and add a new part (21 CFR 515) to provide for feed mill licensing in accordance with the ADAA. The proposed regulation implements the requirements for feed mill licensing set forth in the ADAA. Under this proposal, those medicated feeds exempted from the MFA requirement

under 21 CFR 558.4 will also be exempt from the requirement of a medicated feed mill license.

Timetable:

Action	Date	FR Cite
NPRM	07/30/97	62 FR 40765
NPRM Comment Period End	10/28/97	

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

Agency Contact: William D. Price, Special Assistant, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-200), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1724

RIN: 0910-AB18

1151. • EXEMPTION FROM PREEMPTION OF STATE AND LOCAL CIGARETTE AND SMOKELESS TOBACCO REQUIREMENTS; APPLICATIONS FOR EXEMPTION SUBMITTED BY VARIOUS STATE GOVERNMENTS; GROUP 1; GROUP 2

Priority: Substantive, Nonsignificant**Legal Authority:** 21 USC 360k; 21 USC 371**CFR Citation:** 21 CFR 808**Legal Deadline:** None

Abstract: FDA published a notice of proposed rulemaking on November 7, 1996, announcing that the agency would be accepting applications for exemption from Federal preemption for State and local cigarette and smokeless tobacco requirements. The notice explained that FDA would consider the applications in two groups and set deadlines for submitting applications. Group 1 applications, due December 9, 1996, pertain to State and local requirements governing the sale and distribution of cigarettes and smokeless

tobacco that are different from, or in addition to, FDA requirements under section 897.14(a) and section 897.14(b) of the final tobacco rule (the age and identification requirements). Group 2 applications, due May 6, 1997, pertain to State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco that are different from, or in addition to, all other requirements under the final tobacco rule.

Timetable:**Group 1**

NPRM 02/19/97 (62 FR 7390)
NPRM Comment Period End 06/23/97
Final Action 12/00/97

Group 2

NPRM 12/00/97

Groups 1 and 2

Notice 11/07/96 (61 FR 57685)

Small Entities Affected: None**Government Levels Affected:** State, Local**Additional Information:** Formerly listed under RIN 0910-AB03.

Agency Contact: Anne M. Kirchner, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy (HFD-11), 5600 Fishers Lane, Room 14-72, Rockville, MD 20857
Phone: 301 827-5321
Fax: 301 443-5169

RIN: 0910-AB19

1152. • REGULATIONS REQUIRING MANUFACTURERS TO ASSESS THE SAFETY AND EFFECTIVENESS OF NEW DRUGS AND BIOLOGICAL PRODUCTS IN PEDIATRIC PATIENTS

Regulatory Plan: This entry is Seq. No. 27 in Part II of this issue of the **Federal Register**.

RIN: 0910-AB20

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

Final Rule Stage

1153. NEW ANIMAL DRUG APPROVAL PROCESS; IMPLEMENTATION OF TITLE I OF THE GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT (GADPTRA)

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

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 360b; 21 USC 371; 21 USC 379e; 21 USC 381

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 NADA revisions are expected to include regulations to implement the provisions of the Animal Drug Availability Act of 1996, specifically the definitions of substantial evidence and flexible labeling, and implement parts of the President's National Performance Report "Reinventing the Regulation of Animal Drugs," May 1996. In the reinventing regulations report, FDA proposed to revise its regulations to reflect numerous new process changes and programs that will maintain safety and effectiveness of new animal drugs and enable a more streamlined animal drug application review and approval

process which will result in less regulatory burden upon industry and FDA. 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:

Action	Date	FR Cite
ANPRM	11/21/96	61 FR 59209
ANPRM Comment	01/21/97	
Period End		

New Animal Drug Approval Process
 NPRM 12/17/91 (56 FR 65544)
 NPRM 12/00/98

Reporting Requirements for Marketed Animal Drugs
 NPRM 12/17/91 (56 FR 65581)
 Final Action 11/00/97

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: Margaret Miller, Deputy Director, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-100), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 594-1620

RIN: 0910-AA02

1154. 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. This 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	08/01/94	
Period End		
Final Action	01/00/98	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Federal

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
 Phone: 301 594-2041
 Fax: 301 827-5562

RIN: 0910-AA08

HHS—FDA

Final Rule Stage

1155. MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992

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

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

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 mechanisms for this is oversight of all mammography facilities through a certification, accreditation, and inspection programs. Only facilities certified by the Secretary are permitted to produce, process, or interpret mammographic images. One of the requirements for certification is accreditation by an approved accreditation body. 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 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)
Final Action 10/00/97

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)
Final Action 10/00/97

Mammography Quality Standards Act of 1992; Inspection Fees

Notice 03/17/95 (60 FR 14584)

Personnel Requirements

NPRM 04/03/96 (61 FR 14898)
Final Action 10/00/97

Quality Standards for Mammography Equipment and QA

NPRM 04/03/96 (61 FR 14908)
Final Action 10/00/97

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)
Final Action 10/00/97

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Local, Federal

Additional Information: Previously reported under RIN 0905-AE07.

Agency Contact: Ruth Fischer, 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: 301 594-3311

RIN: 0910-AA24

1156. 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 355; 21 USC 371

CFR Citation: 21 CFR 211

Legal Deadline: None

Abstract: 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 action is in response to the 1991 tampering incidents and requires use of the term "tamper-evident" instead of "tamper-resistant", and that all OTC human drug products marketed in two-piece, hard gelatin capsules be sealed.

Timetable:

Action	Date	FR Cite
NPRM	01/18/94	59 FR 2542
NPRM Comment Period End	03/21/94	
Final Action	12/00/97	
Final Action Effective	12/00/98	

Small Entities Affected: Businesses

Government Levels Affected: Federal

Additional Information: Previously reported under RIN 0905-AE27.

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA26

1157. 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 a clinical investigator who participates in a covered study is not a party to any certain financial interests and arrangements that could potentially bias the outcome of the study, or disclose such interests and arrangements if they exist. This information will enable FDA to subject clinical research data to an appropriate level of scrutiny and help assure 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	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

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

1158. 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: In August, 1995 the Food and Drug Administration (FDA) published a proposed rule that specified standards for the distribution and quality of useful prescription medication information, designed for patients, that voluntary, private-sector efforts should supply to patients receiving new prescriptions. On August 6, 1996, section 601 of the Agriculture Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1997 was enacted which places the proposed rule as it relates to a voluntary program in abeyance. The legislation did not address the provisions that would have required mandatory Medication Guides in relatively rare instances where a product poses a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. FDA is currently considering its options concerning whether and how to finalize the requirement for mandatory Medication Guides for these products.

Timetable:

Action	Date	FR Cite
NPRM	08/24/95	60 FR 44182
Final Action	10/00/97	

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

1159. 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 finalizing revisions to the current good manufacturing practice (CGMP) regulations at 21 CFR parts 210 and 211 regarding finished pharmaceuticals. The new regulations codify current agency policies or current industry practices. Among other things, the rule will create or clarify requirements for process and methods validation, appropriate laboratory testing procedures, and protection against contamination. The rule 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
NPRM	05/03/96	61 FR 20104
NPRM Comment Period End	09/30/96	
Final Action	03/00/98	
Final Action Effective	06/00/98	

Small Entities Affected: Businesses

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AA45

HHS—FDA

Final Rule Stage

1160. 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 eliminates Type I Drug Master Files, 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	12/00/97	
Final Action Effective	06/00/98	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas Kuchenburg, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AA78

1161. OVER-THE-COUNTER HUMAN DRUGS; LABELING REQUIREMENTS

Regulatory Plan: This entry is Seq. No. 28 in Part II of this issue of the **Federal Register**.

RIN: 0910-AA79

1162. INVESTIGATIONAL NEW DRUG APPLICATIONS AND NEW DRUG APPLICATIONS

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 379; 42 USC 262

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

Abstract: The final rule will 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 will require IND sponsors to tabulate 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	12/00/97	
Final Action Effective	06/00/98	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal

Agency Contact: Nancy E. Derr, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-5), 1451 Rockville Pike, Suite 6027, Rockville, MD 20852

Phone: 301 594-5400

Fax: 301 594-6197

RIN: 0910-AA82

1163. 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 will 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	10/27/94	59 FR 54046
Final Action	02/00/98	
Final Action Effective	08/00/98	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AA85

1164. 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 will 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 and are described in the annual report.

Timetable:

Action	Date	FR Cite
NPRM	06/04/86	51 FR 20310
Final Action	01/00/98	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Leanne Cusumano, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852

HHS—FDA

Final Rule Stage

Phone: 301 594-2041
 Fax: 301 827-5562
 RIN: 0910-AA87

1165. DEFINITION OF ADEQUATE AND WELL - CONTROLLED STUDIES

Priority: Substantive, Nonsignificant

Legal Authority: PL 104-250

CFR Citation: 21 CFR 514.117

Legal Deadline: NPRM, Statutory, April 9, 1997.

Abstract: FDA, as directed by the Animal Drug Availability Act of 1996,

is publishing a proposed regulation to further define the term “adequate and well-controlled” to require that field investigations be designed and conducted in a scientifically sound manner and generate data that are reliable and sufficiently controlled to permit evaluation by FDA.

Timetable:

Action	Date	FR Cite
ANPRM	11/21/96	61 FR 59209
ANPRM Comment Period End	01/21/97	
NPRM	05/08/97	62 FR 25153
Final Action	04/00/98	

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: Marty Schoenemann, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-120), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 827-0220

RIN: 0910-AB01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Long-Term Actions

Food and Drug Administration (FDA)

1166. 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 a proposed rule on July 9, 1996, that will establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and reports for the production of infant formulas. This proposal was issued in response to the Infant Formula Act of 1986.

Timetable:

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

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: 202 401-9858

RIN: 0910-AA04

1167. 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, 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 the interim rule. 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. The FDA's Office of Financial Management completed a fee study of the color certification program in May 1997 which supports the maintenance of the existing fee schedule.

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 Financial Management (HFA-120), 5600 Fishers Lane, Rockville, MD 20857

HHS—FDA

Long-Term Actions

Phone: 301 827-5004

Fax: 301 443-6242

RIN: 0910-AA07

1168. IMPLEMENTATION OF THE SAFE MEDICAL DEVICES ACT OF 1990

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

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 that marketed devices are safe and effective, that FDA learns quickly of device problems, and that FDA 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 transitional device in class III, or reclassify it in class I or II. Good Manufacturing Practices for Medical Devices--FDA has added preproduction design validation to the CGMP regulations. Exemption of Humanitarian Devices--The final rule establishes 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 summaries of substantial equivalence determinations. Recall of Medical

Devices--A final rule sets forth procedures for using authority to order device recalls and notifications. Reports of Removal and Corrections--FDA finalized 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 revised existing regulations to conform with procedural changes mandated 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:

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;Availblty) 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 10/07/96 (61 FR 52602)

Final Action Effective Date 06/01/97

Distributor Reporting

NPRM 00/00/00

Exemption of Humanitarian Devices

NPRM 12/21/92 (57 FR 60491)

Final Action 06/26/96 (61 FR 33232)

Stay of Effective Date 10/29/96 (61 FR 55741)

Medical Device Recall Authority

NPRM 06/14/94 (59 FR 30656)

NPRM (Correction) 06/23/94 (59 FR 32489)

Final Action 11/20/96 (61 FR 59004)

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 05/19/97 (62 FR 27183)

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 04/05/96 (61 FR 15180)

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

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-215), 1350 Piccard Drive, Rockville, MD 20850

Phone: 301 594-4765

RIN: 0910-AA09

1169. 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

HHS—FDA

Long-Term Actions

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. 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.

FDA published a final rule on August 2, 1996, on nutrient content claims 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 published a final rule on August 7, 1996, describing provisions for an exemption for small businesses from the requirements for nutrition labeling and providing instructions on how to file a notice claiming the exemption. FDA published on August 16, 1996, final guidelines in the voluntary declaration of nutrition labeling for raw produce and fish.

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 40320)
- Misleading Containers; Nonfunctional Slack Fill**
NPRM 01/06/93 (58 FR 2957)
Final Action 05/10/94 (59 FR 24232)
- Nutrient Content Claims and Health Claims; Restaurant Foods**
NPRM 06/15/93 (58 FR 33055)
Final Action 08/02/96 (61 FR 40320)
- 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 08/07/96 (61 FR 40963)
- Voluntary Guidelines for Nutrition Labeling Produce**
NPRM 07/18/94 (59 FR 36379)
Final Action 08/16/96 (61 FR 42742)

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AD89.

Agency Contact: Elizabeth J. Campbell, 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

1170. 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	11/29/96	61 FR 60661
ANPRM Comment	04/28/97	
Period End		
NPRM	00/00/00	

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: 202 205-4605
Fax: 202 260-8957
RIN: 0910-AA20

1171. 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 dental material for the patient.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: None

HHS—FDA

Long-Term Actions

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-215), 1350 Piccard Drive, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA33

1172. CLASSIFICATION OF COMPUTER SOFTWARE PROGRAMS THAT ARE MEDICAL DEVICES

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321(h); 21 USC 351; 21 USC 352; 21 USC 360; 21 USC 360c to 360l; 21 USC 371 to 374

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: FDA is considering whether to classify stand-alone computer software products that fit the definition of a medical device under the Federal Food, Drug, and Cosmetic Act. Although the Secretary has not made a final decision to initiate such a program, the Agency is considering classifying these devices by using a risk-based approach as required under the Medical Device Amendments to the act. In addition, the agency would use existing exemptions from regulation where appropriate. 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, good manufacturing practice requirements, and reporting and recordkeeping requirements. High risk devices would be the only products to require premarket submissions. 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

1173. HABIT-FORMING DRUGS

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

Unfunded Mandates: Undetermined

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), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA50

1174. 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

HHS—FDA

Long-Term Actions

Action	Date	FR Cite
NPRM Comment Period End	01/11/96	
Final Action	00/00/00	
Revocation of Certain Regulations; General NPRM 01/25/96 (61 FR 2192) Final Action 07/23/97 (62 FR 29439)		
Revocation of Obsolete Animal Food and Drug Regulations Final Action 07/19/96 (61 FR 37680)		
Revocation of Obsolete Biological Regulations Final Action 08/01/96 (61 FR 40153)		
Revocation of Obsolete Drug Regulations Final Action 06/11/96 (61 FR 29476)		
Revocation of Obsolete Food Regulations Final Action 06/03/96 (61 FR 27771)		
Revocation of Obsolete Medical Device Regulations Final Action 07/19/96 (61 FR 37682)		

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

1175. 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 et seq

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 has initiated rulemaking to retain, revise, or revoke certain of its regulations for food. FDA published an advance notice of proposed rulemaking (ANPR) on December 29, 1995, requesting information on the need to retain, revise, or revoke its food standards of identity regulations and its

common or usual name regulations. In the same issue of the Federal Register FDA proposed to improve the coordination of the food additive, GRAS, and color additive approval process with USDA for substances used in meat and poultry products. FDA proposed to revoke several lower fat milk standards on November 9, 1995. On June 12, 1996, FDA published an ANPR announcing its intention to review (1) its human food labeling regulations pertaining to the exemption for soft drinks from requirements for the type size and placement of certain information on the information panel, requirements for listing "statements of identity," and requirements for flavor labeling; (2) its infant formula regulations to ensure that they fully reflect the Federal Food, Drug, and Cosmetic Act; (3) its regulations pertaining to the discharge of waste aboard casino ships, passenger ships, and ferries; and (4) its food additive regulations to consolidate certain existing regulations. In the same June 12 issue of the Federal Register, FDA published a second ANPR seeking public comment on possible ways to streamline various food additive regulations. FDA also proposed on June 12, 1996, to revoke certain food labeling regulations pertaining to labeling of food with number of servings and labeling Kosher and Kosher-style foods and to revoke the agency's voluntary filing of cosmetic product experiences. The latter was published August 12, 1997.

On October 13, 1995, FDA proposed to revoke certain agency regulations that were obsolete or no longer necessary to achieve public health goals. The final rule (pertaining to food regulations only) published on June 3, 1996. A confirmation of effective date (CED) on those regulations promulgated under the formal rulemaking procedures of section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 USC 371(e)) pertaining to diabetic labeling (21 CFR 105.67) and sodium intake (cont)

Timetable:

Exempt Infant Formula; Plan for Revisions
ANPRM 06/12/96 (61 FR 29701)
Comment Period End 10/10/96
NPRM 00/00/00

Food Standards of Identity, Quality, and Fill of Container
ANPRM 12/29/95 (60 FR 67492)
Comment Period Ends 06/28/96
NPRM 00/00/00

Food, Color Additive, GRAS Regulations
ANPRM 06/12/96 (61 FR 29701)
Comment Period Ends 09/10/96
NPRM 00/00/00

Food, Color, and GRAS; Simult. Pet. Rev. by USDA (Meat/Poultry)
NPRM 12/29/95 (60 FR 67490)
Comment Period End 03/14/96
Extension of Comment Period 06/03/96
Final Action 00/00/00

Notification Procedures for Independent GRAS Determinations
NPRM 04/17/97 (62 FR 18938)
NPRM Comment Period End 07/16/97
Final Action 00/00/00

Revocation of Certain Food Labeling and Cosmetic Regulations
NPRM 06/12/96 (61 FR 29708)
Comment Period Ends 08/26/96
Final Action 08/12/97 (62 FR 43071)

Revocation of Lower Fat Milk Standards
NPRM 11/09/95 (60 FR 56541)
Comment Period Ends 01/23/96
Partial Final 11/20/96 (61 FR 58991)
Confirmation of Effective Date 02/24/97 (62 FR 8163)

Revocation of Lower Fat Yogurt Standards
NPRM 11/09/95 (60 FR 56541)
Confirmation of Effective Date 00/00/00
Final Action (Yogurt) 00/00/00

Revocation of Obsolete Regulations
NPRM 10/13/95 (60 FR 53480)
Comment Period Ends 01/11/96
Final Action 06/03/96 (61 FR 27771)
Confirmation of Eff. Date 08/27/96 (61 FR 43963)

Small Entities Affected: Businesses

Government Levels Affected: State

Additional Information: ABSTRACT CONT: labeling (21 CFR 105.69) was published on August 27, 1996.

In the Federal Register of April 17, 1997 (62 FR 18938), FDA proposed to establish a notification procedure for companies to use for independent GRAS determinations.

