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**Thursday,
November 30, 2000**

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 Executive Order 12866 and the Regulatory Flexibility Act of 1980 require semiannual publication of an agenda outlining all current, projected and recently completed rulemakings. The **Unified Agenda of Federal Regulatory and Deregulatory Actions** informs the public about regulatory actions under development within the Department, and it provides an opportunity for all concerned with the impact of the regulations to participate in their development at an early stage. The last such agenda was published on April 24, 2000.

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 component of the Department as listed below.

SUPPLEMENTARY INFORMATION: The regulatory actions described below continue to reflect the Department's efforts to embody in its rulemaking actions the Administration's continuing efforts to overhaul the Federal regulatory system so that it helps deliver important services to the American people while creating fewer burdens. These regulatory actions also are an indication of policy mandates for HHS, affecting such national priorities as:

securing the confidentiality of Americans' health records; establishing improved access to health services for children; strengthening and modernizing the Medicare and Medicaid programs; assuring the safety of the American food supply; controlling the safety of clinical trials of emerging medical therapies; advances in health-insurance reform; and eliminating waste, fraud and abuse from the health care system. As backdrop to the Department's conduct of its regulatory responsibilities in all of the above-mentioned programmatic areas, there endures at HHS the focus and discipline that the principles of Executive Order 12866 have brought to the Department's regulatory functions.

Public commentary is invited to assist the Department in continuing these efforts. Comments on entries in the agenda 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.

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, 330 Independence Avenue SW.,

Washington, DC 20201; Phone 202-260-0669.

Agency for Health Care Policy and Research: Nancy Werbel, 2101 East Jefferson Street, Suite 603, Rockville, Maryland 20852; Phone 301-594-1455.

Centers for Disease Control: Thena Durham, Executive Secretariat, 1600 Clifton Road, Building 16, Atlanta, Georgia 30333; Phone 404-639-7120.

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 20205; Phone 301-496-4606.

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

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

For this edition of HHS' 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.

Dated: September 25, 2000.

LaVarne Burton,
Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1096	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991-AB06
1097	Revisions and Technical Corrections to 42 CFR Chapter V	0991-AB09
1098	Amending the Regulations Governing Nondiscrimination on the Basis of Race, Color, National Origin, Handicap, Sex, and Age To Conform to the Civil Rights Restoration Act of 1987	0991-AB10

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Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1099	Reproduction and Sale of Official Forms and Publications	0991-AA83
1100	Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
1101	Civil Money Penalty Safe Harbor To Protect Payment of Medicare and Medigap Premiums for ESRD Beneficiaries	0991-AB04
1102	Safe Harbor for Ambulance Restocking	0991-AB05
1103	Standards for Privacy of Individually Identifiable Health Information (Reg Plan Seq. No. 30)	0991-AB08

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

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1104	Civil Money Penalties for Medicare+Choice Organizations and Medicaid Managed Care Organizations	0991-AB03

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
1105	Revised OIG Civil Money Penalties Resulting From Public Law 104-191	0991-AA90
1106	Privacy Act Exempt Record System From the Healthcare Integrity and Protection Data Bank	0991-AA99

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1107	Final and Delegation of Authority To Implement SAMHSA's Accreditation Based System for Opioid Treatment Program Monitoring (Reg Plan Seq. No. 31)	0930-AA06

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

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

Sequence Number	Title	Regulation Identification Number
1108	Substance Abuse Prevention and Treatment Block Grant Applications Due Date Change from March 31 to October 1 for FY 2001 and Beyond	0930-AA04

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1109	Packaging and Handling of Infectious Substances and Select Agents	0920-AA02

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Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1110	Control of Communicable Diseases	0920-AA03

Departmental Management—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1111	Implementation of the Equal Access to Justice Act in Agency Proceedings	0990-AA02

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
1112	Natural Rubber-Containing Drugs; User Labeling	0910-AB56
1113	Implementation of the Import Tolerance Provisions of the Animal Drug Availability Act of 1996	0910-AB71
1114	Substances Prohibited From Use in Animal Food or Feed	0910-AB90
1115	Part 600-Biological Products: General (Section 610 Review)	0910-AC06

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1116	Hearing Aids; Professional and Patient Labeling; Conditions for Sale (Reg Plan Seq. No. 32)	0910-AA39
1117	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910-AA49
1118	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910-AA61
1119	Safety Reporting and Recordkeeping Requirements for Marketed OTC Drugs	0910-AA86
1120	Labeling for Human Prescription Drugs; Revised Format (Reg Plan Seq. No. 33)	0910-AA94
1121	Safety Reporting Requirements for Human Drug and Biological Products (Reg Plan Seq. No. 34)	0910-AA97
1122	Radioactive Drugs for Basic Research	0910-AB00
1123	Administrative Practices and Procedures; Advisory Opinions and Guidelines	0910-AB14
1124	Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products (Reg Plan Seq. No. 35)	0910-AB28
1125	Applications for FDA Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications	0910-AB34
1126	Expanded Access to Investigational Therapies	0910-AB37
1127	Electronic Submission of Adverse Drug Reaction Reports	0910-AB42
1128	Distinguishing Marks for Drug Products Containing Insulin	0910-AB43
1129	Pregnancy Labeling	0910-AB44
1130	Pharmacy and Physician Compounding of Drug Products (Reg Plan Seq. No. 36)	0910-AB58
1131	Drug Products That Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness	0910-AB59
1132	Discontinuation of a Lifesaving Product	0910-AB60
1133	Positron Emission Tomography Drugs; Current Good Manufacturing Practices (Reg Plan Seq. No. 37)	0910-AB63
1134	Current Good Manufacturing Practice for Medicated Feeds	0910-AB70
1135	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV (Lookback) (Reg Plan Seq. No. 38)	0910-AB76
1136	Fixed-Combination Prescription and Over-the-Counter Drugs for Human Use	0910-AB79
1137	Stability Testing of Drugs	0910-AB82
1138	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements (Reg Plan Seq. No. 39)	0910-AB88
1139	Current Good Manufacturing Practice for Blood and Blood Components; Blood Labeling Standards	0910-AB89
1140	Submission in Electronic Format of Certain Labeling Information	0910-AB91
1141	Fees Relating to Drugs; Waiver and Reduction of Fees	0910-AB92
1142	Periodic Testing for Certain Human Drug, Veterinary Drug, and Biological Product Final Specifications	0910-AB93

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Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1143	Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission into the United States	0910-AB95
1144	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection with Imported Food	0910-AB96
1145	Medical Devices, Medical Device Establishment Registration and Listing Requirements; Amendment	0910-AB99
1146	Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Gene Therapy or Xenotransplantation (Reg Plan Seq. No. 40)	0910-AC00
1147	Reporting Information Regarding Potential Fabrication or Falsification	0910-AC02
1148	Examination of Administrative Record and Other Advisory Committee Records	0910-AC03
1149	Status Reports for Quantity Marketed Information for Animal Drug Products Used in Food-Producing Animals	0910-AC04
1150	Additional Safeguards for Children in Clinical Investigations	0910-AC07
1151	Addition to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness	0910-AC08
1152	Labeling Dietary Supplements for Women Who Are or May Become Pregnant	0910-AC09
1153	Overwrap For Inhalation Products Packaged in Low Density Polyethylene (LDPE) Containers	0910-AC10
1154	Revocation of Conditions for Marketing Digoxin Products for Oral Use	0910-AC12
1155	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of "No Residue"	0910-AC13
1156	Control of Salmonella Enteritidis in Shell Eggs During Production and Retail (Reg Plan Seq. No. 41)	0910-AC14
1157	Premarket Notice Concerning Bioengineered Foods (Reg Plan Seq. No. 42)	0910-AC15

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 Identification Number
1158	Over-the-Counter (OTC) Drug Review	0910-AA01
1159	New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTR)	0910-AA02
1160	Biological Products: Reporting of Biological Product Deviations in Manufacturing	0910-AA12
1161	Fruit and Vegetable Juices: Development of HACCP and Label Warning Statements for Juices (Reg Plan Seq. No. 43)	0910-AA43
1162	Bioavailability and Bioequivalence Requirements	0910-AA51
1163	Drugs Used for Treatment of Narcotic Addicts	0910-AA52
1164	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910-AA89
1165	Current Good Manufacturing Practice; Revision of Certain Labeling Controls	0910-AA98
1166	Use of Ozone-Depleting Substances	0910-AA99
1167	Establishment Registration and Listing of Human Cells and Tissue (Reg Plan Seq. No. 44)	0910-AB05
1168	Veterinary Feed Directives	0910-AB09
1169	Exports; Notification and Recordkeeping Requirements	0910-AB16
1170	Foreign Establishment Registration and Listing	0910-AB21
1171	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-AB24
1172	Blood Initiative	0910-AB26
1173	Shell Eggs: Warning, Notice and Safe Handling Labeling Statements and Refrigeration Requirements	0910-AB30
1174	Antibiotic Drug Approval and Exclusivity	0910-AB33
1175	Amendment of Regulations Regarding Certain Label Statements on Prescription Drugs	0910-AB39
1176	Supplements and Other Changes to Approved New Animal Drug Applications	0910-AB49
1177	Bulk Drug Substances for Use in Pharmacy Compounding	0910-AB57
1178	Supplements and Other Changes to an Approved Application	0910-AB61
1179	Food Labeling: Trans Fatty Acids in Nutrition Labeling and Nutrient Content Claims	0910-AB66
1180	Presubmission Conferences	0910-AB68
1181	Citizen Petitions; Actions That Can Be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action	0910-AB73
1182	Surgeon's and Patient Examination Gloves; Reclassification	0910-AB74
1183	180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications	0910-AB80
1184	Postmarketing Studies for Human Drugs and Licensed Biological Products: Status Reports	0910-AB83
1185	Food Additives: Food Contact Substances Notification System	0910-AB94
1186	State Certification of Mammography Facilities	0910-AB98

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Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1187	Addition to the List of Drug Products That Have Been Withdrawn From the Market for Reasons of Safety or Effectiveness	0910-AC01
1188	Efficacy Evidence Needed for Products To Be Used Against Toxic Substances When Human Studies Are Unethical	0910-AC05
1189	Implementing Court Decisions, ANDA Approvals, and 180-Day Exclusivity	0910-AC11

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Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1190	Infant Formula: Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910-AA04
1191	Food Labeling Review	0910-AA19
1192	Medical Foods	0910-AA20
1193	Classification of Computer Software Programs That Are Medical Devices	0910-AA41
1194	Current Good Manufacturing Practice; Amendment of Certain Requirements for Finished Pharmaceuticals	0910-AA45
1195	Reinventing FDA Food Regulations	0910-AA58
1196	Direct-to-Consumer Promotion Regulations	0910-AA90
1197	Investigational Use New Animal Drug Regulations (Section 610 Review)	0910-AB02
1198	Suitability Determination for Donors of Human Cellular and Tissue-Based Products	0910-AB27
1199	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910-AB50
1200	Revisions to the General Safety Requirements for Biological Products; Direct Final Rule	0910-AB51
1201	Mandatory HACCP Regulations for Manufacturers of Rendered Products	0910-AB72
1202	Antibiotic Resistance Labeling	0910-AB78
1203	Repackaging Approval Requirements	0910-AB81

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1204	Debarment Certification Regulations for Drug Applications	0910-AA76
1205	Investigational New Drug Applications; Request for Information and Comments	0910-AA83
1206	Investigational New Drug Applications; Clinical Holds for Drugs for Life-Threatening Illnesses	0910-AA84
1207	Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation	0910-AA88
1208	Classification of Sheep as a Minor Species for All Data Collection Purposes	0910-AB69
1209	Amendment of Various Device Regulations to Reflect Current American Society for Testing and Materials Citations	0910-AB84

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1210	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
1211	Compliance Alternatives for Provision of Uncompensated Services	0906-AA52
1212	National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table	0906-AA55

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Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1213	Final Rule for the Health Professions, Nursing, Public Health, and Allied Health Training Grant Programs Under 42 CFR Parts 57 and 58	0906-AA53

Health Resources and Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1214	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906-AA41
1215	Ricky Ray Hemophilia Relief Fund Program	0906-AA56

Indian Health Service—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1216	Indian Child Protection and Family Violence Prevention Act Minimum Standards of Character	0917-AA02
1217	Contracts Under the Indian Self-Determination Act	0917-AA04

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1218	National Institutes of Health AIDS Research Loan Repayment Program	0925-AA02
1219	Undergraduate Scholarship Program Regarding Professions Needed by the NIH	0925-AA10
1220	National Cancer Institute Clinical Cancer Education Program	0925-AA17
1221	National Institutes of Health Loan Repayment Program for Research	0925-AA18

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1222	Traineeships	0925-AA11
1223	Additional DHHS Protections for Pregnant Women and Human Fetuses Involved as Subjects in Research, and Pertaining to Human In Vitro Fertilization	0925-AA14
1224	National Research Service Awards	0925-AA16
1225	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925-AA19
1226	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	0925-AA20
1227	Federal Policy (Common Rule) for the Protection of Human Subjects	0925-AA21

National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identification Number
1228	NIH Privacy Act System of Records, 09-25-0213, "Administration: Investigative Records"	0925-AA23

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Office of Public Health and Science—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1229	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940-AA01

Office of Public Health and Science—Completed Actions

Sequence Number	Title	Regulation Identification Number
1230	Standards of Compliance for Abortion-Related Services in Family Planning Service Projects	0940-AA00

Health Care Financing Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1231	End Stage Renal Disease (ESRD) Conditions for Coverage (HCFA-3818-P) (Section 610 Review) (Reg Plan Seq. No. 45)	0938-AG82
1232	Criteria for Medicare Coverage of Heart, Liver, and Lung Transplants (HCFA-3835-P) (Reg Plan Seq. No. 46)	0938-AH17
1233	Requirements for Establishing and Maintaining Medicare Billing Privileges (HCFA-6002-P)	0938-AH73
1234	Prospective Fee Schedule for Ambulance Services (HCFA-1002-P)	0938-AI72
1235	DME Surety Bonds (HCFA-6006-P)	0938-AJ64
1236	End Stage Renal Disease Bad Debt Payment (HCFA-1126-P)	0938-AK02
1237	Revisions to Medicaid Upper Payment Limit Requirements for Hospital, Nursing Facility, Intermediate Care Facility Services for the Mentally Retarded and Clinic Services (HCFA-2071-P) (Reg Plan Seq. No. 47)	0938-AK12
1238	Payment for Clinical Psychology Training Programs and Physician Assistant Training Programs (HCFA-1089-P) (Reg Plan Seq. No. 48)	0938-AK15
1239	Prospective Fee Schedule for Ambulance Services (HCFA-1002-P) (Reg Plan Seq. No. 49)	0938-AK30
1240	Elimination of Application of Federal Financial Participation Limits (HCFA-2086-P) (Reg Plan Seq. No. 50)	0938-AK32

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Health Care Financing Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1241	Payment for Nursing and Allied Health Science Education (HCFA-1685-F)	0938-AE79
1242	Home Health Agency (HHA) Conditions of Participation (HCFA-3819-F)	0938-AG81
1243	Additional Supplier Standards (HCFA-6004-F)	0938-AH19
1244	Requirements for Enrollment of Medicaid Recipients Under Cost Effective Employer-Based Group Health Plans (HCFA-2047-F)	0938-AH48
1245	Terms, Definitions, and Addresses: Technical Amendments (HCFA-9877-FC)	0938-AH53
1246	Update of Ratesetting Methodology, Payment Rates and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective for Calendar Year 2000 (HCFA-1885-FC) (Reg Plan Seq. No. 51)	0938-AH81
1247	Standard Unique Health Care Provider Identifier (HCFA-0045-F)	0938-AH99
1248	Medicare Program; Adjustments to Cost Limits for Skilled Nursing Facility Inpatient Routine Service Costs (HCFA-1896-FN)	0938-AI14
1249	Medicare Program; Prospective Payment System for Hospital Outpatient Services (HCFA-1005-F)	0938-AI56
1250	National Standard Employer Identifier (HCFA-0047-F)	0938-AI59
1251	Medicaid Program; Home and Community-Based Services (HCFA-2010-FC)	0938-AI67
1252	Medicaid Managed Care; Regulatory Program To Implement Certain Medicaid Provisions of the Balanced Budget Act of 1997 (HCFA-2001-F)	0938-AI70
1253	Expanded Coverage for Diabetes Outpatient Self-Management Training Services (HCFA-3002-P) (Reg Plan Seq. No. 52)	0938-AI96
1254	External Quality Review of Medicaid Managed Care Organizations (HCFA-2015-F)	0938-AJ06
1255	Protection for Women Who Elect Reconstruction After a Mastectomy (HCFA-2040-IFC) (Reg Plan Seq. No. 53) ..	0938-AJ44
1256	The Children's Health Insurance Program: Implementing the Balanced Budget Act of 1997 (HCFA-2006-F) (Reg Plan Seq. No. 54)	0938-AJ75

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Health Care Financing Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1257	Application of Inherent Reasonableness to All Part B Services Other Than Physician Services (HCFA-1908-F) (Reg Plan Seq. No. 55)	0938-AJ97
1258	Flexibility in Payment Methods for Services of Hospitals, Nursing Facilities, and Intermediate Care Facilities for the Mentally Retarded (HCFA-2004-F)	0938-AK04
1259	Hospital Conditions of Participation; Anesthesia Services (HCFA-3049-F) (Reg Plan Seq. No. 56)	0938-AK08
1260	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships-Phase II (HCFA-1810-FC) (Reg Plan Seq. No. 57)	0938-AK31

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Health Care Financing Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1261	Changes to Peer Review Organization Regulations (HCFA-3135-F)	0938-AD38
1262	"Without Fault" and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (HCFA-6007-F)	0938-AD95
1263	Protection of Income and Resources for Community Spouses of Institutionalized Individuals (HCFA-2023-P)	0938-AE12
1264	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services (HCFA-2028-F)	0938-AE72
1265	Coverage of Screening Pap Smears (HCFA-3705-F)	0938-AE98
1266	Medicaid Payment for Covered Outpatient Drugs Under Rebate Agreements (HCFA-2046-FC)	0938-AF42
1267	Referral to Child Support Enforcement Agencies of Medicaid Families (HCFA-2051-F)	0938-AF68
1268	Disclosure of Confidential PRO and ESRD Network Organization Information for Research Purposes (HCFA-3208-P)	0938-AG33
1269	Effect of Change of Ownership on Provider and Supplier Penalties, Sanctions, Underpayments and Overpayments (HCFA-2215-P)	0938-AG59
1270	Medicaid: Optional Coverage of TB-Related Services for Individuals Infected With Tuberculosis (HCFA-2082-P) ...	0938-AG72
1271	Revision of Medicare/Medicaid Hospital Conditions of Participation (HCFA-3745-F)	0938-AG79
1272	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships-Expanded to Designated Health Services (HCFA-1809-FC)	0938-AG80
1273	Distinct Part Requirements for Nursing Homes and Prohibition on Financial Screening of Applicants for Nursing Home Admission (HCFA-3815-P)	0938-AG84
1274	CLIA Program: Categorization of Waived Tests (HCFA-2225-FC)	0938-AG99
1275	Liability for Third Parties To Pay for Services (HCFA-2080-P)	0938-AH01
1276	State Plan Amendment (SPA) Reconsideration Process (HCFA-2096-P)	0938-AH24
1277	Hospice Care-Conditions of Participation (HCFA-3844-P)	0938-AH27
1278	Medicare Coverage of Services of Speech-Language Pathologists and Audiologists (HCFA-1843-P)	0938-AH37
1279	Medicaid; Estate Recoveries (HCFA-2083-P)	0938-AH63
1280	Individual Market Health Insurance Reform: Portability From Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules (HCFA-2882-F)	0938-AH75
1281	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (HCFA-3887-P)	0938-AH83
1282	Disclosure of Peer Review Organization Information in Response to Beneficiary Complaints (HCFA-3241-P)	0938-AH85
1283	National Standard for Identifiers of Health Plans (HCFA-4145-P)	0938-AH87
1284	Medicaid Program; Amendment to the Preadmission Screening and Annual Resident Review Program (HCFA-2107-P)	0938-AH89
1285	Medically Needy Determinations Under Welfare Reform (HCFA-2109-IFC)	0938-AH92
1286	Medicaid Program; Coverage and Payment for Federally Qualified Health Center Services (HCFA-2043-P)	0938-AH95
1287	Portability and Nondiscrimination in the Group Health Insurance Market (HCFA-2890-F)	0938-AI08
1288	Medicare Program; Improvements To the Appeals Process for Medicare Beneficiaries Enrolled in HMOs, CMPs, and HCPPs (HCFA-4024-P)	0938-AI11
1289	Medicaid: Medical Child Support (HCFA-2081-P)	0938-AI21
1290	Medicare/Medicaid Program; User Fees for Information, Products, and Services (HCFA-6021-P)	0938-AI46
1291	Surety Bond Requirements for Comprehensive Outpatient Rehabilitation Facilities, Rehabilitation Agencies, Community Mental Health Centers, and Independent Diagnostic Testing Facilities (HCFA-6005-P)	0938-AI48
1292	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (HCFA-6003-P)	0938-AI49
1293	Security Signature Standards (HCFA-0049-F)	0938-AI57
1294	State Plan Requirements for Durable Medical Equipment Providers (HCFA-2007-P)	0938-AI63

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

Sequence Number	Title	Regulation Identification Number
1295	Medicare Program; Advance Refunding of Debt and Methodology for Repayment of Loan (HCFA-1777-P)	0938-AI75
1296	Revision of Procedures for Requesting Exceptions to Cost Limits for SNFs and Elimination of Reclassifications (HCFA-1883-P)	0938-AI80
1297	Medicare Program; Medicare Coverage of and Payment for Bone Mass Measurements (HCFA-3004-F)	0938-AI89
1298	Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests (HCFA-3250-F)	0938-AI92
1299	Coverage of Religious Non-Medical Health Care Institutions (HCFA-1909-IFC)	0938-AI93
1300	Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA-3006-IFC)	0938-AJ10
1301	Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance: Millennium Compliance (HCFA-4002-GNC)	0938-AJ15
1302	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions, and Establishment of a Quality Assessment and Improvement Program (HCFA-1910-P)	0938-AJ17
1303	Hospital Conditions of Participation: Laboratory Services (HCFA-3 014-P)	0938-AJ29
1304	Medicare Hospice Care Amendments (HCFA-1022-P)	0938-AJ36
1305	Emergency Medical Treatment and Labor Act (EMTALA) (HCFA-1063-P)	0938-AJ39
1306	Medicare/Medicaid and CLIA Programs: Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories in the State of California (HCFA-2245-N)	0938-AJ47
1307	Medicare Program: Criteria for Making National Coverage Decision (HCFA-3432-P2)	0938-AJ54
1308	Medicare Program: Prospective Payment System for Inpatient Rehabilitation Hospital Services (HCFA-1069-P)	0938-AJ55
1309	Medicare Program; Sustainable Growth Rate for Fiscal Year 2000 (HCFA-1110-N)	0938-AJ60
1310	Medicare and Medicaid Programs; Programs for All-Inclusive Care for the Elderly (PACE) (HCFA-1903-IFC)	0938-AJ63
1311	State Health Insurance Assistance Program (SHIP) (HCFA-4005-IFC)	0938-AJ67
1312	Clinical Social Worker Services (HCFA-1088-P)	0938-AJ71
1313	Medicaid Disproportionate Share Hospital Payments-Institutions for Mental Disease (HCFA-2062-N)	0938-AJ74
1314	HHA Surety Bond (HCFA-6001-P)	0938-AJ81
1315	Medicare Program Update of Ambulatory Surgical Center Payment Rates Effective for Services On or After October 1, 1999 (HCFA-1085-N)	0938-AJ86
1316	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities-Update (HCFA-1112-P)	0938-AJ93
1317	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (HCFA-2065-IFC)	0938-AJ96
1318	Supplier Standards Related to Training Requirements for Oxygen, Orthotics and Prosthetics (HCFA-6010-NPRM)	0938-AJ98
1319	Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded	0938-AJ99
1320	Non-Federal Governmental Plans Exempt From HIPAA (HCFA-2033-IFC)	0938-AK00
1321	Changes to the Appeals Process for Beneficiaries Receiving Home Health Services in the Fee For Service Program (HCFA-4006-IFC)	0938-AK10
1322	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001 (HCFA-1120-P)	0938-AK11
1323	Hospice Wage Index (HCFA-1135-N)	0938-AK13
1324	Practice Expense Data Collection (HCFA-1111-IFC)	0938-AK14
1325	HIPPA Program; Bona Fide Wellness Programs (HCFA-2078-P)	0938-AK19
1326	Providers of the Balanced Budget and Refinement Act; Hospital Inpatient Payments, Rates and Costs of Graduate Medical Education (HCFA-1131-IFC)	0938-AK20
1327	Application of Federal Financial Participation Limits (HCFA-2086-P)	0938-AK22
1328	Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (HCFA-3046-P)	0938-AK23
1329	Clinical Lab Requirements-Revisions to Regs Implementing CLIA (HCFA-2226-F)	0938-AK24
1330	Prospective Payment System for Hospital Outpatient Services: Exception to the Provider-Based Location Criteria for PPS-Exempt Facilities (HCFA-1143-P)	0938-AK25
1331	Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 2001 (HCFA-4010-GNC) ..	0938-AK26
1332	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2001 (HCFA-8007-N)	0938-AK27
1333	Mandatory Transmission of Outcome and Assessment Info. Set for Non-Medicare/Medicaid Patients in Home Health Agencies and Continued Delay of Requirements for Patients Receiving Personal Care Services	0938-AK28
1334	Removal of the Requirements for the Cardiac Pacemaker Registry (HCFA-3045-F)	0938-AK29
1335	Fire Safety Requirements for RNHCL, ASC, Hospices, PACE, Hospitals, and Long-Term Care Facilities	0938-AK35
1336	Conforming Regulations Changes and Statutory Revisions for Approval and Oversight of Accreditation Organizations	0938-AK36

HHS

Health Care Financing Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1337	Payment for Clinical Diagnostic Laboratory Tests (HCFA-1309-F)	0938-AB50
1338	Survey Requirements and Alternative Sanctions for Home Health Agencies (HCFA-2169-F)	0938-AE39
1339	Changes to the Long-Term Care Facility Survey Process (HCFA-3175-FC)	0938-AF02
1340	Requirements for Certain Health Insuring Organizations and OBRA '90 Technical Amendments (HCFA-1018-F) ...	0938-AF15
1341	Provider Reimbursement Determinations and Appeals (HCFA-1727-P)	0938-AF28
1342	Alternative Sanctions for Psychiatric Hospitals (HCFA-2191-P)	0938-AF32
1343	Medicaid: Outstationed Intake Locations for Certain Low-Income Pregnant Women, Infants, and Children Under Age 19 (HCFA-2052-F)	0938-AF69
1344	Assessing Interest Against Medicare Secondary Payer (MSP) Debts (HCFA-6108-P)	0938-AF87
1345	Revised Medicaid Management Information Systems (HCFA-2038-FN)	0938-AG10
1346	Medicare Program: Limitations on Medicare Coverage of Intermittent Positive Pressure Breathing Machine Therapy (HCFA-3781-FN)	0938-AG44
1347	Definition of Skilled Nursing Facility (SNF) for Coverage of Durable Medical Equipment (DME) and Home Health Services (HCFA-1834-P)	0938-AH16
1348	Payment Amount if Customary Charges Are Less Than Reasonable Costs (HCFA-1860-FC)	0938-AH49
1349	Limitations on Liability (HCFA-4859-FC)	0938-AH51
1350	Medicaid Hospice Care (HCFA-2016-P)	0938-AH65
1351	Medicare Technical Conforming Amendments (HCFA-1858-FC)	0938-AH67
1352	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 (HCFA-3235-FC)	0938-AH68
1353	Determination of Substandard Care in SNFs and NFs (HCFA-2240-P)	0938-AH69
1354	Waiver of Staffing Requirements for End Stage Renal Disease (ESRD) Facilities Participating in an Experiment (HCFA-2236-GNC)	0938-AH72
1355	Medicare Program; Medicare Integrity Program (HCFA-7020-F)	0938-AI09
1356	State Child Health; Implementing Regulations for the State Children's Health Insurance Program (HCFA-2006-F)	0938-AI28
1357	Medicare Program; Medicare+Choice Program (HCFA-1030-FC)	0938-AI29
1358	Health Insurance Reform: Standards for Electronic Transactions (HCFA-0149-F)	0938-AI58
1359	State Child Health; State Children's Health Insurance Program Allotments and Payments to States (HCFA-2114-F)	0938-AI65
1360	Elimination of Application of Federal Financial Participation Limits (HCFA-2111-IFC)	0938-AI73
1361	Medicaid Program; Changes to Eligibility of Non-U.S. Citizens (HCFA-2108-P)	0938-AI74
1362	Health Insurance Reform Universal Health Care Identifier (HCFA-0048-NOI)	0938-AI91
1363	Peer Review Organization Contracts: Solicitation of Statements of Interest From In-State Organizations (HCFA-3009-N)	0938-AI99
1364	HHS' Recognition of NAIC Model Standards for Regulation of Medigap Policy (HCFA-2025-N)	0938-AJ07
1365	Home Health Prospective Payment System (HCFA-1059-F)	0938-AJ24
1366	Decision on the Funding for the AIDS Healthcare Foundation START Program, (HCFA-2041-N)	0938-AJ43
1367	Federal Enforcement in Group and Individual Health Insurance Markets (HCFA-2019-FC)	0938-AJ48
1368	Schedules of Per Visit and Per Beneficiary Limitation on Home Health Agency Cost (HCFA-1060-NC)	0938-AJ57
1369	Reapplication of the Community Health Accreditation Program, Incorporated (CHAP) for Continued Approval of Deeming Authority for Health Care Agencies (HHAs) (HCFA-2059-FN)	0938-AJ69
1370	State Allotments for Payments of Medicare Part B Premiums for Qualified Individuals: Federal Fiscal Year 2000 (HCFA-2063-N)	0938-AJ72
1371	Children's Health Insurance Program; Final Allotments to States, Commonwealths and Territories for Fiscal Years 1998 and 1999 (HCFA-2064-N)	0938-AJ77
1372	Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas (HCFA-1055-N)	0938-AJ79
1373	Monthly Actuary Rates and Monthly Supplementary Medical Insurance Premium Rates Beginning January 1, 2000 (HCFA-8006-N)	0938-AJ80
1374	Payment for Upgraded Durable Medical Equipment (HCFA-1084-P)	0938-AJ82
1375	Inpatient Hospital Deductible and Extended Care Services for Coinsurance Amounts for FY 2000 (HCFA-8005-N)	0938-AJ83
1376	Part A Premium for FY 2000 for the Uninsured, Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlements (HCFA-8004-N)	0938-AJ84
1377	Coverage of, and Payment of, Paramedic Intercept Ambulance Services (HCFA-1813-F)	0938-AJ87
1378	Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 2000 (HCFA-4009-GNC) ..	0938-AJ88
1379	Medicare Graduate Medical Education Consortia (HCFA-1094-N)	0938-AJ89
1380	Sustainable Growth Rate for FY 2000 (HCFA-1110-N)	0938-AJ90
1381	Medicare Program; Medicare Disproportionate Share (DSH) Adjustment Calculation: Change in the Treatment of Days in States With 1115 Expansion Waivers (HCFA-1124-IFC)	0938-AJ92

HHS

Health Care Financing Administration—Completed Actions (Continued)

Sequence Number	Title	Regulation Identification Number
1382	State Children's Health Insurance Program; Final Allotments to States, Commonwealths, and Territories for Fiscal Year 2000 (HCFA-2067-N)	0938-AJ94
1383	Process for Requesting Recognition of New Technologies and Certain Drugs, Biologicals and Medical Devices for Special Payment Under Hospital Outpatient PPS (HCFA-1128-N)	0938-AK01
1384	Schedules of Per Visit and Per Beneficiary Limitations on HHA Costs for Cost Reporting Periods Beginning On or After October 1, 2000 (HCFA-1108-NC)	0938-AK03
1385	Reporting Quality Assurance and Performance Improvement Data as Part of the Conditions for Coverage for End Stage Renal Disease Facilities (HCFA-3048-N)	0938-AK05
1386	Medicare Program; Deductible Amount for Medigap High Deductible Options for Calendar Year 2000 (HCFA-2893-N)	0938-AK06
1387	Changes to the Hospital Inpatient Perspective Payment Systems and Fiscal Year 2001 Rates (HCFA-1118-F)	0938-AK09
1388	Health Care and Employment Support Grants for People With Disabilities Beginning Fiscal Year 2000 (HCFA-2076-N)	0938-AK16

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1389	Child Support Enforcement for Indian Tribes	0970-AB73
1390	Program Performance Standards for the Operation of Head Start Programs	0970-AB99
1391	Safeguarding Child Support and Expanded FPLS Information	0970-AC01

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1392	Standards for Safe Transportation	0970-AB24
1393	Construction and Major Renovation of Head Start and Early Head Start Facilities	0970-AB54
1394	Child Support Enforcement Program Omnibus Conforming Regulation	0970-AB81
1395	Incentive Payments and Audit Penalties to States and Political Subdivisions	0970-AB85
1396	Family Child Care Program Option for Head Start Programs	0970-AB90
1397	State Self-Assessments To Determine Compliance With Federal Regulations	0970-AB96
1398	National Medical Support Notice	0970-AB97
1399	Technical Revision of Head Start Regulations To Make Them Conform To Recent Statutory Revisions	0970-AC00

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
1400	Methodology for Determining Whether an Increase in a State's Child Poverty Rate Is the Result of the TANF Program	0970-AB65
1401	Bonus To Reward High Performance States Under the Temporary Assistance for Needy Families Block Grant	0970-AB66
1402	Runaway and Homeless Youth Program	0970-AC04

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1403	Grants for State and Community Programs on Aging, Intrastate Funding Formulas; Training, Research and Discretionary Programs; Vulnerable Elder Rights; and Grants to Indians and Native Hawaiians	0985-AA00

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

Proposed Rule Stage

1096. SAFE HARBOR FOR ARRANGEMENTS INVOLVING FEDERALLY QUALIFIED HEALTH CENTERS

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 100-93, sec 2; PL 100-93, sec 14

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule would set forth a new anti-kickback safe harbor addressing remuneration between Federal Qualified Health Centers and certain service providers where a significant community benefit exists.

Timetable:

Action	Date	FR Cite
NPRM	04/00/01	
NPRM Comment Period End	06/00/01	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991-AB06

1097. REVISIONS AND TECHNICAL CORRECTIONS TO 42 CFR CHAPTER V

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 1320a-7; 42 USC 1320a-7a; 42 USC 1320a-7b; 42 USC 1320a-7d(b); 42 USC 1395u

CFR Citation: 42 CFR 1001; 42 CFR 1003; 42 CFR 1008

Legal Deadline: None

Abstract: This proposed rule sets forth several miscellaneous revisions and technical corrections to the OIG regulations codified in 42 CFR chapter V. Among other revisions, this rule revises or clarifies the term "item or service" contained in part 1003 of this chapter, to the reinstatement procedures relating to exclusions resulting from the default on health education or scholarship obligations set forth in part 1001, and to the statute of limitations for the OIG to impose an exclusion under part 1001.

Timetable:

Action	Date	FR Cite
NPRM	10/20/00	65 FR 63035
NPRM Comment Period End	12/00/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis

Required: No

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-AB09

1098. • AMENDING THE REGULATIONS GOVERNING NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, HANDICAP, SEX, AND AGE TO CONFORM TO THE CIVIL RIGHTS RESTORATION ACT OF 1987

Priority: Other Significant

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Federal

Agency Contact: Kathryn Ellis, Deputy Director, Office of Civil Rights, Department of Health and Human Services, Office of the Secretary, Room 596-F, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0403
Fax: 202 619-3818
Email: kellis@as.dhhs.gov

RIN: 0991-AB10

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

Final Rule Stage

1099. REPRODUCTION AND SALE OF OFFICIAL FORMS AND PUBLICATIONS

Priority: Info./Admin./Other

Legal Authority: 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. It amends existing prohibitions against "misuse of symbols, emblems, or names in reference to Social Security or Medicare." Section 312 also prohibits the "unauthorized reproduction,

HHS—OS

Final Rule Stage

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 written 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	11/00/00	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None

Agency Contact: Michael Herrell, 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: 202 690-5739

RIN: 0991-AA83**1100. 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 duplication, or streamline requirements.

Legal Authority: 42 USC 1302; 42 USC 1320a-7b; 42 USC 1395hh

CFR Citation: 42 CFR 1001**Legal Deadline:** Final, Statutory, January 1, 1997.

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

entity at “substantial financial risk” for the cost or utilization of the items or services that the individual or entity is obligated to provide.

Timetable:

Action	Date	FR Cite
ANPRM	05/23/97	62 FR 28410
ANPRM Comment Period End	06/09/97	
Interim Final Rule	11/19/99	64 FR 63504
Final Rule	03/00/01	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None

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

RIN: 0991-AA91**1101. CIVIL MONEY PENALTY SAFE HARBOR TO PROTECT PAYMENT OF MEDICARE AND MEDIGAP PREMIUMS FOR ESRD BENEFICIARIES****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: Social Security Act, sec 1128A(a)(5)

CFR Citation: 42 CFR 1003**Legal Deadline:** None

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

Timetable:

Action	Date	FR Cite
NPRM	05/02/00	65 FR 25460
NPRM Comment Period End	07/03/00	
Final Action	04/00/01	

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** No**Government Levels Affected:** None

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

RIN: 0991-AB04**1102. SAFE HARBOR FOR AMBULANCE RESTOCKING****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 100-93, sec 2; PL 100-93, sec 14

CFR Citation: 42 CFR 1001**Legal Deadline:** None

Abstract: This rule will set forth restocking arrangements between municipal and nonprofit ambulance companies and hospitals.

Timetable:

Action	Date	FR Cite
NPRM	05/22/00	65 FR 32060
NPRM Comment Period End	07/21/00	
Final Action	03/00/01	

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** No**Government Levels Affected:** None

Agency Contact: Joel Jay Schaeer, 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-AB05

HHS—OS

Final Rule Stage

1103. STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

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

RIN: 0991-AB08

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

Long-Term Actions

1104. CIVIL MONEY PENALTIES FOR MEDICARE+CHOICE ORGANIZATIONS AND MEDICAID MANAGED CARE ORGANIZATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320a-7a; 42 USC 1395mm; 42 USC 1395w-27; 42 USC 1396b; 42 USC 1396u-2

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This proposed rule would reflect OIG's authority to impose civil money penalties against

Medicare+Choice organizations that engage in certain abusive practices, including failure to provide medically necessary care and discriminatory enrollment procedures. This rule would specifically address the Medicare+Choice provisions set forth in Public Law 105-33 (the Balanced Budget Act of 1997), and the Medicaid managed care provisions.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0991-AB03

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

Completed Actions

1105. REVISED OIG CIVIL MONEY PENALTIES RESULTING FROM PUBLIC LAW 104-191

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Final Action	04/26/00	65 FR 24400

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0991-AA90

1106. PRIVACY ACT EXEMPT RECORD SYSTEM FROM THE HEALTHCARE INTEGRITY AND PROTECTION DATA BANK

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 56

Completed:

Reason	Date	FR Cite
Final Action	06/01/00	65 FR 34986

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0991-AA99

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

Final Rule Stage

1107. ● FINAL AND DELEGATION OF AUTHORITY TO IMPLEMENT SAMHSA'S ACCREDITATION BASED SYSTEM FOR OPIOD TREATMENT PROGRAM MONITORING

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

RIN: 0930-AA06

Department of Health and Human Services (HHS)

Long-Term Actions

Substance Abuse and Mental Health Services Administration (SAMHSA)

1108. SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT APPLICATIONS DUE DATE CHANGE FROM MARCH 31 TO OCTOBER 1 FOR FY 2001 AND BEYOND**Priority:** Routine and Frequent**Legal Authority:** Not Yet Determined**CFR Citation:** 45 CFR 96; 45 CFR 96.122(d); 45 CFR 96.130(e); 45 CFR 96.134(d)**Legal Deadline:** None**Abstract:** The Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly, the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA)) has permitted applicants for its Substance Abuse Prevention and Treatment

(SAPT) Block Grant program to submit an application for a grant as late as March 31 of the fiscal year for which it is applying. Starting with the fiscal year 2001 applications, SAMHSA is proposing a new date for receipt of the applications for SAPT Block Grants of October 1 of the fiscal year for which Block Grant funding is being requested. However, the deadline for two application components required to be submitted by that due date may be extended for a limited period, not to extend beyond December 31 of the same fiscal year when good cause is demonstrated.

Timetable:

Action	Date	FR Cite
NPRM	02/04/00	65 FR 5474

Action	Date	FR Cite
NPRM Comment Period End	03/20/00	
Next Action	Undetermined	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** State**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Thomas Reynolds, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 13C-20, Parklawn, Rockville, MD 20857
Phone: 301 443-0179**RIN:** 0930-AA04

Department of Health and Human Services (HHS)

Final Rule Stage

Centers for Disease Control and Prevention (CDC)

1109. PACKAGING AND HANDLING OF INFECTIOUS SUBSTANCES AND SELECT AGENTS**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 264; 42 USC 271; 42 USC 262 note; 31 USC 9701; 18 USC 3559; 18 USC 3571**CFR Citation:** 42 CFR 72.6 (Renumbered); 42 CFR 72.7 (Renumbered); 42 CFR 72.1-5 (Revision)**Legal Deadline:** None**Abstract:** The purpose of this NPRM is to update regulations governing the packaging, labeling, and shipment of infectious agents. Materials must be packaged in such a way as to prevent damage and leakage during transport in order to protect workers and the public from exposure.**Timetable:**

Action	Date	FR Cite
NPRM	10/28/99	64 FR 58022
Final Rule	01/00/01	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None**Federalism:** Undetermined**Agency Contact:** Dr. Jonathan Y. Richmond, Director, Office on Health and Safety, Department of Health and Human Services, Centers for Disease Control and Prevention, MS F05, 1600 Clifton Road NE, Atlanta, GA 30333
Phone: 404 639-2453**RIN:** 0920-AA02

Department of Health and Human Services (HHS)

Long-Term Actions

Centers for Disease Control and Prevention (CDC)

1110. CONTROL OF COMMUNICABLE DISEASES**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Legal Authority:** 42 USC 216; 42 USC 243; 42 USC 264; 42 USC 271**CFR Citation:** 21 CFR 1240**Legal Deadline:** None**Abstract:** CDC proposes to recodify certain regulatory responsibilities of 21

CFR part 1240 that relate to interstate quarantine of persons, following transfer of these responsibilities from FDA to CDC. Department officials have agreed to transfer this authority.

Timetable:

Action	Date	FR Cite
Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined**Government Levels Affected:** State**Federalism:** Undetermined**Agency Contact:** Chuck Gollmar, Deputy Director, Department of Health and Human Services, Centers for Disease Control and Prevention, MS D23, 1600 Clifton Road NE., Atlanta, GA 30333
Phone: 404 639-7070
Email: cgollar@cdc.gov**RIN:** 0920-AA03

Department of Health and Human Services (HHS)
Departmental Management (HSDM)

Final Rule Stage

**1111. 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	11/00/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0990-AA02

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

Prerule Stage

**1112. NATURAL RUBBER-
CONTAINING DRUGS; USER
LABELING**
Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 374; 21 USC 379; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: The advance notice of proposed rulemaking requests comments on requirements under consideration for labeling statements on products regulated as drugs (including combination products regulated under drug labeling provisions) that contain natural rubber that contacts humans.

Timetable:

Action	Date	FR Cite
ANPRM	05/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AB56

**1113. IMPLEMENTATION OF THE
IMPORT TOLERANCE PROVISIONS
OF THE ANIMAL DRUG AVAILABILITY
ACT OF 1996**
Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 360b

CFR Citation: 21 CFR 556

Legal Deadline: None

Abstract: Section 4 of the Animal Drug Availability Act of 1996 (ADAA) (Pub. L. 104-250) permits the Secretary of HHS to establish tolerances for animal drugs used or intended for use in animals grown in an exporting nation from which an edible portion is imported into the United States. The standards used to establish tolerances are to be similar to the food safety criteria used by the Secretary to establish tolerances for drugs administered to animals grown in the United States. The data used for establishing the tolerances may be from the manufacturer and include data upon which a foreign approval is based or data available to an international organization such as the Codex Alimentarius Commission. This rule would implement the provisions in ADAA.

Timetable:

Action	Date	FR Cite
ANPRM	02/00/01	
NPRM	12/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Claire Lathers, Director, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, HFV-100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1620

RIN: 0910-AB71

**1114. SUBSTANCES PROHIBITED
FROM USE IN ANIMAL FOOD OR
FEED**
Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 589

Legal Deadline: None

Abstract: After determining that dioxins were present in some clays used as anti-caking agents in animal feeds, the agency is considering proposing a rule that would prohibit the use of these clays unless they meet certain conditions under the Federal Food, Drug, and Cosmetic Act. At this time, it is not clear whether there are other types of mined clay products that contain dioxins or whether the relatively low concentrations found in recent samples of mined clay products would have a significant impact on the public health. Thus, the advance notice of proposed rulemaking will request

HHS—FDA

Prerule Stage

further information regarding the presence of dioxins in mined clay products used in animal feeds or feed ingredients and the significance of these dioxins to the public health.

Timetable:

Action	Date	FR Cite
ANPRM	06/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Randall A. Lovell, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, HFV-222, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-0176

Fax: 301 827-1484

Email: rlovell@cvm.fda.gov

RIN: 0910-AB90

1115. PART 600-BIOLOGICAL PRODUCTS: GENERAL (SECTION 610 REVIEW)

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 353; 21 USC 355; 21 USC 360; 21 USC 360(i); 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263(a); 42 USC 264; 42 USC 300aa-25

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: Parts 600 through 680 (21 CFR parts 600 through 680) describe regulations applicable to biological products. Part 600 describes regulations for general establishment standards, establishment inspections, and the reporting of adverse experiences applicable to manufacturers of licensed biological products. FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulations in part 600. The purpose of this review is to determine if any of the regulations in part 600 should be continued without change, or should be amended or rescinded, to minimize adverse economic impacts on small entities. FDA will consider, and solicit comments on the following: (1) the continued need for a regulation in part 600; (2) the nature of complaints or comments received concerning a regulation in part 600; (3) the complexity of a regulation in part 600; (4) the extent to which a regulation in

part 600 overlaps, duplicates, or conflicts with other Federal, State, or government rules; and (5) the degree to which technology, economic conditions or other factors have changed in the area affected by a regulation in part 600.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	04/03/00	
End Review	04/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Steven F. Falter, Director, Regulations and Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210
Fax: 301 594-1944
Email: falter@cber.fda.gov

RIN: 0910-AC06

Department of Health and Human Services (HHS)

Proposed Rule Stage

Food and Drug Administration (FDA)

1116. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE

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

RIN: 0910-AA39

1117. REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

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 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 207

Legal Deadline: None

Abstract: The proposed rule would revise the regulations under part 207 to clarify the requirements for registration and listing and to consolidate and reorganize the regulations. The proposal would also require the electronic submission of establishment registration and product listing information.

Timetable:

Action	Date	FR Cite
NPRM	03/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA49

1118. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371

HHS—FDA

Proposed Rule Stage

CFR Citation: 21 CFR 312.110**Legal Deadline:** None

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/01	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-74 (HF-23), Office of Policy, Planning and

Legislation, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-3380
Email: pchao@oc.fda.gov

RIN: 0910-AA61**1119. SAFETY REPORTING AND RECORDKEEPING REQUIREMENTS FOR MARKETED OTC DRUGS**

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

Unfunded Mandates: Undetermined

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

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

Legal Deadline: None

Abstract: The proposed rule would require manufacturers of marketed nonprescription human drug products to report to FDA information they receive about adverse drug reactions, maintain records of adverse drug reactions, and permit access by FDA to adverse drug reaction records.

Timetable:

Action	Date	FR Cite
NPRM	09/00/01	

Regulatory Flexibility Analysis Required: Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined

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

RIN: 0910-AA86**1120. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT**

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

RIN: 0910-AA94**1121. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS**

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

RIN: 0910-AA97**1122. RADIOACTIVE DRUGS FOR BASIC RESEARCH**

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 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	06/00/01	

Regulatory Flexibility Analysis Required: Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: mitchellw@cder.fda.gov

RIN: 0910-AB00

HHS—FDA

Proposed Rule Stage

1123. ADMINISTRATIVE PRACTICES AND PROCEDURES; ADVISORY OPINIONS AND GUIDELINES

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

Unfunded Mandates: Undetermined

Legal Authority: 15 USC 1451 to 1461; 42 USC 262; 42 USC 263b; 42 USC 264; 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

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.

Timetable:

Action	Date	FR Cite
NPRM	04/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB14

1124. CURRENT GOOD TISSUE PRACTICE FOR MANUFACTURERS OF HUMAN CELLULAR AND TISSUE-BASED PRODUCTS

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

RIN: 0910-AB28

1125. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS

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

Unfunded Mandates: Undetermined

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

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041

RIN: 0910-AB34

1126. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 360bbb

CFR Citation: 21 CFR 312

Legal Deadline: None

Abstract: The proposed rule would revise the investigational new drug regulations to clarify the conditions under which individual patients may receive investigational drugs for treatment use; to clarify the conditions under which a small group of patients may receive investigational drugs for treatment use under an expanded

access protocol; and to clarify the criteria under which sponsors can recover costs for providing investigational drugs to patients for certain treatment uses.

Timetable:

Action	Date	FR Cite
NPRM	06/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Joseph Griffin, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, (HFD-40), Center for Drug Evaluation and Research, 1451 Rockville Pike, Suite 6021, Rockville, MD 20852
Phone: 301 594-6758
Fax: 301 594-5298

RIN: 0910-AB37

1127. ELECTRONIC SUBMISSION OF ADVERSE DRUG REACTION REPORTS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 216; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 262; 21 USC 263; 21 USC 263a; 21 USC 264; 21 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 251 to 353

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 set forth requirements on the electronic submission of adverse drug reaction reports using international medical terminology, electronic data format, and electronic transmission standards.

Timetable:

Action	Date	FR Cite
ANPRM	11/05/98	63 FR 59746
ANPRM Comment Period End	02/03/99	
NPRM	05/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

HHS—FDA

Proposed Rule Stage

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910—AB42

1128. DISTINGUISHING MARKS FOR DRUG PRODUCTS CONTAINING INSULIN

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: The proposed rule would set forth a new system of distinctive colors and marks to identify different types of insulin-containing drug products.

Timetable:

Action	Date	FR Cite
NPRM	04/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910—AB43

1129. PREGNANCY LABELING

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 360gg to 360ss; 21 USC 371; 21 USC

374; 21 USC 379e; 42 USC 216; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: The proposed rule would revise the regulatory requirements for the pregnancy labeling subsection of the labeling requirements for human drugs and biologics.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Virginia G. Beakes, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: beakesv@cder.fda.gov

RIN: 0910—AB44

1130. PHARMACY AND PHYSICIAN COMPOUNDING OF DRUG PRODUCTS

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

RIN: 0910—AB58

1131. DRUG PRODUCTS THAT PRESENT DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING BECAUSE OF REASONS OF SAFETY OR EFFECTIVENESS

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

Unfunded Mandates: Undetermined

Legal Authority: PL 105-115, sec 127

CFR Citation: 21 CFR 216

Legal Deadline: None

Abstract: Section 127 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) added section 503A to the Food, Drug, and Cosmetic Act (21 U.S.C. 353a). Section 503A governs the application of Federal law

to the practice of pharmacy compounding, and exempts compounded drug products, under certain circumstances, from several key provisions of the Food, Drug, and Cosmetic Act. Section 503A(b)(3)(A) directs FDA to issue by regulation a list of drug products that, if compounded, will not qualify for these exemptions because their compounding would be demonstrably difficult in terms of assuring the safety or effectiveness of the compounded product.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910—AB59

1132. DISCONTINUATION OF A LIFESAVING PRODUCT

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 356(c)

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: Section 131 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) added section 506C to the Food, Drug, and Cosmetic Act (21 U.S.C. 356c). This proposed rule would set forth requirements on issues related to the implementation of section 131, which requires that the sole manufacturer of certain drug products notify the Secretary of the discontinuance of the manufacture of the product at least six months prior to the discontinuance of the drug.

HHS—FDA

Proposed Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected:

Undetermined

Federalism: Undetermined

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB60

1133. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

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

RIN: 0910-AB63

1134. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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 eliminate existing text in the CFR.

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

CFR Citation: 21 CFR 225**Legal Deadline:** None

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

structure of the medicated feed industry, and enhance uniformity and enforcement.

Timetable:

Action	Date	FR Cite
NPRM	07/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected:

Undetermined

Federalism: Undetermined

Agency Contact: George Graber, Director, Division of Animal Feeds, Department of Health and Human Services, Food and Drug Administration, HFV-220, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-6651
Email: ggraber@cvm.fda.gov

RIN: 0910-AB70

1135. CGMPs FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV (LOOKBACK)

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

RIN: 0910-AB76

1136. FIXED-COMBINATION PRESCRIPTION AND OVER-THE-COUNTER DRUGS FOR HUMAN USE

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 300.50; 21 CFR 330.10

Legal Deadline: None

Abstract: The proposed rule would amend 21 CFR 300.50 and 21 CFR 330.10(a)(4)(iv), which state the conditions under which two or more drugs (for a prescription drug) or active ingredients (for an over-the-counter drug) may be combined in a single dosage form. The proposed rule would state how this provision will apply to products derived from natural sources,

including animal and botanical raw materials.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected:

Undetermined

Federalism: Undetermined

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041

RIN: 0910-AB79

1137. STABILITY TESTING OF DRUGS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 314**Legal Deadline:** None

Abstract: The proposed rule would specify required stability data that must be submitted with new drug applications.

Timetable:

Action	Date	FR Cite
NPRM	04/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected:

Undetermined

Federalism: Undetermined

Agency Contact: Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB82

HHS—FDA

Proposed Rule Stage

1138. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS

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

RIN: 0910—AB88

1139. CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS; BLOOD LABELING STANDARDS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 360; 21 USC 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 21 USC 331; 21 USC 355

CFR Citation: 21 CFR 606.121; 21 CFR 606.122

Legal Deadline: None

Abstract: The proposed rule would amend the regulations governing labeling for human biologic products under 21 CFR 606.121 and 606.122. The rule or revised regulations would eliminate reference to an outdated guidance document on uniform labeling. The rule would also provide for updating the labeling requirements regarding testing and results for communicable disease agents. The regulations currently require that certain information, e.g., product name, donor classification statement, etc., be printed on the label in solid red. The rule would provide the alternative for printing this information in solid red or solid black. This alternative will make it unnecessary for manufacturers to seek an exception under 21 CFR 640.120.

Timetable:

Action	Date	FR Cite
NPRM	03/00/01	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Sharon Carayiannis, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 400S (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210

RIN: 0910—AB89

1140. SUBMISSION IN ELECTRONIC FORMAT OF CERTAIN LABELING INFORMATION

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 350; 21 USC 351; 21 USC 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e; ...

CFR Citation: 21 CFR 314.50; 21 CFR 314.81; 21 CFR 314.94

Legal Deadline: None

Abstract: The Food and Drug Administration is proposing to amend its regulations governing the format in which certain labeling in new drug applications, abbreviated new drug applications, supplements, and annual reports is required to be submitted. The proposal would require that the labeling described under sections 201.56 and 201.57 be submitted to FDA in electronic format.

Timetable:

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910—AB91

1141. FEES RELATING TO DRUGS; WAIVER AND REDUCTION OF FEES

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 379g; 21 USC 379h

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. sections 379g and 379h) require FDA to assess and collect fees related to human drug applications. Section 736(d) of the Act (21 U.S.C. 379h(d)) authorizes the agency to grant a waiver or reduction of such fees in certain circumstances. This proposed rule would establish FDA's criteria for determining whether to grant a waiver or reduction of fees.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910—AB92

1142. PERIODIC TESTING FOR CERTAIN HUMAN DRUG, VETERINARY DRUG, AND BIOLOGICAL PRODUCT FINAL SPECIFICATIONS

Priority: Substantive, Nonsignificant. 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 360(b); 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 211.165; 21 CFR 314; 21 CFR 514; 21 CFR 601; 21 CFR 610

Legal Deadline: None

Abstract: The proposed rule requests comments on when certain finished product laboratory tests to determine satisfactory conformance to final specifications for new human drug, animal drug, animal drugs and biological products may be performed on a periodic basis.

HHS—FDA

Proposed Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	03/00/01	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:**

Undetermined

Federalism: Undetermined**Agency Contact:** Carol Drew,

Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
 Phone: 301 594-2041
 Fax: 301 827-5562

RIN: 0910-AB93

1143. MARKING REQUIREMENTS FOR AND PROHIBITIONS ON THE REIMPORTATION OF IMPORTED FOOD PRODUCTS THAT HAVE BEEN REFUSED ADMISSION INTO THE UNITED STATES

Priority: Routine and Frequent**Legal Authority:** 15 USC 1453, 1454, 1455; 21 USC 321, 343, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 USC 216, 241, 243, 262, 264**CFR Citation:** 21 CFR 1.98**Legal Deadline:** None

Abstract: The proposed rule would require food products which are refused entry into the United States for safety reasons to be marked, "United States Refused Entry." The proposed rule is intended to protect the public health against contaminated or unsafe imported food products and to facilitate FDA's examination of imported products.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis**Required:** No**Small Entities Affected:** No**Government Levels Affected:** None

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-74 (HF-23), Office of Policy, Planning and

Legislation, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 827-3380
 Email: pchao@oc.fda.gov

RIN: 0910-AB95

1144. REQUIREMENTS PERTAINING TO SAMPLING SERVICES AND PRIVATE LABORATORIES USED IN CONNECTION WITH IMPORTED FOOD

Priority: Routine and Frequent**Legal Authority:** 21 USC 331; 21 USC 333; 21 USC 334; 21 USC 335b; 21 USC 335c; 21 USC 342; 21 USC 343; 21 USC 351; 21 USC 352; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 376; 21 USC 381**CFR Citation:** 21 CFR 59**Legal Deadline:** None

Abstract: The proposed rule would establish requirements for importers and other persons who use sampling services and private laboratories in connection with imported food. For example, the proposal would pertain to persons who use sample collection services and private laboratories and would describe some responsibilities for such persons, sample collection services, and private laboratories. These responsibilities might include recordkeeping requirements to ensure that the correct sample is collected and analyzed, and a notification requirement if a person intends to use a private laboratory in connection with imported food. The proposed rule is intended to help insure the integrity and scientific validity of data and results submitted to FDA.