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

1176. DIETARY SUPPLEMENT REGULATIONS IN RESPONSE TO DSHEA

Priority: Other Significant

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

HHS—FDA

Long-Term Actions

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, 1994, modifying the provisions for labeling of dietary supplements. FDA has initiated rulemaking to modify its regulations for dietary supplements accordingly. One proposal would modify the nutrition labeling and ingredient declaration requirements. A second proposal would provide for the use of nutrient content claims and health claims on dietary supplements and establish procedures for the use of a 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. An ANPRM was published in February 1997 seeking public comments on issues related to the establishment of current good manufacturing practices for dietary supplements.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	
CGMPs in the Manufacturing, Packing, or Holding of Dietary Supps.		
ANPRM	02/06/97	(62 FR 5700)
Comment Period End 06/06/97		
High Potency and Antioxidant Terms; Dietary Supplements		
NPRM	12/28/95	(60 FR 67184)
Comment Period End 06/10/96		
Final Action 09/23/97 (62 FR 49808)		
Nutrient Content and Health Claim; Dietary Supplements		
Final Action 09/23/97 (62 FR 49859)		
Nutrient Content and Health Claims; Dietary Supplements		
NPRM	12/28/95	(60 FR 67176)
Comment Period End 06/10/96		
Nutrient Labeling and Ingredient Labeling; Dietary Supplements		
NPRM	12/28/95	(60 FR 67194)
Comment Period End 06/10/96		
Final Action 09/23/97 (62 FR 49826)		

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: Betty Campbell, Acting 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-AA59

1177. EXPORT REQUIREMENTS FOR DRUGS FOR INVESTIGATIONAL USE IN OTHER COUNTRIES

Priority: Substantive, Nonsignificant

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 to foreign countries. The proposed rule would permit an unapproved drug product to be exported under three different options. The first option would permit exportation of a drug under an approved investigational new drug application (IND). This would be consistent with the preexisting rule. The second option would permit exportation of a drug to a country other than one specified in section 802(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act, without an IND or prior FDA approval, provided that adverse event information is reported to the FDA. This would represent a significant change from the existing rule and reflects FDA's experience with drugs exported for investigational use (whereby a minute percentage of all drugs exported for investigational use result in any safety concerns). The third option would permit exportation of drugs for investigational use to one of the countries specified in section 802(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act without an IND or prior FDA approval. This third option would implement part of the FDA Export Reform and Enhancement Act.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

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

1178. REINVENTION OF ADMINISTRATIVE PROCEDURES 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 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

Legal Deadline: None

Abstract: FDA is considering ways to further streamline its administrative procedure 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	06/04/96	61 FR 28116
NPRM	00/00/00	

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal, Federal

HHS—FDA

Long-Term Actions

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

1179. LONG-TERM CONTRACEPTIVE DRUG PRODUCTS AND MEDICAL DEVICES; INFORMED CONSENT REQUIREMENTS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 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 is intended to 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: Next Action Undetermined

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
RIN: 0910-AA75

1180. CERTIFICATION OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

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

Unfunded Mandates: Undetermined

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: Next Action Undetermined

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Wayne Mitchell, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
RIN: 0910-AA77

1181. 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 is evaluating its interim final regulation promulgated December 21, 1990, in light of recommendations made by the Presidential Advisory Committee on Gulf War Veterans' Illnesses as well as other information that has come to its attention. The interim rule established requirements to

allow agency to grant requests for the waiver of informed consent in the use of investigational drugs or biologics in certain military combat circumstances. In examining its interim rule, several areas have engendered significant discussion and debate. Because these issues are complex, on July 31, 1997, FDA published a notice in the Federal Register soliciting comments on the advisability of revoking or amending the interim final rule that permitted the FDA Commissioner to determine that obtaining informed consent from military personnel for the use of an investigational product is not feasible in certain military exigencies. FDA is also soliciting comments identifying the evidence needed to demonstrate safety and effectiveness for such investigational drugs that cannot ethically be tested on humans for purposes of determining their efficacy. The written comments are intended to provide FDA with information to help the agency in making policy decisions on the use of investigational products during military exigencies and appropriate evidence needed to demonstrate safety and effectiveness for drug and biological products used in military or other exigencies when traditional efficacy studies are not feasible. Written comments are to be submitted by October 29, 1997.

Timetable: Next Action Undetermined

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Bonnie M. Lee, Senior Policy Analyst, Office of the Executive Secretariat (HF-40), Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-4433
Fax: 301 443-1863
RIN: 0910-AA89

1182. FDA EXPORT REFORM AND ENHANCEMENT ACT OF 1996; REPORTING AND RECORDKEEPING REQUIREMENTS FOR UNAPPROVED OR VIOLATIVE PRODUCTS IMPORTED FOR FURTHER PROCESSING OR INCORPORATION AND LATER EXPORT

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 381 to 382

CFR Citation: Not yet determined

HHS—FDA

Long-Term Actions

Legal Deadline: None

Abstract: The FDA Export Reform and Enhancement Act of 1996 allows the import of certain FDA regulated products that may not be offered for sale in the United States because they are in violation of the Federal Food, Drug, and Cosmetic Act when the purpose of the importation is to have the articles processed in the United States and then exported. FDA is proposing reporting, recordkeeping, and labeling requirements to enable the importer to assure, and the FDA to monitor, that the imported products are further processed and exported and do not enter domestic commerce.

Timetable: Next Action Undetermined

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Eric Flamm, Senior Policy Advisor, Office of Policy, Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-3344

RIN: 0910-AB06

1183. • ANIMAL DRUG APPROVALS FOR MINOR SPECIES AND MINOR USAGE

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

Legal Authority: PL 104-250

CFR Citation: Not yet determined

Legal Deadline: Other, Statutory, April 9, 1998.

Animal Drug Availability Act of 1996.

Abstract: The Animal Drug Availability Act of 1996 (ADAA) requires FDA to consider legislative and regulatory options for facilitating approval of NAD's intended for use in minor species and for minor uses, and to announce no later than April 9, 1998, proposals for legislative or regulatory change to the approval process for such drugs. Because the markets are small for approved NADs intended for minor species or for minor uses, there are often insufficient economic incentives to motivate sponsors to develop the data necessary to support approvals. Manufacturers have not, in many cases, been willing to fund research to obtain these data, so only small numbers of new animal drugs intended for minor

species or for minor uses have been approved and are legally marketed. Facilitating approvals for minor uses and minor species will bring about an increase in approvals of new animal drugs intended for these uses, which would be desirable to address the scarcity of approved, legally marketed new animal drugs intended for minor species or minor uses.

Timetable:

Action	Date	FR Cite
ANPRM	06/23/97	62 FR 33781
Next Action Undetermined		

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Request for Comments 62 FR 33789, 6/23/97.

Agency Contact: Linda Wilmot, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-112), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-0614

RIN: 0910-AB07

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Food and Drug Administration (FDA)

1184. SPECIFIC REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS; ADDITION OF "GERIATRIC USE" SUBSECTION IN THE LABELING

Priority: Other Significant

CFR Citation: 21 CFR 201

Completed:

Reason	Date	FR Cite
Final Action	08/27/97	62 FR 45313
Final Action Effective	08/27/98	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal

Agency Contact: Thomas Kuchenberg
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Fax: 301 827-5562

RIN: 0910-AA25

1185. ADVERSE EXPERIENCE EXPEDITED REPORTING REQUIREMENTS FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS

Priority: Other Significant

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

Completed:

Reason	Date	FR Cite
Final Action	10/06/97	62 FR 52237
Final Action Effective	04/06/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Audrey Thomas
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA28

1186. LATEX CONDOMS: EXPIRATION DATE LABELING

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

CFR Citation: 21 CFR 801

Completed:

Reason	Date	FR Cite
Final Action	09/26/97	62 FR 50497

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0910-AA32

1187. LATEX WARNING

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 801

Completed:

Reason	Date	FR Cite
Final Action	09/30/97	62 FR 51021

HHS—FDA

Completed Actions

Small Entities Affected: Undetermined
Government Levels Affected: Undetermined
Agency Contact: Joseph M. Sheehan
 Phone: 301 594-4765
RIN: 0910-AA34

1188. HUMAN TISSUE INTENDED FOR TRANSPLANTATION

Priority: Other Significant
CFR Citation: 21 CFR 1270

Completed:

Reason	Date	FR Cite
Final Action	07/29/97	62 FR 40429
Final Action Effective	01/26/98	

Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Paula S. McKeever
 Phone: 301 827-6210
RIN: 0910-AA40

1189. 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.

CFR Citation: 21 CFR 314; 21 CFR 600; 21 CFR 601; 21 CFR 610; 21 CFR 640

Completed:

Reason	Date	FR Cite
Final Action	07/24/97	62 FR 39889
Final Action Effective	10/07/97	

Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Steven F. Falter
 Phone: 301 827-6210
RIN: 0910-AA57

1190. 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.
CFR Citation: 21 CFR 812.18

Completed:

Reason	Date	FR Cite
Withdrawn	06/06/97	62 FR 31023

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Linda Horton
 Phone: 301 827-3344
RIN: 0910-AA62

1191. 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.

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

Completed:

Reason	Date	FR Cite
Final Action	06/25/97	62 FR 34166
Final Action Effective	07/25/97	

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Audrey Thomas
 Phone: 301 594-2041
 Fax: 301 827-5562
RIN: 0910-AA72

1192. NATIONAL ENVIRONMENTAL POLICY ACT; POLICIES AND PROCEDURES

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 25

Completed:

Reason	Date	FR Cite
Final Action	07/29/97	62 FR 40569
Final Action Effective	08/28/97	

Small Entities Affected: Businesses, Organizations
Government Levels Affected: Federal
Agency Contact: Nancy Sager
 Phone: 301 594-5629
 Fax: 301 594-6197
RIN: 0910-AA80

1193. CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICAL; POSITRON EMISSION TOMOGRAPHY

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 211

Completed:

Reason	Date	FR Cite
Final Action	04/22/97	62 FR 19494
Final Action Effective	04/28/97	

Small Entities Affected: Businesses, Organizations
Government Levels Affected: Federal
Agency Contact: Brian L. Pendleton
 Phone: 301 594-2041
 Fax: 301 827-5562

RIN: 0910-AA81

1194. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED; PROTEIN DERIVED FROM RUMINANTS PROHIBITED IN RUMINANT FEED

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 589.2000

Completed:

Reason	Date	FR Cite
Final Action	06/05/97	62 FR 30955
Final Action Effective	08/04/97	

Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: G.A. Mitchell
 Phone: 301 827-0139
RIN: 0910-AA91

1195. TREATMENT USE OF INVESTIGATIONAL DEVICE EXEMPTIONS

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 812

HHS—FDA

Completed Actions

Completed:

Reason	Date	FR Cite
Final Action	09/18/97	62 FR 48940

Small Entities Affected: Undetermined
Government Levels Affected: None
Agency Contact: Joseph M. Sheehan
 Phone: 301 594-4765
RIN: 0910-AA92

1196. REVISION OF THE REQUIREMENTS FOR A RESPONSIBLE HEAD FOR BIOLOGICAL ESTABLISHMENTS

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 600; 21 CFR 601; 21 CFR 606

Completed:

Reason	Date	FR Cite
Final Action	10/15/97	62 FR 53536
Final Action Effective	10/15/97	

Small Entities Affected: Businesses
Government Levels Affected: None
Agency Contact: Astrid Szeto
 Phone: 301 827-6210
RIN: 0910-AA93

1197. DISQUALIFICATION OF A CLINICAL INVESTIGATOR

Priority: Substantive, Nonsignificant
CFR Citation: 21 CFR 312

Completed:

Reason	Date	FR Cite
Final Action	09/05/97	62 FR 46875

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Thomas Kuchenberg
 Phone: 301 594-2041
 Fax: 301 827-5562
RIN: 0910-AA95

1198. EXEMPTION FROM PREEMPTION OF STATE AND LOCAL CIGARETTE AND SMOKELESS TOBACCO REQUIREMENTS; APPLICATIONS FOR EXEMPTION SUBMITTED BY VARIOUS STATE GOVERNMENTS

Priority: Substantive, Nonsignificant
CFR Citation: 21 CFR 808

Completed:

Reason	Date	FR Cite
NPRM	02/19/97	62 FR 7390
Notice of Opportunity for Oral Hearing	02/19/97	62 FR 7395
Withdrawn - Currently listed under RIN 0910-AB19	03/25/97	

Small Entities Affected: None
Government Levels Affected: State, Local
Agency Contact: Anne M. Kirchner
 Phone: 301 827-5321
RIN: 0910-AB03

1199. • CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS; PREGNANCY LABELING SECTION; NOTICE OF PUBLIC HEARING; REQUEST FOR COMMENTS

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: FDA is announcing a public hearing regarding the regulations that set forth requirements for the content and format of the pregnancy subsection of labeling for human prescription drugs (21 CFR 201.57(f)(6)). The purpose of the public hearing is to elicit comment on pregnancy labeling categories to help the agency identify the range of problems associated with the categories and identify and evaluate options that might address identified problems, including alternative ways of presenting information on reproductive and developmental risk, and advising clinicians and patients on use of drugs in pregnant women and women of child bearing potential.

Timetable:

Action	Date	FR Cite
Notice of Public Hearing	07/31/97	62 FR 41061

Small Entities Affected: Undetermined
Government Levels Affected: Undetermined

Agency Contact: Joseph Griffin, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 1451 Rockville Pike, Suite 3047, Rockville, MD 20852
 Phone: 301 594-2041
 Fax: 301 827-5562

RIN: 0910-AB15

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

Proposed Rule Stage

1200. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: CORPORATE SHIELD

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 11131
CFR Citation: 45 CFR 60
Legal Deadline: None

Abstract: This NPRM proposes to require that in addition to reporting the National Practitioner Data Bank medical malpractice payments made where physicians or other health care practitioners are named in judgments or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgements or settlements but who

furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the "corporate shield" to prevent the health care practitioner from being reported.

It would also allow, in very limited circumstances when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified, the name of the hospital or health care organization for whose benefit the payment was made, the amount of payment, and the name (if known) of any hospital or health care organization with which the practitioner is affiliated or associated.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas C. Croft, Director, Division of Quality Assurance, Bureau of Health Professions, HRSA, Department of Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 8A-55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-2300

RIN: 0906-AA41

1201. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: CHARGE FOR SELF-QUERIES

Priority: Info./Admin./Other

Legal Authority: 42 USC 11137

CFR Citation: 45 CFR 60

Legal Deadline: None

Abstract: The NPRM proposes to amend the existing regulations for the National Practitioner Data Bank to give the Data Bank the authority to charge a fee to practitioners requesting information about themselves (self-queries). The current \$10 cost per self-query is being underwritten by health care provider organizations which query the Data Bank directly and are charged a fee based on the number of transmissions and payment. The NPRM would amend the existing fee structure so that the Data Bank can fully recover its cost, as required by law, in an equitable manner.

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas C. Croft, Director, Division of Quality Assurance, Bureau of Health Professions, HRSA, Department of Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 8A-55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-2300

RIN: 0906-AA42

1202. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: REPORTING ADVERSE AND NEGATIVE ACTIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396r-2, note

CFR Citation: 45 CFR 60

Legal Deadline: None

Abstract: Public Law 100-93 amended section 1921 of the Social Security Act to require that each State have in effect a system of reporting disciplinary licensure actions taken against all licensed health care practitioners and entities. It also requires States to report any negative action or finding which a peer review organization, private accreditation entity or a State has concluded against a health care practitioner or entity. Section 1921 directs the Secretary to provide for maximum appropriate coordination in the implementation of these reporting requirements with those of the Health Care Quality Improvement Act of 1986 (title IV of Public Law 99-660).

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas C. Croft, Director, Division of Quality Assurance, Bureau of Health Professions, Department of Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 8A-55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-2300

RIN: 0906-AA43

1203. DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS

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 254b; 42 USC 254e

CFR Citation: 42 CFR 5; 42 CFR 51c

Legal Deadline: None

Abstract: This rule would consolidate the process for designating areas of health professional shortage and medical underservice that apply in several department programs, and would improve the criteria for designating medically underserved populations (MUPs) and Primary Care Health Professional Shortage Areas (HPSAs).

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	
NPRM Comment	03/00/98	
Period End		

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Richard Lee, Public Health Analyst, Bureau of Primary Health Care, Department of Health and Human Services, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, MD 20814
Phone: 301 594-3729

RIN: 0906-AA44

1204. HEALTH CARE FRAUD AND ABUSE

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320a-7e

CFR Citation: 42 CFR 61 (New)

Legal Deadline: None

Abstract: This Notice of Proposed Rulemaking proposes to implement the requirements of section 1128E of the Social Security Act, as added by sec. 221(a) of the Health Insurance Portability and Accountability Act of 1996. Section 1128E directs the Secretary of Health and Human Services to establish a national health care fraud and abuse data collection

HHS—HRSA

Proposed Rule Stage

program for the reporting and disclosure of certain final adverse actions taken against health care providers, suppliers, or practitioners. The statute also requires the Secretary to implement the national health care fraud and abuse data collection program in such a manner as to avoid duplication with reporting requirements established for the National Practitioner Data Bank under the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.).

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: Thomas C. Croft, Director, Division of Quality Assurance, Bureau of Health Professions, Department of Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 8A-55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-3014

RIN: 0906-AA46

1205. • NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PROVIDERS: CLARIFICATION AND MODERNIZATION OF REGULATORY TERMS

Priority: Substantive, Nonsignificant

Legal Authority: 45 USC 11101 to 11152

CFR Citation: 45 CFR 60

Legal Deadline: None

Abstract: Since the opening of the Data Bank, the Department has received feedback that several terms defined in the regulations have caused a great deal of confusion. Based on this feedback, the Department reviewed the Health Care Quality Improvement Act of 1986 and its regulations. Through this review, the Department recognizes the need to clarify and/or broaden certain definitions due to the rapid evolution of the health care system in order to fully implement Congressional intent, which was to give access to Data Bank information to those health care organizations reviewing the quality of physician care in order to protect

patients from incompetent practitioners with previous damaging or incompetent performance. Since these terms, as defined in the regulations, particularly "health care entity," "formal peer review process" and "clinical privileges" are not currently fully implementing Congressional intent and have caused a great deal of confusion, the Department proposes to clarify them.

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas C. Croft, Director, Division of Quality Assurance, Bureau of Health Professions, Department of Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 8-A55, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-2300

RIN: 0906-AA48

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

Final Rule Stage

1206. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK RULES

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

RIN: 0906-AA32

1207. • GRANTS FOR RESIDENCY TRAINING AND ADVANCED EDUCATION IN THE GENERAL PRACTICE OF DENTISTRY; TECHNICAL AMENDMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 293m

CFR Citation: 42 CFR 57 subpart L

Legal Deadline: None

Abstract: This technical amendment revises the Grants for Residency Training and Advanced Education in the General Practice of Dentistry program regulations to modify the review criteria to be consistent with current agency streamlining efforts, and provide the flexibility required to adequately meet the needs and requirements of the program and its constituents.

Timetable:

Action	Date	FR Cite
Final Action	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Bernice Parlak, Acting Director, Division of Associated Dental and Public Health Professions, Department of Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 8-101, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-6853
Fax: 301 443-1164

RIN: 0906-AA47

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

Long-Term Actions

**1208. DRUG PRICING PROGRAM:
 PRIME VENDOR USER CHARGE**

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: PL 102-585
CFR Citation: 45 CFR 8

Legal Deadline: None
Abstract: This rule proposes to include a user charge (not over 1/2 of 1% of total drug sale revenue) to be paid by the prime vendor to HRSA. It is intended to cover costs that HRSA incurs in providing information and services essential to prime vendor operations.
Timetable: Next Action Undetermined
Small Entities Affected: None

Government Levels Affected: None
Agency Contact: Annette Byrne, Director, Office of Drug Pricing, Department of Health and Human Services, Health Resources and Services Administration, 4350 East/West Highway, Bethesda, MD 20814
 Phone: 301 594-4353
 Fax: 301 594-4992
RIN: 0906-AA45

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

Completed Actions

**1209. HEALTH EDUCATION
 ASSISTANCE LOAN (HEAL)
 PROGRAM: LENDERS'/ HOLDERS'
 PERFORMANCE STANDARDS**

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 60

Completed:

Reason	Date	FR Cite
Withdrawn	09/17/97	

Small Entities Affected: None
Government Levels Affected: None

Agency Contact: Michael Heningburg
 Phone: 301 443-1173
RIN: 0906-AA33

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Indian Health Service (IHS)

Proposed Rule Stage

**1210. 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	12/00/97	

Small Entities Affected: None
Government Levels Affected: Tribal

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

**1211. INDIAN CHILD PROTECTION
 AND FAMILY VIOLENCE PREVENTION
 ACT MINIMUM STANDARDS OF
 CHARACTER**

Priority: Info./Admin./Other
Legal Authority: 25 USC 3201 et seq
CFR Citation: 42 CFR 36
Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	
NPRM Comment Period End	01/00/98	

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)
National Institutes of Health (NIH)

Proposed Rule Stage

1212. 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 487A of the Public Health Service Act creates a program through which appropriately qualified health professionals may obtain federally funded repayment of educational loans by conducting AIDS research as NIH employees.