Timetable:

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:**

Undetermined

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

RIN: 0910-AB96

1145. MEDICAL DEVICES, MEDICAL DEVICE ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS; AMENDMENT

Priority: Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374**CFR Citation:** Not Yet Determined**Legal Deadline:** None

Abstract: FDA is considering revising its present establishment registration and device listing regulations. More particularly, FDA is considering whether to: (1) merge establishment registration and device listing into a single system and single reporting form; (2) encourage the electronic submission of the establishment registration and device listing information; (3) require premarket submission application numbers; (4) amend time frames for providing and updating registration and listing data; (5) shift registration and listing responsibilities to parent company level; and (6) require notification of transfer of ownership for premarket notifications.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	

Regulatory Flexibility Analysis**Required:** Undetermined**Government Levels Affected:** None

Agency Contact: Bryan H. Benesch, Special Assistant to the Director, Office of Compliance, Department of Health and Human Services, Food and Drug Administration, HFZ-300, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, MD 20850
 Phone: 301 549-4699
 Fax: 301 594-4715
 Email: bhb@cdrh.fda.gov

RIN: 0910-AB99

1146. AVAILABILITY FOR PUBLIC DISCLOSURE AND SUBMISSION TO FDA FOR PUBLIC DISCLOSURE OF CERTAIN DATA AND INFORMATION RELATED TO GENE THERAPY OR XENOTRANSPLANTATION

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

RIN: 0910-AC00

HHS—FDA

Proposed Rule Stage

1147. REPORTING INFORMATION REGARDING POTENTIAL FABRICATION OR FALSIFICATION

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 355(i); 21 USC 360(j); 21 USC 349; 42 USC 262

CFR Citation: 21 CFR 312.3; 21 CFR 312.56; 21 CFR 812.46; 21 CFR 170.3; 21 CFR 171.1; 21 CFR 510.3; 21 CFR 511.1

Legal Deadline: None

Abstract: The proposed rule would require sponsors to submit information in their possession indicating that fabrication or falsification may have been committed by a person involved in proposing, designing, conducting, recording, or reporting human subject trials.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: None

Agency Contact: Leanne Cusumano, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, (HFD-7), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 594-2041
Fax: 301 827-0951
Email: cusumanol@cder.fda.gov

RIN: 0910-AC02

1148. EXAMINATION OF ADMINISTRATIVE RECORD AND OTHER ADVISORY COMMITTEE RECORDS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321

CFR Citation: 21 CFR 14.75

Legal Deadline: None

Abstract: FDA is amending its administrative regulations in 21 CFR 14.75(a) to state that written information for consideration by an advisory committee at an advisory committee meeting is available for public disclosure, whenever practicable, before or at the time of the meeting.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	
Direct Final Rule	01/00/01	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AC03

1149. STATUS REPORTS FOR QUANTITY MARKETED INFORMATION FOR ANIMAL DRUG PRODUCTS USED IN FOOD-PRODUCING ANIMALS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 360(b)

CFR Citation: 21 CFR 524

Legal Deadline: None

Abstract: After approving a new animal drug application, the Food and Drug Administration (FDA) requires the sponsor to submit adverse experience and use information on the product. The currently submitted distribution data are insufficient to provide the use information needed by FDA. Because of concern about the effect of the use of antimicrobial drugs in food-producing animals on the development rate and extent of resistance in human pathogens, FDA published a document describing a proposed framework for evaluating and protecting human health. The Framework Document describes the need for more detailed drug distribution information to permit the evaluation of a correlation between changes in resistance and the use of antimicrobial drugs in food-producing animals. The regulatory proposal would require the reporting of the total number of distributed units of each size, strength, or potency (distribution data or quantity marketed data) and provide FDA with the more detailed information needed to assess the correlation between resistance in

human pathogens and the use of antimicrobial drugs in food-producing animals.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: William Keller, Division Director, Division of Surveillance, Department of Health and Human Services, Food and Drug Administration, (HFV-210), Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-6642

RIN: 0910-AC04

1150. • ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c-f; 21 USC 360h-j; 21 USC 371; 21 USC 379e; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b-n

CFR Citation: 21 CFR 50; 21 CFR 56

Legal Deadline: None

Abstract: The proposed rule would provide additional protection for children involved as subjects in clinical investigations of drug products.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: None

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

HHS—FDA

Proposed Rule Stage

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910—AC07

1151. • ADDITION TO THE LIST OF DRUG PRODUCTS THAT HAVE BEEN WITHDRAWN OR REMOVED FROM THE MARKET FOR REASONS OF SAFETY OR EFFECTIVENESS**Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 353a**CFR Citation:** 21 CFR 216.24**Legal Deadline:** None

Abstract: The NPRM proposes to amend 21 CFR 216.24 by adding three drug products, grepafloxacin, troglitazone, and cisapride to the list of drug products that may not be used for pharmacy compounding under the exemptions provided by section 503A of the Federal Food, Drug, and Cosmetic Act because they have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis**Required:** No**Small Entities Affected:** No**Government Levels Affected:** None

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: mitchellw@cder.fda.gov

RIN: 0910—AC08

1152. • LABELING DIETARY SUPPLEMENTS FOR WOMEN WHO ARE OR MAY BECOME PREGNANT**Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 321(n); 21 USC 342(f); 21 USC 343(r)(6)**CFR Citation:** Not Yet Determined**Legal Deadline:** None

Abstract: The Food and Drug Administration (FDA) is proposing to require manufacturers to label their dietary supplements with a caution statement for women who are or may become pregnant unless there is evidence demonstrating that use in pregnancy is safe. FDA is including in this proposal a list of products that would not require this caution statement, as well as a petition process by which a product may be exempted from this process or qualify for a pregnancy claim. FDA is proposing this rule because of the special safety concerns associated with use of any product during pregnancy.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis**Required:** Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined

Agency Contact: Leanne Cusumano, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, (HFD-7), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 594-2041
Fax: 301 827-0951
Email: cusumanol@cder.fda.gov

RIN: 0910—AC09

1153. • OVERWRAP FOR INHALATION PRODUCTS PACKAGED IN LOW DENSITY POLYETHYLENE (LDPE) CONTAINERS**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 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375**CFR Citation:** 21 CFR 200**Legal Deadline:** None

Abstract: The proposed rule would require overwrap on all inhalation products packaged in low density polyethylene (LDPE) containers to prevent ingress of contaminants.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** None

Agency Contact: Carol Drew, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910—AC10

1154. • REVOCATION OF CONDITIONS FOR MARKETING DIGOXIN PRODUCTS FOR ORAL USE**Priority:** Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360b-f; 21 USC 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263b-n

CFR Citation: 21 CFR 310.500**Legal Deadline:** None

Abstract: The proposed rule would revoke the regulation (21 CFR 310.500) that established conditions for marketing digoxin products for oral use.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** None

Agency Contact: Mary E. Catchings, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, HFD-7, Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-0951

RIN: 0910—AC12

HHS—FDA

Proposed Rule Stage

1155. • REGULATION OF CARCINOGENIC COMPOUNDS USED IN FOOD-PRODUCING ANIMALS; DEFINITION OF “NO RESIDUE”**Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360b; 21 USC 371**CFR Citation:** 21 CFR 500.82; 21 CFR 500.84; 21 CFR 500.88**Legal Deadline:** None**Abstract:** The Food and Drug Administration (FDA) is proposing to amend its regulations relating to the operational definition of the term “no residue.” The definition is used in determining whether any residue of carcinogenic compounds used in food-producing animals would “be found in food produced from those animals under conditions of use reasonably certain to be followed in practice” (21 CFR 500.80(a)). Under the current

operational definition of no residue, it is possible for a residue detected by a method approved by FDA to be considered “no residue.” FDA is revising its regulations to make them consistent with a 1995 Department of Justice opinion regarding this definition. The proposed changes would revise the definition of “no residue” to mean that no residue is detected with an approved regulatory method. FDA would propose several conditions that sponsors of carcinogenic compounds must satisfy with respect to the sponsors’ proposed regulatory methods.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None**Agency Contact:** Steven Brynes, Regulatory Scientist, Department ofHealth and Human Services, Food and Drug Administration, HFV-151, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-6975
Email: sbrynes@cvm.fda.gov**RIN:** 0910–AC13**1156. • CONTROL OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION AND RETAIL****Regulatory Plan:** This entry is Seq. No. 41 in Part II of this issue of the **Federal Register**.**RIN:** 0910–AC14**1157. • PREMARKET NOTICE CONCERNING BIOENGINEERED FOODS****Regulatory Plan:** This entry is Seq. No. 42 in Part II of this issue of the **Federal Register**.**RIN:** 0910–AC15

Department of Health and Human Services (HHS)

Final Rule Stage

Food and Drug Administration (FDA)

1158. 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; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371**CFR Citation:** 21 CFR 310; 21 CFR 340; 21 CFR 341; 21 CFR 342; 21 CFR 343; 21 CFR 344; 21 CFR 345; 21 CFR 330; 21 CFR 333; 21 CFR 334; 21 CFR 335; 21 CFR 336; 21 CFR 337; 21 CFR 338; 21 CFR 339; ...**Legal Deadline:** None**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. NOTE: NPRM for “Antidotes, Toxic Ingestion Products” was

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

HHS—FDA

Final Rule Stage

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.)
 12/00/00
 Final Action (Amendment)
 (Overindulgence) 12/00/01

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.) 04/00/01
 Final Action 04/00/01

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)
 NPRM (Amendment) (Indications)
 07/22/99 (64 FR 39452)
 Final Action 08/29/00 (65 FR 52302)
 NPRM (Amendment) Clotrimazole
 12/00/00

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)
 Final Action (Diaper Rash) 03/00/04

Antiperspirant Products

ANPRM 10/10/78 (43 FR 46694)
 NPRM 08/20/82 (47 FR 36492)
 Final Action 04/00/01

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)

Final Action 10/23/98 (63 FR 56802)

Aspirin (OTC Professional Use Warning)

NPRM 11/16/88 (53 FR 46204)
 NPRM 10/20/93 (58 FR 54224)
 NPRM (Amendment) 06/13/96 (61 FR
 30002)

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

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)

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)(Diphenhydramine)
 08/29/97 (62 FR 45767)
 Final Action 12/00/00

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) (Warning) 07/06/89
 (54 FR 28442)
 NPRM (Amendment) 10/02/89 (54 FR
 40412)

Final Action (Amendment) (Warning)
 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)(Diphenhydramine)
 08/29/97 (62 FR 45767)

NPRM (Amendment)(Flammability)
 07/20/98 (63 FR 38762)

Final Action (Amendment)(Flammability)
 08/01/00 (65 FR 46864)

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)

Final Action (Amendment) (Ephedrine)
 02/00/01

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)

NPRM (Amendment) (Ephedrine Combo)
 02/00/01

Final Action 04/00/01

Cough/Cold (Diphenhydramine) Products

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

HHS—FDA

Final Rule Stage

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

ANPRM 09/09/76 (41 FR 38312)
 NPRM 07/09/82 (47 FR 30002)
 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) 04/00/01

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 12/20/99 (64 FR 71062)
 Final Action 11/00/00

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 12/00/01

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)

First Aid Antiseptic

ANPRM 09/13/74 (39 FR 33103)
 NPRM 01/06/78 (43 FR 1210)
 NPRM (Revised) 07/22/91 (56 FR 33644)
 Final Action 12/00/01

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)

Healthcare Antiseptic Products

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

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 (Amendment)(Sodium Bicarbonate)
 02/02/94 (59 FR 5068)
 NPRM (Prof. Labeling)(Acute MI) 06/13/96
 (61 FR 30002)
 NPRM (Amendment)(Alcohol Warning)
 11/14/97 (62 FR 61041)
 Final Action (Alcohol Warning) 10/23/98
 (63 FR 56789)
 Final Action (Aspirin Prof. Label) 10/23/98
 (63 FR 56802)
 Final Action (Sodium Bicarbonate)
 04/00/01
 Final Action
 (Amendment)(Overindulgence) 12/00/01

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 (Sodium Labeling) 04/25/91 (56 FR
 19222)
 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)
 Final Action (Sodium Labeling) 04/22/96
 (61 FR 17798)
 NPRM (Calcium/Magnesium/Potassium)
 04/22/96 (61 FR 17807)
 Withdrawal (Unless a doctor tells you)
 02/27/97 (62 FR 9024)
 Final Action (Format/Examples) 03/17/99
 (64 FR 13254)
 Final Action (Technical Amendment)
 01/03/00 (65 FR 7)
 Final Action (Ca/Mg/K/Na) 04/00/01

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 (Sodium Phosphates)
 05/21/98 (63 FR 27836)
 NPRM (Amendment)(Phosphates Label)
 05/21/98 (63 FR 27886)
 NPRM (Amendment)(Stim. Laxative)
 06/19/98 (63 FR 33592)
 Final Action; stay (Na Phos. Enema)
 12/07/98 (63 FR 67399)
 Part. With. (Na Phos. Prof. Lab.) 12/09/98
 (63 FR 67817)
 Final Action (Phenolphthalein) 01/29/99
 (64 FR 4535)
 Final Action 08/00/01
 Final Action (Stim. Laxative) 12/00/03

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)
 Final Action 12/00/01

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

ANPRM 01/05/82 (47 FR 436)

NDA Labeling Exclusivity

NPRM 11/09/93 (58 FR 59622)

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)

HHS—FDA

Final Rule Stage

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)
 Final Action 03/00/01

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)
 NPRM (Amendment) (Warning) 02/23/98 (63 FR 8888)
 Final Action 06/21/00 (65 FR 38426)

Oral Discomfort (Relief) Products

ANPRM 05/25/82 (47 FR 22712)
 NPRM 09/24/91 (56 FR 48302)
 Final Action 06/00/02

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)
 ANPRM (Plaque/Gingivitis) 04/00/01
 NPRM 04/00/01

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) 08/17/99 (64 FR 44671)
 Final Action 08/10/00 (65 FR 48902)

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)
 Final Action 12/00/01

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)
 NPRM (Labeling Amendment) 04/00/01

Phenylpropanolamine Products (Labeling)

NPRM 02/14/96 (61 FR 3912)

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

ANPRM 09/07/82 (47 FR 39412)

Poison Treatment Products

NPRM 01/15/85 (50 FR 2244)
 NPRM (Amendment) 12/00/01
 Final Action 12/00/01

Quinine for Malaria

NPRM 04/19/95 (60 FR 19650)
 Final Action 03/20/98 (63 FR 13526)

Salicylate (Reye Syndrome)

NPRM (Amendment)(Warning) 05/05/93 (58 FR 26886)

ANPRM 10/20/93 (58 FR 54228)
 Final Action (Warning) 04/00/01

Skin Bleaching Products

ANPRM 11/03/78 (43 FR 51546)
 NPRM 09/03/82 (47 FR 39108)
 NPRM (Reproposed) 01/00/03

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 (Astringent) 01/00/01
 Final Action (Poison Ivy) 01/00/01
 Final Action 01/00/01

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)

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)
 Final Action 04/22/98 (63 FR 19799)
 Final Action 08/24/98 (53 FR 44996)

Stimulant (Overindulgence) Products

NPRM (Amendment) 12/24/91 (56 FR 66758)
 Final Action 12/00/01

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)

Final Action 05/21/99 (64 FR 27666)

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)
 Final Action 07/00/01

Vaginal Contraceptive Products

ANPRM 12/12/80 (45 FR 82014)
 NPRM 02/03/95 (60 FR 6892)
 NPRM (Amendment) 04/00/01

Vaginal Drug Products

ANPRM 10/13/83 (48 FR 46694)
 Withdrawal 02/03/95 (60 FR 5226)
 NPRM (Douches) 12/00/01

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 (Phenylpropanolamine) 04/00/01

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AA06.

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

Agency Contact: Rosemary Cook, Supervisor, Project Management Staff, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD-560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 827-2222

RIN: 0910-AA01

1159. 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

HHS—FDA

Final Rule Stage

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 these regulations through detailed guidance 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 definition of 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 the 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 Period End	01/21/97	

New Animal Drug Approval Process

NPRM 12/17/91 (56 FR 65544)
NPRM To Be Determined

Records and Reports Concerning Experience with Approved New Animal Drugs

NPRM 12/17/91 (56 FR 65581)
Final Action 12/00/00

Regulatory Flexibility Analysis Required: Yes**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, 301 827-6642.

For further information concerning generic animal drugs, contact Lonnie W. Luther, Chief, Quality Assurance Support Team, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301 827-0209.

The federalism implications for the new animal drug approval process are undetermined.

Agency Contact: Claire Lathers, Director, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, HFV-100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1620

RIN: 0910-AA02**1160. BIOLOGICAL PRODUCTS: REPORTING OF BIOLOGICAL PRODUCT DEVIATIONS IN MANUFACTURING****Priority:** Other Significant

Legal Authority: 21 USC 321; 42 USC 216; 42 USC 262 to 264; 42 USC 300aa-25; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 600; 21 CFR 606**Legal Deadline:** None

Abstract: FDA is amending the regulations that require licensed manufacturers of biological products to report biological product deviations in manufacturing that may affect the safety, purity, or potency of a product. FDA defines terms used; establishes a reporting period for all licensed

biological products; and amends the current good manufacturing practice (CGMP) regulations for blood and blood components to require biological product deviations reporting by unlicensed registered blood establishments and transfusion services currently reporting on a voluntary basis. The reporting requirements will expedite reporting of biological product deviations 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 manufacturing deviations 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 final 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	12/00/00	

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AD67.

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

RIN: 0910-AA12

HHS—FDA

Final Rule Stage

1161. FRUIT AND VEGETABLE JUICES: DEVELOPMENT OF HACCP AND LABEL WARNING STATEMENTS FOR JUICES

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

RIN: 0910-AA43

1162. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 320

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	11/19/98	63 FR 64222
NPRM Comment Period End	02/02/99	
Final Action	03/00/01	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA51

1163. DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Priority: Substantive, Nonsignificant

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

Legal Authority: 21 USC 355; 21 USC 371; 21 USC 823; 42 USC 241; 42 USC 257a; 42 USC 290; 42 USC 300

CFR Citation: 21 CFR 291; 42 CFR 8

Legal Deadline: None

Abstract: The final rule will revise the regulations under part 291 and title 42 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 nonprofit 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 final rule will provide for a transition period for programs operating under the existing regulatory system.

Timetable:

Action	Date	FR Cite
NPRM	07/22/99	64 FR 39810
Final Action	01/00/01	

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

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

Agency Contact: Elsworth Dory, Investigator, Division of Scientific Investigations, Department of Health and Human Services, Food and Drug Administration, (HFD-49), Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD 20855
Phone: 301 827-7264

RIN: 0910-AA52

1164. DETERMINATION THAT INFORMED CONSENT IS INFEASIBLE OR IS CONTRARY TO THE BEST INTEREST OF RECIPIENTS

Priority: Other Significant

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

USC 263b; 42 USC 263e; 42 USC 263f; 42 USC 263g; 42 USC 263h; 42 USC 263i; 42 USC 263j; 42 USC 263k; 42 USC 263l; 42 USC 263m; 42 USC 263n; 42 USC 263c; 42 USC 263d

CFR Citation: 21 CFR 50; 21 CFR 312

Legal Deadline: None

Abstract: The Food and Drug Administration is planning to publish a final rule that would finalize its 1999 interim final rule (64 FR 54180) that: (1) revoked its December 21, 1990, interim final regulations that permitted the Commissioner to determine that obtaining informed consent from military personnel for the use of investigational products is not feasible in certain military combat situations; and (2) established strengthened criteria and standards for the President to apply in making a determination that informed consent is not feasible or is contrary to the best interest of military personnel engaged in specific military operations. The agency is taking this final action after reviewing comments it received in response to a July 1997 Request for Comment as to whether the agency should revise or revoke the rule and its 1999 interim final regulation soliciting comments on this action, and in light of the enactment of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 under which the President is authorized to waive the Federal Food, Drug, and Cosmetic Act's informed consent requirements in military operations, if the President finds that obtaining consent is infeasible or contrary to the best interests of recipients and on an additional ground that obtaining consent is contrary to national security interests.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/05/99	64 FR 54180
Final Action	06/00/01	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Federal

Agency Contact: Bonnie M. Lee, Health Issues Analyst, Division of Compliance Policy, Office of Enforcement, Department of Health and Human Services, Food and Drug Administration, HFC-230, Office of Regulatory Affairs, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-0415

RIN: 0910-AA89

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1165. CURRENT GOOD MANUFACTURING PRACTICE; REVISION OF CERTAIN LABELING CONTROLS**Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 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 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	06/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562**RIN:** 0910-AA98**1166. USE OF OZONE-DEPLETING SUBSTANCES****Priority:** Other Significant**Legal Authority:** 15 USC 402; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 361; 21 USC 371; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351**CFR Citation:** 21 CFR 2**Legal Deadline:** None**Abstract:** FDA is amending the regulation that permits the use of ozone-depleting substances in particular circumstances to set the standard FDA will use to determine when the use of ozone-depleting substances (ODS) is no longer essential under the Clean Air Act (CAA) and set

a new standard to determine when a new essential-use designation should be granted after the effective date of the rule. FDA is also amending the regulations to better conform to other statutes and regulations relating to ozone-depleting substances to eliminate potential confusion and conflicts. FDA is eliminating out-of-date transitional provisions and making other nonsubstantive housekeeping changes to its regulations on ozone-depleting substances. The intended effect of the rule is to protect the health and safety of medical product users while complying with the CAA and the Montreal Protocol.

Timetable:

Action	Date	FR Cite
ANPRM	03/06/97	62 FR 10242
ANPRM Comment Period End	05/05/97	
NPRM	09/01/99	64 FR 47719
NPRM Comment Period End	11/30/99	
Final Action	03/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Leanne Cusumano, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, (HFD-7), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 594-2041
Fax: 301 827-0951
Email: cusumanol@cdcr.fda.gov**RIN:** 0910-AA99**1167. ESTABLISHMENT REGISTRATION AND LISTING OF HUMAN CELLS AND TISSUE****Regulatory Plan:** This entry is Seq. No. 44 in Part II of this issue of the **Federal Register**.**RIN:** 0910-AB05**1168. VETERINARY FEED DIRECTIVES****Priority:** Other Significant**Legal Authority:** PL 104-250**CFR Citation:** 21 CFR 510; 21 CFR 514; 21 CFR 558**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, for 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; that persons involved in the distribution and use of a VFD drug maintain copies of the VFD; and that persons distributing animal feed provide a one time notice upon first engaging in the distribution of VFD drugs. The final 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	07/02/99	64 FR 35966
Final Action	12/00/00	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** None**Agency Contact:** George Graber, Director, Division of Animal Feeds, Department of Health and Human Services, Food and Drug Administration, HFV-220, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-6651
Email: ggraber@cvm.fda.gov**RIN:** 0910-AB09**1169. EXPORTS; NOTIFICATION AND RECORDKEEPING REQUIREMENTS****Priority:** Routine and Frequent**Legal Authority:** 15 USC 1453 to 1455; 21 USC 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 381**CFR Citation:** 21 CFR 1.101**Legal Deadline:** None**Abstract:** The final rule would establish the notification recordkeeping requirements for persons exporting human drugs, animal drugs, biological

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products, and devices under the FDA Export Reform and Enhancement Act.

Timetable:

Action	Date	FR Cite
NPRM	04/02/99	64 FR 15944
Extension	06/17/99	64 FR 32442
NPRM Comment Period End	07/16/99	
Final Action	11/00/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

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

RIN: 0910-AB16

1170. FOREIGN ESTABLISHMENT REGISTRATION AND LISTING

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 374; 42 USC 216; 42 USC 262; 21 USC 331; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b to 360c; 21 USC 360e; 21 USC 360i to 360j; 21 USC 371

CFR Citation: 21 CFR 207; 21 CFR 607; 21 CFR 807

Legal Deadline: None

Abstract: The final rule would amend the establishment registration and product listing regulations for human drugs, biological products, animal drugs, and devices to require foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of such products that are imported or offered for import into the United States to register and to register the name of a United States agent for the foreign establishment.

Timetable:

Action	Date	FR Cite
NPRM	05/14/99	64 FR 26330
NPRM Comment Period Reopen	08/09/99	
NPRM Comment Period End	10/08/99	
Final Action	11/00/00	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0910-AB21

1171. 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: 15 USC 1453 to 1455; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 216; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 1.84

Legal Deadline: None

Abstract: The final rule would establish reporting and recordkeeping requirements to implement sections 801(d)(3) and 801(d)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) as amended by the Food and Drug Administration (FDA) Export Reform and Enhancement Act of 1996. Section 801(d)(3) of the Act provides that, under prescribed conditions, drug and device components, food and color additives, and dietary supplements may be imported if they are to be further processed or incorporated into products that are to be exported from the United States in accordance with sections 801(e) or 802 of the Act or section 351(h) of the Public Health Service (PHS) Act. Section 801(d)(4) of the Act provides that blood, blood components, source plasma, or source leukocytes, or a component, accessory, or part thereof, may not be imported under section 801(d)(3) of the Act unless the importation complies with section 351(a) of the PHS Act or FDA permits the importation under FDA-determined appropriate circumstances and conditions. Additionally, section 801(d)(4) of the Act prohibits the importation of tissue or a component or part of tissue under section 801(d)(3) of the Act unless the importation

complies with section 361 of the PHS Act.

Timetable:

Action	Date	FR Cite
NPRM	11/24/98	63 FR 64930
NPRM Comment Period End	02/08/99	
Final Action	03/00/01	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

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

RIN: 0910-AB24

1172. BLOOD INITIATIVE

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

Legal Authority: 21 USC 321; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa-25; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; 21 CFR 640; 21 CFR 660; 21 CFR 680

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on a comprehensive review of the regulations that has been performed by FDA. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on House Resources and Intergovernmental Relations; the General Accounting Office; the Institute of Medicine; as well as public comments. Some of the subjects intended to be addressed in the rulemakings include: "Lookback" requirements for hepatitis C virus; notification of consignees and end

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users of product safety information for plasma derivative products; notification of deferred donors; requirements for donor suitability and testing and infectious agent clearance. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:**Albumin (Human), Plasma Protein Fraction (Human) and Immune Globulin (Human); Rev. of Reqs.**

Direct Final Rule 05/14/99 (64 FR 26282)
NPRM 05/14/99 (64 FR 26344)
DFR: Confirmation in Part and Tech.
Amendment 03/14/00 (65 FR 13678)
Final Action 08/28/00 (65 FR 52016)

Gen. Reqs. for Blood, Blood Compon., and Plasma Derivatives; Notification of Deferred Donors

NPRM 08/19/99 (64 FR 45355)
Final Action 03/00/01

Infectious Agent Clearance

NPRM 06/00/01

Plasma Derivatives and Other Blood-Derived Products; Reqs. for Tracking and Notification

ANPRM 08/19/99 (64 FR 45383)
NPRM 09/00/01

Reqs. for Testing Human Blood Donors for Evid. of Infection Due to Communicable Disease Agents

NPRM 08/19/99 (64 FR 45340)
Final Action 03/00/01

Rev. to the Requirements Applicable to Blood, Blood Components, and Source Plasma

Direct Final Rule 08/19/99 (64 FR 45366)
NPRM 08/19/99 (64 FR 45375)
Final Action 03/00/01

Suitability Reqs. for Whole Blood and Source Plasma Donors

NPRM 09/00/01

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: See RIN 0910-AB76.

Agency Contact: Steven F. Falter, Director, Regulations and Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210
Fax: 301 594-1944
Email: falter@cber.fda.gov

RIN: 0910-AB26

1173. SHELL EGGS: WARNING, NOTICE AND SAFE HANDLING LABELING STATEMENTS AND REFRIGERATION REQUIREMENTS

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

Legal Authority: 21 USC 321; 42 USC 264

CFR Citation: 21 CFR 101.17(h); 21 CFR 115.50; 21 CFR 16.5

Legal Deadline: None

Abstract: There have been numerous foodborne outbreaks of salmonellosis, principally due to salmonella enteritidis (SE), that have been traced to the consumption of temperature abused and/or undercooked shell eggs. The Food and Drug Administration has received petitions from Rose Acres Farm, Inc., and the Center for Science in the Public Interest that request, in part, that FDA establish safe handling statements for shell eggs. FDA intends to require safe handling statements on labeling of shell eggs that have not been treated to destroy salmonella microorganisms that may be present. In accordance with amendments to the Egg Products Inspection Act, USDA published on August 27, 1998, a final rule to require that shell eggs be stored at an ambient temperature of 7.2 degrees Celsius (45 degrees Fahrenheit). However, the USDA rulemaking does not include refrigeration at retail. FDA intends to mandate that shell eggs be stored for retail sale at 7.2 degrees Celsius (45 degrees Fahrenheit) or less. FDA is requiring these measures to ensure that shell eggs are handled in a manner to decrease the possible growth of any SE that may be present in shell eggs. All of these actions are intended to reduce the occurrence of illnesses and deaths associated with the consumption of improperly cooked shell eggs.

Timetable:

Action	Date	FR Cite
ANPRM	05/19/98	63 FR 27502
ANPRM Comment	08/17/98	
Period End		

Economic Analysis for Refrigeration and Labeling of Shell Eggs

NPRM 07/06/99 (64 FR 36492)
NPRM Comment Period End 09/20/99 (64 FR 36492)
Final Action 11/00/00

Refrigeration and Labeling of Shell Eggs

NPRM 07/06/99 (64 FR 36492)
NPRM Comment Period End 09/20/99 (64 FR 36492)
Final Action 11/00/00

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal, State

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

Agency Contact: Geraldine A. June, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, (HFS-822), Center for Food Safety and Applied, Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-4168

Email: gaj@cfsan.fda.gov

RIN: 0910-AB30

1174. ANTIBIOTIC DRUG APPROVAL AND EXCLUSIVITY

Priority: Substantive, Nonsignificant

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: PL 105-115, sec 125

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: The final rule would implement the incorporation of antibiotics, which were formerly regulated under authority of section 507 of the Federal Food, Drug, and Cosmetic Act, into the new drug regulatory scheme under section 505 of the Act. The regulation will describe which antibiotics are excepted under section 125(d) of the Food and Drug Administration Modernization Act of 1997 from certain provisions in section 505, including the exclusivity provisions under sections 505(c) and 505(j) of the Act.

Timetable:

Action	Date	FR Cite
NPRM	01/24/00	65 FR 3623
NPRM Comment	04/24/00	
Period End		
Final Action	05/00/01	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Pauli C. Varki, Regulatory Counsel, Regulatory Policy

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Phone: 301 827-5562
Email: varkip@cder.fda.gov

RIN: 0910—AB33

1175. AMENDMENT OF REGULATIONS REGARDING CERTAIN LABEL STATEMENTS ON PRESCRIPTION DRUGS

Priority: Substantive, Nonsignificant

Legal Authority: PL 105-115, sec 126

CFR Citation: 21 CFR 201; 21 CFR 250; 21 CFR 310; 21 CFR 329; 21 CFR 361; 21 CFR 369; 21 CFR 290

Legal Deadline: None

Abstract: This final rule revises 21 CFR parts 201, 250, 310, 361, 606, and 610 by removing the requirement that prescription drugs be labeled "Caution: Federal law prohibits dispensing without prescription" and substituting a requirement that prescription drugs be labeled "Rx only." The rule also revises 21 CFR parts 201, 329, and 369 by removing the requirement that certain habit-forming drugs bear the statement "Warning—May be habit forming." The rule also revises 21 CFR part 290 to clarify that drugs that are controlled substances under the Federal Controlled Substances Act are prescription drugs.

Timetable:

Action	Date	FR Cite
NPRM	04/21/00	65 FR 21378
Final Action	06/00/01	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
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RIN: 0910—AB39

1176. SUPPLEMENTS AND OTHER CHANGES TO APPROVED NEW ANIMAL DRUG APPLICATIONS

Priority: Other Significant

Legal Authority: 21 USC 356a

CFR Citation: 21 CFR 514.8

Legal Deadline: None

Abstract: Section 116 of the Food and Drug Administration Modernization Act of 1997 added a new section to the Federal Food, Drug, and Cosmetic Act that sets forth categories for the reporting of manufacturing changes to a drug product (21 U.S.C. 356a). These categories are based on the potential of the change to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of the drug. The rulemaking will establish the procedures for determining what information the agency would require before drugs manufactured subject to these changes may be distributed. The Center for Veterinary Medicine is amending the regulations regarding supplementary new animal drug regulations to incorporate the requirements of section 116.

Timetable:

Action	Date	FR Cite
NPRM	10/01/99	64 FR 53281
Final Rule	04/00/01	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: William Marnane, Director, Division of Manufacturing Technologies, Department of Health and Human Services, Food and Drug Administration, HFV-140, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-6966

RIN: 0910—AB49

1177. BULK DRUG SUBSTANCES FOR USE IN PHARMACY COMPOUNDING

Priority: Other Significant

Legal Authority: PL 105-115, sec 127

CFR Citation: 21 CFR 216

Legal Deadline: None

Abstract: Section 127 of the Food and Drug Administration Modernization Act

of 1997 (Pub. L. 105-115) added section 503A to the Food, Drug, and Cosmetic Act (21 U.S.C. 353a). Section 503A governs the application of Federal law to the practice of pharmacy compounding. Section 503A(b)(1)(A) directs FDA to issue by regulation a list of bulk drug substances that may be used in compounding that are not covered by a United States Pharmacopeia (USP) or National Formulary (NF) monograph and are not components of FDA-approved drugs. Bulk drug substances that do not appear on the list may not be used in compounding under section 127 unless such substances are covered by USP or NF monograph or are components of approved drugs.

Timetable:

Action	Date	FR Cite
NPRM	01/07/99	64 FR 996
NPRM Comment Period End	03/23/99	
Final Action	03/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910—AB57

1178. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 356a

CFR Citation: 21 CFR 314

Legal Deadline: None

Abstract: Section 116 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) added section 506A to the Food, Drug, and Cosmetic Act (21 U.S.C. 356a). Pursuant to section 116, the rulemaking will revise current procedures for approving manufacturing changes and generally classify such changes into four categories. Major manufacturing changes, which are of a type

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determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of a drug, require prior approval of a supplemental application. A second category of changes may be made if FDA has not notified the company within 30 days after the submission of a supplement that prior approval is required. A third category of changes may be made upon submission of a supplement to the agency. The rule would also identify another category of changes that may be made without the submission of a supplement but which must be reported in an annual report.

Timetable:

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

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

Agency Contact: Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB61**1179. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING AND NUTRIENT CONTENT CLAIMS****Priority:** Economically Significant**Legal Authority:** 21 USC 321; 21 USC 343; 21 USC 371**CFR Citation:** 21 CFR 101**Legal Deadline:** None

Abstract: Section 403(q) of the Federal Food, Drug, and Cosmetic Act, which was added by the Nutrition Labeling and Education Act of 1990, requires that the label or labeling of food products bear nutrition information. Among other things, section 403(q) authorizes the Food and Drug Administration (FDA) to add or delete nutrients that are to be declared on the labels or labeling of food products by regulation if it finds such action necessary to assist consumers in maintaining healthy dietary practices.

FDA issued final regulations implementing these provisions in 1993. FDA subsequently received a citizen petition requesting that FDA amend its regulations on food labeling to require that the amount of trans fatty acids be listed in the nutrition label and be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disqualifying levels and disclosure levels. In response to this petition and based on new evidence, FDA proposed the actions requested in the petition on November 17, 1999 (64 FR 62746). In addition, FDA proposed to define the claim "trans fat free."

Timetable:

Action	Date	FR Cite
NPRM	11/17/99	64 FR 62746
Final Rule	06/00/01	

Regulatory Flexibility Analysis**Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None

Agency Contact: Susan Thompson, Chemist, Department of Health and Human Services, Food and Drug Administration, (HFS-832), Center for Food Safety and Applied, Nutrition, 200 C Street SW, Washington, DC 20204
Phone: 202 205-5587
Email: snt@cfsan.fda.gov

RIN: 0910-AB66**1180. PRESUBMISSION CONFERENCES****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 360b**CFR Citation:** 21 CFR 514**Legal Deadline:** None

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

Timetable:

Action	Date	FR Cite
NPRM	08/25/00	65 FR 51782
Final Rule	09/00/01	

Regulatory Flexibility Analysis**Required:** Undetermined**Government Levels Affected:**

Undetermined

Federalism: Undetermined

Agency Contact: Gail Schmerfeld, Special Assistant, Department of Health and Human Services, Food and Drug Administration, HFV-100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1620

RIN: 0910-AB68**1181. CITIZEN PETITIONS; ACTIONS THAT CAN BE REQUESTED BY PETITION; DENIALS, WITHDRAWALS, AND REFERRALS FOR OTHER ADMINISTRATIVE ACTION****Priority:** Info./Admin./Other

Legal Authority: 5 USC 551 to 558; 21 USC 1034; 28 USC 2112; 42 USC 201; 42 USC 262; 42 USC 263b to 263n; 42 USC 264; 5 USC 701 to 706; 15 USC 1451 to 1461; 21 USC 41 to 50; 21 USC 141 to 149; 21 USC 321 to 393; 21 USC 467f; 21 USC 679; 21 USC 821

CFR Citation: 21 CFR 10**Legal Deadline:** None

Abstract: The final rule would amend the agency's regulations pertaining to citizen petitions by specifying the types of actions that could be requested through a petition. The final rule would also revise the content requirements for citizen petitions and would allow the agency to take various administrative actions in response to citizen petitions. These changes are intended to improve the citizen petition mechanism by focusing FDA's resources on important public health issues.

Timetable:

Action	Date	FR Cite
NPRM	11/30/99	64 FR 66822
NPRM Comment	02/28/00	
Period End		
Final Action	01/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

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

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

RIN: 0910-AB73

1182. SURGEON'S AND PATIENT EXAMINATION GLOVES; RECLASSIFICATION

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 331; 21 USC 351 to 352; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360; 21 USC 360j

CFR Citation: 21 CFR 801.437; 21 CFR 878.4460; 21 CFR 878.4461; 21 CFR 880.6250; 21 CFR 880.6251; 21 CFR 801.440

Legal Deadline: None

Abstract: FDA is considering revising its present regulations governing the classification of surgeon's and patient examination gloves. The present rule classifies surgeon's and patient examination gloves as class I devices. FDA is considering reclassifying surgeon's and patient examination gloves as class II devices subject to special controls. FDA is also considering requiring additional labeling concerning powder and protein levels for these devices.

Timetable:

Action	Date	FR Cite
NPRM	07/30/99	64 FR 41710
Final Action	06/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0910-AB74

1183. 180-DAY GENERIC DRUG EXCLUSIVITY FOR ABBREVIATED NEW DRUG APPLICATIONS

Priority: Substantive, Nonsignificant

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 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 314.107

Legal Deadline: None

Abstract: The final rule will amend regulations governing 180-day generic drug exclusivity to clarify existing eligibility requirements and conditions for abbreviated new drug application sponsors, to modify current eligibility requirements, and to impose new eligibility conditions. These revisions are the result of a court decision in *Mova Pharmaceutical v. Shalala*, 140 F. 3d 1060 (D.C. Cir. 1998), invalidating an eligibility requirement for exclusivity.

Timetable:

Action	Date	FR Cite
NPRM	08/06/99	64 FR 42873
NPRM Comment Period End	10/04/99	
Final Action	02/00/01	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Virginia G. Beakes, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: beakesv@cdcr.fda.gov

RIN: 0910-AB80

1184. POSTMARKETING STUDIES FOR HUMAN DRUGS AND LICENSED BIOLOGICAL PRODUCTS: STATUS REPORTS

Priority: Substantive, Nonsignificant

Legal Authority: PL 105-115

CFR Citation: 21 CFR 314.81; 21 CFR 601.37; 21 CFR 601.70

Legal Deadline: Other, Statutory, October 1, 2001, Section 130(b) requires

the FDA to report by October 1, 2001 to the House and Senate committees summarizing postmarketing study reports submitted by sponsors to FDA.

Abstract: Section 130(a) of the Food and Drug Administration Modernization Act of 1997 adds a new section 506B to the Federal Food, Drug, and Cosmetic Act requiring a drug sponsor that has agreed to conduct a postmarketing study to submit within one year after the drug's approval and annually thereafter until the study's conclusion, a progress report, or an explanation of why the sponsor has not conducted the study. Any information pertaining to postmarketing study reports will be considered public to identify the sponsor or explain the status of the study, including why it has not been carried out. FDA is required to publish annually in the Federal Register a report concerning the status of postmarketing studies that sponsors have agreements to conduct.

Timetable:

Action	Date	FR Cite
NPRM	12/01/99	64 FR 67207
NPRM Comment Period End	02/14/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Nathaniel Geary, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210
Email: mckeever@cber.fda.gov

RIN: 0910-AB83

1185. FOOD ADDITIVES: FOOD CONTACT SUBSTANCES NOTIFICATION SYSTEM

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 550; 5 USC 552; 21 USC 321 to 393; 21 USC 1401 to 1403; 18 USC 1905; 17 USC 2531 to 2582; 40 CFR 1500 to 1508; 42 USC 216; 42 USC 241 to 242a; 42 USC 242i; 42 USC 242n; 42 USC 243; 42 USC 262 to 263; 42 USC 263b to 264a; 42 USC 265; 42 USC 4321; 42 USC 4332; EO 11524, 3 CFR 1971 Comp. 0531-533 as

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amended by EO 11991; 42 USC 300a to 300e; 42 USC 300aa-1; ...

CFR Citation: 21 CFR 25.20; 21 CFR 25.32; 21 CFR 20.100; 21 CFR 58.3; 21 CFR 170.3; 21 CFR 170.100; 21 CFR 170.101; 21 CFR 170.102; 21 CFR 170.103; 21 CFR 170.104; 21 CFR 170.105; 21 CFR 171.1; 21 CFR 171.4; 21 CFR 174.5; 21 CFR 179.25; 21 CFR 170.106; ...

Legal Deadline: None

Abstract: In November of 1997, Congress amended the Federal Food, Drug, and Cosmetic Act (FFD&C) to establish a notification process whereby manufacturers and suppliers of components of food contact materials may notify FDA 120 days prior to marketing a new food contact substance. If FDA does not object to the notification within 120 days, the substance may be marketed with the same status as a regulated food additive. FDA is authorized to publish regulations outlining the information required to be submitted in premarket notifications for food-contact substances submitted to the agency. FDA is also authorized to publish regulations that identify when a food additive petition is required in lieu of a premarket notification. FDA is not required to accept a premarket notification in any fiscal year for which an appropriation is not specifically made for this program. FDA expects that the majority of food-contact substances that are currently the subject of food additive petitions will be the subject of premarket notifications. FDA also expects that substances currently reviewed under the agency's threshold of regulation process will be reviewed as premarket notifications under the new process. Unlike food additive regulations, premarket notifications will be specific to the notifier. The proposed use of a similar or identical substance produced by another manufacturer will require a separate premarket notification submission. Also unlike food additive petitions, the existence of the notification and any otherwise releasable data within the notification is not publicly available until the 120-day period has expired. FDA expects to keep a publicly available list of effective premarket notifications to assist manufacturers, distributors, and users of food packaging and other food-contact materials. FDA expects to publish a proposed rule on the

notification process for food contact substances during FY 2000.

Timetable:

Action	Date	FR Cite
NPRM	07/13/00	65 FR 43269
Final Rule	09/00/01	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Mitchell Alan Cheeseman, Team Leader, Department of Health and Human Services, Food and Drug Administration, HFS-215, Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204
Phone: 202 418-3083
Fax: 202 418-3131
Email: mcheesem@cfsan.fda.gov

RIN: 0910-AB94

1186. STATE CERTIFICATION OF MAMMOGRAPHY FACILITIES

Priority: Other Significant

Legal Authority: 21 USC 360(i); 21 USC 360(nn); 21 USC 374(e); 42 USC 263(b)

CFR Citation: 21 CFR 900.2; 21 CFR 900.20; 21 CFR 900.21; 21 CFR 900.22; 21 CFR 900.23; 21 CFR 900.24; 21 CFR 900.25

Legal Deadline: None

Abstract: FDA is considering regulations to implement section (q) of the Mammography Quality Standards Act of 1992 (the MQSA). This section permits FDA to authorize individual States to certify mammography facilities, to conduct the inspection of the facilities, to enforce the MQSA quality standards, and to administer other related functions. FDA retains oversight responsibility for the activities of the States to which this authority has been delegated and mammography facilities certified by those States must continue to meet the quality standards established by FDA for mammography facilities nationwide. The rule would include procedures for application, approval, evaluation, and withdrawal of approval of States as Certification Agencies. It also would include standards to be met by States receiving this authority.

Timetable:

Action	Date	FR Cite
NPRM	03/30/00	65 FR 16847

Action	Date	FR Cite
NPRM Comment Period End	06/28/00	
Final Rule	05/00/01	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

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

RIN: 0910-AB98

1187. ADDITION TO THE LIST OF DRUG PRODUCTS THAT HAVE BEEN WITHDRAWN FROM THE MARKET FOR REASONS OF SAFETY OR EFFECTIVENESS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 353a

CFR Citation: 21 CFR 216.24

Legal Deadline: None

Abstract: The final rule will amend 21 CFR 216.24 by adding two drug products, aminopyrine and astemizole, to the list of drug products that may not be used for pharmacy compounding under the exemptions provided by section 503A of the Federal Food, Drug, and Cosmetic Act because they have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective.

Timetable:

Action	Date	FR Cite
NPRM	01/04/00	65 FR 256
NPRM Comment Period End	03/20/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human

HHS—FDA

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Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910-AC01

1188. EFFICACY EVIDENCE NEEDED FOR PRODUCTS TO BE USED AGAINST TOXIC SUBSTANCES WHEN HUMAN STUDIES ARE UNETHICAL

Priority: Other Significant

Legal Authority: 15 USC 1451 to 1561; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b; 21 USC 321; PL 105-115, sec 122, 111 stat 2322 (21 USC 355 note)

CFR Citation: 21 CFR 601; 21 CFR 314**Legal Deadline:** None

Abstract: The agency plans to publish a final rule that would amend its new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances when adequate and well-controlled efficacy studies in humans cannot be ethically conducted because they would involve administering a potentially lethal or permanently disabling toxic substance or organism

to healthy human volunteers without a proven treatment and field trials (assessment of use of the product after accidental or hostile exposure to the substance) are not feasible. FDA is taking this action because it recognized the importance of improving medical response capabilities to the use of lethal or permanently disabling chemical, biological, radiological, and nuclear substances in order to protect individuals exposed to these substances.

Timetable:

Action	Date	FR Cite
NPRM	10/05/99	64 FR 53960
Final Action	03/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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Email: mitchellw@cder.fda.gov

RIN: 0910-AC05

1189. • IMPLEMENTING COURT DECISIONS, ANDA APPROVALS, AND 180-DAY EXCLUSIVITY

Priority: Substantive, Nonsignificant

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

353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

CFR Citation: 21 CFR 314.107(e)**Legal Deadline:** None

Abstract: The interim rule will amend regulations governing 180-day generic drug exclusivity to redefine the term court decision. The definition of court decision will be changed to the decision of a District Court deciding the relevant patent litigation case. The regulations will then correctly define court decision in accordance with recent court holdings addressing the definition.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/13/00	65 FR 43233
Final Rule	01/00/01	

Regulatory Flexibility Analysis**Required:** No**Small Entities Affected:** No**Government Levels Affected:** None

Agency Contact: Virginia G. Beakes, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910-AC11

Department of Health and Human Services (HHS)

Long-Term Actions

Food and Drug Administration (FDA)

1190. INFANT FORMULA: GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, NOTIFICATION REQUIREMENTS, AND RECORDS AND REPORTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371

CFR Citation: 21 CFR 106; 21 CFR 107**Legal Deadline:** None

Abstract: The agency published a proposed rule on July 9, 1996 that

would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formulas. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. Two final rules will be published: one, on Quality Factors and the second, on Good Manufacturing Practice, Quality Control Procedures Notification Requirements, and Records and Reports.

Timetable:

Current Good Mfg. Practices; Qual. Control Proc.

NPRM 07/09/96 (61 FR 36154)
NPRM Comment Period End 12/06/96
Final Action To Be Determined

Infant Form Cons Comp, Micro Test & Recd Retention Req

NPRM 01/26/89 (54 FR 3783)
NPRM Comment Period End 03/27/89
Final Rule 12/24/91 (56 FR 66566)

Infant Formula Quality Factors

NPRM 07/09/96 (61 FR 36154)
NPRM Comment Period End 12/06/96
Final Action To Be Determined

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Long-Term Actions

Regulatory Flexibility Analysis**Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AC46.**Agency Contact:** Darla Danford, Supervisory Nutritionist, Department of Health and Human Services, Food and Drug Administration, (HFS-800), Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-5365

RIN: 0910-AA04**1191. FOOD LABELING REVIEW****Priority:** Routine and Frequent**Legal Authority:** 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371**CFR Citation:** 21 CFR 100; 21 CFR 101; 21 CFR 102; 21 CFR 161**Legal Deadline:** None

Abstract: The Nutrition Labeling and Education Act of 1990 (NLEA) requires that most foods bear nutrition labeling. The agency issued final rules implementing most of the provisions contained in the NLEA on January 6, 1993. Subsequently, however, the agency has identified additional areas that should be the subject of rulemaking. FDA issued a proposal on January 6, 1993, to establish requirements for the identification of certain ingredients on food labels. FDA proposed on June 15, 1993, to amend its January 6, 1993, final rules on nutrient content and health claims to remove the provisions that exempted restaurant menus from the requirements for how nutrient content claims and health claims are to be made. The agency proposed on 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 implementing the provisions for exemptions from nutrition labeling 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, implementing the 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 on 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 8752)**Misleading Containers; Nonfunctional Slack Fill**NPRM 01/06/93 (58 FR 2957)
Final Action 12/06/93 (58 FR 64123)**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) To Be Determined**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)**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** State, Federal**Federalism:** This action may have federalism implications as defined in EO 13132.**Additional Information:** Previously reported under RIN 0905-AD89.

Federalism: Yes for Protein Hydrolysates; Broth in Tuna; and/or Labeling

Agency Contact: Christine L. Lewis, Director, Office of Nutritional Products, Labeling and Dietary Supplements, Department of Health and Human Services, Food and Drug Administration, (HFS-800), Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-4561

RIN: 0910-AA19**1192. MEDICAL FOODS****Priority:** Other Significant**Legal Authority:** 21 USC 321; 21 USC 360ee; 21 USC 371; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 350; 21 USC 350a; 21 USC 351; 21 USC 352; 21 USC 355**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 U.S.C. 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	To Be Determined	

Regulatory Flexibility Analysis**Required:** Yes

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Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Federalism: Undetermined

Additional Information: Previously reported under RIN 0905-AD91.

Agency Contact: Sue A. Anderson, Department of Health and Human Services, Food and Drug Administration, (HFS-831), Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-4240

RIN: 0910-AA20

1193. 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	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE58.

Agency Contact: Charles S. Furfine, Regulatory Review Scientist/Software Expert, Department of Health and Human Services, Food and Drug Administration, HFZ-143, Center for Devices and Radiological, Health, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-2536

RIN: 0910-AA41

1194. CURRENT GOOD MANUFACTURING PRACTICE; AMENDMENT OF CERTAIN REQUIREMENTS FOR FINISHED PHARMACEUTICALS

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 210.3; 21 CFR 211.113; 21 CFR 211.115; 21 CFR 211.160; 21 CFR 211.166; 21 CFR 211.192; 21 CFR 211.220; 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; ...

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	10/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: None

Agency Contact: Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA45

1195. 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 145; 21 CFR 146; 21 CFR 150; 21 CFR 152; 21 CFR 155; 21 CFR 156; 21 CFR 102; 21 CFR 103; 21 CFR 131; 21 CFR 133; 21 CFR 135; 21 CFR 136; 21 CFR 137; 21 CFR 139; ...

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 (ANPRM) 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 ANPRM 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,

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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 ANPRM 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) was published on June 3, 1996. A confirmation of effective date 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 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 to inform FDA of a company's determination that use of a substance in food is generally recognized as safe (GRAS).

Timetable:**Exempt Infant Formula; Plan for Revisions**

ANPRM 06/12/96 (61 FR 29701)
Comment Period Ended 10/10/96
NPRM To Be Determined

Food Standards of Identity, Quality, and Fill of Container

ANPRM 12/29/95 (60 FR 67492)
Comment Period Ended 06/28/96
NPRM To Be Determined

Food, Color, and GRAS; Simult. Pet. Rev. by USDA (Meat/Poultry)

NPRM 12/29/95 (60 FR 67490)
Comment Period Ended 03/14/96
Extension of Comment Period 06/03/96
Final Action 08/25/00 (65 FR 51758)

Notification Procedures for GRAS**Determinations**

NPRM 04/17/97 (62 FR 18938)
NPRM Comment Period Ended 07/16/97
Final Action To Be Determined

Revocation of Certain Food Labeling and Cosmetic Regulations

NPRM 06/12/96 (61 FR 29708)
Comment Period Ended 08/26/96
Final Rule 08/12/97 (62 FR 43071)

Revocation of Lower Fat Milk Standards

NPRM 11/09/95 (60 FR 56541)
Comment Period Ended 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 To Be Determined

Final Action (Yogurt) To Be Determined

Revocation of Obsolete Regulations

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

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

Additional Information: Federalism: Yes for Food Standards of Identity, Quality, and Fill of Container

Agency Contact: L. Robert Lake, Director, Office of Regulations and Policy, Department of Health and Human Services, Food and Drug Administration, (HFS-4), Center for Food Safety and Applied, Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-4561

RIN: 0910-AA58

1196. 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 360k; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 331; 21 USC 334; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360e to 360i

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 type of information shall be contained in the consumer directed advertisements for these products and how the information shall be presented.

Timetable:

Action	Date	FR Cite
NPRM	12/00/02	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Nancy M. Ostrove, Division of Drug Marketing, Advertising, and Communications, Department of Health and Human Services, Food and Drug Administration, (HFD-42), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-2828

RIN: 0910-AA90

1197. INVESTIGATIONAL USE NEW ANIMAL DRUG REGULATIONS (SECTION 610 REVIEW)

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

CFR Citation: 21 CFR 511; 21 CFR 512

Legal Deadline: None

Abstract: FDA is proposing to revise its regulations governing investigational use of new animal drugs by proposing to delete 21 CFR 511 and establish in 21 CFR part 512 revised investigational use of new animal drug regulations. The investigational use new animal drug regulations are expected to include regulations to implement provisions of the Animal Drug Availability Act of 1996, specifically

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presubmission conferences, and implement parts of the President's National Performance Report, "Reinventing the Regulation of Animal Drugs," May 1996. In the reinventing regulations report, FDA proposed to revise its regulations to reflect numerous new process changes and programs that will enable a more streamlined animal drug application review and approval process, and that would result in less regulatory burden upon industry and FDA while maintaining the safety and effectiveness of new animal drugs. In addition, FDA is initiating a review of this rule under section 610 of the Regulatory Flexibility Act. The purpose of the section 610 review is to determine if the rule should be amended to minimize adverse economic impacts on small entities. FDA will consider and solicit comments on the following: (1) the continued need for the rule; (2) the nature of complaints or comments received concerning the rule; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal, State or local government rules; and (5) the degree to which technology, economic conditions or other factors have changed in the area affected by the rule.

Timetable:

Action	Date	FR Cite
ANPRM	11/21/96	61 FR 59209
ANPRM Comment Period End	01/21/97	
Begin Review	04/03/00	
Proposed Rule	09/00/02	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0910-AB02

1198. SUITABILITY DETERMINATION FOR DONORS OF HUMAN CELLULAR AND TISSUE-BASED PRODUCTS

Priority: Other Significant

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

Legal Authority: 42 USC 216; 42 USC 243; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/30/99	64 FR 52696
NPRM Comment Period Reopened	04/18/00	65 FR 20774
NPRM Comment Period End	07/17/00	
Final Action	10/00/01	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses

Government Levels Affected: State

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

Agency Contact: Valerie A. Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448

Phone: 301 827-6210

RIN: 0910-AB27

1199. REQUIREMENTS FOR LIQUID MEDICATED FEED AND FREE-CHOICE MEDICATED FEED

Priority: Substantive, Nonsignificant

Legal Authority: PL 104-25; 21 USC 360b

CFR Citation: 21 CFR 558.5; 21 CFR 510.455

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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

RIN: 0910-AB50

HHS—FDA

Long-Term Actions

1200. REVISIONS TO THE GENERAL SAFETY REQUIREMENTS FOR BIOLOGICAL PRODUCTS; DIRECT FINAL RULE**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 351**CFR Citation:** 21 CFR 610.11(g)**Legal Deadline:** None

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

Timetable:

Action	Date	FR Cite
Direct Final Rule	04/20/98	63 FR 19399
Proposed Rule - Companion Document to Direct Final Rule	04/20/98	63 FR 19431
Direct Final Rule Confirmation in Part	08/05/98	63 FR 41718
Direct Final Rule Withdrawn in Part	08/05/98	63 FR 41718
Final Action	10/00/01	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None

Agency Contact: Stephen M. Ripley, Team Leader, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210

RIN: 0910-AB51**1201. MANDATORY HACCP REGULATIONS FOR MANUFACTURERS OF RENDERED PRODUCTS****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371**CFR Citation:** 21 CFR 589**Legal Deadline:** None

Abstract: During the notice and comment rulemaking for 21 CFR part 589, "Listing of Specific Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed," FDA received several comments supporting the application of mandatory Hazard Analysis Critical Control Point (HACCP) regulations for renderers. Some of these comments were from renderers. Because of the need to expedite the rulemaking for 21 CFR part 589, FDA stated that it would take up the HACCP regulations for renderers as a separate initiative. This rulemaking is to address the need expressed in the comments to 21 CFR part 589 by promulgating mandatory HACCP regulations for renderers.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined

Agency Contact: Daniel G. McChesney, Deputy Director, Office of Surveillance and Compliance, Department of Health and Human Services, Food and Drug Administration, HFV-200, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-6648

RIN: 0910-AB72**1202. ANTIBIOTIC RESISTANCE LABELING****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 321; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; ...**CFR Citation:** 21 CFR 201.24**Legal Deadline:** None

Abstract: The final rule would require the inclusion of statements on antibiotic prescription drug labeling concerning inappropriate antibiotic use and the prevalence of drug resistant microorganisms.