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	

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
 Phone: 301 496-4606
 Fax: 301 402-0169
 Email: moorej@od31emi.nih.gov
RIN: 0925-AA02

1213. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NIH

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 288-4
CFR Citation: 42 CFR 68b
Legal Deadline: None

Abstract: Section 487D of the 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	02/00/98	

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

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
 Phone: 301 402-4606
RIN: 0925-AA10

1214. TRAINEESHIPS (TERMINATION POLICIES)

Priority: Info./Admin./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	11/00/97	

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
 Phone: 301 496-4606
 Fax: 301 402-0169
 Email: moorej@od31emi.nih.gov
RIN: 0925-AA11

1215. ADDITIONAL DHHS PROTECTIONS FOR PREGNANT WOMEN AND HUMAN FETUSES INVOLVED AS SUBJECTS IN RESEARCH, AND PERTAINING TO HUMAN IN VITRO FERTILIZATION

Priority: Other Significant
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 and human fetuses in research.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: Undetermined
Government Levels Affected: Undetermined

Agency Contact: E. William Dommel, Jr., J.D., Senior Policy Analyst, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, 6100 Executive Blvd., Ste. 3B01, MSC 7507, Rockville, MD 20892-7507
 Phone: 301 496-7005
 Fax: 301 402-2803
 Email: wd3u@nih.gov
RIN: 0925-AA14

1216. NATIONAL RESEARCH SERVICE AWARDS

Priority: Info./Admin./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 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

HHS—NIH

Proposed Rule Stage

support, by engaging in a second year of NRSA supported research training.

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	

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-AA16

1217. REMOVAL OF NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM

Priority: Info./Admin./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
NPRM	10/00/97	

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

1218. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 288-3

CFR Citation: 42 CFR 68d

Legal Deadline: None

Abstract: Regulations will be issued to govern the awarding of educational loan repayments for research authorized under section 487C of the Public Health Service Act, as added by provisions of the NIH Revitalization Act of 1993.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	

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, 9000 Rockville Pike, Room 1B25, 31 Center Drive MSC 2075, Bethesda, MD 20892-0275
 Phone: 301 496-4606
 Fax: 301 496-0125
 Email: moorej@od31em1.nih.gov
RIN: 0925-AA18

1219. NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288-2

CFR Citation: 42 CFR 68c

Legal Deadline: None

Abstract: Section 487B of the Public Health Service Act creates a program through which appropriately qualified health professionals may obtain federally funded repayment of education loans by conducting research with respect to contraception and/or infertility. The initial implementation of the program will be limited to employees of the three NICHD Contraception Research Centers and two NICHD Infertility Research Centers due to limited availability of funds.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

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, 9000 Rockville Pike, Room 1B25, 31 Center DR MSC 2075, Bethesda, MD 20892-2075
 Phone: 301 496-4607
 Fax: 301 402-0169
 Email: moorej@od31em1.nih.gov
RIN: 0925-AA19

1220. SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT 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 282(b)(6); 42 USC 284(c)(3); 42 USC 289a; 42 USC 290aa-3

CFR Citation: 42 CFR 52h

Legal Deadline: None

Abstract: NIH staff have been reexamining the peer review process as part of its reinvention initiatives and have found ambiguities, misstatements, and voids in the existing regulations governing peer review in NIH, SAMHSA, and HRSA. These regulations, which govern the first level of review, would be amended to reflect current policies and procedures.

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	

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, 9000 Rockville Pike, Room 1B25, Bethesda, MD 20892-2075
 Phone: 301 496-4606
 Fax: 301 402-0169
 Email: moorej@od31em1.nih.gov
RIN: 0925-AA20

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
National Institutes of Health (NIH)

Final Rule Stage

1221. NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS

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 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 285o-4; 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 make them generally applicable 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	09/05/95	
Period End		
Final Action	10/00/97	

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
 Phone: 301 496-4606
 Fax: 301 402-0169
 Email: moorej@od31emi.nih.gov
RIN: 0925-AA04

Legal Deadline: None

Abstract: Regulations will 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	02/10/97	62 FR 5953
NPRM Comment	04/11/97	
Period End		
Final Action Effective	11/00/97	

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
 Phone: 301 496-4606
 Fax: 301 402-0169
 Email: moorej@od31emi.nih.gov
RIN: 0925-AA09

1222. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Office of Assistant Secretary for Health (OASH)

Long-Term Actions

1223. 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	08/09/93	58 FR 34024
Period End		
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: Previously reported under RIN 0905-AE03.

Agency Contact: Thomas C. Kring, Acting 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., 4350 East-West Highway, Bethesda, MD 20814
 Phone: 301 594-4000

RIN: 0937-AA00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Proposed Rule Stage

Public Health Service (PHS)

1224. PUBLIC HEALTH SERVICE STANDARDS FOR THE PROTECTION OF RESEARCH MISCONDUCT WHISTLEBLOWERS

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 94

Legal Deadline: None

Abstract: To implement section 493(e) of the Public Health Service Act (added by section 163 of the NIH Revitalization Act of 1993, Public Law 103-43), the Department is proposing to add a new Part 94 to title 42 of the Code of Federal Regulations. Under this

proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: (1) persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to an allegation of, research misconduct, and (2) persons who cooperate in good faith with an investigation of research misconduct.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Action	Date	FR Cite
NPRM Comment Period End	03/00/98	

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State

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

RIN: 0905-AE71

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Prerule Stage

Health Care Financing Administration (HCFA)

1225. MEDICARE PROGRAM: MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICARE INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 1998 (OACT-055-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395r

CFR Citation: 45 CFR 900

Legal Deadline: Final, Statutory, September 30, 1997.

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, 1998. It also announces the monthly SMI premium rate to be paid by all enrollees during the 12 months beginning January 1, 1998

Timetable:

Action	Date	FR Cite
ANPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Carter Warfield, Deputy Director, Division of Medicare and Medicaid Cost Estimates, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786-6396

RIN: 0938-AI03

1226. • MEDICARE PROGRAM; PHYSICIAN FEE SCHEDULE UPDATE FOR CALENDAR YEAR 1998 AND PHYSICIAN VOLUME PERFORMANCE STANDARD RATES OF INCREASE FOR FEDERAL FISCAL YEAR 1998 (BPD-893-FN)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395w-4

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the calendar year 1998 updates to the Medicare physician fee schedule and the Federal fiscal year 1998 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
ANPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Terrence Kay, Center for Health Plans and Providers, Division of Practitioner and Ambulatory Care, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., C4-10-26, Baltimore, MD 21244

Phone: 410 786-4497

RIN: 0938-AI16

1227. • HEALTH INSURANCE PORTABILITY: NEWBORNS' AND MOTHERS' HEALTH PROTECTION (BPD-892-IFC)

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

Legal Authority: 42 USC 300gg-4; 42 USC 300gg-51

CFR Citation: 45 CFR 146.136; 45 CFR 148.151

Legal Deadline: None

Abstract: This interim final rule implements the Newborns' and Mothers' Health Protection Act of 1996. It provides that a health insurance issuer that covers hospital length of stay in connection with childbirth may not restrict the stay for the mother or newborn to less than 48 hours following a normal vaginal delivery or 96 hours following a cesarean section. However, discharge may occur earlier if the attending provider in consultation with the mother decides to discharge earlier.

Timetable:

Action	Date	FR Cite
ANPRM	11/00/97	

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Mark Thomas, Health Insurance Standards Team, Department of Health and Human Services, Health

HHS—HCFA

Prerule Stage

Care Financing Administration, 7500

Security Blvd, C4-02-16, Baltimore, MD 21244

Phone: 410 786-7154

RIN: 0938-AI17

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)

Proposed Rule Stage

1228. "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 401; 42 CFR 403.310; 42 CFR 405; 42 CFR 410.1; 42 CFR 411.23; 42 CFR 411.28; 42 CFR 413.20; 42 CFR 413.153; 42 CFR 447.31; 42 CFR 466.86; 42 CFR 466.94; 42 CFR 473.14; 42 CFR 493.1834

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 circumstances involving Medicare overpayments.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-719

Agency Contact: David Walczak, Center for Health Plans and Providers, Plan & Provider Purchasing Policy Group, 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

1229. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (BPD-727-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g(a); 42 USC 1395l; 42 USC 1395x(v); 42 USC 1395x(v)(1)A; 42 USC 1395hh; 42 USC 1395ii; 42 USC 1395oo; 42 USC 1395ww; 42 USC 405; 42 USC 300e; 42 USC 300e-5; 42 USC 300e-9; 31 USC 9701

CFR Citation: 42 CFR 405.1801 to 405.1889; 42 CFR 413.30 to 413.64; 42 CFR 417.576; 42 CFR 417.810

Legal Deadline: None

Abstract: Section 1878 of the Social Security Act and 42 CFR Part 405, subpart R provide for administrative and judicial review in accordance with prescribed requirements, of certain disputes regarding Medicare reimbursement for participating providers of services. This proposed rule would revise, update, and clarify various provisions of the regulations pertaining to provider appeals and make conforming changes to other regulations

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-727

Agency Contact: Morty Marcus, Center for Health Plans and Providers, 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

1230. 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 1395x(aa); 42 USC 1395y(a)(14); 42 USC 1396a(a)(13)(E); 42 USC 263a; 42 USC 1302; 42 USC 1395hh

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 '86, '87, '89, and '90 and would propose administrative changes that clarify policy related to sharing space between rural health clinics 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. Some changes pertain to federally qualified health centers as well as rural health clinics.

Timetable:

Action	Date	FR Cite
NPRM	05/00/98	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: BPD-764

Agency Contact: Helen Klein, Center for Health Plans and Providers, Division of Integrated Services, 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

HHS—HCFA

Proposed Rule Stage

1231. ALTERNATIVE SANCTIONS FOR RENAL DIALYSIS FACILITIES (HSQ-204-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395rr(c); 42 USC 1395rr(g)

CFR Citation: 42 CFR 405; 42 CFR 488; 42 CFR 498

Legal Deadline: None

Abstract: This proposed rule would set forth circumstances under which HCFA could impose denial of payment as an alternative sanction instead of terminating coverage when an ESRD facility is not in substantial compliance with the conditions for coverage, but its deficiencies do not pose immediate jeopardy to patient health or safety. Before section 1881 of the Social Security Act was amended by section 12 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (Public Law 100-93), HCFA was authorized to impose alternative sanctions only when an ESRD facility failed to cooperate in the goals and activities of the ESRD network for the area in which the facility is located.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: HSQ-204

Agency Contact: Judith Kari, Center for Medicaid and State Operations, Division of Outcomes and Improvements, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6829

RIN: 0938-AG31

1232. EFFECT OF CHANGE OF OWNERSHIP ON PROVIDER AND SUPPLIER PENALTIES, SANCTIONS, UNDERPAYMENTS AND OVERPAYMENTS (HSQ-215-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g(a); 42 USC 1395hh; 42 USC 1395ii; 42 USC 1395oo; 42 USC 1395xx; 42 USC 1395x(v); 42 USC 1395i

CFR Citation: 42 CFR 405.1803; 42 CFR 405.1811; 42 CFR 405.1835; 42 CFR 405.1843; 42 CFR 405.1805; 42 CFR 489.2; 42 CFR 489.18

Legal Deadline: None

Abstract: This rule would amend the regulations on provider and certain supplier agreements by clarifying the effect a change of ownership has on penalties and sanctions incurred by the former provider or supplier. It also would clarify our policy on changes involving leased departments.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: None

Government Levels Affected: Undetermined

Additional Information: HSQ-215

LEGAL AUTHORITY CONT: 42 USC 1395f(b) 42 USC 1395l 42 USC 1395ww

Agency Contact: Mike Goldman, Division of Integrated Health Systems, Department of Health and Human Services, Health Care Financing Administration, S2-14-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6813

RIN: 0938-AG59

1233. 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(z)

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 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	10/00/97	

Small Entities Affected: None

Government Levels Affected: State, Local

Additional Information: MB-082

Agency Contact: Ingrid Osborne, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-19-24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4461

RIN: 0938-AG72

1234. REVISION OF MEDICARE HOSPITAL CONDITIONS OF PARTICIPATION (BPD-745-P)

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

RIN: 0938-AG79

1235. 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; 42 USC 1396b

CFR Citation: 42 CFR 411.350 to 411.361; 42 CFR 424.22; 42 CFR 435.1012; 42 CFR 455.108; 42 CFR 455.109

Legal Deadline: None

Abstract: This proposed rule would provide that a physician who has (or whose immediate family member 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. In the Medicaid context, this proposed rule would 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 OBRA '93 and section 152 of SSAA '94.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

HHS—HCFA

Proposed Rule Stage

Small Entities Affected: Businesses

Government Levels Affected: State

Additional Information: BPD-809

Agency Contact: Joanne Sinsheimer, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-11-23, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4620

RIN: 0938-AG80

1236. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (BPD-818-P)

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

RIN: 0938-AG82

1237. CLINICAL LABORATORY IMPROVEMENT AMENDMENT (CLIA) FEE SCHEDULE REVISION (HSQ-219-GNC)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395x(e); 42 USC 1395x(s)(11); 42 USC 1395x(s)(12); 42 USC 1395x(s)(13); 42 USC 1395x(s)(14); 42 USC 1395x(s)(15)

CFR Citation: 42 CFR 493.638; 42 CFR 493.639

Legal Deadline: None

Abstract: This general notice with comment period will announce updated certificate 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.

Timetable:

Action	Date	FR Cite
General Notice with Comment Period	08/29/97	
Comment Period End	10/28/97	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: HSQ-219

Agency Contact: Judy Yost, Division of Outcomes and Improvements, 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

1238. 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 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	03/00/98	

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: MB-080

Agency Contact: Robert Nakielny, Center for Medicaid and State Operations, 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

1239. DEFINITION OF SKILLED NURSING FACILITY (SNF) FOR COVERAGE OF DURABLE MEDICAL EQUIPMENT (DME) (BPD-834-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(n); 42 USC 1395i(a)(1); 42 USC 1396r(a)(1)

CFR Citation: 42 CFR 409; 42 CFR 410

Legal Deadline: None

Abstract: This proposed rule would define skilled nursing facilities (SNFs) under section 1819(A)(1) of the Social Security Act for purposes of Medicare coverage of durable medical equipment (DME) and home health services. A Medicare SNF (as defined under

section 1819 of the Social Security Act) cannot be considered a home under Medicare part B for DME and home health coverage. This proposed rule would presume that all Medicare nursing facilities are section 1819(A)(1) facilities and thus would not be considered a home for DME. This proposed rule would presume that all Medicare skilled nursing facilities are section 1819(A)(1) facilities and thus would not be considered a home for DME. This would define non-Medicare nursing homes as skilled facilities based upon the receipt of skilled care by at least once a week by a proportion of its residents population.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-834

Agency Contact: Thomas Hoyer, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-02-16, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4605

RIN: 0938-AH16

1240. ADDITIONAL SUPPLIER STANDARDS (BPD-864-P)

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

RIN: 0938-AH19

1241. STATE PLAN AMENDMENT (SPA) RECONSIDERATION PROCESS (MB-096-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 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 by permitting the State expedited judicial review, without a full administrative hearing, after HCFA has a brief opportunity to reconsider its decision.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: MB-096

Agency Contact: Robert Tomlinson, Center for Medicaid and State Operations, 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

1242. 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 provisions to provide coverage for speech-language pathology services furnished by a qualified pathologist.

Timetable:

Action	Date	FR Cite
NPRM	06/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-843

Agency Contact: Jackie Gordon, Division of Cost Reporting, 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

1243. PAYMENT AMOUNT IF CUSTOMARY CHARGES ARE LESS THAN REASONABLE COSTS (BPD-860-FC)

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 from the regulation text of any reference to the carryover provision. Since payment for durable medical equipment (DME) provided by home health agencies (HHAs) is no longer based on the lesser of the reasonable cost or reasonable charge but rather on 80% of the lesser of the actual charge for the item or the payment amount recognized under the DME fee schedule and, for nominal charge HHAs, on 80% of the DME fee schedule amount, the lesser of costs or charges provision no longer applies and should be deleted from the CFR.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: BPD-860

Agency Contact: Ward Pleines, Chronic Care Purchasing Policy Group, Division of Cost Reporting, Department of Health and Human Services, Health Care Financing Administration, C5-02-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4528

RIN: 0938-AH49

1244. SUPPLIER PARTICIPATION AGREEMENTS AND 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 1395u(h); 42 USC 1395hh; 42 USC 1395rr(b)(1)

CFR Citation: 42 CFR 400; 42 CFR 414

Legal Deadline: None

Abstract: The Deficit Reduction Act of 1984 established a voluntary participation program for physicians and suppliers under which physicians and suppliers enter into an agreement with Medicare that binds them to accept payment on an assignment-related basis for all services they furnish to Medicare beneficiaries. This proposed rule would set forth the terms and conditions of the participation agreements. 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 will revise text in the CFR to reduce burden or duplication, or streamline requirements. It will give beneficiaries the opportunity to make informed consumer decisions regarding the choice of Medicare Part B services.

Timetable:

Action	Date	FR Cite
NPRM	08/00/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-862

Agency Contact: Anita Heygster, Center for Health Plans & Providers, 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

1245. REVISION TO ACCRUAL BASIS OF ACCOUNTING POLICY (BPD-876-P)

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 413.100

Legal Deadline: None

Abstract: The proposed rule would specify the providers' share of the costs of FICA and other employee payroll taxes that will be allowable under Medicare when the payroll period ends subsequent to the end of the reporting period. The proposed rule would allow that portion of employees FICA or other taxes that have accrued up to the end of the reporting period to be credited as allowable cost in the current reporting period and the remainder in the following period.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-876

Agency Contact: John Eppinger, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C5-03-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4518

RIN: 0938-AH61

1246. MEDICAID; ESTATE RECOVERIES (MB-083-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a; 42 USC 1396p

CFR Citation: 42 CFR 433.36

Legal Deadline: None

Abstract: This proposed rule is being developed as a result of the OBRA 1993 provisions that mandated States to seek adjustment or recovery from the estates of Medicaid beneficiaries for amounts correctly spent by Medicaid on permanently institutionalized individuals (any age) and individuals age 55 or older for certain services. The OBRA 1993 provision also defines "estate," and further requires States to establish hardship procedures, in accordance with standards specified by the Secretary for waiver of recovery in

cases where undue hardship would result.