Timetable:

Action	Date	FR Cite
NPRM Final Rule	09/19/00 11/00/01	65 FR 5611

Regulatory Flexibility Analysis Required: Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined

Agency Contact: Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB78**1203. REPACKAGING APPROVAL 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 371; 21 USC 374; 21 USC 379e**CFR Citation:** 21 CFR 314**Legal Deadline:** None

Abstract: The proposed rule would set forth requirements for FDA prior approval of certain types of repackaging of approved drug products by persons

HHS—FDA

Long-Term Actions

who are not holders of approved applications for the products. The proposed rule would ensure that FDA approves changes to drug product containers and closure systems by both application holders and repackagers.

Timetable:

Action	Date	FR Cite
NPRM	01/00/02	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected:

Undetermined

Federalism: Undetermined

Agency Contact: Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-

7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AB81

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

Completed Actions

1204. DEBARMENT CERTIFICATION REGULATIONS FOR DRUG APPLICATIONS

Priority: Other Significant

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

Completed:

Reason	Date	FR Cite
Withdrawn	07/13/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Leanne Cusumano
Phone: 301 594-2041
Fax: 301 827-0951
Email: cusumanol@cder.fda.gov

RIN: 0910-AA76

1206. INVESTIGATIONAL NEW DRUG APPLICATIONS; CLINICAL HOLDS FOR DRUGS FOR LIFE-THREATENING ILLNESSES

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 312

Completed:

Reason	Date	FR Cite
Final Action	06/01/00	65 FR 34963

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Andrea C. Masciale
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA84

1208. CLASSIFICATION OF SHEEP AS A MINOR SPECIES FOR ALL DATA COLLECTION PURPOSES

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 514.1

Completed:

Reason	Date	FR Cite
Final Action	08/03/00	65 FR 47668

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Margaret Oeller
Phone: 301 827-7581

RIN: 0910-AB69

1205. INVESTIGATIONAL NEW DRUG APPLICATIONS; REQUEST FOR INFORMATION AND COMMENTS

Priority: Other Significant

CFR Citation: 21 CFR 56; 21 CFR 312

Completed:

Reason	Date	FR Cite
Withdrawn	07/28/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Joseph Griffin
Phone: 301 594-6758
Fax: 301 594-5298

RIN: 0910-AA83

1207. STERILITY REQUIREMENTS FOR AQUEOUS-BASED DRUG PRODUCTS FOR ORAL INHALATION

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 200

Completed:

Reason	Date	FR Cite
Final Action	05/26/00	65 FR 34082

Regulatory Flexibility Analysis

Required: Yes

Government Levels Affected: None

Agency Contact: Carol Drew
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA88

1209. AMENDMENT OF VARIOUS DEVICE REGULATIONS TO REFLECT CURRENT AMERICAN SOCIETY FOR TESTING AND MATERIALS CITATIONS

Priority: Routine and Frequent

CFR Citation: 21 CFR 801.410; 21 CFR 801.430

Completed:

Reason	Date	FR Cite
Final Rule	07/18/00	65 FR 44435

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Philip L. Chao
Phone: 301 827-3380
Email: pchao@oc.fda.gov

RIN: 0910-AB84

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

Proposed Rule Stage

1210. 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). This NPRM will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

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

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Richard C. 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: 301 594-4280

RIN: 0906-AA44

1211. COMPLIANCE ALTERNATIVES FOR PROVISION OF UNCOMPENSATED SERVICES

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 300s(3)

CFR Citation: 42 CFR 124, subpart F

Legal Deadline: None

Abstract: The proposed rules apply to facilities obligated under the Hospital Survey and Construction Act, commonly known as the Hill-Burton Act. The proposed rules would revise a compliance alternative that provides more flexible compliance standards for facilities that principally serve nonpaying patient populations by reducing the amount of time needed to qualify for certification under the alternative and by providing for provisional certification, where a facility is unable to qualify for full certification. The proposed rules would also provide a compliance alternative for facilities with histories of uncompensated services deficits, to enable them to make up the deficits on a timely basis. These revisions would have the effect of making it easier for facilities with an uncompensated services obligation to meet that obligation, while still ensuring the availability of uncompensated services to persons unable to pay.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
NPRM Comment Period End	12/00/00	
Final Action	06/00/01	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Eulas Dortch, Director, Division of Facilities Compliance and Recovery, OSP, Department of Health and Human Services, Health Resources and Services Administration, Room 10C-16, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 443-8007

Fax: 301 443-0619

Email: edortch@hrsa.gov

RIN: 0906-AA52

1212. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE

Priority: Substantive, Nonsignificant

Legal Authority: PL 106-170

CFR Citation: 42 CFR 100

Legal Deadline: None

Abstract: This NPRM proposes several changes to the Vaccine Injury Table (Table) (42 CFR 100.3), which will have an effect upon petitions for compensation under the National Childhood Vaccine Injury Compensation Program including the following: (1) amending the Table by adding the injury of intussusception to the Table for vaccines containing live, oral, rhesus-based rotavirus, a category of rotavirus vaccines; (2) removing residual seizure disorder and early onset Hib disease from the Table's Qualifications and Aids to Interpretation; (3) removing hemophilus influenzae type b polysaccharide vaccines from and adding pneumococcal conjugate vaccines to the Table; and (4) changing certain dates of coverage under the Table.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, BHPR, Department of Health and Human Services, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 443-4198
 Fax: 301 443-8196
 Email: gevans@hrsa.gov

RIN: 0906-AA55

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

Final Rule Stage

1213. FINAL RULE FOR THE HEALTH PROFESSIONS, NURSING, PUBLIC HEALTH, AND ALLIED HEALTH TRAINING GRANT PROGRAMS UNDER 42 CFR PARTS 57 AND 58

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 105-392

CFR Citation: 42 CFR 57; 42 CFR 58

Legal Deadline: None

Abstract: This final rule rescinds and removes various Public Health Service health professions, nursing, public health, and allied health training grant regulations from the CFR at 42 CFR parts 57 and 58. The existing training grant regulations are fundamentally and extensively inconsistent with the new law, Health Professions Education Partnerships Act of 1998 (Pub. L. 105-392), enacted November 13, 1998.

There are structural problems in implementing the new statute under the current program regulations. The general focus of this legislation is to reauthorize and consolidate 44 different Federal health professions training programs currently authorized under titles VII and VIII, PHS Act. These 44 programs are consolidated into seven general categories of authorities and offer more flexibility for program implementation. These categories are designed to train health practitioners most inclined to enter practice in rural and other medically underserved areas. Because the statute always take precedence over regulations, and the existing regulations are inconsistent with the new law that takes an interdisciplinary approach (and thus inhibits the achievement of the statute's clustered objectives), we are removing the grant regulations from the Code of Federal Regulations. Program specific guidance and information for preparing applications are now provided in the

grant application materials (which makes them now self-contained).

Timetable:

Action	Date	FR Cite
Final Action	12/00/00	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Steve Tise, Acting Chief, Planning, Evaluation and Legislation Branch/ORP, BHP, Department of Health and Human Services, Health Resources and Services Administration, Room 8-67 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 443-2381
 Fax: 301 443-8003
 Email: stise@hrsa.gov

RIN: 0906-AA53

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

Long-Term Actions

1214. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: MEDICAL MALPRACTICE PAYMENTS REPORTING REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 11131

CFR Citation: 45 CFR 60.7

Legal Deadline: None

Abstract: This NPRM proposes to require that, in addition to reporting to the National Practitioner Data Bank medical malpractice payments made where physicians or other health care practitioners are named in medical malpractice actions or claims, judgments or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgments or settlements but who furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health

care entity to "shield" the parties. It would also require malpractice payers, in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified by the amount of the payment.

Timetable:

Action	Date	FR Cite
NPRM	12/24/98	63 FR 71255
NPRM Comment Period End	02/22/99	
Next Action	Undetermined	

Regulatory Flexibility Analysis Required: No

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, Room 8A-55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 443-2300

RIN: 0906-AA41

1215. • RICKY RAY HEMOPHILIA RELIEF FUND PROGRAM

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 300c-22 note

CFR Citation: 42 CFR 130

Legal Deadline: None

Abstract: The Ricky Ray Hemophilia Relief Fund Act of 1998 established the Ricky Ray Hemophilia Relief Fund Program. It was designed to provide compassionate payments to certain individuals with blood-clotting disorders, such as hemophilia, who contracted HIV through the use of antihemophilic factor administered between July 1, 1982 and December 31, 1987. The Act also provides for payments to certain individuals who contracted HIV from the foregoing persons. The final rule establishes procedures and requirements for documentation of eligibility and the mechanism for providing compassionate payments to qualified individuals under the statute.

HHS—HRSA

Long-Term Actions

Timetable:

Action	Date	FR Cite
NPRM	08/02/00	65 FR 47438
Next Action Undetermined		

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Neil H. Sampson, Deputy Associate Administrator, Bureau of Health Professions, Department of Health and Human

Services, Public Health Service, Room 8-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-5974

RIN: 0906-AA56

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

Final Rule Stage

1216. INDIAN CHILD PROTECTION AND FAMILY VIOLENCE PREVENTION ACT MINIMUM STANDARDS OF CHARACTER

Priority: Info./Admin./Other

Legal Authority: 25 USC 3201 et seq

CFR Citation: 42 CFR 36

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/25/99	64 FR 14559
NPRM Comment Period End	07/26/99	
Final Action	01/00/01	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Tribal

Agency Contact: Ramona D. Williams, Child Protection Coordinator, Department of Health and Human Services, Indian Health Service, Suite 605, 12302 Twinbrook Parkway, Rockville, MD 20857
Phone: 301 443-1589

RIN: 0917-AA02

1217. CONTRACTS UNDER THE INDIAN SELF-DETERMINATION ACT

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 2003; 25 USC 13

CFR Citation: 42 CFR 36.201-237

Legal Deadline: None

Abstract: The Department of Health and Human Services and the Department of the Interior published, on June 24, 1996, joint regulations

implementing section 107 of the Indian Self-Determination Act, as amended. This joint rule 25 CFR part 900 replaced 42 CFR sections 36.201 through 36.237 among other parts.

Timetable:

Action	Date	FR Cite
NPRM	02/01/00	65 FR 4797
NPRM Comment Period End	04/03/00	
Final Rule	11/00/00	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Tribal

Agency Contact: Betty J. Penn, Regulations Officer, Department of Health and Human Services, Indian Health Service, Suite 450, 12300 Twinbrook Parkway, Rockville, MD 20857

Phone: 301 443-1116
Email: bpenn@hqe.ihs.gov

RIN: 0917-AA04

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

Proposed Rule Stage

1218. 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	02/00/01	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AD18.

RFA: N

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC

7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov

RIN: 0925-AA02

1219. 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

HHS—NIH

Proposed Rule Stage

Abstract: Section 487D of the Public Health Service Act, as added by the National Institutes of Health Revitalization Act of 1993, creates a program offering scholarships, in an amount not to exceed \$20,000 per year of academic study, to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for careers in professions needed by the NIH. For each year of scholarship support, the recipient agrees to service (employment) after graduation, at the NIH, for one year. Additionally, the individual agrees to at least 10 consecutive weeks of service (employment) at the NIH during which the individual is attending the educational institution and receiving the NIH scholarship. The proposed new regulations will cover this program.

Timetable:

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis**Required:** No**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, Room 601 MSC7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov**RIN:** 0925-AA10**1220. NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM****Priority:** Info./Admin./Other**Legal Authority:** 42 USC 216**CFR Citation:** 42 CFR 52d**Legal Deadline:** None**Abstract:** Current regulations relating to the National Cancer Institute (NCI) Clinical Cancer Education Program will be amended to update various aspects of the regulation.**Timetable:**

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov**RIN:** 0925-AA17**1221. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 288-3**CFR Citation:** 42 CFR 68d**Legal Deadline:** None**Abstract:** Regulations will be issued to govern the awarding of educational loan repayments to qualified health professionals who agree to conduct research as employees of the National Institutes of Health.**Timetable:**

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov**RIN:** 0925-AA18

Department of Health and Human Services (HHS)

National Institutes of Health (NIH)

Final Rule Stage

1222. TRAINEESHIPS**Priority:** Info./Admin./Other**Legal Authority:** 42 USC 216; 42 USC 284(b)(1)(C); 42 USC 286b-3; 42 USC 285a-2(b)(3); 42 USC 287c-21(a)**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	10/30/98	63 FR 58336
Final Rule	11/00/00	

Regulatory Flexibility Analysis**Required:** No**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, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov**RIN:** 0925-AA11**1223. 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.

HHS—NIH

Final Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	05/20/98	63 FR 27794
Final Rule	11/00/00	

Regulatory Flexibility Analysis**Required:** Undetermined**Government Levels Affected:**

Undetermined

Agency Contact: Michele Russell-Einhorn J.D., Director of Regulatory Affairs, Department of Health and Human Services, National Institutes of Health, MSC 7507, Suite 3B01, Office for Protection from Research Risks, 6100 Executive Boulevard, Rockville, MD 20892-7507
Phone: 301 435-5649

RIN: 0925-AA14**1224. NATIONAL RESEARCH SERVICE AWARDS****Priority:** Info./Admin./Other**Legal Authority:** 42 USC 216; 42 USC 288**CFR Citation:** 42 CFR 66**Legal Deadline:** None

Abstract: Current HHS regulations will be amended to reflect provisions of the ADAMHA Reorganization Act and the National Institutes of Health Revitalization Act of 1993. New language concerning the service payback obligation will be set forth, specifically, that a service payback obligation is incurred only during the first 12 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 12 months of support, by engaging in a second year of NRSA supported research training.

Timetable:

Action	Date	FR Cite
NPRM	06/30/99	64 FR 35119
Final Rule	12/00/00	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606

Email: jm40@nih.gov

RIN: 0925-AA16**1225. 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.

Timetable:

Action	Date	FR Cite
NPRM	12/10/99	64 FR 69213
Final Rule	02/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov

RIN: 0925-AA19**1226. 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 216; 42 USC 282(b)(6); 42 USC 284(c)(3); 42 USC 289a; 42 USC 290aa-3**CFR Citation:** 42 CFR 52h**Legal Deadline:** None

Abstract: NIH staff have been reexamining the peer review process as

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

Timetable:

Action	Date	FR Cite
NPRM	09/21/00	65 FR 57132
Final Action	03/00/01	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852
Phone: 301 496-4606
Email: jm40@nih.gov

RIN: 0925-AA20**1227. FEDERAL POLICY (COMMON RULE) FOR THE PROTECTION OF HUMAN SUBJECTS****Priority:** Other Significant**Legal Authority:** 5 USC 301; 42 USC 289; 42 USC 300v-1(b)**CFR Citation:** 45 CFR 46**Legal Deadline:** None

Abstract: In compliance with the President's Memorandum of March 27, 1997, this interim final rule would amend the Federal Policy (common rule) for the Protection of Human Subjects to add a new section that applies only to classified research involving human subjects. The new section would modify the Federal Policy by: (1) prohibiting any executive branch agency from engaging in classified research involving human subjects unless the agency has adopted the Federal Policy and the interim final rule; (2) eliminating the availability of waiver of informed consent and expedited review for classified research involving human subjects; (3) enhancing the informed consent requirements and allowing for disclosure of classified information if necessary; and (4) changing the composition of the institutional review board (IRB) and establishing a process for individual IRB approvals of classified research.

HHS—NIH

Final Rule Stage

Timetable:

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

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Michele Russell-Einhorn J.D., Director of Regulatory Affairs, Department of Health and Human Services, National Institutes of Health, MSC 7507, Suite 3B01, Office

for Protection from Research Risks, 6100 Executive Boulevard, Rockville, MD 20892-7507
Phone: 301 435-5649

RIN: 0925-AA21

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

Completed Actions

1228. NIH PRIVACY ACT SYSTEM OF RECORDS, 09-25-0213, "ADMINISTRATION: INVESTIGATIVE RECORDS"

Priority: Info./Admin./Other**CFR Citation:** 45 CFR 5b**Completed:**

Reason	Date	FR Cite
Final Rule	06/14/00	65 FR 37288

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Timothy Wheelles
Phone: 301 402-5347
Fax: 301 402-0169

RIN: 0925-AA23

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

Proposed Rule Stage

1229. PUBLIC HEALTH SERVICE STANDARDS FOR THE PROTECTION OF RESEARCH MISCONDUCT WHISTLEBLOWERS

Priority: Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 241; 42 USC 289b**CFR Citation:** 42 CFR 94**Legal Deadline:** None

Abstract: To implement section 493(e) of the Public Health Service Act (added by section 163 of the National Institutes of Health Revitalization Act of 1993, 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	11/00/00	
NPRM Comment Period End	01/00/01	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State

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

RIN: 0940-AA01

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

Completed Actions

1230. STANDARDS OF COMPLIANCE FOR ABORTION-RELATED SERVICES IN FAMILY PLANNING SERVICE PROJECTS

Priority: Substantive, Nonsignificant**CFR Citation:** 42 CFR 59**Completed:**

Reason	Date	FR Cite
Final Rule	07/03/00	65 FR 41270

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Mireille Kanda
Phone: 301 594-4001

RIN: 0940-AA00

Department of Health and Human Services (HHS)
Health Care Financing Administration (HCFA)

Proposed Rule Stage

1231. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (HCFA-3818-P) (SECTION 610 REVIEW)

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

RIN: 0938-AG82

1232. CRITERIA FOR MEDICARE COVERAGE OF HEART, LIVER, AND LUNG TRANSPLANTS (HCFA-3835-P)

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

RIN: 0938-AH17

1233. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (HCFA-6002-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 424

Legal Deadline: None

Abstract: This rule would establish a requirement that all providers and suppliers (other than physicians who have entered into a private contract with a beneficiary) must complete an enrollment form, submit specified information to us, and periodically update and certify the accuracy of the enrollment information in order to receive and maintain billing privileges in the Medicare program. The information must clearly identify the provider or supplier and its place of business, provide documentation that it is qualified to perform the services for which it is billing, and assure that it is not currently excluded from the Medicare program. If we determine the information submitted is incomplete, invalid, or insufficient to meet Medicare requirements, we would reject, deny, inactivate, or revoke billing privileges.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Additional Information: Formerly known as HCFA-1023-P

Agency Contact: Michael Collett, OFM, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-6121

RIN: 0938-AH73

1234. PROSPECTIVE FEE SCHEDULE FOR AMBULANCE SERVICES (HCFA-1002-P)

Priority: Other Significant

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

Legal Authority: PL 105-33, sec 4531(b)

CFR Citation: 42 CFR 410

Legal Deadline: Final, Statutory, January 1, 2000.

Abstract: This proposed rule would establish a fee schedule for the payment of ambulance services under the Medicare program, implementing section 1834(l) of the Social Security Act. As required by that section, this proposed fee schedule for ambulance services was the product of a negotiated rulemaking process that was carried out consistent with the Federal Advisory Committee Act. The fee schedule described in this proposed rule would replace the current retrospective reasonable cost reimbursement system for providers and the reasonable charge system for suppliers of ambulance services. In addition, this proposed rule would require that payment for ambulance services would be made only on an assignment related basis; establish new codes to be reported on claims for ambulance services; establish increased payment for ambulance services furnished in rural areas based on the location of the beneficiary at the time the patient is placed on board the ambulance; and revise the physician certification requirements for coverage of non-emergency ambulance services.

Timetable:

Action	Date	FR Cite
Notice of Intent To Negotiate	01/22/99	64 FR 3474
NPRM	12/00/00	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: None

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 Boulevard, Baltimore, MD 21244-1850
 Phone: 410 786-4531
 Email: nedwards@hcfa.gov

Robert Niemann, Program Analyst, Division of Special Payment Programs, Department of Health and Human Services, Health Care Financing Administration, 1-A-5, ELR, 6325 Security Boulevard, Baltimore, MD 21207

Phone: 301 966-4569

RIN: 0938-AI72

1235. DME SURETY BONDS (HCFA-6006-P)

Priority: Economically Significant

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

Legal Authority: PL 105-33, sec 4312(a); 42 USC 1395m(a)(16)

CFR Citation: 42 CFR 424.57

Legal Deadline: NPRM, Statutory, January 1, 1998.

Abstract: This rule would implement the provision of the Balanced Budget Act of 1997 that requires a Medicare supplier of durable medical equipment (DME) to furnish HCFA with a surety bond.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Charles Waldhauser, Division of Provider/Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850
 Phone: 410 786-6140

Ralph Goldberg, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500

HHS—HCFA

Proposed Rule Stage

Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-4870
 Email: rgoldberg@hcfa.gov
 RIN: 0938-AJ64

1236. END STAGE RENAL DISEASE BAD DEBT PAYMENT (HCFA-1126-P)

Priority: Other Significant
Legal Authority: Section 1861(v)(1)(A); 42 USC 1395x(v)(1)(A)
CFR Citation: 42 CFR 413.178
Legal Deadline: None

Abstract: This rule would remove the cap on end stage renal disease bad debts as stated in 42 CFR 413.178, which limits reimbursement of medicare bad debts to the end stage renal disease facility's uncovered costs. A final rule would be effective for cost reporting periods beginning on or after January 1, 2001.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	
NPRM Comment Period End	02/00/01	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses
Government Levels Affected: None

Agency Contact: Katie Walker, Office of Hospital Policy, Department of Health and Human Services, Health Care Financing Administration, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244-1850
 Phone: 410 786-7278

RIN: 0938-AK02

1237. • REVISIONS TO MEDICAID UPPER PAYMENT LIMIT REQUIREMENTS FOR HOSPITAL, NURSING FACILITY, INTERMEDIATE CARE FACILITY SERVICES FOR THE MENTALLY RETARDED AND CLINIC SERVICES (HCFA-2071-P)

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

RIN: 0938-AK12

1238. • PAYMENT FOR CLINICAL PSYCHOLOGY TRAINING PROGRAMS AND PHYSICIAN ASSISTANT TRAINING PROGRAMS (HCFA-1089-P)

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

RIN: 0938-AK15

1239. • PROSPECTIVE FEE SCHEDULE FOR AMBULANCE SERVICES (HCFA-1002-P)

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

RIN: 0938-AK30

1240. • ELIMINATION OF APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2086-P)

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

RIN: 0938-AK32

Department of Health and Human Services (HHS)
 Health Care Financing Administration (HCFA)

Final Rule Stage

1241. PAYMENT FOR NURSING AND ALLIED HEALTH SCIENCE EDUCATION (HCFA-1685-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: None

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	57 FR 43659
Final Rule	12/00/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Rebecca Hirshorn, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-06-06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3411
 RIN: 0938-AE79

1242. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (HCFA-3819-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 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bbb

CFR Citation: 42 CFR 484

Legal Deadline: None

Abstract: This rule will revise home health agency conditions of participation to center on the patient, using outcome-oriented measures. Most of the current HHA conditions of participation have remained unchanged since home health services became a

HHS—HCFA

Final Rule Stage

Medicare benefit in 1966. Some limited modifications have been made over the years to comply with legislative changes. As a result, most of the conditions of participation continue to be structure- and process-oriented.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Final Rule	12/00/00	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Janice Stevenson, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4882

Mary Vienna, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6940

RIN: 0938-AG81

1243. ADDITIONAL SUPPLIER STANDARDS (HCFA-6004-F)

Priority: Other Significant

Legal Authority: PL 105-33, sec 4552(c)

CFR Citation: 42 CFR 424.57

Legal Deadline: None

Abstract: This rule would implement the provision of the Balanced Budget Act of 1997 (BBA '97) that requires the Secretary to establish service standards for persons seeking payment under part B of title XVIII of the Social Security Act for the providing of oxygen and oxygen equipment to beneficiaries within their homes. It would also establish additional standards for suppliers of diabetic footwear, home infusion equipment, and customized orthotics and prosthetics.

Timetable:

Action	Date	FR Cite
NPRM	01/20/98	63 FR 2926
Final Action	11/00/00	

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected:

Undetermined

Agency Contact: Charles Waldhauser, Division of Provider/Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6140

Ralph Goldberg, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4870

Email: rgoldberg@hcfa.gov

RIN: 0938-AH19

1244. REQUIREMENTS FOR ENROLLMENT OF MEDICAID RECIPIENTS UNDER COST EFFECTIVE EMPLOYER-BASED GROUP HEALTH PLANS (HCFA-2047-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a(a)(10); 42 USC 1396a(u)(1); 42 USC 1396d(a); 42 USC 1396a(a)(25); 42 USC 1396a(e); 42 USC 1396e

CFR Citation: 42 CFR 435; 42 CFR 436

Legal Deadline: None

Abstract: This rule amends our regulations to incorporate a statutory action that States may require, as a condition of Medicaid eligibility, enrollment of certain Medicaid eligibles in employer-based group health plans determined cost-effective by States under guidelines approved by HCFA. If this option is elected by the State, it also requires States to pay all premiums, deductibles, coinsurance, and other cost-sharing obligations under these group health plans for services otherwise covered under the approved Medicaid State plans. In addition, this rule provides for Medicaid payment of premiums for certain individuals who are entitled to elect continuation coverage provided for in the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272, under a group health plan provided by an employer with 75 or more employees.

This rule conforms our regulations to sections 4402 and 4713 of the Omnibus Budget Reconciliation Act of 1990 and section 4741 of 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	59 FR 31569
Final Action	12/00/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Additional Information: Previously published under RIN 0938-AF64.

Agency Contact: Gwendolyn Talvert, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-15-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-5928

Email: gtalvert@hcfa.gov

RIN: 0938-AH48

1245. TERMS, DEFINITIONS, AND ADDRESSES: TECHNICAL AMENDMENTS (HCFA-9877-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 1395x(v)(1)(A); 42 USC 1395hh

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

Legal Deadline: None

Abstract: This rule 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 Action	12/00/00	

Regulatory Flexibility Analysis

Required: No

HHS—HCFA

Final Rule Stage

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Luisa V. Iglesias, Division of Regulation and Issuances, Department of Health and Human Services, Health Care Financing Administration, Room 409-B, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC
Phone: 202 690-6383

RIN: 0938-AH53

1246. UPDATE OF RATESETTING METHODOLOGY, PAYMENT RATES AND THE LIST OF COVERED SURGICAL PROCEDURES FOR AMBULATORY SURGICAL CENTERS EFFECTIVE FOR CALENDAR YEAR 2000 (HCFA-1885-FC)

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

RIN: 0938-AH81

1247. STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (HCFA-0045-F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1320d-2

CFR Citation: 42 CFR 160; 42 CFR 162

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

Abstract: This rule addresses the health care industry's need for a standardized provider identifier. It implements one of the requirements for administrative simplification in section 262 of the Health Insurance Portability and Accountability Act of 1996. A standard provider identifier will save the health insurance industry significant costs incurred in maintaining multiple identifier systems.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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

Additional Information: None

Agency Contact: Patricia Peyton, Office of Information Services, Department of Health and Human Services, Health Care Financing Administration, N3-20-05, 7500 Security Boulevard, Baltimore, MD 21224-1850
Phone: 410 786-1812

RIN: 0938-AH99

1248. MEDICARE PROGRAM; ADJUSTMENTS TO COST LIMITS FOR SKILLED NURSING FACILITY INPATIENT ROUTINE SERVICE COSTS (HCFA-1896-FN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This notice eliminates an adjustment that is made to Medicaid cost limits for skilled nursing facility routine services, when the final rate of change in the market basket index for a calendar year is used to set the limits that differ from the estimated rate of change and the index by at least 0.3 percentage points.

Timetable:

Action	Date	FR Cite
NPRM	10/01/97	62 FR 51551
NPRM Comment Period End	12/01/97	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Additional Information: This RIN was incorrectly reported as "Completed" in the October 1997 edition of the Unified Agenda.