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: State

Additional Information: MB-083

Agency Contact: Ingrid Osborne, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-22-06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4461

RIN: 0938-AH63

1247. MEDICAID HOSPICE CARE (MB-007-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395hh; 42 USC 1302

CFR Citation: 42 CFR 418.24; 42 CFR 418.28; 42 CFR 418.98; 42 CFR 440.167; 42 CFR 440.250(q); 42 CFR 441; 42 CFR 447

Legal Deadline: None

Abstract: This proposed rule would provide for optional Medicaid coverage of hospice care for terminally ill recipients who elect to receive care from a participating hospice, establish eligibility requirements, covered services, reimbursement procedures, and conditions that a hospice must meet to provide services to Medicaid recipients, and makes conforming technical revisions to the Medicare regulations governing hospice care.

Timetable:

Action	Date	FR Cite
NPRM	04/00/98	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local

Additional Information: MB-007

Agency Contact: Tom Shenk, Center for Medicaid and State Operations, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-13-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3295

RIN: 0938-AH65

1248. PROVIDER AND SUPPLIER BILLING WHEN MEDICARE IS SECONDARY PAYOR TO LIABILITY INSURANCE (BPD-848-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 1395cc; 42 USC 1395dd; 42 USC 1395hh; 42 USC 1395ww; 42 USC 1395x; 42 USC 1395aa

CFR Citation: 42 CFR 411; 42 CFR 489

Legal Deadline: None

Abstract: This proposed rule would revise current regulations to require that providers and suppliers attempt to collect payment from the proceeds of liability insurance during the "promptly period." This rule would also permit providers and suppliers to choose either to pursue collection of payment from the proceeds of liability insurance after the "promptly period" has ended or to bill Medicare.

Timetable:

Action	Date	FR Cite
NPRM	09/00/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-848

Agency Contact: Anita Heygster, Center for Health Plans and Providers, Division of Integrated Services, Department of Health and Human Services, Health Care Financing Administration, C4-08-25, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4486

RIN: 0938-AH66

1249. ELIMINATION OF CERTAIN REQUIREMENTS FOR PEER REVIEW ORGANIZATIONS IN THE UTILIZATION AND QUALITY REVIEW PROCESS AND A CHANGE IN THE LENGTH OF PEER REVIEW ORGANIZATION CONTRACTS (HSQ-235-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

HHS—HCFA

Proposed Rule Stage

duplication, or streamline requirements.

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 462.107; 42 CFR 466.71; 42 CFR 466.73

Legal Deadline: None

Abstract: This proposed rule would eliminate the requirement that Peer Review Organizations (PROs) conduct quarterly random sample reviews of hospital discharges. It would also change the period for PRO contracts from 2 years to 3 years and would eliminate certain notification requirements regarding contract awards.

Timetable:

Action	Date	FR Cite
NPRM	09/00/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: HSQ-235-FC

Agency Contact: Bill Roskey, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S1-09-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0433

RIN: 0938-AH68

1250. UPDATE OF RATESETTING METHODOLOGY, PAYMENT RATES AND THE LIST OF COVERED SURGICAL PROCEDURES FOR AMBULATORY SURGICAL CENTERS EFFECTIVE FOR CALENDAR YEAR 1998 (BPD-885-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 13951(i)

CFR Citation: 42 CFR 416.61(b); 42 CFR 416.65(a)(4); 42 CFR 416.65(c); 42 CFR 416.120(c)(1); 42 CFR 416.125; 42 CFR 416.130; 42 CFR 416.140(a); 42 CFR 416.140(b)

Legal Deadline: None

Abstract: This proposed rule discusses several policy changes affecting coverage of and payment for Ambulatory Surgical Center (ASC) facility services as provided under sections 1833(i)(1A) and (2A) of the Social Security Act. It would include the criteria for identifying procedures that are appropriate and safely performed in an ASC; the method used

to set ASC payment rates; and the schedule for publishing and implementing payment and coverage updates.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-885-P

Agency Contact: Joan Sanow, Division of Practitioner and Ambulatory Care, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-5723

RIN: 0938-AH81

1251. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (BPD-887-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 416

Legal Deadline: None

Abstract: This proposed rule would revise the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement. The focus would be to improve outcomes of health care and satisfaction for Medicare beneficiaries, while streamlining structural and procedural requirements where possible.

Timetable:

Action	Date	FR Cite
NPRM	04/00/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-887

Agency Contact: Judy Goldfarb, Office of Clinical Standards & Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, S2-199.06, Baltimore, MD 21244
Phone: 410 786-6747

RIN: 0938-AH83

1252. DISCLOSURE OF PEER REVIEW ORGANIZATION INFORMATION IN RESPONSE TO BENEFICIARY COMPLAINTS (HSQ-241-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1320c-3(a)(14); 42 USC 1395hh

CFR Citation: 42 CFR 466.70(a); 42 CFR 476.101; 42 CFR 476.107; 42 CFR 476.132; 42 CFR 476.133(b)(4)

Legal Deadline: None

Abstract: This proposed rule would change our policy regarding the disclosure of peer review organization (PRO) information in responding to beneficiary complaints about physicians, other practitioners, and other institutional and non-institutional providers of health care, including Health Maintenance Organizations and Competitive Medical Plans. Under the proposal, we would permit the disclosure of PRO information about physicians and other individual practitioners without their permission to the extent necessary to comply with section 1154(a)(14) of the Social Security Act. This section requires PROs to conduct reviews of beneficiary complaints about the quality of services that do not meet professionally recognized standards of health care and inform each beneficiary of the final disposition of his or her complaint.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: William Roskey, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, S1-09-07, Baltimore, MD 21244
Phone: 410 786-0433

RIN: 0938-AH85

1253. MEDICARE PROGRAM; BENEFICIARY INCENTIVES PROGRAMS (BPO-144-P)

Priority: Other Significant

Legal Authority: PL 104-191, sec 203

CFR Citation: 42 CFR 420.400; 42 CFR 420.405; 42 CFR 420.410

Legal Deadline: Final, Statutory, October 21, 1996.

Abstract: This proposed rule would establish a program for payment to individuals who provide information on Medicare fraud and abuse. It would also establish a program to collect suggestions to improve Medicare program efficiency and allow for payment to the individuals who provide the suggestions. Overall, it would implement sections 203(b) and 203(c) of the Health Insurance Portability and Accountability Act of 1996.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: BPO-144-P

Agency Contact: Bambi Straw, Program Integrity Group, Office of Financial Management, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, S3-08-05, Baltimore, MD 21244
Phone: 410 786-7539

RIN: 0938-AH86

1254. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (BPO-145-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320d; 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 421.100; 42 CFR 421.200; 42 CFR 424.5; 42 CFR 434.6; 42 CFR 442.12; 42 CFR 447.3; 45 CFR 142

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPO-145

Agency Contact: Faye Broseker, Center for Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, Bureau of Program Operations, S3-04-05, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-3342

RIN: 0938-AH87

1255. MEDICARE COVERAGE OF CERTIFIED NURSE-MIDWIFE SERVICES (BPD-496-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(s); 42 USC 1395x(gg)

CFR Citation: 42 CFR 405.2411; 42 CFR 405.2414; 42 CFR 405.2415; 42 CFR 410.10; 42 CFR 410.77

Legal Deadline: None

Abstract: This proposed rule would implement section 4073 of OBRA 1987 by amending Medicare regulations to reflect part B coverage of the services of certified nurse-midwives furnished without the supervision of a physician. It would define "certified nurse-midwife" and "certified nurse-midwife services."

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-496-P

Agency Contact: Roberta Epps, Center for Health Plans and Providers, Division of Practitioner & Ambulatory Care, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, C4-0516, Baltimore, MD 21244
Phone: 410 786-4475

RIN: 0938-AH96

1256. NATIONAL STANDARD HEALTH CARE PROVIDER IDENTIFIER (BDM-45-P)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1320d

CFR Citation: 45 CFR 142; 42 CFR 421.100; 42 CFR 421.200; 42 CFR 424.5; 42 CFR 434.6; 42 CFR 442.12; 42 CFR 447.3; 42 CFR 489.10

Legal Deadline: None

Abstract: This rule would address the health care industry's need for a

standardized provider identifier. It would implement one of the requirements for administrative simplification in section 262 of the Health Insurance Portability and Accountability Act of 1996. A standard provider identifier would save the health insurance industry significant costs incurred in maintaining multiple identifier systems.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: BDM-45-P

Agency Contact: Karen Trudel, Office of Information Services, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., N3-06-13, Baltimore, MD 21224
Phone: 410 786-9937

RIN: 0938-AH99

1257. MEDICARE PROGRAM; MEDICARE INTEGRITY PROGRAM (OFH-020-P)

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

RIN: 0938-AI09

1258. MEDICARE PROGRAM; IMPROVEMENTS TO THE APPEALS PROCESS FOR MEDICARE BENEFICIARIES ENROLLED IN HMOs, CMPS, AND HCPPS (OMC-024-P)

Priority: Other Significant

Legal Authority: 42 USC 1395mm(c)(5)

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This proposed rule would establish new administrative review requirements for Medicare beneficiaries enrolled in health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans. This rule would implement section 1876(c)(5) of the Social Security Act, which specifies the appeal and grievance rights of Medicare enrollees in HMOs and CMPs. This rule would reduce time lines for nonurgent denials of care and make other improvements. We will also address

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related requirements of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Cheryl Slay, Director, Division of Beneficiary Protections, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6478

RIN: 0938-AI11

1259. • MENTAL HEALTH PARITY AND NEWBORNS' AND MOTHERS' HEALTH PROTECTION

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 100

CFR Citation: 45 CFR 300

Legal Deadline: None

Abstract: This needs information.

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ann White, Regulations Coordinator, Department of Health and Human Services, Health Care Financing Administration, 200 Independence Avenue, Washington, DC 20201
Phone: 202 690-6824

RIN: 0938-AI13

1260. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1999 RATES (HCFA-1001-P)

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

RIN: 0938-AI22

1261. • CHILDREN'S HEALTH INSURANCE: PROGRAM IMPLEMENTATIONS; STATE PLAN APPROVAL; STATE PAYMENT; COORDINATION WITH STATE MEDICAID PROGRAM

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

RIN: 0938-AI28

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Health Care Financing Administration (HCFA)

1262. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (BPD-309-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1995g; 42 USC 1395k; 42 USC 1395l; 42 USC 1395x; 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395tt; 42 USC 1395ww; 42 USC 1396b

CFR Citation: 42 CFR 405; 42 CFR 413; 42 CFR 414; 42 CFR 424; 42 CFR 431; 42 CFR 447

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 will set forth the methods by which the fee schedules will be updated and will 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

Action	Date	FR Cite
NPRM Comment Period End	10/18/93	
Final Action	09/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-309

Agency Contact: Charles Spalding, Center for Medicaid and State Operations, Division of Acute Care, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4496

RIN: 0938-AB50

1263. 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. It also establishes appeal rights and procedures for entities that are dissatisfied with effective date determinations.

Timetable:

Action	Date	FR Cite
NPRM	10/08/92	57 FR 46362
NPRM Comment Period End	12/07/92	
Final Action	11/00/97	

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: HSQ-139

Agency Contact: Diane Bavaria, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6773

RIN: 0938-AC88

HHS—HCFA

Final Rule Stage

1264. 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); 44 USC 3501 to 3511

CFR Citation: 42 CFR 400; 42 CFR 411

Legal Deadline: None

Abstract: This rule will codify in the CFR the Medicare secondary payer (MSP) provision, under the Social Security Act, 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
Comment Period End	05/08/90	
Comment Period End	10/30/92	
Final Rule	08/31/95	60 FR 45344
Effective Date	10/02/95	
Final Action	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-482

Agency Contact: Herbert Pollock, Center for Health Plans and Providers, Division of Integrated Services, 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

1265. REVISIONS TO REGULATIONS IMPLEMENTING CLIA (HSQ-226-F)

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

RIN: 0938-AE47

1266. RESIDENT ASSESSMENT IN LONG-TERM CARE FACILITIES (HSQ-180-F)

Priority: Other Significant

Legal Authority: 42 USC 1395i-3; 42 USC 1396r

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This final rule will provide Medicare and Medicaid nursing homes the requirements for a comprehensive, standardized, reproducible resident assessment instrument. All certified nursing homes are currently required to assess residents using a standardized data set known as the minimum data set (MDS). Nursing homes have been collecting this information manually since October 1990. Most States implemented a second generation assessment instrument, known as MDS 2.0, on January 1, 1996. The use of the MDS as the core of the comprehensive assessment requirement has improved the quality of nursing home services by assuring that the assessment is consistently based on all information that is necessary to evaluate a resident's needs. Accurate and comprehensive resident assessments have improved the accuracy of the care planning process and ultimately, the care provided by the nursing home. However, in order to realize the full benefits of the MDS, the information needs to be computerized, and reconfigured as an analytical tool. Publication of this rule will allow this goal to be realized by requiring electronic reporting of MDS data and provide support for the computerization of the MDS.

Timetable:

Action	Date	FR Cite
NPRM	12/28/92	57 FR 61614
NPRM Comment Period End	02/26/93	
Final Action	10/00/97	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: HSQ-180

Agency Contact: Cindy Hake, Center for Medicaid and State Operations, Elderly and Disabled Programs Group, Department of Health and Human Services, Health Care Financing Administration, S2-20-08, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3404

RIN: 0938-AE61

1267. 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 (HMOs) or competitive medical plans (CMPs) that cease to contract with HCFA under section 1876 of the Social Security Act to arrange for supplemental coverage for former Medicare enrollees who would otherwise be subject to a pre-existing condition exclusion under a Medicare supplemental policy; 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 furnish a copy of an executed enrollment application form to Medicare applicants; and, require health care prepayment plans to comply with HMO/CMP beneficiary application procedures. We will also address relative requirements of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	03/11/94	59 FR 11230
NPRM Comment Period End	05/09/94	
Final Action	11/00/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: OMC-003

Agency Contact: Tracy Jensen, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

HHS—HCFA

Final Rule Stage

Phone: 410 786-1033

RIN: 0938-AE63

1268. 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: Final, Statutory, June 30, 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 address 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	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-685

Agency Contact: Marc Hartstein, Center for Health Plans & Providers, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4539

RIN: 0938-AE79

1269. COVERAGE OF SCREENING PAP SMEARS (BPD-705-F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 410.10; 42 CFR 410.32; 42 CFR 410.56; 42 CFR 411.15

Legal Deadline: None

Abstract: This rule establishes 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	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-705

Agency Contact: Joyce Eng, Office of Clinical Standards and Quality, 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

1270. REQUIREMENTS FOR CERTAIN HEALTH INSURING ORGANIZATIONS AND OBRA'90 TECHNICAL AMENDMENTS (OMC-018-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396b(m); 42 USC 1396a(e)(2)(A)

CFR Citation: 42 CFR 434.20 to 72; 42 CFR 435.212; 42 CFR 435.326

Legal Deadline: None

Abstract: This final rule amends the Medicaid regulations to apply Medicaid regulations governing prepaid health plans to those health insuring organizations that provide or arrange for health care services to Medicaid recipients but are not subject to the requirements for health maintenance organizations (HMOs) set forth in section 1903(m)(2)(A) of the Social Security Act. It also incorporates technical amendments relating to HMO and/or competitive medical plan

enrollment, disenrollments, guaranteed eligibility, and provisional status included in OBRA '90 and the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	05/09/94	59 FR 23820
NPRM Comment Period End	07/08/94	
Final Action	04/00/98	

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: OMC-018

Agency Contact: Jane McClard, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S3-02-14, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4460

RIN: 0938-AF15

1271. MEDICAID PAYMENT FOR COVERED OUTPATIENT DRUGS UNDER REBATE AGREEMENTS (MB-046-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 1396a(a); 42 USC 1396r-8; 42 USC 1396b(a); 42 USC 1302

CFR Citation: 42 CFR 447; 42 CFR 441

Legal Deadline: None

Abstract: This final rule with comment period 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 reflect statutory revisions mandated by the Veteran's Health Care Act of 1992 and OBRA '93. Revision of the drug rebate dispute resolution process is part of the Department's regulatory reinvention initiative.

HHS—HCFA

Final Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	09/19/95	60 FR 48442
NPRM Comment Period End	11/20/95	
Final Action	02/00/98	

Small Entities Affected: Businesses

Government Levels Affected: State

Additional Information: MB-046

Agency Contact: Sue Williamson, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-15-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-3334

RIN: 0938-AF42

1272. RETROACTIVE ENROLLMENT AND DISENROLLMENT IN RISK HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS (OMC-015-F)

Priority: Other Significant

Legal Authority: 42 USC 1395mm; 42 USC 300e; 42 USC 300e-5; 42 USC 300e-9; 42 USC 1302; 42 USC 1395hh; 31 USC 9701

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; 42 CFR 417.436

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 (of the Social Security Act) risk contract through an employer health plan. In addition, the rule will permit the Secretary to authorize retroactive disenrollment in specific cases. We will also address related requirements of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	12/27/93	58 FR 68366
Comment Period End	02/25/94	
Final Action	06/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: OMC-015

Agency Contact: Anne Manley, Center for Health Plans and Providers,

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-AF98

1273. 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 finalizes 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 "operating costs of inpatient hospital services" 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	10/00/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-731

Agency Contact: Nancy Edwards, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C5-06-27, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4531

RIN: 0938-AG00

1274. 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	11/00/97	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: BPD-748

Agency Contact: Bernadette Schumaker, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4568

RIN: 0938-AG03

1275. 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: 45 CFR 500

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	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-781

Agency Contact: Francine Spencer, Office of Clinical Standards and Quality, Coverage and Analysis Group, 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

1276. 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: 45 CFR 300

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	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-782

Agency Contact: Francine Spencer, Office of Clinical Standards and Quality, Coverage and Analysis Group, 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

1277. TELEPHONE 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 1302; 42 USC 1395ff(b); 42 USC 1395hh; 42 USC 1395u(b)(3)(C)

CFR Citation: 42 CFR 405.802; 42 CFR 405.807

Legal Deadline: None

Abstract: This rule will make it easier for beneficiaries, providers, and physicians (and other suppliers) who are entitled to appeal Medicare part B initial claim determinations to request review of the carrier's initial determination. Currently, these appeals must be in writing. This expanded rule will also allow appeals to be made by telephone, which will expedite the appeal process, and save time and costs for all parties. Allowing the use of telephone requests will supplement, not replace, the current review procedures. By providing quick and easy access to the appeals process, this rule will also improve carrier

relationships with the provider and beneficiary communities.

Timetable:

Action	Date	FR Cite
NPRM	07/10/95	60 FR 35544
NPRM Comment Period End	09/08/95	
Final Action	03/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPO-121

Agency Contact: Rosalind Little, Center for Beneficiary Services, 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

1278. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (BPD-819-F)

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

RIN: 0938-AG81

1279. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HSQ-225-F)

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

RIN: 0938-AG99

1280. AMBULANCE SERVICES (BPD-813-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 410.40; 42 CFR 410.41; 42 CFR 424.124

Legal Deadline: None

Abstract: This rule updates and revises policy on coverage of ambulance services. It bases coverage and payment for ambulance services on the medical services needed to treat the beneficiary's condition. It also clarifies Medicare policy on coverage of non-emergency ambulance services for Medicare beneficiaries. It defines an ambulance by describing the requirements for furnishing both basic

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and advanced life support levels of ambulance services. The rule would require use of additional HCFA common procedure coding systems (HCPCS) codes to show the origin and destination of the ambulance transportation on the billing form. It requires use of international classification of diseases, 9th revision, clinical modification (ICD-9-CM) codes to bill the Medicare program for basic and advanced levels of ambulance services.

Timetable:

Action	Date	FR Cite
NPRM	06/17/97	62 FR 32715
NPRM Comment Period End	08/17/97	
Final Action	04/00/98	

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: None

Additional Information: BPD-813

Agency Contact: Margot Blige, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4642

RIN: 0938-AH13

1281. ADJUSTMENT IN PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES (BPD-831-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 1395k(a)(2); 42 USC 1395l; 42 USC 2630

CFR Citation: 42 CFR 416

Legal Deadline: NPRM, Statutory, October 31, 1995.

Abstract: This rule establishes 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 ambulatory surgical centers. This rule is part of HCFA's regulatory reform initiative.

Timetable:

Action	Date	FR Cite
NPRM	09/04/97	62 FR 46698
Final Action	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-831

Agency Contact: Cathaleen Ahern, Center for Health Plans and Providers, Division of Practitioner & Ambulatory Care, 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

1282. CLIA PROGRAM: CYTOLOGY PROFICIENCY TESTING (HSQ-233-N)

Priority: Other Significant

Legal Authority: 42 USC 263a(f)(4)(B)(iv)

CFR Citation: 42 CFR 493.855

Legal Deadline: None

Abstract: This notice announces the withdrawal of a proposed rule on cytology proficiency testing that was published in the Federal Register November 30, 1995, and instead, announces a supplement to the rulemaking record of a final rule published February 28, 1992. In publishing the proposed rule, HHS complied with a Federal court order requiring publication of a proposal that would require that cytology proficiency testing be conducted to the extent practicable, under normal working conditions. As required, we proposed 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 solicited comments on the use of computer facsimile representations of cytology specimens, as an alternative to glass-slide proficiency testing. After the proposed rule was published, the appeals court revised the lower court's order, allowing us to withdraw the proposed rule and supplement the record to the final rule.

Timetable:

Action	Date	FR Cite
NPRM	11/30/95	60 FR 61509

Action	Date	FR Cite
NPRM Comment Period End	01/29/96	
Final Action	03/00/98	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: HSQ-233-N. We are publishing a notice to advise the public that no final rule is necessary because the court decided the case in our favor.

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

1283. LIMITATIONS ON LIABILITY (BPD-859-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 1302hh; 42 USC 1395pp

CFR Citation: 42 CFR 411.404

Legal Deadline: None

Abstract: This final rule with comment period will implement section 1879 (h) of the Social Security Act, which limits beneficiary liability for certain medical equipment and supplies. This rulemaking is part of the Reinventing Government effort. We are working with industry representatives to develop guidelines that will streamline requirements, reduce burden and duplication, and give beneficiaries the opportunity to make informed consumer decisions regarding certain medical equipment and supplies.

Timetable:

Action	Date	FR Cite
Final Action	05/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-859

Agency Contact: Denis Garrison, Division of Beneficiary Protections, Department of Health and Human

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Services, Health Care Financing Administration, C4-06-21, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-5643
RIN: 0938-AH51

1284. TERMS, DEFINITIONS, AND ADDRESSES: TECHNICAL AMENDMENTS (BPD-877-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: 42 USC 1302; 42 USC 1395x(v)(1)(A); 42 USC 1395hh

CFR Citation: 42 CFR 413.118; 42 CFR 413.122

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
Final Rule With Comment Period	11/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-877

Agency Contact: Luisa Iglesias, Division of Regulation and Issuances, Department of Health and Human Services, Health Care Financing Administration, Room 409-B Humphry Bldg, 200 Independence Ave SW., Washington, DC
 Phone: 202 690-6383

RIN: 0938-AH53

1285. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1998 RATES (BPD-878-F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395ww

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

Legal Deadline: NPRM, Statutory, May 1, 1997. Final, Statutory, September 1, 1997.

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 announce the prospective payment rates for operating and capital-related costs for FY 1998. We will also revise the Medicare hospital inpatient prospective payment systems for operating costs and capital-related costs to implement necessary changes resulting from the Balanced Budget Act of 1997, Public Law 105-33, and changes arising from our continuing experience with the systems. 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 will be applicable to discharges occurring on or after October 1, 1997.

Timetable:

Action	Date	FR Cite
NPRM	06/02/97	62 FR 29902
NPRM Comment Period End	08/01/97	
Final Action	10/00/97	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Federal

Additional Information: BPD-878

Agency Contact: Tzvi Hefter, Division of Acute Care, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-1304

RIN: 0938-AH55

1286. HOME HEALTH AGENCY PHYSICIAN CERTIFICATION REGULATIONS (BPD-875-NC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395nn; 42 USC 1395hh; 42 USC 1395f; 42 USC 1395n

CFR Citation: 42 CFR 424.22

Legal Deadline: None

Abstract: This notice with comment period will deal with the applicability

of current Medicare regulations pertaining to the indirect compensation of physicians who certify or recertify the need for home health services or who establish or review the home plan of care.

Timetable:

Action	Date	FR Cite
Notice With Comment Period	10/00/97	
Final Action	00/00/00	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: BPD-875

Agency Contact: Jennifer Carter, Chronic Care Purchasing Policy Group, Department of Health and Human Services, Health Care Financing Administration, C4-07-05, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4615

RIN: 0938-AH59

1287. MEDICARE PROGRAM; ESTABLISHMENT OF AN EXPEDITED REVIEW PROCESS FOR MEDICARE BENEFICIARIES ENROLLED IN HMOs, CMPS, AND HCPPS (OMC-25-FC)

Priority: Other Significant

Legal Authority: 42 USC 1395mm(c)(5)

CFR Citation: 42 CFR 417.600; 42 CFR 417.604; 42 CFR 417.606; 42 CFR 417.608; 42 CFR 417.609; 42 CFR 417.614; 42 CFR 417.616; 42 CFR 417.617; 42 CFR 417.618; 42 CFR 417.620

Legal Deadline: None

Abstract: This final rule establishes a new administrative review requirement for Medicare beneficiaries enrolled in health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs) and will apply to part C Medicare choice plans. This rule implements section 1876(c)(5) of the Social Security Act, which specifies the appeal and grievance rights for Medicare enrollees and HMOs and CMPs. This rule requires that an HMO, CMP, or HCPP establish and maintain, as part of the health plan's appeals procedures, an expedited process for making organization determinations and reconsider determinations when an adverse determination could seriously jeopardize the life or health of the

enrollee or the enrollee's ability to regain maximum function. This rule also revises the definition of appealable determinations to clarify that it includes a decision to discontinue services.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/30/97	62 FR 23368
Final Action	12/00/97	

Small Entities Affected: None

Government Levels Affected: Federal

Additional Information: OMC-25-F

Agency Contact: Maureen Miller, Division of Integrated Delivery Systems, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, S3-21-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1097

RIN: 0938-AH62

1288. UTILIZATION CONTROL AND DISCONTINUED REVIEW ACTIVITIES; MEDICAID (MB-101-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 1395hh; 42 USC 1396a(a)(26); 42 USC 1396(a)(30); 42 USC 1396a(a)(31); 42 USC 1396(a)(44); 42 USC 1396b(g)

CFR Citation: 42 CFR 400; 42 CFR 431; 42 CFR 456

Legal Deadline: None

Abstract: This proposed rule would codify in regulations the statutory requirements that make physician certification and development of plan of care and utilization review State plan requirements under the Medicaid program. States would no longer be required to make quarterly showings that they have complied with those requirements and other provisions would be removed. Regulatory provisions on regional staff subsampling of State Medicaid quality control.

Timetable:

Action	Date	FR Cite
Final Action	12/00/97	

Small Entities Affected: Businesses

Government Levels Affected: State

Additional Information: MB-101

Agency Contact: Wanda White, Office of Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-2638

RIN: 0938-AH64

1289. USE OF THE OASIS AS PART OF THE CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES (HSQ-238-F)

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

RIN: 0938-AH74

1290. INDIVIDUAL MARKET HEALTH INS. REFORM PORTABILITY FROM GROUP TO INDIV. COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIV. MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (BPD-882-F)

Priority: Other Significant. Major under 5 USC 801.

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

Legal Authority: 42 USC 201

CFR Citation: 45 CFR 148

Legal Deadline: None

Abstract: This final rule addresses comments received on the interim final rule published on April 8, 1997 and further clarifies the Departmental position on HIPAA requirements in the individual market.

Timetable:

Action	Date	FR Cite
Interim Final Rule with Comment Period	04/08/97	62 FR 16985
Interim Rule Effective Date	04/08/97	
Interim Rule Public Comment Period End	07/07/97	
Final Action	04/00/98	

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Federal

Additional Information: BPD-882-F

Agency Contact: Gertrude Saunders, Insurance Standards Team, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-5888

RIN: 0938-AH75

1291. MEDICAID PROGRAM; REDETERMINATIONS OF MEDICAID ELIGIBILITY DUE TO WELFARE REFORM (MB-105-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 42 CFR 435.1003

Legal Deadline: None

Abstract: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 and the Contract With America Advancement Act of 1996 made statutory changes affecting the eligibility of large numbers of Medicaid recipients. Changes were made to the definition of disability for children and eligibility requirements of non-U.S. citizens and individuals receiving disability cash assistance based on a finding of alcoholism and drug addiction. In order to protect Federal financial participation in State Medicaid expenditures for States with unusual volumes of eligibility redeterminations caused by these statutory changes, we published a final rule with comment period on January 13, 1997. That rule changed our regulations to provide additional time for States to process redeterminations and provide services pending the redeterminations. We are analyzing the public comments to the January 13 rule in preparation of a final rule.

Timetable:

Action	Date	FR Cite
Final Rule With Comment Period	01/13/97	62 FR 1682
Final Action Effective	01/13/97	
Final Action	04/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Bob Tomlinson, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, Medicaid Bureau, C4-20-21, 7500 Security Blvd., Baltimore, MD 21244

HHS—HCFA

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Phone: 410 786-4463

RIN: 0938-AH76

1292. CLIA PROGRAM; SIMPLIFYING CLIA REGULATIONS TO ACCREDITATION EXEMPTION OF LABORATORIES UNDER A STATE LICENSURE PROGRAM, AND PROFICIENCY TESTING AND INSPECTION (HSQ-239-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 263a; 42 USC 1302; 42 USC 1395x(e); 42 USC 1395x(s)(11) to 1395x(s)(16)

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This final rule with comment period will respond to various comments received on an earlier final rule with a comment period implementing the Clinical Laboratory Improvement Amendments of 1988, which was published in the Federal Register on February 28, 1992, in the areas of proficiency testing and inspections for clinical laboratories. This rule will follow the Administration's regulatory reform initiative by reducing duplicative material, emphasizing outcome-oriented results, and simplifying regulations. We also are streamlining our regulation in the areas of State exemption, and granting deemed status to laboratories accredited by an approved accreditation organization.

Timetable:

Action	Date	FR Cite
Final Action	12/00/97	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: HSQ-239

Agency Contact: Judy Yost, Center for Medicaid and State Operations, Division of Outcomes and Improvement, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-3531

RIN: 0938-AH82

1293. FINAL LIMITATIONS ON AGGREGATE PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS: FEDERAL FISCAL YEAR 1997 (MB-110-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396(a)(13); 42 USC 1396r-4(f)

CFR Citation: 42 CFR 447.297; 42 CFR 447.298; 42 CFR 447.299

Legal Deadline: Other, Statutory, April 1997.

Regulatory Deadline

Abstract: This notice announces the final Federal fiscal year 1997 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs.

Timetable:

Action	Date	FR Cite
Notice	11/00/97	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: MB-110

Agency Contact: Richard Strauss, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., C4-17-27, Baltimore, MD 21244
Phone: 410 786-2019

RIN: 0938-AH93

1294. MEDICARE PROGRAM; REVISIONS TO PAYMENT POLICIES AND ADJUSTMENTS TO THE RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE, OTHER PART B PAYMENT POLICIES FOR CALENDAR YEAR 1998 (BPD-884-FC)

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

RIN: 0938-AH94

1295. REVISION TO THE DEFINITION OF AN UNEMPLOYED PARENT (MB-106-FC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 607; 42 USC 1369u-1

CFR Citation: 45 CFR 233

Legal Deadline: None

Abstract: This final rule with comment period will make a change necessary for a State to further facilitate coordination of its Medicaid and foster care program in cases where coverage has been expanded under its Temporary Assistance for Needy Families beyond the definition of unemployed parent contained in existing Aid to Families with Dependent Children regulations. This rule revises the definition of unemployment of a principal wage earner for purposes of coverage of dependent children of unemployed parents. It will also allow States to eliminate inequitable policies that are a disincentive to family unity.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/97	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: MB-106

Agency Contact: Judith Rhoades, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., CA-20-05, Baltimore, MD 21244
Phone: 410 786-4462
Fax: 410 786-3252

RIN: 0938-AH98

1296. HEALTH INSURANCE REFORM: PARITY IN THE APPLICATION OF CERTAIN LIMITS TO MENTAL HEALTH BENEFITS (BPD-891-IFC)

Priority: Other Significant

Legal Authority: 42 USC 300gg-5

CFR Citation: 45 CFR 146

Legal Deadline: None

Abstract: This interim final rule will impose requirements on the group health plan market. It will require parity of mental health benefits with medical and surgical benefits under a group health plan in the application of aggregate lifetime limits and annual limits. It will implement sections 702 and 703 of the Mental Health Parity Act of 1996.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/00/97	

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

HHS—HCFA

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Government Levels Affected: State, Local, Federal

Agency Contact: Marc Thomas, Center for Medicaid & State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-7154

RIN: 0938-AI05

1297. PORTABILITY AND NONDISCRIMINATION IN THE GROUP HEALTH INSURANCE MARKET (BPD-890-F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 201

CFR Citation: 45 CFR 146

Legal Deadline: None

Abstract: This final rule addresses comments received on the interim final rule published April 8, 1997. It also further clarifies the Department's position on the minimum requirements applicable with respect to group health plans and health insurance issuers offering group health insurance coverage. A group health plan or health insurance issuer offering group health coverage may provide greater rights to participants and beneficiaries than those currently provided. This rule includes the following: (1) limitations on preexisting condition exclusion periods; (2) certification and disclosure of previous coverage; (3) special enrollment periods for individuals (and dependents) losing other coverage; (4) use of affiliation period by HMOs as alternative to preexisting condition exclusion; (5) prohibited discrimination against individual participants and beneficiaries based on health status; and (6) guaranteed renewability in multiemployer plans and multiple employer welfare arrangements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Effective Date	06/07/97	
Comment Period End	07/07/97	
Final Rule	03/00/98	

Small Entities Affected: Businesses

Government Levels Affected: Federal

Additional Information: BPD-890-IFC

Agency Contact: Dave Holstein, Insurance Standards Team, Department

of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-1564

RIN: 0938-AI08

1298. PART A PREMIUM FOR 1998 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (OACT-056-N)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395i-2; 42 USC 1395i-20

CFR Citation: 45 CFR 300

Legal Deadline: Other, Statutory, September 30, 1997.
Notice publication

Abstract: This notice announces the hospital insurance premium for calendar year 1998 under 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
Notice	11/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Wandishin, Deputy Director, Division of Medicare and Medicaid Cost Estimates, Department of Health and Human Services, Health Care Financing Administration, N3-26-00, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6389

RIN: 0938-AI10

1299. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR 1998 (OACT-057-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395e

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1998 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formula to be used to determine these amounts.

Timetable:

Action	Date	FR Cite
Notice	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Wandishin, Deputy Director, Division of Medicare and Medicaid Cost Estimates, Department of Health and Human Services, Health Care Financing Administration, N3-36-24, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6389

RIN: 0938-AI12

1300. • MEDICARE PROGRAM: UPDATE OF AMBULATORY SURGICAL CENTER PAYMENT RATES EFFECTIVE FOR SERVICES ON OR BEFORE OCTOBER 1, 1997 (BPD-897-N)

Priority: Other Significant

Legal Authority: 42 USC 1395e(a)(2)(f)i; 42 USC 1395e(i)(1)a

CFR Citation: 42 CFR 416.25

Legal Deadline: None

Abstract: This notice implements section 1833(i)(2)(c) of the Social Security Act, which mandates an inflation adjustment to Medicare payment amounts for ambulatory surgical center (ASC) facility services during the years when the payment amounts are not updated based on a survey of the actual audited costs incurred by ASCs.

Timetable:

Action	Date	FR Cite
Final Action	10/00/97	

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Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joan Sanow, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., C4-11-16, Baltimore, MD 21244
Phone: 410 786-5763

RIN: 0938-AI18

1301. • SCHEDULE OF LIMITS ON HOME HEALTH AGENCY COST PER VISIT FOR COST REPORTING PERIODS BEGINNING ON OR AFTER OCTOBER 1, 1997 (BPD-904-FC)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 100

CFR Citation: 42 CFR 50

Legal Deadline: None

Abstract: This notice sets forth an updated schedule of limits on home health agency costs that may be paid under the Medicare program. As required by section 4602 of the Balanced Budget Act of 1997, Public Law number 105-33 this notice supersedes the limits that were effective 07/01/97. It also reinstates the effect of the freeze on payment increases from 07/01/94 to 06/30/96 (Section 4601).

Timetable:

Action	Date	FR Cite
Final Action Effective	01/01/98	

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Ann White, Regulations Coordinator, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, C4-10-26, Baltimore, MD 21244
Phone: 202 690-6824

RIN: 0938-AI24

1302. • SOLVENCY STANDARDS FOR PROVIDER-SPONSORED ORGANIZATIONS; INTENT TO FORM NEGOTIATED RULEMAKING COMMITTEE

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 238

CFR Citation: 45 CFR 700

Legal Deadline: None

Abstract: The Balanced Budget Act of 1997, Pub. L. 105-33 requires the Secretary to establish a Negotiated Rulemaking Committee under the Federal Advisory Committee Act (FACA). The Committee's purpose will be to negotiate the solvency standards for provider-sponsored organizations under part C of the Medicare program. The Committee will consist of representatives of interests that are likely to be significantly affected by the solvency rule. The Committee will be assisted by a neutral facilitator.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/00/98	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Maureen Miller, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786-1097

RIN: 0938-AI25

1303. • MEDICARE PROGRAM; NOTICE FOR THE SOLICITATION FOR PROPOSALS FOR A DEMONSTRATION PROJECT FOR CONGESTIVE HEART FAILURE CASE MANAGEMENT ORD-104-N

Priority: Info./Admin./Other

Legal Authority: 42 USC 1395 b-1

Legal Deadline: None

Abstract: This notice announces HCFA's solicitation for proposals for a demonstration project to test the applicability of cost-effective, existing clinical case management delivery models for beneficiaries with congestive heart failure in the Medicare fee-for-service program. Section 402 (axi) of the Social Security Amendments of 1967 (P.L. 90-248) authorizes projects for one of eleven specified purposes. HCFA solicits proposals for demonstrations that will use innovative case management interventions to improve clinical outcomes and quality of life for Medicare beneficiaries with congestive heart failure while saving Medicare funds.