Agency Contact: Richard Strauss, Deputy Director, Division of Financial Management, Department of Health and Human Services, Health Care Financing Administration, S3-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-2019
Email: rstrauss@hcfa.gov

RIN: 0938-AI14

1249. MEDICARE PROGRAM; PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES (HCFA-1005-F)

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 105-33, sec 4521; PL 105-33, sec 4522; PL 105-33, sec 4523; PL 99-509, sec 9343(c)

CFR Citation: 42 CFR 409.10; 42 CFR 413.124; 42 CFR 413.130; 42 CFR 413; 42 CFR 489.20; 42 CFR 1003.105; 42 CFR 410.2; 42 CFR 410.27; 42 CFR 410.28; 42 CFR 410.30; 42 CFR 411.15; 42 CFR 412.50; 42 CFR 413.118; 42 CFR 413.122; 42 CFR 1003.101; 42 CFR 1003.102

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

Abstract: The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, provides for implementation of a Prospective Payment System (PPS) for hospital outpatient services (and for part B services furnished to inpatients who have no part A coverage) furnished on or after January 1, 1999. In the proposed rule published on September 8, 1998, HCFA indicated that implementation of the system would be delayed because of systems concerns. This system will also apply to partial hospitalization services furnished by community mental health centers. The BBA also requires a new method for calculating beneficiary copayments for the hospital outpatient services included under the PPS. The PPS will consist of about 340 groups of services, called "Ambulatory Payment Classifications" or APCs, that are related clinically and in terms of their resource use. We will assign a group weight to each group, based on the median cost (operating and capital) of the services included in the group. We will convert the weights for each group to payment rates using a national conversion factor, taking into account group weights and the projected volume of services for each group. In addition, this rule would establish the requirements for designating certain entities as provider-based or as a department of a hospital.

HHS—HCFA

Final Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	09/08/98	63 FR 47551
Correction Notice	06/30/99	64 FR 35258
NPRM Comment Period End	07/30/99	
Final Action	12/00/00	

Regulatory Flexibility Analysis**Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None

Agency Contact: Chuck Braver, Department of Health and Human Services, Health Care Financing Administration, Center for Health Plans and Providers, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6719

RIN: 0938-AI56**1250. NATIONAL STANDARD EMPLOYER IDENTIFIER (HCFA-0047-F)****Priority:** Economically Significant. Major under 5 USC 801.**Legal Authority:** PL 104-191; 42 USC 1320d to 1320-d-8**CFR Citation:** 45 CFR 162**Legal Deadline:** Final, Statutory, February 21, 1998.

Abstract: This rule institutes the employer identification number (EIN) as the standard for identifying employers for purposes of administrative simplification, as required by the Health Insurance Portability and Accountability Act of 1996. Use of one standard in the health care industry will reduce the cost of identifying employers in electronic health care transactions.

Timetable:

Action	Date	FR Cite
NPRM	06/16/98	63 FR 32784
NPRM Comment Period End	08/17/98	
Final Action	12/00/00	

Regulatory Flexibility Analysis**Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** State

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

Agency Contact: Mary Emerson, Office of Information Services, Department of

Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, N2-12-22, Baltimore, MD 21244
Phone: 410 786-7065
Email: memerson@hcfa.gov

RIN: 0938-AI59**1251. MEDICAID PROGRAM; HOME AND COMMUNITY-BASED SERVICES (HCFA-2010-FC)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1396n(c)(5)**CFR Citation:** 42 CFR 440; 42 CFR 441**Legal Deadline:** None

Abstract: This rule expands State flexibility in providing prevocational, educational and supported employment services under the Medicaid home and community-based services waiver provisions of section 1915(c) of the Social Security Act.

Timetable:

Action	Date	FR Cite
Final Action	12/00/00	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** State

Agency Contact: Bill Coons, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5921

RIN: 0938-AI67**1252. MEDICAID MANAGED CARE; REGULATORY PROGRAM TO IMPLEMENT CERTAIN MEDICAID PROVISIONS OF THE BALANCED BUDGET ACT OF 1997 (HCFA-2001-F)****Priority:** Other Significant. Major under 5 USC 801.

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

Legal Authority: PL 105-33, sec 4701 to 4710**CFR Citation:** 42 CFR 438; 42 CFR 430; 42 CFR 431; 42 CFR 434; 42 CFR 435; 42 CFR 438; 42 CFR 440; 42 CFR 447**Legal Deadline:** None

Abstract: This rulemaking establishes rules for Medicaid managed care

programs that involve quality of care and services under Medicaid managed care programs. It implements certain provisions in sections 4701 through 4710 of the Balanced Budget Act of 1997 (Pub. L. 105-33).

Timetable:

Action	Date	FR Cite
NPRM	09/29/98	63 FR 52021
NPRM Comment Period End	11/30/98	
Final Action	12/00/00	

Regulatory Flexibility Analysis**Required:** Undetermined

Small Entities Affected: Businesses, Organizations, Governmental Jurisdictions

Government Levels Affected: Federal, Local, Tribal, State**Federalism:** Undetermined

Agency Contact: Michael Fiore, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0623

RIN: 0938-AI70**1253. EXPANDED COVERAGE FOR DIABETES OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES (HCFA-3002-P)**

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

RIN: 0938-AI96**1254. EXTERNAL QUALITY REVIEW OF MEDICAID MANAGED CARE ORGANIZATIONS (HCFA-2015-F)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 42 USC 1302**CFR Citation:** 42 CFR 438**Legal Deadline:** None

Abstract: This rule amends the regulation to conform with the provisions of section 4705 of the Balanced Budget Act of 1997. It also requires State agencies that contract with managed care organizations to implement quality improvement strategies that address access and other aspects of care and services directly related to the quality of care provided

HHS—HCFA

Final Rule Stage

by these managed care organizations and performance through annual external, independent reviews conducted by accrediting organizations that are approved by HCFA.

Timetable:

Action	Date	FR Cite
NPRM	12/01/99	64 FR 67223
NPRM Comment Period Ended	01/31/00	
Final Action	04/00/01	

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: State

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

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

RIN: 0938-AJ06

1255. PROTECTION FOR WOMEN WHO ELECT RECONSTRUCTION AFTER A MASTECTOMY (HCFA-2040-IFC)

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

RIN: 0938-AJ44

1256. THE CHILDREN'S HEALTH INSURANCE PROGRAM: IMPLEMENTING THE BALANCED BUDGET ACT OF 1997 (HCFA-2006-F)

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

RIN: 0938-AJ75

1257. APPLICATION OF INHERENT REASONABLENESS TO ALL PART B SERVICES OTHER THAN PHYSICIAN SERVICES (HCFA-1908-F)

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

RIN: 0938-AJ97

1258. FLEXIBILITY IN PAYMENT METHODS FOR SERVICES OF HOSPITALS, NURSING FACILITIES, AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED (HCFA-2004-F)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302; 42 USC 1396a(a)(13); 42 USC 1396d(o)(3); 42 USC 1396r-4

CFR Citation: 42 CFR 447.205; 42 CFR 447.250 to 447.257; 42 CFR 447.271; 42 CFR 447.272; 42 CFR 447.280

Legal Deadline: None

Abstract: This rule proposes to amend the Medicaid regulations that deal with payment for the services of hospitals and long-term care facilities. It proposes to remove all references to sections 447.253 and 447.255 (the Boren Amendment), and to add more flexible rules for States changing rates

or payment methodologies for hospitals and long-term care facilities. These revisions will conform the regulations to the Social Security Act, as revised by section 4711 of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	10/06/99	64 FR 54263
Final Rule	12/00/00	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Marge Lee, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4361

RIN: 0938-AK04

1259. • HOSPITAL CONDITIONS OF PARTICIPATION; ANESTHESIA SERVICES (HCFA-3049-F)

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

RIN: 0938-AK08

1260. • PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS-PHASE II (HCFA-1810-FC)

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

RIN: 0938-AK31

**Department of Health and Human Services (HHS)
Health Care Financing Administration (HCFA)**

Long-Term Actions

1261. CHANGES TO PEER REVIEW ORGANIZATION REGULATIONS (HCFA-3135-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 1320c; 42 USC 1396a(a)(30); 42 USC 1395cc(a)

CFR Citation: 42 CFR 400.200; 42 CFR 466.1; 42 CFR 466.71; 42 CFR 466.76; 42 CFR 466.78; 42 CFR 466.83; 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

Legal Deadline: None

Abstract: This rule will set forth several changes to regulations that govern Peer Review Organizations (PROs) and is based on statutory changes contained in COBRA '85 and OBRA '86. In addition, several technical changes will be included as a result of experience gained with the PRO program by HCFA. This rule also implements the new quality review requirements for certain Medicaid

HHS—HCFA

Long-Term Actions

health maintenance organization contracts.

Timetable:

Action	Date	FR Cite
NPRM	03/16/88	53 FR 8654
NPRM Comment Period End	05/16/88	53 FR 8654

Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: William 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 21244-1850
Phone: 410 786-0433

RIN: 0938-AD38

1262. "WITHOUT FAULT" AND BENEFICIARY WAIVER OF RECOVERY AS IT APPLIES TO MEDICARE OVERPAYMENT LIABILITY (HCFA-6007-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 1395gg

CFR Citation: 42 CFR 401; 42 CFR 466.86; 42 CFR 466.94; 42 CFR 473.14; 42 CFR 493.1834; 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

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: Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: David Walczak, Center for Health Plans and Providers, Plan and Provider Purchasing Policy Group, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4475

Barbara Wright, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C3-14-00, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4292

RIN: 0938-AD95

1263. PROTECTION OF INCOME AND RESOURCES FOR COMMUNITY SPOUSES OF INSTITUTIONALIZED INDIVIDUALS (HCFA-2023-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 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	To Be	Determined

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Local, State

Federalism: Undetermined

Agency Contact: Roy Trudel, Department of Health and Human Services, Health Care Financing Administration, C4-20-15, Center for

Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-3417

RIN: 0938-AE12

1264. EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT) SERVICES (HCFA-2028-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 (the Act), added by section 6403 of OBRA '89, defines the following EPSDT services: screening services, vision services, dental services and hearing services. EPSDT services also are defined to include such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects, illnesses and conditions discovered by the screening services whether or not the services are covered under the State plan. Section 1902(a)(43) of the Act requires States to report to the Secretary certain information about EPSDT services provided under the plan during each fiscal year. This rule would set forth requirements to implement these statutory provisions.

Timetable:

Action	Date	FR Cite
NPRM	10/01/93	58 FR 51288
NPRM Comment Period End	11/30/93	58 FR 51288

Next Action Undetermined

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: Local, State

Federalism: Undetermined

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 21244-1850

Phone: 410 786-5916

RIN: 0938-AE72

HHS—HCFA

Long-Term Actions

1265. COVERAGE OF SCREENING PAP SMEARS (HCFA-3705-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	
Next Action Undetermined		

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None

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 Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4619

Sharon Lappalainen, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 2108
Phone: 410 786-9262

RIN: 0938-AE98**1266. MEDICAID PAYMENT FOR COVERED OUTPATIENT DRUGS UNDER REBATE AGREEMENTS (HCFA-2046-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 rule will incorporate section 4401 of OBRA '90 to add specific requirements for Medicaid payment for covered outpatient drugs. The requirements concern: denial of Federal financial participation unless rebate agreements and drug use review are in effect; prohibiting some State plan drug access limitations for drugs covered under a rebate agreement; and the content of the rebate agreements. (The drug rebate agreement was previously published in the Federal Register on February 21, 1991 (56 FR 7049)). This rule will 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.

Timetable:

Action	Date	FR Cite
NPRM	09/19/95	60 FR 48442
NPRM Comment Period End	11/20/95	60 FR 48442
Next Action Undetermined		

Regulatory Flexibility Analysis**Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** State**Federalism:** Undetermined

Agency Contact: Larry Reed, Chief, Medicaid Noninstitutional Payment Policy Branch, Department of Health and Human Services, Health Care Financing Administration, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3325

Peggy Rahn, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3284

RIN: 0938-AF42**1267. REFERRAL TO CHILD SUPPORT ENFORCEMENT AGENCIES OF MEDICAID FAMILIES (HCFA-2051-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	58 FR 49272
Next Action Undetermined		

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** State**Federalism:** Undetermined

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

RIN: 0938-AF68**1268. DISCLOSURE OF CONFIDENTIAL PRO AND ESRD NETWORK ORGANIZATION INFORMATION FOR RESEARCH PURPOSES (HCFA-3208-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. The research must be directly related to the purposes of the PRO or ESRD program. 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

HHS—HCFA

Long-Term Actions

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: Next Action Undetermined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Alfreda Staton, Program Analyst, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, 2-D-2 Meadows East Building, 6300 Security Boulevard, Baltimore, MD 21207
Phone: 410 786-6940

RIN: 0938-AG33

1269. EFFECT OF CHANGE OF OWNERSHIP ON PROVIDER AND SUPPLIER PENALTIES, SANCTIONS, UNDERPAYMENTS AND OVERPAYMENTS (HCFA-2215-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 405; 42 USC 1395ww; 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 13951

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	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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 21244-1850
Phone: 410 786-6813

RIN: 0938-AG59

1270. MEDICAID: OPTIONAL COVERAGE OF TB-RELATED SERVICES FOR INDIVIDUALS INFECTED WITH TUBERCULOSIS (HCFA-2082-P)

Priority: Economically 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	09/10/99	64 FR 49121
Next Action Undetermined		

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local

Federalism: Undetermined

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

RIN: 0938-AG72

1271. REVISION OF MEDICARE/MEDICAID HOSPITAL CONDITIONS OF PARTICIPATION (HCFA-3745-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 1395x; 42 USC 1302; 42 USC 1395(cc); 42 USC 1395(hh); 42 USC 1320(b)(8)

CFR Citation: 42 CFR 416; 42 CFR 482; 42 CFR 485; 42 CFR 489

Legal Deadline: None

Abstract: This rule will revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care and the outcomes of that care, reflect a cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are necessary to reflect advances in health care practices since the requirements were last revised in 1986.

Timetable:

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66726
NPRM Comment Period End	03/20/98	
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Stephanie Dyson, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S3-06-25, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9226

RIN: 0938-AG79

HHS—HCFA

Long-Term Actions

1272. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS-EXPANDED TO DESIGNATED HEALTH SERVICES (HCFA-1809-FC)

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

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

CFR Citation: 42 CFR 411.1; 42 CFR 411.350 to 411.361; 42 CFR 424.22; 42 CFR 435.1002; 42 CFR 435.1012; 42 CFR 455.100 to 455.103; 42 CFR 455.108; 42 CFR 455.109

Legal Deadline: None

Abstract: This final rule with 90-day comment period (Phase I of this rulemaking) incorporates into regulations the provisions in paragraphs (a), (b), and (h) of section 1877 of the Social Security Act (the Act). Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services (DHS) under the Medicare program, unless an exception applies.

In addition, section 1877 of the Act provides that an entity may not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for DHS furnished under a prohibited referral, nor may we make payment for a designated health service furnished under a prohibited referral.

Timetable:

Action	Date	FR Cite
NPRM	01/09/98	63 FR 1659
NPRM Comment Period End	05/11/98	

Next Action Undetermined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Joanne Sinsheimer, Technical Assistant, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4620

RIN: 0938-AG80

1273. DISTINCT PART REQUIREMENTS FOR NURSING HOMES AND PROHIBITION ON FINANCIAL SCREENING OF APPLICANTS FOR NURSING HOME ADMISSION (HCFA-3815-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: This rule 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 rule would also prohibit nursing homes from financially screening private pay applicants for admission. Instead, nursing homes would be permitted to charge private pay applicants up to a two-month deposit before admission to ensure that sufficient funds are available to pay for care that the individual may receive before discharge.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Nancy Archer, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 401 786-0596

RIN: 0938-AG84

1274. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HCFA-2225-FC)

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 263a

CFR Citation: 42 CFR 493.2; 42 CFR 493.39; 42 CFR 493.45; 42 CFR 493.47; 42 CFR 493.49; 42 CFR 493.53; 42 CFR

493.1775; 42 CFR 493.7; 42 CFR 493.8; 42 CFR 493.9; 42 CFR 493.15; 42 CFR 493.20; 42 CFR 493.25; 42 CFR 493.35; 42 CFR 493.37

Legal Deadline: None

Abstract: As part of the CLIA program, this rule will revise our current process of evaluating tests against generic criteria. A waiver will be granted to any test that meets the statutory criteria, provided that scientifically valid data are submitted verifying that the criteria were met.

Timetable:

Action	Date	FR Cite
NPRM	09/13/95	60 FR 47534
NPRM Comment Period End	11/13/95	60 FR 47534

Next Action Undetermined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Judy Yost, Division of Outcomes and Improvements, Department of Health and Human Services, Health Care Financing Administration, S2-09-28, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-3531

RIN: 0938-AG99

1275. LIABILITY FOR THIRD PARTIES TO PAY FOR SERVICES (HCFA-2080-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(25)(A); 42 USC 1396b(o)

CFR Citation: 42 CFR 433

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 an individual's right to payment by a third party.

HHS—HCFA

Long-Term Actions

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal, State

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

RIN: 0938-AH01

1276. STATE PLAN AMENDMENT (SPA) RECONSIDERATION PROCESS (HCFA-2096-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 1316; 42 USC 1396a(a)

CFR Citation: 42 CFR 430.18; 42 CFR 430.60

Legal Deadline: None

Abstract: This 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	To Be	Determined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Robert Tomlinson Jr., Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-08-24, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4463

RIN: 0938-AH24

1277. HOSPICE CARE-CONDITIONS OF PARTICIPATION (HCFA-3844-P)

Priority: Other Significant

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

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

CFR Citation: 42 CFR 418

Legal Deadline: None

Abstract: This 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	To Be	Determined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Mary Rossi Coajou, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6051

RIN: 0938-AH27

1278. MEDICARE COVERAGE OF SERVICES OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS (HCFA-1843-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 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	To Be	Determined

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Jacqueline Gordon, Division of Cost Reporting, Department of Health and Human Services, Health Care Financing Administration, C4-07-14, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4517

RIN: 0938-AH37

1279. MEDICAID; ESTATE RECOVERIES (HCFA-2083-P)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302; 42 USC 1396p(b)

CFR Citation: 42 CFR 433

Legal Deadline: None

Abstract: This 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.

HHS—HCFA

Long-Term Actions

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** State**Federalism:** Undetermined

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

RIN: 0938-AH63

1280. INDIVIDUAL MARKET HEALTH INSURANCE REFORM: PORTABILITY FROM GROUP TO INDIVIDUAL COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIVIDUAL MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (HCFA-2882-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 300gg-41 et seq**CFR Citation:** 45 CFR 148**Legal Deadline:** None

Abstract: This rule will address comments received on the interim final rule published on April 8, 1997, and further clarifies the departmental position on Public Health Service Act insurance reform requirements in the individual market.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16985
Interim Final Rule Effective Date	04/08/97	
Interim Final Rule Comment Period End	07/07/97	
Next Action	Undetermined	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations**Government Levels Affected:** Federal, State, Local**Federalism:** Undetermined

Agency Contact: Gertrude Saunders, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5888
Email: gsaunders@hcfa.gov

RIN: 0938-AH75

1281. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (HCFA-3887-P)

Priority: Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 416**Legal Deadline:** None

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis**Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Federalism:** Undetermined

Agency Contact: Judy Goldfarb, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S2-199.06, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6747

Marcia Newton, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5265

RIN: 0938-AH83

1282. DISCLOSURE OF PEER REVIEW ORGANIZATION INFORMATION IN RESPONSE TO BENEFICIARY COMPLAINTS (HCFA-3241-P)

Priority: Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh; 42 USC 1320c-3(a)(14)**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 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	To Be	Determined

Regulatory Flexibility Analysis**Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Federalism:** Undetermined

Agency Contact: Alfreda Staton, Program Analyst, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1910

RIN: 0938-AH85

HHS—HCFA

Long-Term Actions

1283. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (HCFA-4145-P)

Priority: Other Significant. Major under 5 USC 801.

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

CFR Citation: 45 CFR 162

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

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	To Be	Determined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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

Agency Contact: Faye Broseker, Center for Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, S1-07-06, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-3342

RIN: 0938-AH87

1284. MEDICAID PROGRAM; AMENDMENT TO THE PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW PROGRAM (HCFA-2107-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 1302

CFR Citation: 42 CFR 405; 42 CFR 431; 42 CFR 433; 42 CFR 441; 42 CFR 483

Legal Deadline: None

Abstract: This 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 rule would also 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: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Jan Earle, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-15-10, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-9004

RIN: 0938-AH89

1285. MEDICALLY NEEDY DETERMINATIONS UNDER WELFARE REFORM (HCFA-2109-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 rule 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	To Be	Determined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Jackie Wilder, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-17-18, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4579

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RIN: 0938-AH92

1286. MEDICAID PROGRAM; COVERAGE AND PAYMENT FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES (HCFA-2043-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 rule would incorporate and interpret 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, Public Law 105-33.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

HHS—HCFA

Long-Term Actions

Federalism: Undetermined

Agency Contact: David Worgo, Center for Health Plans and Providers, Division of Integrated Services, Department of Health and Human Services, Health Care Financing Administration, C4-15-18, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5919

RIN: 0938-AH95

1287. PORTABILITY AND NONDISCRIMINATION IN THE GROUP HEALTH INSURANCE MARKET (HCFA-2890-F)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 300gg et seq

CFR Citation: 45 CFR 146

Legal Deadline: None

Abstract: This rule will address comments received on the interim final rule published April 8, 1997. It will also further clarify the Department's position on the minimum requirements applicable 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 will include 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; (6) guaranteed availability in the small group market; and (7) guaranteed renewability in the large and small group markets.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Effective	06/07/97	
Interim Final Rule Comment Period End	07/07/97	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Federal

Federalism: Undetermined

Additional Information: None

Agency Contact: Dave Holstein, Insurance Standards Team, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1564

RIN: 0938-AI08

1288. MEDICARE PROGRAM; IMPROVEMENTS TO THE APPEALS PROCESS FOR MEDICARE BENEFICIARIES ENROLLED IN HMOs, CMPS, AND HCPPS (HCFA-4024-P)

Priority: Other Significant

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

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This 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 timelines for nonurgent denials of care and make other improvements. We will also address related requirements of the Balanced Budget Act of 1997.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Beverly Sgroi, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-7638

RIN: 0938-AI11

1289. MEDICAID: MEDICAL CHILD SUPPORT (HCFA-2081-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1396a(a)(60); 42 USC 1396g

CFR Citation: 42 CFR 433; 42 CFR 433.135; 42 CFR 433.170

Legal Deadline: None

Abstract: This 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 (Pub. L. 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 that would result in greater enrollment opportunities for children, facilitate the filing of claims by custodial parents, and establish new payment disbursement criteria.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State

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

RIN: 0938-AI21

1290. MEDICARE/MEDICAID PROGRAM; USER FEES FOR INFORMATION, PRODUCTS, AND SERVICES (HCFA-6021-P)

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 9701

CFR Citation: 42 CFR 401

Legal Deadline: None

Abstract: This rule would establish regulations relating to user fees for services we provide that confer benefits on specific individuals that are over and above those benefits received by the general public.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

HHS—HCFA

Long-Term Actions

Agency Contact: David Escobedo, Office of Financial Management, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5401

RIN: 0938–AI46

1291. SURETY BOND REQUIREMENTS FOR COMPREHENSIVE OUTPATIENT REHABILITATION FACILITIES, REHABILITATION AGENCIES, COMMUNITY MENTAL HEALTH CENTERS, AND INDEPENDENT DIAGNOSTIC TESTING FACILITIES (HCFA-6005-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395x(v); 42 USC 1395hh; 42 USC 1395x(cc)(2); 42 USC 1395x(p)

CFR Citation: 42 CFR 413; 42 CFR 489

Legal Deadline: None

Abstract: The Balanced Budget Act of 1997 (BBA 1997) requires suppliers of durable medical equipment, home health agencies, comprehensive outpatient rehabilitation facilities, and rehabilitation agencies to furnish us with a surety bond in order to participate in the Medicare Program. The BBA 1997 also affords us the discretion to require other health care providers (other than physicians or other practitioners) to furnish us with a surety bond to participate in the Medicare program. This rule discusses the implementation of these provisions to require comprehensive outpatient rehabilitation facilities, rehabilitation agencies, and certain other providers and suppliers we have selected to furnish us with a surety bond on a continuing basis in order to participate in the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Ralph Goldberg, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4870
Email: rgoldberg@hcfa.gov

RIN: 0938–AI48

1292. APPEALS OF CARRIER DETERMINATION THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (HCFA-6003-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b)

CFR Citation: 42 CFR 405.874

Legal Deadline: None

Abstract: This rule would establish an administrative appeal process whereby suppliers can request an appeal for a determination that affects their Medicare part B billing number. The purpose of this rule is to update and clarify our policy and extend administrative appeal rights to all current and prospective suppliers who are denied enrollment in the Medicare program or whose Medicare billing privileges are revoked. This rule does not apply to those suppliers covered under the appeals provisions for our regulations at 42 CFR 498.

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Charles Waldhauser, Division of Provider/Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6140

RIN: 0938–AI49

1293. SECURITY SIGNATURE STANDARDS (HCFA-0049-F)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 104-191; 42 USC 1320d-2

CFR Citation: 45 CFR 162

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

Abstract: This rule implements some of the requirements of the

Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996. It establishes standards for the security of health information used by health plans, health care clearinghouses, and certain health care providers. These entities would use the security standards to develop and maintain the security of all electronic health information.

Timetable:

Action	Date	FR Cite
NPRM	08/12/98	63 FR 43242
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State, Local, Tribal, Federal

Federalism: Undetermined

Agency Contact: Barbara Clark, Office of Information Services, Department of Health and Human Services, Health Care Financing Administration, N2-14-10, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-3017

RIN: 0938–AI57

1294. STATE PLAN REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT PROVIDERS (HCFA-2007-P)

Priority: Other Significant

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

Legal Authority: 42 USC 1396a(a)(65)(B)

CFR Citation: 42 CFR 441

Legal Deadline: None

Abstract: This rule would establish a requirement that durable medical equipment suppliers be required to furnish Medicaid State agencies with a surety bond in order to participate in the Medicaid program. This rule would implement section 4724(g) of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Governmental Jurisdictions, Businesses

Government Levels Affected: State, Local, Tribal

HHS—HCFA

Long-Term Actions

Agency Contact: Mary Linda Morgan, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-26-12, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-2011
Email: mmorgan@hcfa.gov

RIN: 0938—AI63

1295. MEDICARE PROGRAM; ADVANCE REFUNDING OF DEBT AND METHODOLOGY FOR REPAYMENT OF LOAN (HCFA-1777-P)

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

Unfunded Mandates: Undetermined

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

CFR Citation: 42 CFR 413

Legal Deadline: None

Abstract: This rule would amend current regulations to clarify our policies regarding the treatment of interest expense. The rule would require that, when only part of the interest on a loan is allowable, repayment would be made first to that portion of the loan on which expense is allowable. This rule would also clarify how this policy is to be applied in situations in which there are multiple loans, and one or more of the loans are not related to patient care. In addition, we would define the allowable costs associated with advance refunding of debt, and clarify the treatment of revenue and expenses.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Ann Pash, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4516
Email: apash@hcfa.gov

RIN: 0938—AI75

1296. REVISION OF PROCEDURES FOR REQUESTING EXCEPTIONS TO COST LIMITS FOR SNFS AND ELIMINATION OF RECLASSIFICATIONS (HCFA-1883-P)

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: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 413.30

Legal Deadline: None

Abstract: This rule would revise the procedures for granting exceptions to the cost limits for skilled nursing facilities and retain the current procedures for exceptions to the cost limits for home health agencies. It would remove the provision allowing reclassification for SNFs and HHAs.

Timetable:

Action	Date	FR Cite
NPRM	08/11/98	63 FR 42797
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Steve Raitzyk, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4599

RIN: 0938—AI80

1297. MEDICARE PROGRAM; MEDICARE COVERAGE OF AND PAYMENT FOR BONE MASS MEASUREMENTS (HCFA-3004-F)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395rr(b)(1); 42 USC 4106

CFR Citation: 42 CFR 410; 42 CFR 414

Legal Deadline: Other, Statutory, July 1, 1998, BBA Section 4106.

Abstract: This rule provides for uniform coverage of, and payment for, bone mass measurements for qualified Medicare beneficiaries for services furnished on or after July 1, 1998. It implements provisions in section 4106(a) of the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/24/98	63 FR 34320
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: William Larson, Office of Communications & Operations Support, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4639

RIN: 0938—AI89

1298. MEDICARE PROGRAM; COVERAGE AND ADMINISTRATIVE POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (HCFA-3250-F)

Priority: Other Significant

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

Legal Authority: PL 105-33, sec 4554(b)(1)

CFR Citation: 42 CFR ch 410

Legal Deadline: Final, Statutory, January 1, 1999, BBA Section 4106.

Abstract: This rule would establish national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare part B to promote Medicare program integrity and national uniformity, and simplify administrative requirements for clinical diagnostic laboratory services. A Negotiated Rulemaking Committee (the Committee) developed the proposed policies as directed by section 4554(b)(1) of the Balanced Budget Act of 1997 (the BBA).

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Long-Term Actions

Timetable:

Action	Date	FR Cite
Notice of Intent To Negotiate	06/03/98	63 FR 30166
Next Action	Undetermined	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** State, Local, Tribal**Federalism:** Undetermined

Agency Contact: Jacqueline Sheridan, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4635

RIN: 0938-AI92**1299. COVERAGE OF RELIGIOUS NON-MEDICAL HEALTH CARE INSTITUTIONS (HCFA-1909-IFC)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395i-5; 42 USC 1395x(e); 42 USC 1395x(y); 42 USC 1395x(ss); 42 USC 1395ff; 42 USC 1395oo; 42 USC 1302**CFR Citation:** 42 CFR 403; 42 CFR 440.170; 42 CFR 488.2; 42 CFR 488.6; 42 CFR 489.102; 42 CFR 412.90; 42 CFR 412.98; 42 CFR 431.610; 42 CFR 440.155; 42 CFR 442.12; 42 CFR 456.351; 42 CFR 456.601; 42 CFR 466.1**Legal Deadline:** Final, Statutory, July 1, 1998, BBA, Section 4106.

Abstract: This rule implements section 4454 of the Balanced Budget Act of 1997 (BBA 1997), which amended section 1861 of the Social Security Act (the Act) and added a new section 1821 to the Act. Section 4454 of BBA 1997 removed all references to Christian Science and Christian sanatoria from the Act and substituted religious nonmedical health care institutions in their place. This change permits any religious organization to apply for payment for furnishing nonmedical services under Medicare. Section 4454 also authorizes payment for such services as an option benefit under State Medicaid plans. The rule sets forth minimum requirements and conditions of participation to qualify as a religious nonmedical health care institution for purposes of receiving payment for services furnished under Medicare and Medicaid.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/30/99	64 FR 67028
Final Action	To Be Determined	

Regulatory Flexibility Analysis**Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** None**Federalism:** Undetermined

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

RIN: 0938-AI93**1300. REPORTING OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA AS PART OF THE CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES (HCFA-3006-IFC)****Priority:** Substantive, Nonsignificant**Unfunded Mandates:** This action may affect State, local or tribal governments and the private sector.**Legal Authority:** 42 USC 1302; 42 USC 1395(hh)**CFR Citation:** 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68**Legal Deadline:** None

Abstract: This rule requires electronic reporting of data from the Outcome and Assessment Information Set (OASIS) as a condition of participation for Home Health Agencies (HHAs). Specifically, this rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or contractor in collecting and transmitting this information to HCFA. This rule also sets forth provisions concerning the privacy of patient identifiable information generated by the OASIS.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/25/99	64 FR 3748
Next Action	Undetermined	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** State, Local, Tribal**Federalism:** Undetermined

Agency Contact: Tracey Mummert, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3398

RIN: 0938-AJ10**1301. MEDICARE PROGRAM; CRITERIA AND STANDARDS FOR EVALUATING INTERMEDIARY AND CARRIER PERFORMANCE: MILLENNIUM COMPLIANCE (HCFA-4002-GNC)****Priority:** Info./Admin./Other**Legal Authority:** 42 USC 1395(h); 42 USC 1395 (u)**CFR Citation:** 42 CFR ch IV**Legal Deadline:** None

Abstract: This notice revises the criteria and standards to be used for evaluating the performance of our contractors in administering the Medicare program. The revisions establish a performance standard requiring contractors to meet requirements for millennium compliance. We require contractors to certify that they have made all necessary system(s) changes and have tested those systems in accordance with our guideline.

Timetable:

Action	Date	FR Cite
Notice	12/11/98	63 FR 68464
Next Action	Undetermined	

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** None**Federalism:** Undetermined

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: Sue Lathroum, Center for Beneficiary Service, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7409

RIN: 0938-AJ15

HHS—HCFA

Long-Term Actions

1302. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS, AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (HCFA-1910-P)**Priority:** Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 405**Legal Deadline:** None

Abstract: This rule would amend our requirements to revise certification and payment requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997 (BBA 1997). It would include new refinements of what constitutes a qualifying rural shortage area in which a Medicare RHC must be located; establish criteria for identifying RHCs essential to delivery of primary care services that can continue to be approved as Medicare RHCs in areas no longer designated as medically underserved; and include recent statutory provisions that provide a temporary waiver of certain nonphysician practitioner staffing requirements. It would impose payment limits on provider based RHCs, and would prohibit commercial use, the use of RHC space or equipment, and other RHC resources by another entity. The rule also requires establishment of a quality assessment and performance improvement program.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** Businesses**Government Levels Affected:** Federal

Agency Contact: David Worgo, Center for Health Plans and Providers, Division of Integrated Services, Department of Health and Human Services, Health Care Financing Administration, C4-15-18, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5919

RIN: 0938-AJ17**1303. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (HCFA-3 014-P)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 482.27**Legal Deadline:** None

Abstract: This rule would require hospitals that transfuse blood and blood products to: (1) prepare and follow written procedures for appropriate action when it is determined that blood and blood products are at increased risk for transmitting hepatitis C virus (HCV); (2) quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; (3) notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and (4) maintain records for at least 10 years.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** Organizations**Government Levels Affected:** None**Federalism:** Undetermined

Agency Contact: Mary Collins, OCSQ, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3189

RIN: 0938-AJ29**1304. MEDICARE HOSPICE CARE AMENDMENTS (HCFA-1022-P)****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** PL 105-33, sec 4441(a); PL 105-33, sec 4442 to 4446; PL 105-33, sec 4448**CFR Citation:** 42 CFR 418**Legal Deadline:** None

Abstract: This rule would implement sections 4441(a), 4442 to 4446, and 4448 of the Balanced Budget Act of 1997. Specific changes include updating hospice payment rates, specifying payment according to the

site of service, modifying the hospice benefit periods, clarifying the services covered under the benefit, allowing hospices to contract for physician services, allowing waivers of certain staffing requirements for hospice care provided in non-urbanized areas, and extending the period for physician certification of an individual's terminal illness. Additionally, the rule would clarify other current policies.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** Undetermined**Federalism:** Undetermined

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

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

RIN: 0938-AJ36**1305. EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) (HCFA-1063-P)****Priority:** Other Significant**Unfunded Mandates:** Undetermined**Legal Authority:** 42 USC 1395cc; 42 USC 1395dd**CFR Citation:** 42 CFR 489.24**Legal Deadline:** None

Abstract: This rule clarifies the extent of the Emergency Medical Treatment and Labor Act (EMTALA) application.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined

Agency Contact: George Morey, CHPP, Department of Health and Human

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Long-Term Actions

Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4653

RIN: 0938-AJ39

1306. MEDICARE/MEDICAID AND CLIA PROGRAMS: CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 EXEMPTION OF LABORATORIES IN THE STATE OF CALIFORNIA (HCFA-2245-N)

Priority: Other Significant

Legal Authority: 42 USC 263a

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This notice grants all State-licensed or approved laboratories in California exemption from the requirements of the Clinical Laboratory Improvement Amendments of 1998, based on the State's demonstrated compliance with all the exemption requirements.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, State

Agency Contact: Jim Cometa, CMSO, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6720

RIN: 0938-AJ47

1307. MEDICARE PROGRAM: CRITERIA FOR MAKING NATIONAL COVERAGE DECISION (HCFA-3432-P2)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule would set forth the general criteria we propose to use to make coverage decisions. It would also set forth the basis for the development of more specific guidance documents in which we would explain the application of these general criteria to

specific sectors of medical care, such as surgical procedures, medical devices, or durable medical equipment.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Ron Milhourn, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5666
Email: rmilhourn@hcfa.gov

RIN: 0938-AJ54

1308. MEDICARE PROGRAM: PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITAL SERVICES (HCFA-1069-P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 105-33, sec 4421; 42 USC 1395ww(j)

CFR Citation: None

Legal Deadline: NPRM, Statutory, October 1, 2000.

Abstract: This rule would implement the new prospective payment system for rehabilitation facilities as added by section 4421 of the BBA and as amended by section 125 of the Balanced Budget Refinement Act of 1999.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Laurence Wilson, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-7-04, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-4603

RIN: 0938-AJ55

1309. MEDICARE PROGRAM; SUSTAINABLE GROWTH RATE FOR FISCAL YEAR 2000 (HCFA-1110-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395w-4(d)(f)

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the methodology for calculating the sustainable growth rate.

Timetable:

Action	Date	FR Cite
Final Action	04/10/00	65 FR 19000
Next Action	Undetermined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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

RIN: 0938-AJ60

1310. MEDICARE AND MEDICAID PROGRAMS; PROGRAMS FOR ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) (HCFA-1903-IFC)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule establishes requirements for Programs of All-Inclusive Care for the Elderly (PACE) under Medicare and Medicaid. These are pre-paid, capitated programs for beneficiaries who meet special eligibility requirements and who elect to enroll. Programs must apply for approval and are evaluated in terms of specific criteria. Only a limited number of programs can be approved. Priority consideration will be given to applicants that have been operating under ongoing PACE demonstration projects.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/24/99	64 FR 66233
Next Action	Undetermined	

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Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:**

Undetermined

Federalism: Undetermined

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 21244-1850
Phone: 410 786-9161

RIN: 0938-AJ63**1311. STATE HEALTH INSURANCE ASSISTANCE PROGRAM (SHIP) (HCFA-4005-IFC)****Priority:** Info./Admin./Other**Legal Authority:** 42 USC 1935w-7**CFR Citation:** 42 CFR 403.502; 42 CFR 403.504; 42 CFR 403.508**Legal Deadline:** None

Abstract: This rule modifies several terms and conditions that apply to State Medicare beneficiary counseling and assistance grants and implements several minor technical clarifications affecting programs compliance. This rule also specifies our policies regarding the treatment of other funds associated with the management of this program, including user fee assessments not in effect when prior regulations were issued.

Timetable:

Action	Date	FR Cite
Interim Final Rule	To Be	Determined

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** State, Local**Federalism:** Undetermined

Agency Contact: Eric Lang, Health Insurance Specialist, Office of Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, Room 600, EHR, 6325 Security Boulevard, Baltimore, MD 21207
Phone: 410 966-3193

RIN: 0938-AJ67**1312. CLINICAL SOCIAL WORKER SERVICES (HCFA-1088-P)****Priority:** Substantive, Nonsignificant**Unfunded Mandates:** This action may affect the private sector under PL 104-4.**Legal Authority:** 42 USC 1395x**CFR Citation:** 42 CFR 410**Legal Deadline:** None

Abstract: This rule would permit clinical social workers to bill Medicare part B separately for services rendered to residents in skilled nursing facilities.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis**Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** None**Federalism:** Undetermined

Agency Contact: Paul Kim, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7410

RIN: 0938-AJ71**1313. MEDICAID DISPROPORTIONATE SHARE HOSPITAL PAYMENTS-INSTITUTIONS FOR MENTAL DISEASE (HCFA-2062-N)****Priority:** Economically Significant. Major under 5 USC 801.**Legal Authority:** 42 USC 1396r-4(a)(2); 42 USC 1396(f); 42 USC 1396(h); PL 105-33**CFR Citation:** None**Legal Deadline:** None

Abstract: This rule announces the Federal share disproportionate share hospital (DSH) allotments for Federal fiscal years (FFYs) 1998 through 2002. It also describes the methodology for calculating the Federal share DSH allotments for FFY 2003 and thereafter, and announces the FFY 2000 and 2001 limitations on aggregate DSH payments that States may make to institutions for mental disease (IMDs) and other mental health facilities. In addition, it adds rules regarding the annual DSH report mandated by the Balanced Budget Act of 1997 (BBA '97). The Federal DSH

allotments apply to FFYs beginning October 1, 1997 and thereafter. The IMD limitations published in this notice apply to Medicaid DSH payments made in FFY 2000 and FFY 2001. The provisions concerning DSH annual reporting apply to DSH expenditures reported annually beginning with FFY 1999. The annual report for FFY 1999 was due by March 1, 2000.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** State**Federalism:** Undetermined

Agency Contact: Christine Hinds, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, S2-05-27, Baltimore, MD 21244
Phone: 410 786-4578

RIN: 0938-AJ74**1314. HHA SURETY BOND (HCFA-6001-P)****Priority:** Economically Significant**Unfunded Mandates:** This action may affect the private sector under PL 104-4.**Legal Authority:** PL 105-33, sec 431ff; PL 105-33, sec 4724ff; PL 105-33, sec 1861(o)(8); PL 105-33, sec 1861(v)(1); PL 105-33, sec 1866(b)(2); PL 105-33, sec 1891(b); PL 105-33, sec 1902(a)(10)(D); PL 105-33, sec 1903(I); PL 105-33, sec 1905(a)(7)**CFR Citation:** 42 CFR 413; 42 CFR 440; 42 CFR 441; 42 CFR 489**Legal Deadline:** NPRM, Statutory, June 15, 2000.

Abstract: This rule would amend our regulations to require an HHA surety bond of \$50,000. We would remove the 15 percent provision based on concerns expressed by Congress, the home health industry, surety association representatives, and comments published in a report by the General Accounting Office. This rule would require that HHAs obtain a surety bond by October 1, 2000. Although the bond must be effective January 1, 1998, we are proposing not to hold sureties liable

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for excessive interim payments attributable to the implementation of the interim payment systems made between October 1, 1997 and September 30, 2000. Other suggestions recommended by GAO were to require a single \$50,000 bond for both the Medicare and Medicaid programs and provide an exemption of those HHAs that demonstrate fiscal responsibility. However, these recommendations require congressional action. The final recommendation was to eliminate the HHA's option for substituting a Treasury note, U.S. bond, or other Federal public debt obligation for a surety bond. We generally agree with these recommendations except for the elimination of substituting a Treasury note, etc., for a surety bond.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Additional Information: RIN 0938-AJ08 in the October 1998 Unified Agenda provides information about rulemaking actions taken and withdrawn in 1998 concerning surety bond requirements for home health agencies.

Agency Contact: Ralph Goldberg, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4870
Email: rgoldberg@hcfa.gov

RIN: 0938-AJ81

1315. MEDICARE PROGRAM UPDATE OF AMBULATORY SURGICAL CENTER PAYMENT RATES EFFECTIVE FOR SERVICES ON OR AFTER OCTOBER 1, 1999 (HCFA-1085-N)

Priority: Other Significant

Legal Authority: Social Security Act, sec 1832(a)(2)(F); Social Security Act, sec 1833(i)(1); Social Security Act, sec 1833(i)(2)

CFR Citation: Not Yet Determined

Legal Deadline: Other, Statutory, October 1, 1999, Section 4201(c)(I) of BBA of 1997.

Abstract: This rule 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 audited costs incurred by ASCs.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Bob Cereghino, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, C4-03-06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4645

RIN: 0938-AJ86

1316. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES-UPDATE (HCFA-1112-P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 411; 42 CFR 489

Legal Deadline: None

Abstract: This rule sets forth updates for the forthcoming fiscal year to the payment rates used under the prospective payment system for skilled nursing facilities. Annual updates to the prospective payment system rates are required by section 4432 of the Balanced Budget Act of 1997, and as amended by the Medicare, Medicaid and State Child Health Insurance Program Balanced Budget Refinement Act of 1999, related to Medicare payments and consolidated billing for skilled nursing facilities. In addition, this rule sets forth certain conforming revisions to the regulations that are necessary in order to implement section 103 of the Medicare, Medicaid and State Child Health Insurance Program Balanced Budget Refinement Act of 1999.

Timetable:

Action	Date	FR Cite
NPRM	04/10/00	
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Susan Burris, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C5-06-27, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6655
Email: sburris@hcfa.gov

RIN: 0938-AJ93

1317. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (HCFA-2065-IFC)

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

Unfunded Mandates: Undetermined

Legal Authority: Social Security Act, sec 1905(a)(16); Social Security Act, sec 1905(h)

CFR Citation: 42 CFR 441; 42 CFR 483

Legal Deadline: None

Abstract: This rule establishes a new condition of participation that psychiatric residential treatment facilities that are not hospitals must meet to provide, or to continue to provide, the Medicaid inpatient psychiatric services benefit to individuals under age 21. Specifically, this rule establishes standards for the use of restraint or seclusion that residential treatment facilities must have in place to protect the health and safety of residents. This new COP acknowledges a resident's right to be free from restraint or seclusion except in emergency safety situations. We also are requiring residential facilities to notify a resident and his or her parent or legal guardian of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that occurs while the resident is in the program. We believe these added requirements will provide

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minimum safeguards to protect residents against the inappropriate use of restraint or seclusion.

Timetable:

Action	Date	FR Cite
Interim Final Rule	To Be	Determined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected:

Undetermined

Federalism: Undetermined

Agency Contact: Mary Kay Mullen, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5480

RIN: 0938-AJ96

1318. SUPPLIER STANDARDS RELATED TO TRAINING REQUIREMENTS FOR OXYGEN, ORTHOTICS AND PROSTHETICS (HCFA-6010-NPRM)

Priority: Substantive, Nonsignificant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 424.57

Legal Deadline: None

Abstract: As required by the BBA, this rule proposes service standards for oxygen providers. In addition, as recommended by the OIG, it proposes training standards for suppliers of customized orthotics and prosthetics, including diabetic footwear.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Charles Waldhauser, Division of Provider/Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-6140

RIN: 0938-AJ98

1319. CONDITIONS OF PARTICIPATION FOR INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1302

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule would revise the conditions of participation for ICFs/MR. It would set forth these requirements that ICFs/MR must meet to adhere to current trends in the field of developmental disabilities.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Nancy Archer, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 401 786-0596

RIN: 0938-AJ99

1320. NON-FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA (HCFA-2033-IFC)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 45 CFR 146

Legal Deadline: None

Abstract: This rule amends 45 CFR part 146, as promulgated at 62 FR 16894 April 8, 1997 (BPD-890-IFC). This rule makes a technical correction to 45 CFR 146.150, Guaranteed Availability of Coverage for Employers in the Small Group Market.

Timetable:

Action	Date	FR Cite
Interim Final Rule	To Be	Determined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses

Government Levels Affected:

Undetermined

Agency Contact: Dave Holstein, Insurance Standards Team, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1564

RIN: 0938-AK00

1321. • CHANGES TO THE APPEALS PROCESS FOR BENEFICIARIES RECEIVING HOME HEALTH SERVICES IN THE FEE FOR SERVICE PROGRAM (HCFA-4006-IFC)

Priority: Other Significant

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1155; Social Security Act, sec 1869(b); 42 USC 1302, subpart G; 42 USC 1320C-4, subpart G; 42 USC 1395ff(6), subpart G; 42 USC 1395hh, subpart G; 42 USC 1395pp, subpart G; Social Security Act, sec 1102, subpart H; Social Security Act, sec 1842(b)(3)(C), subpart H; Social Security Act, sec 1869(b), subpart H; Social Security Act, sec 1871, subpart H; 42 USC 1302, subpart H; 42 USC 1395(b)(3)(C), subpart H; 42 USC 1395ff(b), subpart H; 42 USC 1395hh, subpart H; ...

CFR Citation: 42 CFR 405

Legal Deadline: Other, Statutory, January 3, 2001, Section 4611 (BBA of 1997).

Abstract: This regulation will clarify the home health appeals process and will also address problems created by the BBA provisions to split payment for home health services between Medicare part A and part B funds.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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 21244-1850

Phone: 410 786-6972

RIN: 0938-AK10

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1322. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2001 (HCFA-1120-P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1395w-4

CFR Citation: 42 CFR 414

Legal Deadline: None

Abstract: This rule proposes updates to physician payments by Medicare as required by section 1848 of the Social Security Act. In this proposal we set forth several policy changes involving resource-based practice expense and relative value units.

Timetable:

Action	Date	FR Cite
NPRM	07/17/00	65 FR 44176
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Diane Milstead, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3355

RIN: 0938-AK11

1323. • HOSPICE WAGE INDEX (HCFA-1135-N)

Priority: Routine and Frequent

Legal Authority: 42 USC 1395f(i)(1)

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This notice announces the annual update to the hospice wage index as required by statute. This update is effective October 1, 2000 through September 30, 2001. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published in the Federal Register on August 8, 1997.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Undetermined

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

RIN: 0938-AK13

1324. • PRACTICE EXPENSE DATA COLLECTION (HCFA-1111-IFC)

Priority: Substantive, Nonsignificant

Legal Authority: sec 212 of BBRA of 1999; 42 USC 1395w-4

CFR Citation: 42 CFR 414

Legal Deadline: None

Abstract: This interim final rule establishes criteria for physician and non-physician specialty groups for submitting supplemental practice expense survey data for use in determining payments under the physician fee schedule. This interim final rule solicits public comments on the criteria for supplemental surveys.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Kenneth Marsalek, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, Room 1-H-5, Division of Medical Services Reimbursement, ELR, 6325 Security Boulevard, Baltimore, MD 21207
Phone: 301 594-1115

RIN: 0938-AK14

1325. • HIPPA PROGRAM; BONA FIDE WELLNESS PROGRAMS (HCFA-2078-P)

Priority: Substantive, Nonsignificant

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

Legal Authority: PL 104-191

CFR Citation: 45 CFR 146

Legal Deadline: None

Abstract: This proposed rule would implement and clarify the term “bona

fide wellness programs” as it relates to regulations implementing the nondiscrimination provisions of the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act, as added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Ruth Bradford, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration
Phone: 410 786-2636

RIN: 0938-AK19

1326. • PROVIDERS OF THE BALANCED BUDGET AND REFINEMENT ACT; HOSPITAL INPATIENT PAYMENTS, RATES AND COSTS OF GRADUATE MEDICAL EDUCATION (HCFA-1131-IFC)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1302; 12 USC 1395hh; PL 106-113

CFR Citation: 42 CFR 410.152; 42 CFR 412.90; 42 CFR 412.102; 42 CFR 412.103; 42 CFR 412.105; 42 CFR 412.108; 42 CFR 413.40; 42 CFR 413.70; 42 CFR 413.86; ...

Legal Deadline: None

Abstract: This interim final rule with comment period implements, or incorporates into regulations, certain statutory provisions relating to Medicare payments to hospitals for inpatient services that are contained in the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (Pub. L. 106-113). These provisions relate to reclassification of hospitals from urban to rural status, reclassification of certain hospitals for purposes of payment during Federal fiscal year 2000, critical access hospitals, payments to hospitals excluded under the hospital inpatient prospective payment system, and payments for indirect and direct graduate medical education costs.

Many of the provisions of Public Law 106-113 modify changes to the Social

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Security Act made by the Balanced Budget Act of 1997 (Pub. L. 105-33). These provisions are already in effect in accordance with Public Law 106-113.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/01/00	65 FR 47026
Interim Final Rule Effective	08/01/00	
Interim Final Rule Comment Period End	08/31/00	

Next Action Undetermined

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Stephen Phillips, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4548

RIN: 0938-AK20

1327. • APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2086-P)

Priority: Other Significant

Legal Authority: 42 USC 1302

CFR Citation: 42 CFR 435

Legal Deadline: None

Abstract: This proposed rule would eliminate the current requirement that limits on Federal Financial Participation (FFP) must be applied to States that use less restrictive income methodologies than those used by related cash assistance programs in determining eligibility for Medicaid.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Roy Trudel, Department of Health and Human Services, Health Care Financing Administration, C4-20-15, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-3417

RIN: 0938-AK22

1328. • CONDITIONS OF PARTICIPATION OF INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION (HCFA-3046-P)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

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

Legal Deadline: None

Abstract: This rule would revise the Conditions of Participation for Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR). It would set forth new requirements that an ICF/MR must meet to participate in the Medicaid program, as well as adhere to current trends in the field of developmental disabilities. It would also increase our focus on client-directed choices, while maintaining essential client protections that reinforce our mandate to protect the health, safety, and welfare of the clients we serve.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Nancy Archer, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 401 786-0596

RIN: 0938-AK23

1329. • CLINICAL LAB REQUIREMENTS-REVISIONS TO REGS IMPLEMENTING CLIA (HCFA-2226-F)

Priority: Other Significant

Legal Authority: PL 100-578

CFR Citation: 42 CFR 493

Legal Deadline: None

Abstract: This rule revises regulations applicable to clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. The regulations apply to laboratories that examine human

specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. This rule concludes the phase-in for certain quality control and personnel requirements, and addresses comments received on previously promulgated CLIA rules. In addition, this rule consolidates and reorganizes the requirements for patient test management, quality control and quality assurance in a manner that parallels the path of a specimen through the testing process. While this regulation pertains to complex technical requirements, plain language is used whenever possible, as mandated by the Regulatory Reform Initiative.

Timetable:

Action	Date	FR Cite
Final Action	To Be Determined	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Cecelia Hinkel, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration
Phone: 410 786-3347

RIN: 0938-AK24

1330. • PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES: EXCEPTION TO THE PROVIDER-BASED LOCATION CRITERIA FOR PPS-EXEMPT FACILITIES (HCFA-1143-P)

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

Legal Authority: sec 1102 of the Social Security Act; 42 USC 1302; 42 USC 1395(b); 42 USC 1395(g); 42 USC 1395(l); 42 USC 1395(o); 42 USC 1395(i); 42 USC 1395(i); 42 USC 1395(n); 42 USC 1395x(v); 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395tt; 42 USC 1385ww; ...

CFR Citation: 42 CFR 413

Legal Deadline: None

Abstract: This rule would revise the criteria related to provider-based status requirements for hospitals excluded from the hospital inpatient prospective payment system (PPS) under section 4417 of the Balanced Budget Act of

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1997 (BBA). We are proposing to require that satellites of a hospital that qualifies for a PPS exclusion under section 4417 of BBA must be located within the same Metropolitan Statistical Area as the hospital, instead of requiring that these satellites meet the existing requirement of location within the immediate vicinity of the hospital. The satellites of these excluded hospitals would still be required to comply with the other provider-based status criteria.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael Lefkowitz, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration

Phone: 410 786-5316

RIN: 0938-AK25

1331. • CRITERIA AND STANDARDS FOR EVALUATING INTERMEDIARY AND CARRIER PERFORMANCE DURING FY 2001 (HCFA-4010-GNC)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 421.122

Legal Deadline: None

Abstract: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries and carriers in the administration of the Medicare program beginning October 1, 2000.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Kristy McCarthy, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S1-01-26, 7500 Security Blvd, Baltimore, MD 21207

Phone: 410 786-7139

RIN: 0938-AK26

1332. • INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2001 (HCFA-8007-N)

Priority: Economically Significant. Major under 5 USC 801.

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

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, September 30, 2000.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2001 under Medicare's hospital insurance program (Medicare part A). The Medicare statute specifies the formulae used to determine these amounts.

The inpatient hospital deductible will be \$792. The daily coinsurance amounts will be: (a) \$198 for the 61st through 90th day of hospitalization in a benefit period; (b) \$396 for lifetime reserve days; and (c) \$99 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

Timetable:

Action	Date	FR Cite
Final Action	To Be	Determined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, OACT, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6390

RIN: 0938-AK27

1333. • MANDATORY TRANSMISSION OF OUTCOME AND ASSESSMENT INFO. SET FOR NON-MEDICARE/MEDICAID PATIENTS IN HOME HEALTH AGENCIES AND CONTINUED DELAY OF REQUIREMENTS FOR PATIENTS RECEIVING PERSONAL CARE SERVICES

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This notice announces to home health agencies (HHAs), State survey agencies, Medicare and Medicaid beneficiaries, software vendors, and the general public, changes to and effective dates for, the mandatory encoding, masking, and transmission of Outcome and Assessment Information Set (OASIS) data for Non-Medicare and Non-Medicaid patients receiving skilled care. In addition, changes to the Health Care Financing Administration (HCFA) OASIS State-based system will be made to accommodate masking and to ensure that private vendor software complies with current HCFA-defined data submission specifications. We are continuing to delay the requirements regarding OASIS use, collection, encoding, and transmission for at least two more years for patients receiving only personal care services regardless of payer source.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Mary Weakland, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6835

RIN: 0938-AK28

1334. • REMOVAL OF THE REQUIREMENTS FOR THE CARDIAC PACEMAKER REGISTRY (HCFA-3045-F)

Priority: Substantive, Nonsignificant

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1819; Social Security Act, sec 1861; Social Security Act, sec 1864; Social Security Act, sec 1866; Social Security Act, sec 1871; ...

CFR Citation: 42 CFR 409; 42 CFR 410; 42 CFR 489; 42 CFR 498

Legal Deadline: None

Abstract: The Federal Drug Administration has eliminated the Cardiac Pacemaker Registry. This rule

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removes all references to the registry from 42 CFR.