Timetable:

Action	Date	FR Cite
Notice	10/00/97	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Catherine Jansto, Social Science Research Analyst, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, C3-15-06, Baltimore, MD 21244

Phone: 410 786-7762
Email: cjansto@hcfa.gov

RIN: 0938-AI26

1304. • GME: INCENTIVE PAYMENTS UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS (HCFA-1003-IFC)

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

Legal Authority: 42 USC 1395ww(h); PL 105-33, Sec 4626

CFR Citation: 42 CFR 413

Legal Deadline: Other, Statutory, February 5, 1998. Interim final regulations with comment period must be published within 6 months of the date of enactment of the Balanced Budget Act 1997 (August 5, 1997).

Abstract: Under current law and regulations, hospitals are paid for direct medical education based on the number of residents participating in accredited graduated medical education programs. This interim final rule would implement section 4626 of the Balanced Budget Act of 1997 which allows hospitals to apply to received incentive payments in exchange for reducing the number of residents in training. The hospital must submit a plan to the Secretary outlining how they will make voluntary residency reductions.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment Period	11/00/97	

Small Entities Affected: Businesses

Government Levels Affected: State, Local, Federal

Additional Information: HCFA-1003-IFC

Agency Contact: Marc Hartstein, Health Insurance Specialist,

HHS—HCFA

Final Rule Stage

Department of Health and Human Services, Health Care Financing Administration, Center for Health Plans and Providers, C5-08-16, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4539

RIN: 0938-AI27

1305. • MEDICARE + CHOICE PROGRAM; REGULATORY PROGRAM TO IMPLEMENT CERTAIN MEDICARE PROVISIONS OF THE BALANCED BUDGET ACT OF 1997 (OMC-030-IFC)

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

RIN: 0938-AI29

1306. • SURETY BOND AND CAPITALIZATION REQUIREMENTS FOR HOME HEALTH AGENCIES (BPO-152-FC)

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

RIN: 0938-AI31

1307. • HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) OF 1996: ADMINISTRATIVE SIMPLIFICATION

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

RIN: 0938-AI32

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)**

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1308. DEDUCTION OF INCURRED MEDICAL EXPENSES (SPENDDOWN) (MB-020-F)

Priority: Substantive, Nonsignificant
Unfunded Mandates: This action may affect State, local or tribal governments.
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. The revisions permit States greater flexibility by offering options that will allow them to simplify the administration of their Medicaid programs.

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	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: MB-020

Agency Contact: Jackie Wilder, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-23-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4579

RIN: 0938-AB07

1309. 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 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 COBRA '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 Action Effective	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

Additional Information: BPD-393

Agency Contact: Tzvi Hefter, Center for Health Plans and providers, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Blvd., Baltimore, MD 21244

HHS—HCFA

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Phone: 410 786-1304

RIN: 0938-AC58

1310. CRITERIA AND PROCEDURES FOR DEVELOPING MEDICAL SERVICES COVERAGE POLICY (BPD-432-F)

Priority: Other Significant

Legal Authority: 42 USC 1395y

CFR Citation: 42 CFR 400.404; 42 CFR 405.201; 42 CFR 405.203; 42 CFR 405.205; 42 CFR 405.207; 42 CFR 405.211

Legal Deadline: None

Abstract: This rule will announce generally applicable criteria and procedures for determining whether a service is "reasonable and necessary" under the Medicare program. It will also announce generally applicable criteria and procedures for determining whether a service is "reasonable and necessary" under the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	01/30/89	54 FR 4302
NPRM Comment Period End	03/31/89	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-432

Agency Contact: Ron Milhorn, Office of Clinical Standards and Quality, 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

1311. MEDICARE COVERAGE OF OUTPATIENT OCCUPATIONAL THERAPY SERVICES (BPD-425-P)

Priority: Substantive, Nonsignificant

Legal Authority: 2 USC 1302; 42 USC 1395hh; 42 USC 1395k; 42 USC 1395l; 42 USC 1395w-4; 42 USC 1395x(s); 42 USC 1395x(p); 42 USC 1395cc(e); 44 USC 3501 to 3511

CFR Citation: 42 CFR 400; 42 CFR 410; 42 CFR 424; 42 CFR 484; 42 CFR 485; 42 CFR 486; 42 CFR 488; 42 CFR 489; 42 CFR 498

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	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-425

Agency Contact: Sheridan Gladhill, Center for Health Plans and Providers, Division of Chronic Care Management, 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

1312. PROHIBITION ON UNBUNDLING OF HOSPITAL OUTPATIENT SERVICES (BPD-426-F)

Priority: Other Significant

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 Department's Office of Inspector General (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	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-426

Agency Contact: Janet Wellham, Center for Health Plans and Providers, Division of Practitioner and Ambulatory Care, Department of Health and Human Services, Health Care Financing Administration, C4-11-16, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4510

RIN: 0938-AD33

1313. 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

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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	10/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: HSQ-135

Agency Contact: Bill Roskey, Office of Clinical Standards and Quality, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S1-09-18, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-0433

RIN: 0938-AD38

1314. OMNIBUS NURSING HOME REFORM REQUIREMENTS (BPD-488-F)

Priority: Other Significant. Major under 5 USC 801.

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 431; 42 CFR 482; 42 CFR 483; 42 CFR 488

Legal Deadline: None

Abstract: This final rule will implement several provisions of OBRA '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.

Timetable:

Action	Date	FR Cite
NPRM	02/05/92	57 FR 4516

Action	Date	FR Cite
NPRM Comment Period End	04/06/92	
Final Action	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPD-488

Agency Contact: Bill Ullman, Office of Clinical Standards and Quality, 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

1315. 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: This rule would interpret statutory changes made in 1988, 1989, 1990 and 1993 that allocate income and resources between an institutionalized spouse and the spouse remaining in the the community. It would also provide special post-eligibility rules for institutionalized individuals who have spouses in the community to retain more income to meet living expenses.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: State, Local

Additional Information: MB-023

Agency Contact: Roy Trudel, Center for Medicaid & State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-20-15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3417

RIN: 0938-AE12

1316. SURVEY REQUIREMENTS AND ALTERNATIVE SANCTIONS FOR HOME HEALTH AGENCIES (HSQ-169-F)

Priority: Other Significant

Legal Authority: 42 USC 1395bb; 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 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

Additional Information: HSQ-169

TIMETABLE CONT: Pending completion of RIN 0938-AG81 (BPD-819)

Agency Contact: Wayne Smith, Ph.D., Director, Division of Integrated Health Systems, Department of Health and Human Services, Health Care Financing Administration, S2-11-07, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6762

RIN: 0938-AE39

1317. 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

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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

Additional Information: MB-028

Agency Contact: Cindy Ruff, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-16-08, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5916

RIN: 0938-AE72

1318. MEDICARE COVERAGE OF, AND APPLICATION OF THE OUTPATIENT MENTAL HEALTH TREATMENT LIMITATION TO, CLINICAL PSYCHOLOGIST AND CLINICAL SOCIAL WORKER SERVICES (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 OBRA '89 and OBRA '90. OBRA '89 provides the services of clinical psychologists (CPs) and clinical social workers. It requires 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. OBRA '90 unbundled CP services from the definition of "inpatient hospital services." It also implements two sections (psychology services in hospitals and 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	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-706

Agency Contact: Regina Walker, Center for Health Plans and Providers, Division of Practitioner & Ambulatory Care, 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

1319. 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. This rule is part of the Administration's reinventing government and regulatory reform initiatives. Publication of this regulation is dependent upon court approval which has been sought.

Timetable:

Action	Date	FR Cite
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: HSQ-175

TIMETABLE: This regulation may be published only with the concurrence of the U.S. District Court in Smith v. Shalala.

Agency Contact: Helene Fredeking, Director, Division of Outcomes and Improvements, 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

1320. 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 431.54; 42 CFR 440.169; 42 CFR 440.250; 42 CFR 441.10; 42 CFR 441.18; 42 CFR 447.327

Legal Deadline: None

Abstract: This rule will incorporate provisions of COBRA '85, OBRA '86, TEFRA '86, OBRA '87 and TMRA '88 dealing with case management services. It 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	

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Small Entities Affected: None
Government Levels Affected: State, Local

Additional Information: MB-027

Agency Contact: Pat Helphenstine, Disabled & Elderly Health Program Group, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-13-13, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-5900

RIN: 0938-AF07

1321. 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. Alternative sanctions could be imposed instead of, or in addition to, terminating a psychiatric hospital's participation in the Medicare and Medicaid programs when deficiencies do not pose immediate jeopardy to the health and safety of psychiatric hospital patients. These amendments are necessary to conform HCFA regulations to changes made by OBRA '89 and OBRA '90. The statutory and regulatory revisions are intended to encourage correction of deficiencies that do not jeopardize patient health and safety before termination of a facility becomes necessary.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Federal

Additional Information: HSQ-191

Agency Contact: Robert Streimer, Center for Medicaid and State Operations, Disabled and Elderly Health Program Group, Department of Health and Human Services, Health Care Financing Administration, S2-14-

27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6810

RIN: 0938-AF32

1322. REFERRAL TO CHILD SUPPORT ENFORCEMENT AGENCIES OF MEDICAID FAMILIES (MB-051-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396k; 42 USC 1302

CFR Citation: 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.151; 42 CFR 433.160

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	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: MB-051

Agency Contact: Robert Nakielny, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-21-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4466

RIN: 0938-AF68

1323. 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; 42 CFR 435.3

Legal Deadline: None

Abstract: This rule will finalize the interim final rule that requires State Medicaid agencies to 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 applications for cash assistance under title IV-A of the Social Security Act. 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	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: MB-052

Agency Contact: Robert Tomlinson, Center for Medicaid and State Operations, 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-AF69

1324. ASSESSING INTEREST AGAINST MEDICARE SECONDARY PAYER (MSP) DEBTS (BPO-108-P)

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 3711; 42 USC 1395y(b)(2)(B)

CFR Citation: 42 CFR 405.378; 42 CFR 411.24(m); 42 CFR 411.39

Legal Deadline: None

Abstract: This proposed rule would amend the regulations 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 all parties would have a clear understanding of the period subject to payment of interest charges.

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Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None
Government Levels Affected: None
Additional Information: BP0-108
Agency Contact: John Albert, Office of Financial Management, 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

1325. REVISIONS TO RULES ON HEALTH CARE PREPAYMENT PLANS (OMC-016-P)

Priority: Other Significant
Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 300e; 42 USC 300e-5; 42 USC 300e-9; 42 USC 31; 42 USC 9701
CFR Citation: 42 CFR 471.800; 42 CFR 417.801; 42 CFR 417.806; 42 CFR 417.812; 42 CFR 417.814; 42 CFR 417.816; 42 CFR 417.818; 42 CFR 417.820; 42 CFR 417.822; 42 CFR 417.824

Legal Deadline: None
Abstract: This regulation would impose a range of requirements on health care prepayment plans (HCPP) 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 HCPP program. We will also address related requirements of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	10/00/98	

Small Entities Affected: None
Government Levels Affected: None
Additional Information: OMC-016
Agency Contact: Tracy Jensen, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, S3-23-25, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-1033
RIN: 0938-AF97

1326. 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	00/00/00	

Small Entities Affected: None
Government Levels Affected: State
Additional Information: MB-038
Agency Contact: Richard Friedman, Center for Medicaid and State Operations, 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-AG10

1327. DESCRIPTION OF HCFA'S EVALUATION METHODOLOGY FOR THE PEER REVIEW ORGANIZATIONS FIFTH SCOPE OF WORK CONTRACTS (HSQ-207-NC)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1302; 42 USC 1320c; 42 USC 1320c-2
CFR Citation: 42 CFR 462
Legal Deadline: None

Abstract: This notice with comment period will provide general criteria and standards that will be used to evaluate the effective and efficient performance of Utilization and Quality Control Peer Review Organizations (known as PROs) for new contracts entered into on or after April 1, 1996.

Timetable:

Action	Date	FR Cite
NPRM	07/02/97	62 FR 35824
NPRM Comment	09/02/97	

Period End
 Next Action Undetermined
Small Entities Affected: None
Government Levels Affected: None
Additional Information: HSQ-207
Agency Contact: Heidi Gelzer, Office of Clinical Standards and Quality, 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

1328. DISCLOSURE OF CONFIDENTIAL PRO AND ESRD NETWORK ORGANIZATION INFORMATION FOR RESEARCH PURPOSES (HSQ-208-P)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1320c-9; 42 USC 1302
CFR Citation: 42 CFR 405.2115; 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 and allows the Secretary to provide for disclosure in the regulations while assuring adequate protection of the rights and interests of patients, health care practitioners, and 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 would make confidential PRO information accessible to researchers while still protecting the identities of beneficiaries and practitioners from unwarranted disclosure.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

HHS—HCFA

Long-Term Actions

Small Entities Affected: None
Government Levels Affected: None
Additional Information: HSQ-208
Agency Contact: Bill Roskey, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S1-09-26, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-0433
RIN: 0938-AG33

1329. SALARY EQUIVALENCY GUIDELINES FOR PHYSICAL THERAPY, RESPIRATORY THERAPY, SPEECH PATHOLOGY, AND OCCUPATIONAL THERAPY (BPD-808-F)

Priority: Other Significant
Legal Authority: 42 USC 1395x(v)(5)
CFR Citation: 42 CFR 413.106
Legal Deadline: None
Abstract: This final rule will revise 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. It also sets forth initial salary equivalency guidelines for speech language pathology and occupational therapy services furnished by providers under arrangements with an outside contractor. The guidelines are to be used by Medicare fiscal intermediaries to determine the maximum allowable costs of those services.

Timetable:

Action	Date	FR Cite
NPRM	03/28/97	62 FR 14851
NPRM Comment Period End	05/27/97	
Final Action	00/00/00	

Small Entities Affected: Businesses, Organizations
Government Levels Affected: None
Additional Information: BPD-808
Agency Contact: Jacqueline Gordon, Center for Health Plans and Providers, 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

1330. DISTINCT PART REQUIREMENTS FOR NURSING HOMES AND PROHIBITION OF FINANCIAL SCREENING OF APPLICANTS FOR NURSING HOME ADMISSION (BPD-815-P)

Priority: Other Significant
Legal Authority: 42 USC 1395i-3; 42 USC 1396r(a); 42 USC 1302; 42 USC 1395hh
CFR Citation: 42 CFR 409; 42 CFR 483
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. This proposed rule would also prohibit nursing homes from financially screening private pay applicants for admission. Instead, nursing homes would be permitted private pay applications 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: Businesses
Government Levels Affected: None
Additional Information: BPD-815
Agency Contact: William Ullman, 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

1331. 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: As part of the CLIA program (see RIN 0938-AE47), this rule will develop criteria for simple and easy-to-use test systems that have demonstrated accuracy and precision through scientific studies. We have proposed to 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. We also proposed that a small number of surveys 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
Additional Information: HSQ-222
Agency Contact: Judy Yost, Center for Medicaid and State Operations, Division of Outcomes and Improvement, 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-AG98

1332. MEDICARE COVERAGE OF ORGAN 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 organ transplantations.
Timetable:

Action	Date	FR Cite
Proposed Notice	00/00/00	

Small Entities Affected: Businesses
Government Levels Affected: None

HHS—HCFA

Long-Term Actions

Additional Information: BPD-835
Agency Contact: Jacqueline Sheridan, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-4653
RIN: 0938-AH17

1333. CRITERIA AND PROCEDURES FOR EXTENDING COVERAGE TO CERTAIN DEVICES AND RELATED SERVICES (BPD-841-F)

Priority: Other Significant
Legal Authority: 42 USC 1395y(a)(1)(A)
CFR Citation: 42 CFR 405.201 TO 215; 42 CFR 411.15; 42 CFR 411.406
Legal Deadline: None

Abstract: We published a final rule with comment period that certain medical devices with an investigational device exemption approved by the FDA may be covered under Medicare. It set forth the process by which the FDA is to assist HCFA in identifying nonexperimental investigational devices that may be potentially covered under Medicare. This final rule responds to comments on that rule and restates the policy after considering the comments.

Timetable:

Action	Date	FR Cite
Final Rule	09/19/95	60 FR 48417
Comment Period End	10/20/95	
Effective Date	11/01/95	
Next Action Undetermined		

Small Entities Affected: None
Government Levels Affected: None
Additional Information: BPD-841

Agency Contact: Sharon Hippler, Office of Clinical Standards & Quality, 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

1334. DELEGATION OF CIVIL MONEY PENALTIES (BPO-135-FC)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 405(a); 42 USC 1302; 42 USC 1320a to 7a; 42 USC

1395cc; 42 USC 1395u(j)(2); 42 USC 1395hh; 42 USC 1395ii
CFR Citation: 42 CFR 402
Legal Deadline: None
Abstract: This final rule with comment period will contain the processes and procedures to be undertaken in the imposition of civil money penalties and assessments and in the appeals process.

Timetable:

Action	Date	FR Cite
Final Action	00/00/00	

Small Entities Affected: None
Government Levels Affected: None
Additional Information: BPO-135
Agency Contact: Joel Cohen, Office of Financial Management, Department of Health and Human Services, Health Care Financing Administration, S3-11-26, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-3349
RIN: 0938-AH22

1335. 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); 42 USC 1395hh

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.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Organizations
Government Levels Affected: None

Additional Information: BPD-844
Agency Contact: Thomas Saltz, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-4480
RIN: 0938-AH27

1336. REQUIREMENTS FOR ENROLLMENT OF MEDICAID RECIPIENTS UNDER COST EFFECTIVE EMPLOYER-BASED GROUP HEALTH PLANS (MB-047-FC)

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; 42 CFR 436
Legal Deadline: None

Abstract: This rule will 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. Medicaid recipients may be required to apply for enrollment in employer-based cost eligibility; require State agencies to pay for premiums, eligibility. This rule also requires 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." In addition, this rule incorporates the changes to section 1906 due to the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	06/20/94	59 FR 31569
NPRM Comment Period End	08/19/94	
Final Action	10/00/98	

Small Entities Affected: None
Government Levels Affected: None
Additional Information: MB-047
 Previously published under RIN 0938-AF64.