Timetable:

Action	Date	FR Cite
Final Action	To Be	Determined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Shana Olshan, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-10-07, 7500 Security Boulevard, Baltimore, MD 21244-1850
Phone: 410 786-5246

RIN: 0938-AK29

1335. ● FIRE SAFETY REQUIREMENTS FOR RNHCI, ASC, HOSPICES, PACE, HOSPITALS, AND LONG-TERM CARE FACILITIES

Priority: Substantive, Nonsignificant

Legal Authority: sec 1101 of the Social Security Act; sec 1871 of the Social Security Act

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

Legal Deadline: None

Abstract: This rule would update current fire safety requirements to the 2000 edition of the life safety code, published by the National Fire Protection Association.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Tamara Syrek, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration
Phone: 410 786-3529

RIN: 0938-AK35

1336. ● CONFORMING REGULATIONS CHANGES AND STATUTORY REVISIONS FOR APPROVAL AND OVERSIGHT OF ACCREDITATION ORGANIZATIONS

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: PL 104-134, sec 516(b); sec 1865(b) of the Social Security Act

CFR Citation: 42 CFR 488.1; 42 CFR 488.5; 42 CFR 488.6; 42 CFR 488.8

Legal Deadline: None

Abstract: This proposed rule would implement, or conform to regulations, certain statutory provisions relating to hospital oversight, and other policy updates for approval and oversight of accreditation. It would incorporate statutory timeframes and procedures for processing national accreditation organizations' applications for approval, under section 1865(b) of the Social Security Act.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected:

Undetermined

Agency Contact: Joan C. Berry, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7233
Email: jberry@hcfa.gov

RIN: 0938-AK36

Department of Health and Human Services (HHS) Health Care Financing Administration (HCFA)

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1337. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (HCFA-1309-F)

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Cathy Black
Phone: 410 786-4544

RIN: 0938-AB50

1338. SURVEY REQUIREMENTS AND ALTERNATIVE SANCTIONS FOR HOME HEALTH AGENCIES (HCFA-2169-F)

Priority: Other Significant

CFR Citation: 42 CFR 488; 42 CFR 489; 42 CFR 498

Completed:

Reason	Date	FR Cite
Withdrawn	08/10/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Local, State, Federal

Agency Contact: Patricia Miller
Phone: 410 786-6780

RIN: 0938-AE39

1339. CHANGES TO THE LONG-TERM CARE FACILITY SURVEY PROCESS (HCFA-3175-FC)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 442; 42 CFR 488

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Helene Fredeking
Phone: 410 786-7304

RIN: 0938-AF02

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Completed Actions

1340. REQUIREMENTS FOR CERTAIN HEALTH INSURING ORGANIZATIONS AND OBRA '90 TECHNICAL AMENDMENTS (HCFA-1018-F)**Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 434.20 to 72; 42 CFR 435.212; 42 CFR 435.326**Completed:**

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis**Required:** Yes**Government Levels Affected:** None**Agency Contact:** Betty Stanton
Phone: 410 786-3247**RIN:** 0938-AF15**1341. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (HCFA-1727-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 405.1801 to 405.1889; 42 CFR 413.30 to 413.64; 42 CFR 417.576; 42 CFR 417.810**Completed:**

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Morton Marcus
Phone: 410 786-4477**RIN:** 0938-AF28**1342. ALTERNATIVE SANCTIONS FOR PSYCHIATRIC HOSPITALS (HCFA-2191-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 488**Completed:**

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis**Required:** Yes**Government Levels Affected:** State, Federal**Agency Contact:** Shirley Eldridge
Phone: 410 786-6836**RIN:** 0938-AF32**1343. MEDICAID: OUTSTATIONED INTAKE LOCATIONS FOR CERTAIN LOW-INCOME PREGNANT WOMEN, INFANTS, AND CHILDREN UNDER AGE 19 (HCFA-2052-F)****Priority:** Substantive, Nonsignificant**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**Completed:**

Reason	Date	FR Cite
Withdrawn	08/15/00	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** State**Agency Contact:** Robert Tomlinson
Phone: 410 786-4463**RIN:** 0938-AF69**1344. ASSESSING INTEREST AGAINST MEDICARE SECONDARY PAYER (MSP) DEBTS (HCFA-6108-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 405.378; 42 CFR 411.24(m); 42 CFR 411.39**Completed:**

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** John W. Albert
Phone: 410 786-7457**RIN:** 0938-AF87**1345. REVISED MEDICAID MANAGEMENT INFORMATION SYSTEMS (HCFA-2038-FN)****Priority:** Substantive, Nonsignificant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Withdrawn	10/26/00	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** State**Agency Contact:** Richard H. Friedman
Phone: 410 786-4451**RIN:** 0938-AG10**1346. MEDICARE PROGRAM: LIMITATIONS ON MEDICARE COVERAGE OF INTERMITTENT POSITIVE PRESSURE BREATHING MACHINE THERAPY (HCFA-3781-FN)****Priority:** Substantive, Nonsignificant**CFR Citation:** 45 CFR 500**Completed:**

Reason	Date	FR Cite
Withdrawn	10/26/00	

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Francine Spencer
Phone: 410 786-4614**RIN:** 0938-AG44**1347. DEFINITION OF SKILLED NURSING FACILITY (SNF) FOR COVERAGE OF DURABLE MEDICAL EQUIPMENT (DME) AND HOME HEALTH SERVICES (HCFA-1834-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 409; 42 CFR 410**Completed:**

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis**Required:** Yes**Government Levels Affected:** None**Agency Contact:** Thomas E. Hoyer
Phone: 410 786-4605**RIN:** 0938-AH16**1348. PAYMENT AMOUNT IF CUSTOMARY CHARGES ARE LESS THAN REASONABLE COSTS (HCFA-1860-FC)****Priority:** Other Significant**CFR Citation:** 42 CFR 413.13**Completed:**

Reason	Date	FR Cite
Final Action	02/22/00	65 FR 8660

Regulatory Flexibility Analysis**Required:** No**Government Levels Affected:** None**Agency Contact:** Ward Pleines
Phone: 410 786-4528**RIN:** 0938-AH49

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Completed Actions

1349. LIMITATIONS ON LIABILITY (HCFA-4859-FC)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 411.404

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Denis M. Garrison
Phone: 410 786-5643

RIN: 0938-AH51

1350. MEDICAID HOSPICE CARE (HCFA-2016-P)

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Withdrawn	08/16/00	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State, Local

Agency Contact: Tom Shenk
Phone: 410 786-3295

RIN: 0938-AH65

1351. MEDICARE TECHNICAL CONFORMING AMENDMENTS (HCFA-1858-FC)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 409.50; 42 CFR 409.61; 42 CFR 410.152

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Martha Kuespert
Phone: 410 786-4605

RIN: 0938-AH67

1352. 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 (HCFA-3235-FC)

Priority: Substantive, Nonsignificant

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

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: William Roskey
Phone: 410 786-0433

RIN: 0938-AH68

1353. DETERMINATION OF SUBSTANDARD CARE IN SNFS AND NFS (HCFA-2240-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 488.301

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal, State, Local

Agency Contact: Patricia Miller
Phone: 410 786-6780

RIN: 0938-AH69

1354. WAIVER OF STAFFING REQUIREMENTS FOR END STAGE RENAL DISEASE (ESRD) FACILITIES PARTICIPATING IN AN EXPERIMENT (HCFA-2236-GNC)

Priority: Other Significant

CFR Citation: 42 CFR 405.2136; 42 CFR 405.2161; 42 CFR 405.2162; 42 CFR 405.2163

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: William Roskey
Phone: 410 786-0433

RIN: 0938-AH72

1355. MEDICARE PROGRAM; MEDICARE INTEGRITY PROGRAM (HCFA-7020-F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 400; 42 CFR 421

Completed:

Reason	Date	FR Cite
Withdrawn	08/17/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Brenda Thew
Phone: 410 786-4889

RIN: 0938-AI09

1356. STATE CHILD HEALTH; IMPLEMENTING REGULATIONS FOR THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM (HCFA-2006-F)

Priority: Economically Significant

CFR Citation: 42 CFR 457

Completed:

Reason	Date	FR Cite
Duplicate of RIN 0938- AJ75	08/10/00	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: Federal, State, Local

Agency Contact: Cheryl Austein-Casnoff
Phone: 410 786-4196Cynthia Shirk
Phone: 410 786-6614

RIN: 0938-AI28

1357. MEDICARE PROGRAM; MEDICARE+CHOICE PROGRAM (HCFA-1030-FC)

Priority: Other Significant

CFR Citation: 42 CFR 417; 42 CFR 422

Completed:

Reason	Date	FR Cite
Final Action	06/29/00	65 FR 40170

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Tony Culotta
Phone: 410 786-4661

RIN: 0938-AI29

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Completed Actions

1358. HEALTH INSURANCE REFORM: STANDARDS FOR ELECTRONIC TRANSACTIONS (HCFA-0149-F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 160; 45 CFR 162

Completed:

Reason	Date	FR Cite
Final Action	08/17/00	65 FR 50312

Regulatory Flexibility Analysis

Required: Yes

Government Levels Affected: State

Agency Contact: Joy Glass

Phone: 410 786-6125

RIN: 0938-AI58

1359. STATE CHILD HEALTH; STATE CHILDREN'S HEALTH INSURANCE PROGRAM ALLOTMENTS AND PAYMENTS TO STATES (HCFA-2114-F)

Priority: Other Significant

CFR Citation: 42 CFR 447.88; 42 CFR 457.220; 42 CFR 457.222; 42 CFR 457.224; 42 CFR 457.226; 42 CFR 457.228; 42 CFR 457.202; 42 CFR 457.204; 42 CFR 457.206; 42 CFR 457.208; 42 CFR 457.210; 42 CFR 457.212; 42 CFR 457.216; 42 CFR 457.218; 42 CFR 457.200; ...

Completed:

Reason	Date	FR Cite
Final Rule	05/24/00	65 FR 33616

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Federal, State

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

Agency Contact: Richard Strauss

Phone: 410 786-2019

Email: rstrauss@hcfa.gov

RIN: 0938-AI65

1360. ELIMINATION OF APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2111-IFC)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 435

Completed:

Reason	Date	FR Cite
Withdrawn	08/10/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Agency Contact: Jackie Wilder

Phone: 410 786-4579

Email: jwilder@hcfa.gov

RIN: 0938-AI73

1361. MEDICAID PROGRAM; CHANGES TO ELIGIBILITY OF NON-U.S. CITIZENS (HCFA-2108-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 435; 42 CFR 440

Completed:

Reason	Date	FR Cite
Withdrawn	08/16/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Robert Tomlinson

Phone: 410 786-4463

RIN: 0938-AI74

1362. HEALTH INSURANCE REFORM UNIVERSAL HEALTH CARE IDENTIFIER (HCFA-0048-NOI)

Priority: Other Significant

CFR Citation: 42 CFR ch IV

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Mary Emerson

Phone: 410 786-7065

Email: memerson@hcfa.gov

RIN: 0938-AI91

1363. PEER REVIEW ORGANIZATION CONTRACTS: SOLICITATION OF STATEMENTS OF INTEREST FROM IN-STATE ORGANIZATIONS (HCFA-3009-N)

Priority: Other Significant

CFR Citation: 42 CFR ch IV

Completed:

Reason	Date	FR Cite
Notice	07/29/98	63 FR 40534

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Udo Nwachukwu

Phone: 410 786-7234

RIN: 0938-AI99

1364. HHS' RECOGNITION OF NAIC MODEL STANDARDS FOR REGULATION OF MEDIGAP POLICY (HCFA-2025-N)

Priority: Other Significant

CFR Citation: 42 CFR ch IV

Completed:

Reason	Date	FR Cite
Final Action	12/04/98	63 FR 67078

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Larry Cutler

Phone: 410 786-5903

RIN: 0938-AJ07

1365. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM (HCFA-1059-F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR ch IV

Completed:

Reason	Date	FR Cite
Final Action	07/03/00	65 FR 41128

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Robert Wardwell

Phone: 410 786-3254

RIN: 0938-AJ24

1366. DECISION ON THE FUNDING FOR THE AIDS HEALTHCARE FOUNDATION START PROGRAM, (HCFA-2041-N)

Priority: Info./Admin./Other

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	03/04/99	64 FR 10479

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Wayne Smith

Phone: 410 786-6762

RIN: 0938-AJ43

HHS—HCFA

Completed Actions

1367. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (HCFA-2019-FC)

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 150

Completed:

Reason	Date	FR Cite
Final Action	08/20/99	64 FR 45785

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Agency Contact: Rochelle Shevitz
Phone: 410 786-1570

RIN: 0938-AJ48

1368. SCHEDULES OF PER VISIT AND PER BENEFICIARY LIMITATION ON HOME HEALTH AGENCY COST (HCFA-1060-NC)

Priority: Other Significant

CFR Citation: 42 CFR 413.30

Completed:

Reason	Date	FR Cite
Notice	08/05/99	64 FR 42766

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Michael Bussacca
Phone: 410 786-4602

RIN: 0938-AJ57

1369. REAPPLICATION OF THE COMMUNITY HEALTH ACCREDITATION PROGRAM, INCORPORATED (CHAP) FOR CONTINUED APPROVAL OF DEEMING AUTHORITY FOR HEALTH CARE AGENCIES (HHAS) (HCFA-2059-FN)

Priority: Substantive, Nonsignificant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	02/22/00	65 FR 8725

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Joan Berry
Phone: 410 786-7233
Email: jberry@hcfa.gov

RIN: 0938-AJ69

1370. STATE ALLOTMENTS FOR PAYMENTS OF MEDICARE PART B PREMIUMS FOR QUALIFIED INDIVIDUALS: FEDERAL FISCAL YEAR 2000 (HCFA-2063-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	05/30/00	65 FR 34478

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Agency Contact: Miles McDermott
Phone: 410 786-3722
Email: mmcdermott@hcfa.gov

RIN: 0938-AJ72

1371. CHILDREN'S HEALTH INSURANCE PROGRAM; FINAL ALLOTMENTS TO STATES, COMMONWEALTHS AND TERRITORIES FOR FISCAL YEARS 1998 AND 1999 (HCFA-2064-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	05/24/00	65 FR 33634

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State, Local

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

RIN: 0938-AJ77

1372. ANNOUNCEMENT OF ADDITIONAL APPLICATIONS FROM HOSPITALS REQUESTING WAIVERS FOR ORGAN PROCUREMENT SERVICE AREAS (HCFA-1055-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	08/17/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

Agency Contact: Mark Horney
Phone: 410 786-4554

RIN: 0938-AJ79

1373. MONTHLY ACTUARY RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATES BEGINNING JANUARY 1, 2000 (HCFA-8006-N)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	10/22/99	64 FR 57105

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

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

RIN: 0938-AJ80

1374. PAYMENT FOR UPGRADED DURABLE MEDICAL EQUIPMENT (HCFA-1084-P)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 414.225 (New)

Completed:

Reason	Date	FR Cite
Withdrawn	08/09/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

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

RIN: 0938-AJ82

1375. INPATIENT HOSPITAL DEDUCTIBLE AND EXTENDED CARE SERVICES FOR COINSURANCE AMOUNTS FOR FY 2000 (HCFA-8005-N)

Priority: Economically Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	10/22/99	64 FR 56199

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State, Local, Tribal

Agency Contact: Clare McFarland
Phone: 410 786-6390

RIN: 0938-AJ83

HHS—HCFA

Completed Actions

1376. PART A PREMIUM FOR FY 2000 FOR THE UNINSURED, AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENTS (HCFA-8004-N)

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	10/22/99	64 FR 57101

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: State

Agency Contact: Clare McFarland
Phone: 410 786-6390

RIN: 0938-AJ84

1377. COVERAGE OF, AND PAYMENT OF, PARAMEDIC INTERCEPT AMBULANCE SERVICES (HCFA-1813-F)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Action	03/15/00	65 FR 13911

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local

Agency Contact: Robert Niemann
Phone: 301 966-4569

RIN: 0938-AJ87

1378. CRITERIA AND STANDARDS FOR EVALUATING INTERMEDIARY AND CARRIER PERFORMANCE DURING FY 2000 (HCFA-4009-GNC)

Priority: Routine and Frequent

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	12/03/99	64 FR 67920

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Sue Lathroum
Phone: 410 786-7409

RIN: 0938-AJ88

1379. MEDICARE GRADUATE MEDICAL EDUCATION CONSORTIA (HCFA-1094-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	01/05/00	65 FR 494

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Sid Mazumdar
Phone: 410 786-6673

RIN: 0938-AJ89

1380. SUSTAINABLE GROWTH RATE FOR FY 2000 (HCFA-1110-N)

Priority: Economically Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Withdrawn	09/01/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Marc Hartstein
Phone: 410 786-4539

RIN: 0938-AJ90

1381. MEDICARE PROGRAM; MEDICARE DISPROPORTIONATE SHARE (DSH) ADJUSTMENT CALCULATION: CHANGE IN THE TREATMENT OF DAYS IN STATES WITH 1115 EXPANSION WAIVERS (HCFA-1124-IFC)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 412

Completed:

Reason	Date	FR Cite
Merged With RIN	08/01/00	
	0938-AK09	

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

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

Agency Contact: Stephen Phillips
Phone: 410 786-4548

RIN: 0938-AJ92

1382. STATE CHILDREN'S HEALTH INSURANCE PROGRAM; FINAL ALLOTMENTS TO STATES, COMMONWEALTHS, AND TERRITORIES FOR FISCAL YEAR 2000 (HCFA-2067-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	05/24/00	65 FR 33638

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Sharon Brown
Phone: 410 786-0673

Email: sbrown4@hcfa.gov

RIN: 0938-AJ94

1383. PROCESS FOR REQUESTING RECOGNITION OF NEW TECHNOLOGIES AND CERTAIN DRUGS, BIOLOGICALS AND MEDICAL DEVICES FOR SPECIAL PAYMENT UNDER HOSPITAL OUTPATIENT PPS (HCFA-1128-N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	04/07/00	65 FR 18341

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Diane Milstead
Phone: 410 786-3355

RIN: 0938-AK01

1384. SCHEDULES OF PER VISIT AND PER BENEFICIARY LIMITATIONS ON HHA COSTS FOR COST REPORTING PERIODS BEGINNING ON OR AFTER OCTOBER 1, 2000 (HCFA-1108-NC)

Priority: Other Significant

CFR Citation: 42 CFR 413.30

Completed:

Reason	Date	FR Cite
Withdrawn	10/10/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Michael Bussacca
Phone: 410 786-4602

RIN: 0938-AK03

HHS—HCFA

Completed Actions

1385. REPORTING QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT DATA AS PART OF THE CONDITIONS FOR COVERAGE FOR END STAGE RENAL DISEASE FACILITIES (HCFA-3048-N)**Priority:** Substantive, Nonsignificant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Merged With RIN 0938-AG82	08/11/00	

Regulatory Flexibility Analysis Required: No**Government Levels Affected:** None**Agency Contact:** Robert Miller
Phone: 410 786-6797
Email: rmiller1@hcfa.gov**RIN:** 0938-AK05**1386. • MEDICARE PROGRAM; DEDUCTIBLE AMOUNT FOR MEDIGAP HIGH DEDUCTIBLE OPTIONS FOR CALENDAR YEAR 2000 (HCFA-2893-N)****Priority:** Routine and Frequent**Legal Authority:** sec 1882 of the Social Security Act**CFR Citation:** None**Legal Deadline:** None**Abstract:** This notice announced the calendar year 2000 deductible amount for Medigap high deductible options (\$1,530.00).**Timetable:**

Action	Date	FR Cite
Notice	04/10/00	65 FR 18999

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Kathryn McCann, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7623**RIN:** 0938-AK06**1387. • CHANGES TO THE HOSPITAL INPATIENT PERSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2001 RATES (HCFA-1118-F)****Priority:** Economically Significant. Major under 5 USC 801.**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 410; 42 CFR 412; 42 CFR 413; 42 CFR 485**Legal Deadline:** Final, Statutory, August 1, 2000.**Abstract:** We are revising the Medicare hospital inpatient prospective payment system for operating costs to: (1) implement applicable statutory requirements, including a number of provisions of the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (Public Law 106-113); and (2) implement changes arising from our continuing experience with the system. In addition, in the Addendum to this final rule, we describe changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes apply to discharges occurring on or after October 1, 2000. We also set forth rate-of-increase limits and make changes to our policy for hospitals and hospital units excluded from the prospective payment systems.

We are making changes to the policies governing payments to hospitals for the direct costs of graduate medical education, sole community hospitals and critical access hospitals.

We are adding a new condition of participation on organ, tissue, and eye procurement for critical access hospitals that parallels the condition of participation that we previously published for all other Medicare-participating hospitals.

Lastly, we are finalizing a January 20, 2000 interim final rule with comment period (65 FR 3136) that sets forth the criteria to be used in calculating the Medicare disproportionate share adjustment in reference to Medicaid expansion waiver patient days under section 1115 of the Social Security Act.

Timetable:

Action	Date	FR Cite
Proposed Rule	05/05/00	65 FR 26281
Comment Period End	07/05/00	

Action	Date	FR Cite
Final Rule	08/01/00	65 FR 47054
Final Rule Effective	10/01/00	

Regulatory Flexibility Analysis Required: Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Agency Contact:** Stephen Phillips, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4548**RIN:** 0938-AK09**1388. • HEALTH CARE AND EMPLOYMENT SUPPORT GRANTS FOR PEOPLE WITH DISABILITIES BEGINNING FISCAL YEAR 2000 (HCFA-2076-N)****Priority:** Info./Admin./Other**Legal Authority:** None**CFR Citation:** None**Legal Deadline:** None**Abstract:** This notice announces the availability of HCFA funding, through grants, for eligible States under the Ticket to Work and Work Incentives Act of 1999 (TWWIIA). The grant program is designed to assist States in developing infrastructures to support the competitive employment of people with disabilities by extending necessary Medicaid coverage to these individuals. This notice contains information about the grants, application requirements, review procedures, and other relevant information.**Timetable:**

Action	Date	FR Cite
Notice	05/31/00	65 FR 34715

Regulatory Flexibility Analysis Required: No**Small Entities Affected:** No**Government Levels Affected:** State, Federal**Agency Contact:** Aaron Blight, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S2-14-26, 7500 Security Blvd, Baltimore, MD
Phone: 410 786-9560**RIN:** 0938-AK16

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

Proposed Rule Stage

1389. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES

Priority: Other Significant

Legal Authority: 42 USC 655(f)

CFR Citation: 45 CFR 309

Legal Deadline: None

Abstract: This NPRM proposes to 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 objectives of title IV-D, including establishment of paternity, modification and enforcement of support orders, and location of absent parents.

Timetable:

Action	Date	FR Cite
NPRM	08/21/00	65 FR 50800
NPRM Comment Period End	12/19/00	
Final Action	08/00/01	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Tribal

Agency Contact: Paige Biava, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447
 Phone: 202 401-9386

RIN: 0970-AB73

1390. PROGRAM PERFORMANCE STANDARDS FOR THE OPERATION OF HEAD START PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1304

Legal Deadline: None

Abstract: The education component of the Head Start Performance Standards will be revised to ensure the school readiness of children participating in a Head Start program and to assure that Head Start children have certain understandings in the areas of language and numeracy.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: None

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

RIN: 0970-AB99

1391. SAFEGUARDING CHILD SUPPORT AND EXPANDED FPLS INFORMATION

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 652 to 654; 42 USC 663; 42 USC 653A; 42 USC 654A

CFR Citation: 45 CFR 303.21

Legal Deadline: None

Abstract: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 made far-reaching

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

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local

Agency Contact: Eileen C. Brooks, Program Specialist, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, OCSE, DPP, 370 L'Enfant Promenade SW., Washington, DC 20447
 Phone: 202 401-5369
 Email: ebrooks@acf.dhhs.gov

RIN: 0970-AC01

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

Final Rule Stage

1392. 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 and Early 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	11/00/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, Tribal

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

HHS—ACF

Final Rule Stage

Email: dklafehn@acf.dhhs.gov

RIN: 0970—AB24

1393. CONSTRUCTION AND MAJOR RENOVATION OF HEAD START AND EARLY HEAD START FACILITIES

Priority: Other Significant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1309

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	02/08/99	64 FR 6013
NPRM Comment Period End	04/09/99	
Final Action	01/00/01	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, Tribal

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

RIN: 0970—AB54

1394. 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 1302

CFR Citation: 45 CFR 301 to 305

Legal Deadline: None

Abstract: This rule eliminates child support enforcement program regulations rendered obsolete or inconsistent with the Personal

Responsibility and Work Opportunity Reconciliation Act of 1996, and its technical amendments, the Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997, and the Child Support Performance and Incentive Act of 1998.

Timetable:

Action	Date	FR Cite
Interim Final Rule	02/09/99	64 FR 6237
Final Action	01/00/01	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Agency Contact: Anne M. Benson, Program Specialist, Department of Health and Human Services, Administration for Children and Families, MS OCSE, DPP, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-1467
Email: abenson@acf.dhhs.gov

RIN: 0970—AB81

1395. INCENTIVE PAYMENTS AND AUDIT PENALTIES TO STATES AND POLITICAL SUBDIVISIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 609(a)(8); 42 USC 658A

CFR Citation: 45 CFR 305; 45 CFR 302.55; 45 CFR 304.12

Legal Deadline: NPRM, Statutory, April 1999.

Abstract: This regulation implements the requirements in 42 U.S.C. 609(a)(8), which provide 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. It also implements a new incentive system, enacted under Public Law 105-200. Based on 42 U.S.C. 658A, States will receive incentives according to their performance on key statutory indicators and performance standards from a capped pool of funds beginning in FY 2000. These funds must be reinvested in the title IV-D Program.

Timetable:

Action	Date	FR Cite
NPRM	10/08/99	64 FR 55074
Final Action	10/00/00	

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Agency Contact: Joyce Pitts, Department of Health and Human Services, Administration for Children and Families, MS OCSE, DPP, Division of Policy and Planning, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-5374
Email: jpitts@acf.dhhs.gov

RIN: 0970—AB85

1396. FAMILY CHILD CARE PROGRAM OPTION FOR HEAD START PROGRAMS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

CFR Citation: 45 CFR 1304; 45 CFR 1306

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/29/00	65 FR 52394
Final Action	08/00/01	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal

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

RIN: 0970—AB90

1397. STATE SELF-ASSESSMENTS TO DETERMINE COMPLIANCE WITH FEDERAL REGULATIONS

Priority: Substantive, Nonsignificant

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

CFR Citation: 45 CFR 308

Legal Deadline: None

Abstract: The rule requires States to conduct annual reviews on certain aspects of the State title IV-D programs and provide a report to the Secretary.

HHS—ACF

Final Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	10/08/99	64 FR 55102
Final Action	11/00/00	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Jan Rothstein, Program Specialist, Department of Health and Human Services, Administration for Children and Families, DHHS, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-5073
Email: jrothstein@acf.dhhs.gov

RIN: 0970-AB96

1398. NATIONAL MEDICAL SUPPORT NOTICE

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 652(f); 42 USC 666(a)(19)

CFR Citation: 45 CFR 303.32

Legal Deadline: Final, Statutory, November 15, 2000.

Abstract: Joint DHHS/DOL regulations will mandate use of a national medical support notice and include procedures for issuance and transmittal to employers by States to enforce health care coverage in a child support order.

Timetable:

Action	Date	FR Cite
NPRM	11/15/99	64 FR 62074
NPRM Comment	01/14/00	
Period End		
Final Action	11/00/00	

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No

Government Levels Affected: Federal, State, Local, Tribal

Agency Contact: Elizabeth Matheson, Director, Policy and Planning Division, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9386
Email: bmatheson@acf.dhhs.gov

John Seneta, Program Specialist, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-5154
Email: jseneta@acf.dhhs.gov

RIN: 0970-AB97

1399. TECHNICAL REVISION OF HEAD START REGULATIONS TO MAKE THEM CONFORM TO RECENT STATUTORY REVISIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801 et seq

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

Legal Deadline: None

Abstract: This rule will correct several Head Start regulations which define Head Start programs as "nonprofit" agencies. Recent statutory changes now allow "for-profit" agencies to receive Head Start grant funds.

Timetable:

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

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: None

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

RIN: 0970-AC00

**Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)****Completed Actions****1400. METHODOLOGY FOR DETERMINING WHETHER AN INCREASE IN A STATE'S CHILD POVERTY RATE IS THE RESULT OF THE TANF PROGRAM**

Priority: Other Significant

CFR Citation: 45 CFR 284 (New)

Completed:

Reason	Date	FR Cite
Final Action	06/23/00	65 FR 39233

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

Agency Contact: Howard Rolston
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RIN: 0970-AB65

1401. BONUS TO REWARD HIGH PERFORMANCE STATES UNDER THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES BLOCK GRANT

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 45 CFR 270 (New)

Completed:

Reason	Date	FR Cite
Final Action	08/30/00	65 FR 52814

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: State

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RIN: 0970-AB66

1402. RUNAWAY AND HOMELESS YOUTH PROGRAM

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1351

Completed:

Reason	Date	FR Cite
Final Action	08/17/00	65 FR 50139

Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Tribal

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RIN: 0970-AC04

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

Proposed Rule Stage
1403. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, INTRASTATE FUNDING FORMULAS; TRAINING, RESEARCH AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; AND GRANTS TO INDIANS AND 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 1326 to 1328**Legal Deadline:** None**Abstract:** The Administration on Aging (AoA) in consultation with the Office of Management and Budget, has determined that it is no longer necessary to pursue final action on rules proposed earlier 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 2000 to implement the provisions to the next reauthorization of the Older Americans Act, if necessary.**Timetable:**

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis**Required:** Yes**Small Entities Affected:** Businesses, Governmental Jurisdictions**Government Levels Affected:** State, Tribal**Federalism:** Undetermined**Agency Contact:** Edwin Walker, Director, Office of Program Operations and Development, Department of Health and Human Services, Administration on Aging, Room 4733, 330 Independence Avenue SW., Cohen Building, Washington, DC 20201
Phone: 202 619-0011**RIN:** 0985-AA00

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