Agency Contact: Gwendolyn Talvert, Center for Medicaid and State Operations, Department of Health and

HHS—HCFA

Long-Term Actions

Human Services, Health Care Financing Administration, C4-20-20, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-5928
 RIN: 0938-AH48

1337. 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 proposed rule would codify in regulations policies regarding liability insurance, such as structured liability settlements, future medical expenses, provider malpractice, wrongful death, and Federal Tort Claims Act policy. It would also clarify the rules dealing with group health plan bankruptcies, religious orders, and foreign group health plans, and make numerous other changes.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-865

Agency Contact: Herb Pollock, Center for Health Plans & Providers, Division of Integrated Services, Department of Health and Human Services, Health Care Financing Administration, C4-08-27, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-4474

RIN: 0938-AH52

1338. CONDITIONS FOR CERTIFICATION OF COMMUNITY MENTAL HEALTH CENTERS AND COVERAGE REQUIREMENTS FOR PARTIAL HOSPITALIZATION SERVICES (BPD-871-P)

Priority: Other Significant

Legal Authority: 42 USC 1395k; 42 USC 1395x; 42 USC 1395cc

CFR Citation: 42 CFR 410.43; 42 CFR 410.110; 42 CFR 410.150; 42 CFR 410.172

Legal Deadline: None

Abstract: This proposed rule would establish health and safety standards

that Community Mental Health Centers (CMHCs) must meet to participate in the Medicare program. It would also establish requirements for coverage of partial hospitalization services furnished by CMHCs or furnished in hospital outpatient settings. These changes would provide oversight for CMHCs, help curtail inappropriate utilization of partial hospitalization services, and ensure Medicare payment of reasonable and necessary services to eligible individuals.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: BPD-871

Agency Contact: Janet Samen, Center for Health Plans and Policy, 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-AH58

1339. MEDICARE TECHNICAL CONFORMING AMENDMENTS (BPD-858-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 1395k

CFR Citation: 42 CFR 409.50; 42 CFR 409.61; 42 CFR 410.152

Legal Deadline: None

Abstract: This final rule with comment period will update our regulations to reflect that payment for durable medical equipment is on the basis of a fee schedule.

Timetable:

Action	Date	FR Cite
NPRM Comment Period End	10/00/98	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: BPD-858

Agency Contact: Martha Kuespert, Center for Health Plans and Providers, 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-AH67

1340. DETERMINATION OF SUBSTANDARD CARE IN SNFS AND NFS (HSQ-240-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395i-3; 42 USC 1395r

CFR Citation: 42 CFR 488.301

Legal Deadline: None

Abstract: This proposed rule would revise the definition of "substandard quality of care" as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program. "Substandard quality of care" is one type of noncompliance with Federal participation requirements that carries with it statutory consequences to facilities providing such care. The purpose of this proposed revision is to improve the definition of substandard quality of care so that the process can make a more meaningful distinction between facility noncompliance that warrants the consequences mandated by the statute for a finding of substandard quality of care and noncompliance that does not.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Local, Federal

Additional Information: HSQ-240

Agency Contact: Pat Miller, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-19-14, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6780

RIN: 0938-AH69

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Long-Term Actions

1341. WAIVER OF STAFFING REQUIREMENTS FOR END STAGE RENAL DISEASE (ESRD) FACILITIES PARTICIPATING IN AN EXPERIMENT (HSQ-236-GNC)

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 1320; 42 USC 1395x; 42 USC 1395y; 42 USC 1395hh; 42 USC 1395rr

CFR Citation: 42 CFR 405.2136; 42 CFR 405.2161; 42 CFR 405.2162; 42 CFR 405.2163

Legal Deadline: None

Abstract: This general notice with comment period announces our intention to conduct a demonstration that would grant selected ESRD facilities a 2-year waiver of staffing requirements. The ESRD staffing requirements pertain to: the governing body and management, director of a facility, on-duty licensed health care professionals, and providing adequate laboratory, social, and dietetic services. Facilities would be given flexibility to deviate from specified regulation requirements, provided assurances are in place ensuring that quality of care standards are not being compromised.

Timetable:

Action	Date	FR Cite
Final Action	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: HSQ-236

Agency Contact: William Roskey, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S1-09-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0433

RIN: 0938-AH72

1342. INFORMATION REQUIREMENTS FOR MEDICARE PROFESSIONAL SUPPLIERS BILLING PRIVILEGES (BPO-143-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 489

Legal Deadline: None

Abstract: This proposed rule would establish conditions for enrolling providers and suppliers that furnish items or services to Medicare beneficiaries. These conditions would improve current enrollment procedures so as to more accurately identify such providers and suppliers and to secure information and documentation necessary to the effective and efficient administration of the Medicare program. The more accurate identification of providers and suppliers, coupled with the collection of certain information, will facilitate the administration of many aspects of the Medicare program including, but not necessarily limited to, monitoring for compliance with program rules and combating fraud and abuse. Improvements in enrolling providers and suppliers will afford both the Medicare trust funds and program beneficiaries with greater protection.

Timetable:

Action	Date	FR Cite
NPRM	03/08/90	55 FR 8491
Comment Period End	05/08/90	
Final Rule	08/31/95	60 FR 45344
Effective Date	10/02/95	
Comment Period End	10/30/95	
Final Action	00/00/00	

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: BPO-143

Agency Contact: Ralph Goldberg, Center for Health Plans and Providers, Provider Purchasing and Administration Group, Department of Health and Human Services, Health Care Financing Administration, S3-16-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4870

RIN: 0938-AH73

1343. MEDICAID PROGRAM; AMENDMENT TO THE PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW PROGRAM (MB-107-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 1396r(e); 42 USC 1396r(b)

CFR Citation: 42 CFR 405; 42 CFR 431; 42 CFR 433; 42 CFR 441; 42 CFR 483

Legal Deadline: None

Abstract: This proposed rule would make changes to the preadmission screening and annual resident review program in accordance with the provisions of Public Law 104-315, which were included in the Reinventing Government effort. The rule would repeal the Medicaid program requirement for an annual review of nursing facility (NF) residents with mental illness or mental retardation. This proposed rule would add the requirement for NFs to notify the State when there is a significant change in the physical or mental condition of a resident and add a statutory requirement that the State conduct a review promptly after notification of the resident's change in condition.

Timetable:

Action	Date	FR Cite
NPRM	10/00/98	

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State

Additional Information: MB-107

Agency Contact: Jan Earle, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, C4-12-23, Baltimore, MD 21244
Phone: 410 786-3326
Fax: 410 786-3262

RIN: 0938-AH89

1344. ALLOCATION OF ENHANCED FEDERAL MATCHING FUNDS FOR INCREASED ADMINISTRATIVE COSTS (MB-103-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a(a)

CFR Citation: None

Legal Deadline: None

Abstract: This notice will provide a formula for the allocation of a special \$500 million fund for enhanced Federal matching for State Agency's expenditures attributable to additional Medicaid administrative costs of Medicaid eligibility determinations as a result of the provisions of 1931 of the

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Long-Term Actions

Social Security Act as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Timetable:

Action	Date	FR Cite
Notice With Comment Period	05/14/97	62 FR 26545
NPRM Comment Period End	06/13/97	
Final Action	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: MB-103

Agency Contact: Richard Strauss, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, C4-18-26, Baltimore, MD 21244
Phone: 410 786-2019

RIN: 0938-AH90

1345. MEDICALLY NEEDY DETERMINATIONS UNDER WELFARE REFORM (MB-109-IFC)

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 1396a(a)(10)(C)

CFR Citation: 42 CFR 435; 42 CFR 436

Legal Deadline: None

Abstract: This interim final rule with comment period will revise our rules to allow States to include individuals who are described as categorically needy to be covered as medically needy. The State must specify the income and resources criteria for the medically needy group in the State plan. If an individual is also described as categorically needy, the individual would receive Medicaid as categorically needy if the State elected to cover the categorically needy group into which the individual fits. If the State has not elected to cover that group, the individual would be medically needy. This change will allow more individuals to become eligible for Medicaid as medically needy and eliminate an inequity in current regulations. This revision also allows some individuals who would otherwise

lose their Medicaid benefits to retain their eligibility.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment Period	00/00/00	

Small Entities Affected: None

Government Levels Affected: State

Additional Information: MB-109

Agency Contact: Jackie Wilder, Center for Medicaid and State Operations, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, C4-20-06, Baltimore, MD 21244

Phone: 410 786-4579

RIN: 0938-AH92

1346. MEDICAID PROGRAM; COVERAGE AND PAYMENT FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES (MB-43-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a(a)(13); 42 USC 1396d(a)

CFR Citation: 42 CFR 431; 42 CFR 440; 42 CFR 441; 42 CFR 447

Legal Deadline: None

Abstract: This proposed rule would incorporate and interpret in regulations coverage and payment requirements for services furnished by a federally qualified health center (FQHC) under the Medicaid program. This rule will include changes in the payment provisions to FQHCS made by section 4712 of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Additional Information: MB-43

Agency Contact: David Worgo, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, C4-15-18, Baltimore, MD 21244

Phone: 410 786-5919

RIN: 0938-AH95

1347. • MEDICAID PROGRAM: CHARGES FOR VACCINE ADMINISTRATION UNDER THE VACCINES FOR CHILDREN (VCF) PROGRAM (MB-84-N)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1396(2)(62)

CFR Citation: 45 CFR 200

Legal Deadline: None

Abstract: This notice lists, by State, the finalized regional maximum charges that providers may impose for the administration of pediatric vaccines to federally vaccine-eligible children under the Vaccines for Children (VFC) program. This notice also specifies the methodology that HCFA used to establish the revised maximum charges. In addition, this notice provides States that purchase vaccines for all children the option to use these regional maximum charges or devise their own administration fees, and clarifies that State Medicaid agencies may establish lower fees than these maximum charges if the agencies assure access to immunizations for Medicaid-eligible children to the same extent as the general population. This notice also responds to comments on the October 3, 1994 notice with comment period.

Timetable:

Action	Date	FR Cite
Notice With Comment Period	10/03/94	59 FR 50235
Notice	04/10/95	60 FR 18136
Final Notice	00/00/00	

Small Entities Affected: None

Government Levels Affected: None

Additional Information: MB-84

Agency Contact: Marge Sciulli, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-22-06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0691

RIN: 0938-AI20

1348. • MEDICAID: MEDICAL CHILD SUPPORT (MB-081-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1396a(a)(60)

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Long-Term Actions

CFR Citation: 42 CFR 433

Legal Deadline: None

Abstract: This proposed rule would require States to provide assurances satisfactory to the Secretary that the State has in effect laws relating to medical child support. This requirement would implement section 13623 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66), commonly cited as OBRA 1993. The medical child support laws

that the States must have in effect are set forth in section 1908 of the Social Security Act (the Act). These laws would impose requirements on insurers, employers, and State Medicaid agencies.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State

Additional Information: MB-81

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

RIN: 0938-AI21

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)

Completed Actions

1349. FIRE SAFETY STANDARDS FOR HOSPITALS, LONG-TERM CARE FACILITIES, 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.

CFR Citation: 42 CFR 482.41(b)(1); 42 CFR 483.70(a); 42 CFR 483.470(j)(2)(i)(C); 42 CFR 483.470(j)(1)

Completed:

Reason	Date	FR Cite
Withdrawn	09/30/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: James Kenton
Phone: 410 786-5629

RIN: 0938-AE97

1350. PRESUMPTIVE LIMITS ON PAYMENTS TO HMOS, CMPS, AND HCPPS (OMC-006-F)

Priority: Other Significant

CFR Citation: 42 CFR 417.532(a)(3); 42 CFR 417.802; 42 CFR 417.800(c)

Completed:

Reason	Date	FR Cite
Withdrawn	05/22/97	59 FR 8435

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: A. G. D'Alberty
Phone: 410 786-1100

RIN: 0938-AF16

1351. 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.

CFR Citation: 42 CFR 412.113; 42 CFR 413.170; 42 CFR 413.172; 42 CFR 413.174; 42 CFR 413.176; 42 CFR 413.178; 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; ...

Completed:

Reason	Date	FR Cite
Final Action	08/15/97	62 FR 43657

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Michael Powell
Phone: 410 786-4557

RIN: 0938-AG20

1352. WAGE INDEX USED TO ADJUST PAYMENT RATES FOR HOSPICE SERVICES UNDER THE MEDICARE PROGRAM (BPD-820-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.

CFR Citation: 42 CFR 418

Completed:

Reason	Date	FR Cite
Final Action	08/08/97	62 FR 42860

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Janice Flaherty
Phone: 410 786-4637

RIN: 0938-AG93

1353. MEDICAID COVERAGE OF PERSONAL CARE SERVICES (MB-071-F)

Priority: Other Significant

CFR Citation: 42 CFR 440.70; 42 CFR 440.167; 42 CFR 440.170

Completed:

Reason	Date	FR Cite
Final Action	09/11/97	62 FR 49726

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Linda Peltz
Phone: 410 786-3399

RIN: 0938-AH00

1354. UPDATE OF THE REASONABLE COMPENSATION EQUIVALENT LIMITS FOR SERVICES FURNISHED BY PHYSICIANS (BPD-816-N)

Priority: Other Significant

CFR Citation: 42 CFR 405.482(f)

Completed:

Reason	Date	FR Cite
Final Action	05/05/97	62 FR 24483

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ward Pleines

HHS—HCFA

Completed Actions

Phone: 410 786-4528

RIN: 0938-AH14

1355. CHANGES IN COVERAGE AND PAYMENT POLICIES FOR PHYSICIAN ASSISTANT SERVICES (BPD-829-P)

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Withdrawn	10/01/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Roberta Epps
Phone: 410 786-4503

RIN: 0938-AH26

1356. LIMITATIONS ON PAYMENT FOR HOME OXYGEN THERAPY BASED ON INHERENT REASONABLENESS CRITERIA (BPD-845-FN)

Priority: Economically Significant

CFR Citation: 42 CFR 405.502(g); 42 CFR 414.210(d)

Completed:

Reason	Date	FR Cite
Withdrawn - Superseded by Section 4552 of the Balanced Budget Act	08/05/97	62 FR 38100

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: William J. Long
Phone: 410 786-5655

RIN: 0938-AH28

1357. DESIGNATION OF INDEPENDENT RURAL PRIMARY CARE HOSPITALS (RPCHS) (BPD-784-N)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	07/14/97	

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Thomas Hoyer

Phone: 410 786-5661

RIN: 0938-AH60

1358. INITIATIVE TO RECOGNIZE HEMODIALYSIS FACILITIES OF ACHIEVEMENT (HSQ-232-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: 45 CFR 900

Completed:

Reason	Date	FR Cite
Final Action	04/29/97	62 FR 23251

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judith Kari
Phone: 410 786-6829

RIN: 0938-AH71

1359. CLINICAL LABORATORY REQUIREMENTS—EXTENSION OF CERTAIN EFFECTIVE DATES FOR CLINICAL LABORATORY REQUIREMENTS UNDER CLIA (HSQ-237-F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 493.1202; 42 CFR 493.1443; 42 CFR 493.1203

Completed:

Reason	Date	FR Cite
Withdrawn - If final rule is developed, will be addressed in HSQ-226-F	09/10/97	

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Rhonda S. Whalen
Phone: 770 488-7655

RIN: 0938-AH84

1360. MEDICARE PROGRAM; SCHEDULE OF LIMITS ON HOME HEALTH AGENCY COST PER VISIT FOR COST REPORTING PERIODS BEGINNING ON OR AFTER JULY 1, 1997 (BPD-889-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn - Will be addressed in BPD-904-NC	09/10/97	

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Michael Bussacca
Phone: 410 786-4602

RIN: 0938-AH88

1361. MEDICARE APPEALS OF INDIVIDUAL CLAIMS (BPD-453-FC)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 405.717 to 718; 42 CFR 405.724; 42 CFR 405.730; 42 CFR 405.732; 42 CFR 405.750; 42 CFR 405.801 to 803; 42 CFR 405.806; 42 CFR 405.833 to 836; 42 CFR 405.853; 42 CFR 405.855 TO 857; 42 CFR 405.860; 42 CFR 417.634; 42 CFR 473.46

Completed:

Reason	Date	FR Cite
Final Rule (No changes required after evaluating comments).	05/12/97	62 FR 25844

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Morty Marcus
Phone: 410 786-4477

RIN: 0938-AH97

1362. • MEDICARE PROGRAM; ADJUSTMENTS TO COST LIMITS FOR SNF INPATIENT ROUTINE SERVICE COSTS (BPD-896-PN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This is a test. Please fill in correct information.

Timetable:

Action	Date	FR Cite
Notice With Comment Period (Comment Period End - 12/01/97)	10/01/97	62 FR 51551

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ann White,
Regulations Coordinator, Department of

HHS—HCFA

Completed Actions

Health and Human Services, Health Care Financing Administration, 200 Independence Avenue, Washington, DC 20201
 Phone: 202 690-6824
 RIN: 0938-AI14

1363. ● MEDICARE PROGRAM; SCHEDULES OF LIMITS AND PROSPECTIVELY DETERMINED RATES FOR SNF INPATIENT ROUTINE SERVICE COSTS (BPD-895-NC)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 50
CFR Citation: 42 CFR 10
Legal Deadline: None

Abstract: Information needed.

Timetable:

Action	Date	FR Cite
Notice With Comment Period (Comment Period End 12/01/97)	10/01/97	62 FR 51536

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Ann White, Regulations Coordinator, Department of Health and Human Services, Health Care Financing Administration, 200 Independence Avenue, Washington, DC 20201
 Phone: 202 690-6824
 RIN: 0938-AI15

1364. ●MEDICAID PROGRAM: LIMITATION ON PROVIDER-RELATED DONATIONS AND HEALTH CARE-RELATED TAXES; REVISION ON WAIVER CRITERIA FOR TAX PROGRAMS BASED EXCLUSIVELY ON REGIONAL VARIATIONS; CORRECTION

Completed:

Reason	Date	FR Cite
Correcting Amendment for RIN 0938-AF99	10/15/97	62 FR 53571

RIN: 0938-AI30

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Administration for Children and Families (ACF)

Proposed Rule Stage

1365. TITLE IV-E FOSTER CARE ELIGIBILITY REVIEWS AND CHILD AND FAMILY SERVICES STATE PLAN REVIEWS

Priority: Other Significant
Legal Authority: 42 USC 627; 42 USC 671; 42 USC 1302; 42 USC 1320a to 1a
CFR Citation: 45 CFR 1355; 45 CFR 1356; 45 CFR 1357
Legal Deadline: Final, 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. It will also 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 the eligibility of foster care providers and the eligibility of children in foster care.

Timetable:

Action	Date	FR Cite
NPRM	04/00/98	

Small Entities Affected: None
Government Levels Affected: State

Additional Information: This action was previously reported under RIN 0970-AB60.
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

1366. 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	02/00/98	

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

1367. 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	02/00/98	

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

HHS—ACF

Proposed Rule Stage

1368. METHODOLOGY FOR DETERMINING CHILD POVERTY RATES

Priority: Other Significant

Legal Authority: 42 USC 613(i)(5)

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: This NPRM will propose a methodology to be used by States to determine their child poverty rates: section 413(i) of the Social Security Act, as amended, requires that the Secretary establish this methodology by regulation and mentions three specific factors which shall be included in the methodology. States must begin reporting their rates by May 31, 1998.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Don Oellerich, Director, Division of Data and Technical Analysis, Off of the Asst Sec for Plan & Ev, Department of Health and Human Services, Administration for Children and Families, Room 404E, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 690-6805

RIN: 0970-AB65

1369. BONUS TO REWARD HIGH PERFORMANCE STATES UNDER THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES BLOCK GRANT

Priority: Other Significant

Legal Authority: 42 USC 403 (a)(4)

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: The Administration for Children and Families with the National Governors Association and the American Public Welfare Association, will propose a formula for measuring State performance under the Temporary Assistance for Needy Families Block Grant as the basis for payment of a bonus to high performing states

Timetable:

Action	Date	FR Cite
NPRM	04/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Howard Rolston, Director, Office of Planning, Research and Evaluation, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., 7th Floor West, Washington, DC 20447
Phone: 202 401-9220
Fax: 202 205-3598

RIN: 0970-AB66

1370. QUARTERLY WAGE AND UNEMPLOYMENT COMPENSATION CLAIMS REPORTING TO THE NATIONAL DIRECTORY OF NEW HIRES

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 653A(g)(2)(B)

CFR Citation: 45 CFR 303

Legal Deadline: NPRM, Statutory, November 1997.

Abstract: This regulation specifies the information on wages and unemployment compensation paid to individuals that certain State entities will be required to provide to the National Directory of New Hires on a quarterly basis.

Timetable:

Action	Date	FR Cite
NPRM	10/00/97	

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Anne M. Benson, Program Specialist, Department of Health and Human Services, Administration for Children and Families, OCSE, DHHS, 370 L'Enfant Promenade SW., Mail Stop: OCSE/DPP, Washington, DC 20447
Phone: 202 401-1467
Fax: 202 401-5559
Email: abenson@acf.dhhs.gov

RIN: 0970-AB67

1371. STATE CASE REGISTRY AND EXPANSION OF THE FEDERAL PARENT LOCATOR SERVICE (FPLS)

Priority: Substantive, Nonsignificant

Legal Authority: PL 104-193, sec 311 and 316

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: This regulation specifies what constitutes the minimum amount

of information on child support cases recorded in the State Case Registry that is necessary to operate the Federal Case Registry. It also specifies the necessary information to identify the individuals who owe or are owed support and the State or States which have the case.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Anne M. Benson, Program Specialist, Department of Health and Human Services, Administration for Children and Families, OCSE, DHHS, 370 L'Enfant Promenade SW., Mail Stop: OCSE/DPP, Washington, DC 20447
Phone: 202 401-1467
Fax: 202 401-5559
Email: abenson@ach.dhhs.gov

RIN: 0970-AB68

1372. STATE LAW CONCERNING PATERNITY ESTABLISHMENT

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 666(a)(5)

CFR Citation: 45 CFR 302.70; 45 CFR 303.5; 45 CFR 304.20

Legal Deadline: None

Abstract: This regulation covers voluntary paternity establishment services offered by hospitals and birth record agencies and specifies the types of other entities that may offer voluntary paternity establishment services. The provision of such services must include a requirement that such an entity use the same notice provision, materials, training, and evaluation as the ones used by the voluntary paternity establishment programs of hospitals and birth record agencies.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Jan Rothstein, Program Specialist, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, OCSE, DHHS, 370 L'Enfant Promenade SW.,

HHS—ACF

Proposed Rule Stage

Mail Stop: OCSE/DPP, Washington, DC 20447
 Phone: 202 401-5073
 Fax: 202 401-5559
 Email: jrothstein@acf.dhhs.gov
RIN: 0970-AB69

1373. AUTOMATED DATA PROCESSING REQUIREMENTS

Priority: Other Significant
Legal Authority: 42 USC 654(24)
CFR Citation: 45 CFR 302.85; 45 CFR 304.20; 45 CFR 307
Legal Deadline: Final, Statutory, August 22, 1998.

Abstract: This regulation, which should be finalized not later than two years after date of enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (P.L. 104-193), sets a deadline of October 1, 2000, for implementation of new Automated Data Processing requirements for the Child Support Enforcement Program. The deadline, however, shall be extended by one day for each day that the Secretary misses the two-year deadline.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: None
Government Levels Affected: State
Agency Contact: Michael P. Fitzgerald, Senior Computer Specialist, Department of Health and Human Services, Administration for Children and Families, DHHS Room 326F, 200 Independence Avenue SW., Washington, DC 20201
 Phone: 202 401-6403

RIN: 0970-AB70

1374. AUTOMATED DATA PROCESSING FUNDING LIMITATION

Priority: Other Significant
Legal Authority: PL 104-193, sec 344
CFR Citation: 45 CFR 307.30
Legal Deadline: None

Abstract: This regulation will set the allocation formula for the total amount payable to a State for fiscal years 1996 through 2001 based on the \$400 million in federal funds for automated child support enforcement systems enhancements under the Personal

Responsibility and Work Opportunity Reconciliation Act of 1996 (P.L. 104-193).

Timetable:

Action	Date	FR Cite
NPRM	11/00/97	

Small Entities Affected: None
Government Levels Affected: State
Agency Contact: Helen Morgan Smith, Electronic Benefits Transfer Specialist, Department of Health and Human Services, Administration for Children and Families, OPS/OSS/OD, Room 326F, DHHS/HHH, 200 Independence Avenue SW., Washington, DC 20201
 Phone: 202 690-6639
 Fax: 202 401-6400

RIN: 0970-AB71

1375. GRANTS TO STATES FOR ACCESS AND VISITATION PROGRAMS

Priority: Substantive, Nonsignificant
Legal Authority: PL 104-193, sec 391
CFR Citation: 45 CFR 300

Legal Deadline: None

Abstract: This regulation specifies the monitoring, evaluating, and reporting of State grants designed to support and facilitate absent parents' access to and visitation of their children.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	

Small Entities Affected: None
Government Levels Affected: State, Local, Federal
Agency Contact: David Arnaudo, Technical Advisor, Department of Health and Human Services, Administration for Children and Families, OCSE/DHHS, 370 L'Enfant Promenade SW., Mail Stop: OCSE/DPP, Washington, DC 20447
 Phone: 202 401-5364
 Fax: 202 401-5559
 Email: darnaudo@acf.dhhs.gov

RIN: 0970-AB72

1376. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES

Priority: Other Significant
Legal Authority: 42 USC 655(b)
CFR Citation: Not yet determined
Legal Deadline: None

Abstract: This NPRM will specify how tribes can obtain direct payments from the Department of Health and Human Services for provision of child support enforcement services if they submit a plan meeting the requirements of title IV-D.

Timetable:

Action	Date	FR Cite
NPRM	04/00/98	

Small Entities Affected: None
Government Levels Affected: State, Tribal
Agency Contact: Elizabeth C. Matheson, Director, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, OCSE/DHHS, 370 L'Enfant Promenade SW., Mail Stop: OCSE/DPP, Washington, DC 20447
 Phone: 202 401-9386
 Fax: 202 401-5559
 Email: ematheson@acf.dhhs.gov

RIN: 0970-AB73

1377. TEMPORARY ASSISTANCE FOR NEEDY FAMILIES (TANF)

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

RIN: 0970-AB77

1378. REQUIREMENTS FOR THE TRIBAL PROGRAMS

Priority: Other Significant
Legal Authority: 42 USC 612
CFR Citation: 45 CFR 286; 45 CFR 287
Legal Deadline: None

Abstract: This NPRM proposes a process for Tribes that operate a Tribal TANF program a process for reviewing Tribal plans, establishing criteria to determine Tribal plans, establishing criteria to determine minimum work participation requirements and time limits, and a process for determining Tribal family assistance grant funding when there is a disagreement with State submittal data.

The NPRM also proposes procedures for planning and operating a program to make work activities available to Tribal members. Funds for this program are available to Indian tribes and Alaska Native organizations that operated a Job Opportunities and Basic

HHS—ACF

Proposed Rule Stage

Skills Training (JOBS) program in fiscal year 1995. This Tribal work activities program is called the Native Employment Works (NEW) Program.

Timetable:

Action	Date	FR Cite
NPRM	02/00/98	

Small Entities Affected: None

Government Levels Affected: State, Tribal, Federal

Agency Contact: John Bushman, Director, Division of Tribal Services, Department of Health and Human Services, Administration for Children and Families, Office of Community Services, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-2418
Fax: 202 205-5887
Email: jrbushman@acf.dhhs.gov

RIN: 0970-AB78

1379. BONUS TO REWARD DECREASE IN OUT-OF-WEDLOCK BIRTH RATIO

Priority: Other Significant

Legal Authority: 42 USC 603

CFR Citation: 45 CFR 283

Legal Deadline: None

Abstract: This regulation specifies, for each bonus year, the requirements that eligible States must meet to receive grants from the Secretary for reducing their out-of-wedlock birth ratios. The regulation specifies the amount of grant, defines "eligible States," and gives the appropriate years for the grant.

Timetable:

Action	Date	FR Cite
NPRM	01/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Kelleen Kaye, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Administration for Children and Families, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 401-6634
Email: kkaye@osaspe.dhhs.gov

RIN: 0970-AB79

1380. CASE CLOSURE

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 651 to 658; 42 USC 660; 42 USC 663; 42 USC 664; 42 USC 666; 42 USC 667; 42 USC 1302; 42 USC 1396a(a)(25); 42 USC 1396(d)(2); 42 USC 1396b(o); 42 USC 1396b(p); 42 USC 1396(k)

CFR Citation: 45 CFR 303.11

Legal Deadline: None

Abstract: This NPRM proposes to amend regulations governing the case closure process in the child support enforcement program.

Timetable:

Action	Date	FR Cite
NPRM	12/00/97	

Small Entities Affected: None

Government Levels Affected: State, Local, Tribal

Agency Contact: Elizabeth C. Matheson, Director, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Mail Stop: OCSE/DPP, Washington, DC 20447
Phone: 202 401-9385
Fax: 202 401-5559
Email: ematheson@acf.dhhs.gov

RIN: 0970-AB82

1381. REFUGEE RESETTLEMENT PROGRAM: RESPONDING AND CONFORMING TO TANF REPLACING AFDC

Priority: Substantive, Nonsignificant

Legal Authority: 8 USC 1522(a)(9)

CFR Citation: 45 CFR 400

Legal Deadline: None

Abstract: This regulation will revise refugee resettlement program regulations to respond and conform to the Temporary Assistance to Needy Families (TANF) program replacing the Aid to Families with Dependent Children (AFDC) program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Toyo Biddle, Director, Division of Refugee Self-Sufficiency, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9250

RIN: 0970-AB83

1382. ● CHILD SUPPORT NON-PERFORMANCE PENALTY

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 609(a)(8)

CFR Citation: 45 CFR 305

Legal Deadline: None

Abstract: This regulation will implement the requirements in section 409(a) (8) of the Social Security Act which provides for a penalty of 1 percent to 5 percent of a State's Temporary Assistance for Needy Families (TANF) funds if the Secretary of HHS determines that the State failed to meet the paternity establishment percentages or other performance measures established by the Secretary.

Timetable:

Action	Date	FR Cite
NPRM	08/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Elizabeth C. Matheson, Director, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, DHHS/Administration for Children & Families, 370 L'Enfant Promenade SW., Mail Stop OCSE/DPP Washington, DC 20447
Phone: 202 401-9385
Fax: 202 401-5559
Email: ematheson@acf.dhhs.gov

RIN: 0970-AB85

1383. ● CHILD ABUSE AND NEGLECT PREVENTION AND TREATMENT

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 5101 et seq

CFR Citation: 45 CFR 1340

Legal Deadline: None

Abstract: To amend current regs to reflect statutory changes in the CAPTA Amendments of 1996.

HHS—ACF

Proposed Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Emily Cooke, Department of Health and Human Services, Administration for Children and Families, DHHS/ACF/NCCAN, 330 C Street SW., Room 2106, Switzer Building, Washington, DC 20201
Phone: 202 205-8709
Fax: 202 260-9351
Email: ecooke@acf.dhhs.gov

RIN: 0970-AB86

1384. • HEAD START APPEAL TIMELINES

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1303

Legal Deadline: None

Abstract: This proposed amendment to part 1303 will provide timelines for conducting administrative hearings on adverse actions taken against Head Start agencies.

Timetable:

Action	Date	FR Cite
NPRM	06/00/98	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal

Agency Contact: Douglas Klafehn, Deputy Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, DHHS/ACF/ACYF, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB87

1385. • TITLE IV-B PLANNING REQUIREMENTS FOR TRIBES

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 628; 42 USC 629

CFR Citation: 45 CFR 1356; 45 CFR 1357

Legal Deadline: None

Abstract: This NPRM will revise the title IV-B, subpart 1, planning requirements to make the plans more accurately reflect of the amount of funding available to the Indian Tribes/Tribal Organizations through the program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/98	

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Tribal

Agency Contact: Paul Blatt, Child Welfare Specialist, Children's Bureau, Department of Health and Human Services, Administration for Children and Families, DHHS/ACF/ACYF, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8324

RIN: 0970-AB88

1386. • TITLE IV-E TRAINING

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 672; 42 USC 673

CFR Citation: 45 CFR 1356.60; 45 CFR 235.63 to 235.66(a)

Legal Deadline: None

Abstract: This NPRM will revise the title IV-E training regulations. The current title IV-E training regulations are a carryover from the old title IV-A regulations. They have never been revised to reflect the different requirements and emphases that Public Law 96-272 placed on states regarding the removal of children from their homes, the efforts required to prevent removal and work for reunification or

other permanent placements for children in foster care. In addition, there are areas of ambiguity in the current rule which need clarification to assure consistent application of policy.

Timetable:

Action	Date	FR Cite
NPRM	06/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Judith Reich, Training Specialist, Children's Bureau, Department of Health and Human Services, Administration for Children and Families, DHHS/ACYF/ACF, Washington, DC 20013
Phone: 202 205-8713

RIN: 0970-AB89

1387. • DESIGNATION OF FAMILY CHILD CARE AS A PROGRAM OPTION FOR HEAD START PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1306

Legal Deadline: None

Abstract: This Rule Change will allow Head Start Programs to choose Family Child Care as Head Start Program Option.

Timetable:

Action	Date	FR Cite
NPRM	03/00/98	

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start, Bureau, Department of Health and Human Services, Administration for Children and Families, DHHS/ACYF/ACF, PO Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB90

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Administration for Children and Families (ACF)

Final Rule Stage

1388. STANDARDS FOR SAFE TRANSPORTATION

Priority: Other Significant

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	06/15/95	60 FR 31612
NPRM Comment Period End	08/14/95	
Final Action	06/00/98	

Small Entities Affected: 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-AB24

1389. 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
NPRM Comment Period End	01/30/95	
Final Action	02/00/98	

Small Entities Affected: 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-AB31

1390. 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 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	02/00/98	

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

1391. INCOME AND RESOURCE DISREGARDS RELATED TO INTERESTS OF INDIVIDUAL INDIANS IN TRUST OR RESTRICTED LANDS

Priority: Substantive, Nonsignificant

Legal Authority: 25 USC 1408

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 under the Social Security Act or any other Federally assisted program. 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 under the Social Security Act or any other Federally assisted program.

Timetable:

Action	Date	FR Cite
NPRM	10/25/94	59 FR 51536
Final Action	02/00/98	

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

1392. CHILD CARE AND DEVELOPMENT FUND

Priority: Other Significant

Legal Authority: 42 USC 618; 42 USC 9858

CFR Citation: 45 CFR 98.14; 45 CFR 98.33; 45 CFR 98.43; 45 CFR 98.50; 45 CFR 98.51; 45 CFR 98.52; 45 CFR 98.53; 45 CFR 98.60; 45 CFR 98.61; 45 CFR 98.62; 45 CFR 98.63; 45 CFR 98.64; 45 CFR 98.66; 45 CFR 98.81; 45 CFR 98.83; ...

Legal Deadline: None

Abstract: The Administration for Children and Families will amend existing regulations which govern the administration of the Child Care and Development Block Grant program. The purpose of this regulatory package will be to implement the legislative changes contained in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Timetable:

Action	Date	FR Cite
NPRM	07/23/97	62 FR 39610
Final Action	04/00/98	

Small Entities Affected: None

Government Levels Affected: State, Tribal

Agency Contact: Joan Lombardi, Associate Commissioner, Child Care Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013

HHS—ACF

Final Rule Stage

Phone: 202 690-6782

RIN: 0970-AB74

1393. CHILD SUPPORT ENFORCEMENT PROGRAM OMNIBUS CONFORMING REGULATION

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 1102

CFR Citation: 45 CFR 304; 45 CFR 305

Legal Deadline: None

Abstract: This rule eliminates child support enforcement program regulations rendered obsolete or inconsistent with the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Timetable:

Action	Date	FR Cite
Final Action	03/00/98	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Marilyn R. Cohen, Program Specialist, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Mail Stop: OCSE/DPP, Washington, DC 20447

Phone: 202 401-5366

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Email: mcohen@acf.dhhs.gov

RIN: 0970-AB81

1394. PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996 CONFORMING REGULATION

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 601 note; 42 USC prec 601; 42 USC 601 to 610; 42 USC 612; 42 USC 613; 42 USC 615 to 617

CFR Citation: 45 CFR 205; 45 CFR 232; 45 CFR 233; 45 CFR 250; 45 CFR 255; 45 CFR 256; 45 CFR 257

Legal Deadline: None

Abstract: This regulation will eliminate regulations repealed by title I of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (P.L. 104-193).

Timetable:

Action	Date	FR Cite
Final Action	03/00/98	

Small Entities Affected: None

Government Levels Affected: State, Tribal, Federal

Agency Contact: Ann Burek, Program Analyst, Office of Legislative Affairs and Budget, Department of Health and Human Services, Administration for

Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9223

RIN: 0970-AB84

1395. DATA COLLECTION AND REPORTING FOR THE WELFARE TO WORK PROGRAM

Priority: Other Significant

Legal Authority: 42 USC 611

CFR Citation: Not yet determined

Legal Deadline: Final, Statutory, November 5, 1997.

Implementing regulations must be issued within 90 days after the date of enactment.

Abstract: This interim final rule will specify the data collection and reporting requirements for the Welfare-to-Work program.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/97	

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Howard Rolston, Director, Office of Planning, Research and Evaluation, Department of Health and Human Services, Administration for Children and Families, DHHS/ACF, 370 L'Enfant Promenade SW., 7th Floor West, Washington, DC 20447

Phone: 202 401-9220

Fax: 202 205-3598

RIN: 0970-AB92

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Administration for Children and Families (ACF)

1396. DATA COLLECTION AND REPORTING UNDER THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES BLOCK GRANT

Priority: Other Significant

CFR Citation: Not yet determined

Completed:

Reason	Date	FR Cite
Merged With RIN 0970-AB77	10/01/97	

Small Entities Affected: None

Government Levels Affected: State, Local, Tribal

Agency Contact: Howard Rolston
Phone: 202 401-9220
Fax: 202 205-3598

RIN: 0970-AB64

1397. TANF PENALTIES AND ADMINISTRATIVE COSTS

Priority: Other Significant

CFR Citation: 45 CFR 201

Completed:

Reason	Date	FR Cite
Merged With RIN 0970-AB77	10/01/97	

Small Entities Affected: None

Government Levels Affected: State, Tribal, Federal

Agency Contact: Mack Storrs
Phone: 202 401-9289
Fax: 202 205-5887

Email: mstorrs@acf.dhhs.gov

RIN: 0970-AB76

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Administration on Aging (AOA)

Long-Term Actions

1398. 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: 42 USC 3001 et seq

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:

Action	Date	FR Cite
NPRM - OAA Amendments in FY '98	11/00/98	

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 1998 to implement the provisions to the next reauthorization of the Older Americans Act, if necessary.

Agency Contact: Edwin Walker, Director, Office of Program Operations and Development, 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
 [FR Doc. 97-26069 Filed 10-28-97; 8:45 am]

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